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Protocol

Effect of a Mobile Phone Intervention on Quitting Smoking in a Young Adult Population of Smokers: Randomized Controlled Trial Study Protocol

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Abstract

Background: Tobacco use remains the number one cause of preventable chronic disease and death in developed countries worldwide. In North America, smoking rates are highest among young adults. Despite that the majority of young adult smokers indicate wanting to quit, smoking rates among this age demographic have yet to decline. Helping young adults quit smoking continues to be a public health priority. Digital mobile technology presents a promising medium for reaching this population with smoking cessation interventions, especially because young adults are the heaviest users of this technology.

Objective: The primary aim of this trial is to determine the effectiveness of an evidence-informed mobile phone app for smoking cessation, Crush the Crave, on reducing smoking prevalence among young adult smokers.

Methods: A parallel randomized controlled trial (RCT) with two arms will be conducted in Canada to evaluate Crush the Crave. In total, 1354 young adult smokers (19 to 29 years old) will be randomized to receive the evidence-informed mobile phone app, Crush the Crave, or an evidence-based self-help guide known as "On the Road to Quitting" (control) for a period of 6 months. The primary outcome measure is a 30-day point prevalence of abstinence at the 6-month follow-up. Secondary outcomes include a 7-day point prevalence of abstinence, number of quit attempts, reduction in consumption of cigarettes, self-efficacy, satisfaction, app utilization metrics, and use of smoking cessation services. A cost-effectiveness analysis is included.

Results: This trial is currently open for recruitment. The anticipated completion date for the study is April 2016.

Conclusions: This randomized controlled trial will provide the evidence to move forward on decision making regarding the inclusion of technology-based mobile phone interventions as part of existing smoking cessation efforts made by health care providers. Evidence from the trial will also inform the development of future apps, provide a deeper understanding of the factors that drive change in smoking behavior using an app, and improve the design of cessation apps. This trial is among the first to

assess the effect of a comprehensive and evidence-informed mHealth smoking cessation app on a large sample of young adult smokers. Strengths of the trial include the high-quality research design and in-depth assessment of the implementation of the intervention. If effective, the trial has the potential to demonstrate that including mHealth technology as a population-based intervention strategy can cost-effectively reach a greater proportion of the population and help young adult smokers to quit.

Trial Registration: ClinicalTrials.gov NCT01983150; <http://clinicaltrials.gov/ct2/show/NCT01983150> (Archived by WebCite at <http://www.webcitation.org/6VGyc0W0i>).

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KEYWORDS

health behavior; smoking cessation; young adult; mobile phone apps; mHealth

Introduction

Background

Tobacco use remains the number one cause of preventable chronic disease and death in developed countries worldwide [1]. Currently, young adults represent the largest population of smokers across North America [2,3], and this age demographic is particularly vulnerable to the negative health effects of tobacco use [4-9]. Although smoking prevalence increases from adolescence into adulthood, most young adult smokers express a desire to quit. For example, Canadian young adults aged 20 to 24 and 25 to 34 who smoked reported that they were seriously considering quitting in the next 6 months at a prevalence of 61.7% and 71.5%, respectively [2]. Given evidence that quitting before the age of 40 reduces the risk of a tobacco-related death by as much as 90% [10], and that quit attempts decrease with age as patterns of tobacco use become engrained [2], helping young adults successfully quit smoking is a priority.

Finding effective solutions to help young adults quit smoking remains a challenge. Despite the existence of a myriad of evidence-based smoking cessation options [11], research suggests that younger adult smokers are particularly unlikely to seek treatment compared to older smokers [12-14]. For example, according to a survey investigating the use of cessation treatments, young adults aged 18 to 24 were half as likely to have used pharmacological (eg, nicotine replacement therapy NRT) or psychological (eg, advice from a health professional) treatments to aid with cessation as were older adults [14]. The underutilization of smoking cessation interventions by young adults combined with a lack of age-appropriate cessation interventions [15] and comprehensive marketing to younger populations by the tobacco industry [16] are major reasons for the lack of declines in young adult smoking rates. New strategies for reaching young adult smokers are needed. Recently, digital technologies have emerged as promising platforms to enhance tobacco control efforts directed toward this population [17].

Digital technologies have become ever more pervasive in young adults' everyday lives. According to recent statistics, young adults aged 18 to 29 lead the way in the use of mobile phones, both those that run apps (65%) and those that do not (93%) [18]. The use of mobile phone apps has become a focused means for engaging young adults. Not only are young adults most likely to download apps, but they are also the most intense users of apps [19]. It is not surprising, then, that young adults are the most frequent users of health-related apps. It has been reported

that 42% of those who seek health information through apps are young adults [20]. In addition, researchers have alluded to a trend toward increased use of mobile phones among lower socioeconomic status groups [21], increasing the likelihood of successfully delivering mobile phone-based health improvement interventions to traditionally hard-to-reach populations [22].

The use of mobile phone apps for health interventions, such as for smoking cessation, offers many unique benefits compared to traditional approaches, most notably because individuals can access these interventions anytime and in everyday settings [23] since assistance is immediately available when needed (eg, help in dealing with cravings). In addition, individuals have many opportunities to tap into various support networks [24] via their mobile phones, such as through social media. Support networks include those which are intervention related (eg, quit buddies and social networking sites associated with the intervention) and those related to their personal social networks (eg, personal contacts). In fact, social networks have been found to play a key role in young adults' smoking cessation success [13,25,26]. Furthermore, the increasing use of internal sensors in mobile phones provides reliable contextual data that can infer such things as geographical location and has enabled tracking of health behaviors, as well as the delivery of interventions that are tailored to specific contexts [24]. These features enabled by mobile phones are a clear advancement over websites and short message service (SMS) text messaging programs. Their high potential to boost user engagement [27] has been consistently documented as a strong predictor of smoking cessation [28-30].

There is a growing body of evaluative evidence demonstrating that mobile phone-based technologies can support smoking cessation. However, most of this evidence consists of studies evaluating the efficacy of mobile phone SMS text messaging interventions for smoking cessation [31]. Young adults have reported an interest in more intense mobile-based smoking cessation interventions, such as mobile phone apps, versus what is currently offered via SMS text messaging, [12,32,33]. Mobile phone apps have the ability to enrich the user experience with more information, components, and functionality [34]. As well, smoking cessation mobile phone apps now have enormous reach compared to quitlines and SMS text messaging interventions [27]. For these reasons, exploring the effectiveness of mobile phone apps is critical. Only two randomized controlled trials (RCTs) were found that evaluated the efficacy of a smoking cessation mobile phone app. One compared a mobile phone app to an SMS text messaging intervention for smoking cessation [35]. It was reported in this study that both the mobile phone

app and the SMS text messaging intervention predicted a significant increase in 30-day abstinence at 12 weeks [35]. Another pilot study tested the efficacy of a smoking cessation app based on acceptance and commitment therapy and found that it was feasible to deliver a theory-based mobile phone app with quit rates higher than the control condition [27]. Many mobile phone apps for smoking cessation exist that have the potential to integrate education, motivational techniques, quit plan assistance, linkages to support networks, quit coaches, and other functionalities that go beyond SMS text messaging [36]. Despite these functionalities, a recent systematic review reported that very few studies have been conducted to measure the outcomes of these apps, especially long-term outcomes [31]. A methodologically rigorous evaluation of mobile phone cessation technology is an identified gap in the published literature. The findings from this randomized controlled trial (NCT01983150) will help address this gap by determining whether mobile phone apps work for quitting and, more importantly, why they do or do not work. This is critical in light of an increasing push for mHealth scale-up [37].

Study Aims

The primary aim of this study will be to determine the effectiveness of the evidence-informed mobile phone app for smoking cessation, Crush the Crave, on reducing smoking prevalence among young adult smokers after 6 months. Crush the Crave was developed by an expert team based at the University of Waterloo who worked with a technology development team to design, prototype, evaluate, and revise the program over the course of 2 years. This study will represent the first full trial of the program as part of a population-level intervention. We expect that individuals randomized to the evidence-informed mobile phone intervention condition will

have higher 30-day point prevalence quit rates than individuals assigned to the control condition after 6 months.

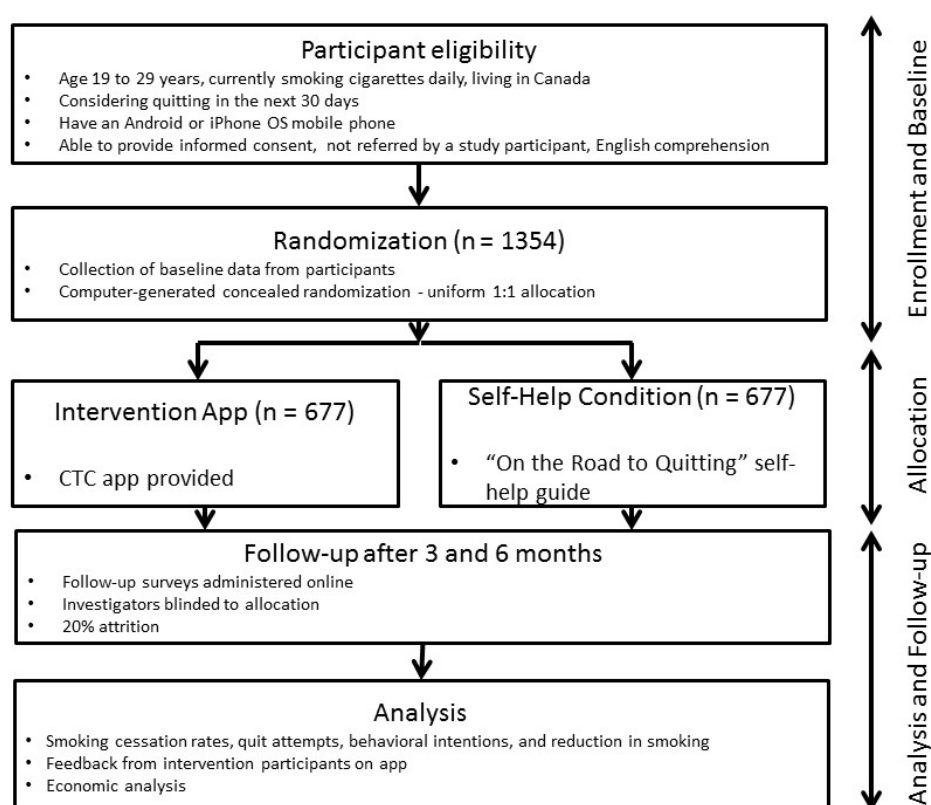
Secondary aims of this study include the following:

1. Examine more proximal outcome measures of cessation behavior, including 7-day point prevalence abstinence (PPA), time to cessation, the number of quit attempts, and the reduction in consumption of cigarettes.
2. Examine satisfaction and patterns of app use at 3 and 6 months, including the extent to which it promotes the use of established smoking cessation services, such as nicotine replacement therapy, health professional consults, medications, and quitline counseling.
3. Examine mediators of cessation outcomes between conditions, such as frequency of app use, use of cessation services, quit intentions, nicotine withdrawal, and the following psychosocial mediators: beliefs and attitudes, stress, social norms, self-efficacy, and perceived social support.
4. Compare the cost-effectiveness of the intervention and control conditions.

Methods

Design

This is a 6-month, two-arm, parallel randomized controlled trial (ClinicalTrials.gov Identifier: NCT01983150) to evaluate an mHealth intervention, Crush the Crave, for young adult smokers. Investigators and data collectors will be blinded to the group assignments. The protocol is in accord with the CONSORT-EHEALTH checklist [38]. See Figure 1 for a CONSORT-EHEALTH diagram of the proposed study design.

Figure 1. CONSORT-EHEALTH diagram of the study design.

Ethical Approval

The research methods to be used in this study have been approved by the Office of Research Ethics of the University of Waterloo (full ethics clearance granted on October 29, 2013, No. 19275).

Study Population

Young adult male and female Canadian smokers are the target population for this study. Participants will be eligible for the study if they are between the ages of 19 and 29, are currently smoking cigarettes daily, are residing in Canada, are considering quitting smoking in the next 30 days, have an Android (version 2.0 to 5.0) or iPhone (version 4.0 to 7.0) OS mobile phone, are able to provide informed consent, are able to comprehend English, and have not been referred to the study by an existing study participant (eg, a friend or family member already participating in the study) to avoid possible contamination bias.

Recruitment

Recruitment will be staggered over 32 weeks and will include online recruitment through Facebook advertisements and Kijiji, an online classified message board, with offline recruitment through classified newspaper ads, and a Can \$35 incentive for registering for the trial. Interested young adults will be referred to a website describing the trial. Potential participants will be screened at the entry webpage where their eligibility will be determined, informed consent will be sought, and registration for the trial will take place. A total of 1354 young adult smokers will be recruited. After providing informed consent and having completed the online baseline questionnaire, a

computer-generated email message will be sent back to the participants confirming registration and participants will then be randomly allocated to either the control or intervention arm. The control group will participate in a usual care, self-help guide intervention called “On the Road to Quitting” [39] and the intervention group will participate in the Crush the Crave program.

Randomization and Blinding

Participants will be allocated to intervention and control groups using a uniform 1:1 (control:intervention) allocation ratio and a computer-generated, simple randomization procedure. We will monitor the comparability between groups and, given the large sample size, the groups will be balanced based on three sources of variability with regard to smoking—sex, age, and cigarette consumption [40]. As documented in similar large trials, the likelihood is remote that, by chance, the two study groups may not be well matched for baseline characteristics [41-43]. Owing to the nature of the intervention, participants will be aware of the group to which they have been assigned. However, investigators and data collectors will be blinded to group allocation until completion of the trial.

Study Intervention

Overview

The intervention group will receive a comprehensive and evidence-informed smoking cessation mobile phone app, Crush the Crave, via the Internet. Crush the Crave enables users to customize a quit plan by choosing a quit date and then deciding whether to quit immediately or reduce the number of cigarettes they smoke every week up to their quit date. Crush the Crave

then assists smokers in staying on track by reminding them of how much money they have saved and how much their health improves over time after quitting. Based on contingency reinforcement, these milestones are tracked as rewards, which smokers can then choose to share with their social network via Facebook and Twitter, and rally support from friends and family. Participants can also link to the Crush the Crave Facebook community for additional support for quitting. Users of the app also receive supportive text messages tailored to their specific quit plan and where they are in the quitting experience. Crush the Crave will allow the intervention group to track their daily smoking habits and cravings as well as understand their craving triggers or psychosocial determinants by recording when, where, and why they were smoking. The app provides both graphic

and tabular performance feedback (see Figure 2). The app also provides online distractions to help smokers deal with their cravings. There are social media tools, such as a YouTube channel and opportunities to chat with friends online to distract a user until the craving subsides a few minutes later. Evidence-based information is available for assisting participants during the quitting experience on topics such as relapse and dealing with cravings. Furthermore, data are collected in real time to both support the user and to track the usage of the app allowing for push notifications, helpful reminders, and ongoing data collection. Finally, Crush the Crave provides access to evidence-based cessation services such as smoking cessation quitlines and explains the benefits of, and dispels myths around, nicotine replacement therapy.

Figure 2. Screenshots of the quit-smoking mobile phone app, CrushtheCrave.



Development of Crush the Crave

Crush the Crave was developed in early 2012 by a team of population health researchers, social media experts, and computer programmers as an evidence-informed, quit-smoking mobile phone and social media app for young adults aged 19 to 29. In addition to the input of key experts in the field of smoking cessation, development of the app incorporated Fiore's

practice guidelines for treating tobacco use and dependence [44] and principles of persuasive technology for behavior change [45]. The app was tested in March 2012 with eight focus groups consisting of 57 male and female young adult smokers on functionality, look and feel, and usability. Young adult smokers were engaged in the design and the naming of the app. Furthermore, the app was pilot-tested by over 300 smokers from April to June 2012. The pilot test revealed substantial

engagement with 319 users triggering 7931 events, including 1444 visits to the quit help page, 1415 visits to the awards page, and 1016 visits to the progress tracking page. The focus groups of young adult smokers provided positive feedback on app functionality and content. In light of evidence that existing smoking cessation mobile phone apps are not developed by health professionals or academics, do not draw on behavior change theories or techniques, and do not have content aligned to clinical guidelines and other evidence-based practices [22,46], Crush the Crave is a relatively novel intervention in the area of smoking cessation.

Standard Self-Help Condition

The control group will receive a standard, print-based self-help guide known as “On the Road to Quitting” [39] that has been recently developed by Health Canada for young adult smokers. This guide builds on an original guide that has been available for adult smokers for more than 10 years and includes evidence-based content for smoking cessation [47]. Participants will be able to both view and download the self-help guide via the Internet and can request a printed version of the guide. A print-based self-help guide was chosen as the control intervention because evidence from systematic reviews and meta-analyses of RCTs using printed self-help materials has demonstrated that there is no smoking cessation benefit from structured self-help printed materials [48-51].

Therefore, it has been determined that the effect of print-based self-help material is comparable to no treatment. In addition, a standard self-help control condition facilitates recruitment as it is problematic to offer participants a no-treatment option for a quit-smoking study.

Data Collection

Baseline Questionnaire

Baseline data will be collected via a self-administered, online questionnaire completed by all consenting participants in both intervention and control groups. The baseline questionnaire will include the following demographic items: age, sex, ethnicity, marital status, education, income, and employment status. The following variables related to tobacco consumption will also be recorded: current smoking status, amount smoked, number and duration of past quit attempts, intentions to quit in the next 6 months, and the degree of nicotine dependence. Participants will also be asked a series of psychosocial questions, including beliefs and attitudes about quitting, self-efficacy or confidence in quitting, perceived stress and social support, and social norms related to smoking. Furthermore, participants will be asked about experience with mobile phone apps and self-help, use of NRT, and other cessation aids/supports, such as quitlines.

Questionnaire for 3- and 6-Month Follow-Up

Follow-up data will be collected from the same participants at 3 and 6 months in the same manner as the baseline questionnaire. In addition to the questions asked at baseline, participants will be asked core smoking status questions, including whether they have smoked any cigarettes or used other tobacco products, even a puff, in the last 30 days, 7-day point prevalence abstinence, number of quit attempts, and the

reduction in cigarette consumption. Participants will then be asked questions on nicotine withdrawal, level of support received from friends and family for quitting smoking, additional cessation services that they sought for helping to quit, overall satisfaction with the app or self-help guide, use of the app or guide, opinions and beliefs about the app or guide, and challenges they experienced in quitting smoking. A modified Dillman method [52] for the online survey questionnaires will be used and up to 10 attempts (email and telephone) will be made to reach participants if they do not complete the online questionnaire within 2 weeks of the 3- and 6-month follow-up periods. Questionnaires will be pilot-tested with a convenience sample of young adult smokers.

Outcome Measures

Primary Outcome Measure

The primary outcome measure will be self-reported, 30-day point prevalence abstinence from smoking at 6 months, operationalized as not having smoked any cigarettes, even a puff, or used other tobacco products in the last 30 days [53]. Biochemical validation of smoking status will not be done as a Cochrane Review of Internet-based interventions for smoking cessation found that very few studies used this method given the difficulties in obtaining samples [54]. In addition, accurate estimates of the prevalence of cigarette smoking among Canadians can be derived from self-reported smoking status data [55].

Secondary Outcome Measures

Secondary outcome measures are as follows:

1. The 7-day point prevalence abstinence at 6 months [53,56], the number of quit attempts (ie, how many times did participants stop using tobacco for 24 hours or longer over the past 6 months [57,58]), and the reduction in consumption of cigarettes [59].
2. Satisfaction, app utilization metrics, such as frequency of use and use of smoking cessation services (eg, NRT, health professional consults, medications, quitline counseling, and e-cigarettes).
3. Beliefs and attitudes, stress [59], social norms [57], behavioral intentions to quit smoking [58], degree of nicotine dependence and nicotine withdrawal [60], self-efficacy [61,62], and perceived social support [61,62].

Recent research on e-cigarette use has found the use of e-cigarettes is increasing rapidly, and research has found evidence of dual-use. Young adult smokers do not necessarily view e-cigarettes as cessation aids, as some consider them a complement and substitute for smoked cigarettes [63,64]. The prevalence of e-cigarette use amongst the cohort of young adult smokers, and the extent to which e-cigarette use mediates the primary outcome, will be investigated.

Process Measures

For process measures, we will monitor downloading of the app and app usage via the tracking of events triggered when participants use the app (eg, connects with social support, seeks information on smoking, and tracks progress). For tracking, we will use Web-analytic data via Google Analytics and a secure

database of app usage which records events triggered with a time stamp. For example, on a per-user basis we will track when a user logs into the app, number of user clicks on the “Smoke” or “Crave” buttons, and achievement of awards. Aggregate Google Analytics metrics will include visits, page view counts, and average time spent on a page.

To obtain a more in-depth understanding of the potential barriers to, and facilitating factors of, uptake of the mobile phone intervention, we will conduct semistructured interviews with a subsample of participants in the intervention group. To maximize variation (eg, age, sex, and level of satisfaction with the app), participants will be purposively recruited via email or telephone to participate. Sampling will be driven by saturation of themes. In keeping with previous studies [65], we anticipate the need to conduct approximately 40 interviews. Interviews will take place via telephone by a project team member with experience in qualitative interviews and will last 30 to 45 minutes. We will seek feedback on the app utilization, opinions and beliefs about the app, acceptability of the mobile phone intervention, participants’ specific likes and dislikes, and their perceived utility and satisfaction with each of the mobile phone intervention components. Interviews will be digitally recorded and transcribed. Interview transcripts and sociodemographic data will be entered as a project in the qualitative data software program, NVivo version 10. Study team members trained in qualitative methods will use an iterative process to understand the themes and key issues arising from the data.

Sample Size and Power Calculations

Sample size calculations are based on a superiority trial [66,67] and are focused on the difference in the objective measure of the primary outcome event—30-day point prevalence abstinence from smoking—between intervention and control groups. Assuming a ratio of 1:1 for intervention to control subjects, an alpha of .05, power of 80%, and an effect size equal to a 50% increase in self-reported abstinence—17% in the intervention versus 11% in the control condition—the required sample size is 524 per group, for a total of 1048 participants using a two-tailed test on proportions [68]. The 50% increase in effect is reasonable and conservative based on trials of interventions using other mobile and Web-based technologies [41,69,70]. The estimated 11% abstinence rate in the control condition is based on the Ontario Tobacco Survey young adult smokers cohort study where in a sample of 592 young adult smokers, 68 (11.5%) were abstinent at the 6-month follow-up [71]. The 11% abstinence rate is what is expected to occur with a standard self-help condition and is similar to other trials that have tested the effect of self-help materials, with validated 6-month cessation rates of 5% to 15% [50,51]. Based on the experience of similar interventions [41,69], an overall estimate of 20% attrition translates into quit rates of 8.8% in the control condition and 13.6% in the intervention. Therefore, the total sample size required for each group is 677, for a total of 1354 participants.

Analysis Plan

Statistical Analysis

The intention-to-treat principle will be followed for statistical analyses and the imputation method for missing data will be

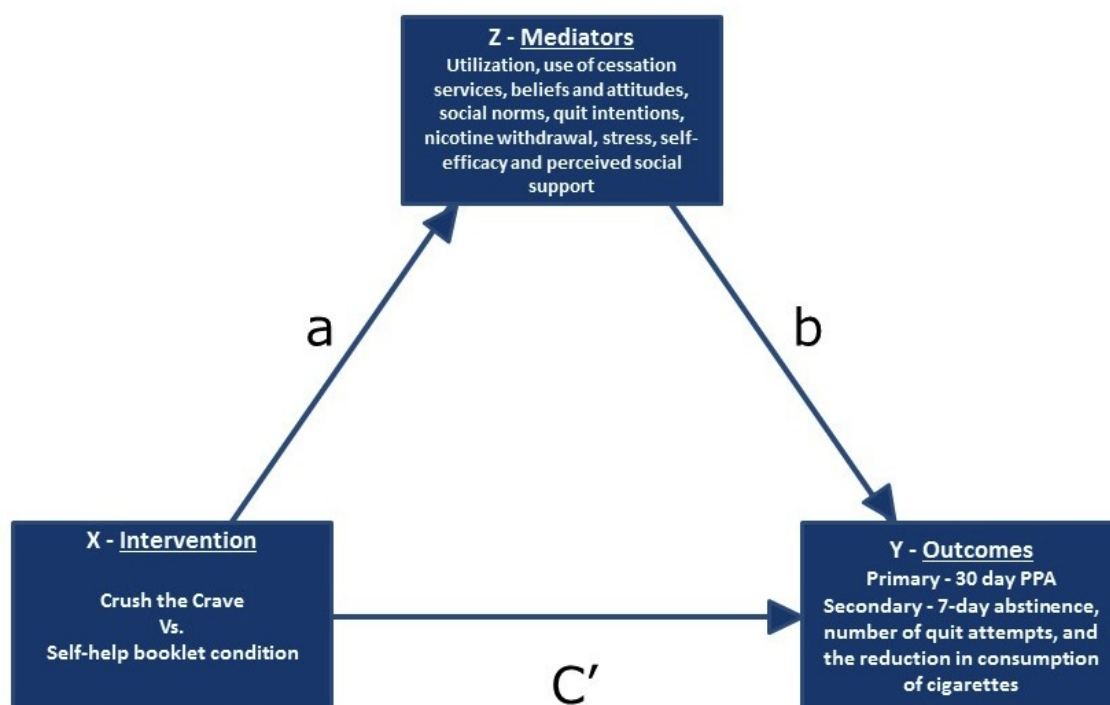
conservative whereby nonresponders will be classified as smokers. Characteristics will be compared between the groups at baseline, at 3-month follow-up, and at 6-month follow-up using independent *t* tests for continuous variables, or chi-square tests for categorical variables as appropriate. Mann-Whitney *U* tests will be used where data are not normally distributed. Preliminary analyses using models appropriate for the distribution of the variables will be undertaken to determine variables that differ between treatment groups, and between those with complete and incomplete follow-up data. Any variables showing a significant difference will be used in models as covariates to adjust for imbalances between the groups.

The primary response variable—30-day abstinence at 6-month follow-up—will be analyzed in a logistic regression model with the treatment group as the main explanatory variable. Age, sex, and level of addiction will be included, as well as other covariates, to adjust for any differences between the groups. The coefficient for the treatment group will be tested at the 5% level using a likelihood ratio test. Evidence against the null hypothesis that the coefficient is zero will indicate a significant difference between the treatment groups, after adjustment for covariates that differ between the groups.

Secondary analyses that involve comparisons of 7-day abstinence, quit attempts, and consumption levels will be conducted using generalized linear models that consider the distribution of the response variable (eg, Poisson models for numbers of quit attempts) and special features of the data (eg, zero-inflated Poisson models for quit attempts, if necessary). Similarly, variables such as satisfaction, use of e-cigarettes, and use of cessation services will be modeled using generalized linear regression models that include the indicator variable for condition.

The Preacher and Hayes bootstrapping method will be used to provide point estimates and confidence intervals to assess the significance or nonsignificance of a mediation effect, as it provides an increase in power and does not require the normality assumption to be met [72]. The mediation analyses will proceed by first estimating the difference in the outcome variable between the treatment and control groups, adjusting for age and sex as necessary, and then estimating the difference between the conditions for the mediating variables using bootstrapping. Finally, mediating variables and the treatment group indicator, along with covariates, will be entered into models for the primary and secondary responses. This will allow for an investigation of the role the mediators play in accounting for the differences between conditions. For example, use of e-cigarettes, higher levels of dependence, lower levels of self-efficacy, and low perceived social support might mediate quit success, for example, lower quit rates (see Figure 3). Additional secondary analyses will look at models for the response variables involving a treatment group indicator, covariates, and interactions between covariates and the treatment group indicator. These models will examine whether the relationships between the outcome and covariates differ between the conditions. They will also help to identify potential mechanisms, for example, frequency of app usage, by which the intervention might be operating. Statistical analyses will be performed using SAS version 9.4.

Figure 3. Mediation model. Conceptual diagram depicting Intervention (X), Outcome (Y), and Mediator (Z) variables, as well as hypothesized relationship (a), action (b), and outcome (C') pathways for examination in the mediation analyses.



Economic Analysis

The lifetime incremental costs and benefits of the Crush the Crave mobile phone app added to current practice will be estimated from a government perspective using a Markov model adopted in previous economic evaluations of smoking cessation interventions [73]. All costs associated with development of the app and research will be excluded. The costs of delivering the intervention will be assessed by measuring and valuing the incremental resources used [73], including the costs of app maintenance (eg, costs to maintain the server and keep the app working on new operating systems) and the cost of the moderator for the social networking component. A number of brief questions will be included in the follow-up questionnaire concerning the use of NRT, quitlines, and other cessation services to ascertain these costs. Following a methodology proposed by Drummond et al [74], cost-effectiveness will be measured in terms of cost per quitter (6-month continuous abstinence—30-day point prevalence), cost per life year gained, and cost per quality-adjusted life year (QALY) gained for smoking-related diseases—lung cancer, stroke, myocardial infarction, chronic obstructive pulmonary disease, and coronary heart disease—between the intervention and control groups. The incremental cost-effectiveness ratio will also be measured in a manner similar to other studies [75]. To account for the timing of events, costs and consequences will be discounted at 3% [74]. To ensure the robustness of our cost-effectiveness estimates, we will conduct multivariate sensitivity analysis using Monte Carlo simulation. Key input parameters to be examined will include, but will not be limited to, discount rate, intervention costs, quit rates, and unit costs of smoking-related diseases.

Results

This trial is currently open for recruitment. The anticipated completion date for the study is April 2016.

Discussion

Principal Findings

The Crush the Crave trial will evaluate a comprehensive evidence-informed mobile phone intervention for reducing smoking prevalence among a large sample of young adult smokers. To the best of our knowledge, this is one of three published mHealth protocols to assess the effect of a comprehensive and evidence-informed mobile phone app for smoking cessation, and one of the first to evaluate the impact of mHealth smoking cessation self-management on a large sample of young adult smokers. At the time of writing, there were eight trials underway regarding smoking cessation and mobile phone apps (ClinicalTrials.gov) and only two studies that have published findings on the effect of mobile phone-delivered smoking cessation interventions [27,35]. Bricker et al [27] conducted a double-blind randomized trial with a small sample of adult smokers on a theory-based mobile phone app as the intervention versus the National Cancer Institute's smoking cessation app as the control and found overall quit rates of 13% in the intervention condition versus 8% in the control condition. Conversely, Buller et al [35] compared a mobile phone app with SMS text messaging for a small sample of young adult smokers. They found that the mobile phone app intervention was feasible for delivering

cessation support but did not appear to move smokers to quit as quickly as SMS text messaging. The large sample of young adult smokers participating in the Crush the Crave trial will allow for a determination of what factors mediate quitting success through the use of an evidence-informed mobile phone app. In addition, it is one of very few studies to our knowledge that considers the cost-effectiveness of an mHealth intervention for smoking cessation among young adults [75].

Common criticisms have been made regarding mHealth research designs and trial descriptions [76]. Few large samples and adequately powered randomized controlled trials have been completed to date and many of those that have been done are of short duration and do not fully describe or assess the implementation of the mobile phone intervention. The Crush the Crave trial has been developed to address these concerns with a rigorous design, large sample size, 3- and 6-month follow-up periods, and attention to monitoring the process of implementation and utilization of the intervention. This will allow for sufficient explanation so that others can replicate the intervention [38]. As mHealth technology evolves rapidly, the Crush the Crave trial will allow researchers and policy makers to know which aspects of the intervention worked and which did not [77]. In addition, the development of Crush the Crave involved the target audience and it has been suggested that

engaging the users of mHealth interventions is a contributing factor to their adoption and success [78].

Limitations

A limitation of this study is the lack of an effect size for the control group self-help condition for determining sample size. However, systematic reviews and RCTs of printed self-help interventions for young adult populations support the effect size estimate chosen [48-51].

Conclusions

It is evident that the young adult population of smokers is interested in mHealth technology for helping them quit smoking [24]. If the proposed trial finds support for effective delivery of smoking cessation interventions via mobile phone apps to help young adults quit, it would provide evidence to move forward and include technology-based interventions as part of existing smoking cessation efforts made by health care providers. It would also inform the development of future apps, provide a deeper understanding of the factors that drive change in smoking behavior, and improve the design of existing apps. This study will provide data on the potential of including mHealth technology in population-based smoking cessation interventions as a strategy to economically and effectively reach young adults, and ultimately reduce the prevalence of smoking in this age demographic.

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Authors' Contributions

NBB led the conceptualization and design of the study and DH, CDN, GEG, RW, CMB, KAG and KSB contributed to the design of the study. NBB and LLS drafted the manuscript. NBB, LLS, DH, CDN, GEG, RW, CMB, KAG and KSB critically revised the manuscript for important intellectual content. NBB and DH are co-principal investigators and CDN, GEG, RW, CMB, KAG and KSB are co-investigators on the research funding application. LLS provided administrative, technical, and material support. NBB and DH supervised the study. NBB is the guarantor.

Conflicts of Interest

None declared.

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Abbreviations

NRT: nicotine replacement therapy

PPA: point prevalence abstinence

QALY: quality-adjusted life year

RCT: randomized controlled trials

SMS: short message service

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Protocol

Clinical Effect Size of an Educational Intervention in the Home and Compliance With Mobile Phone-Based Reminders for People Who Suffer From Stroke: Protocol of a Randomized Controlled Trial

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Abstract

Background: Stroke is the third-leading cause of death and the leading cause of long-term neurological disability in the world. Cognitive, communication, and physical weakness combined with environmental changes frequently cause changes in the roles, routines, and daily occupations of stroke sufferers. Educational intervention combines didactic and interactive intervention, which combines the best choices for teaching new behaviors since it involves the active participation of the patient in learning. Nowadays, there are many types of interventions or means to increase adherence to treatment.

Objective: The aim of this study is to enable patients who have suffered stroke and been discharged to their homes to improve the performance of the activities of daily living (ADL) in their home environment, based on advice given by the therapist. A secondary aim is that these patients continue the treatment through a reminder app installed on their mobile phones.

Methods: This study is a clinical randomized controlled trial. The total sample will consist of 80 adults who have suffered a stroke with moderate severity and who have been discharged to their homes in the 3 months prior to recruitment to the study. The following tests and scales will be used to measure the outcome variables: Barthel Index, the Functional Independence Measure, the Mini-Mental State Examination, the Canadian Neurological Scale, the Stroke Impact Scale-16, the Trunk Control Test, the Modified Rankin Scale, the Multidimensional Scale of Perceived Social Support, the Quality of Life Scale for Stroke, the Functional Reach Test, the Romberg Test, the Time Up and Go test, the Timed-Stands Test, a portable dynamometer, and a sociodemographic questionnaire. Descriptive analyses will include mean, standard deviation, and 95% confidence intervals of the values for each variable. The Kolmogorov-Smirnov (KS) test and a 2x2 mixed-model analysis of variance (ANOVA) will be used. Intergroup effect sizes will be calculated (Cohen's d).

Results: Currently, the study is in the recruitment phase and implementation of the intervention has begun. The authors anticipate that during 2015 the following processes should be completed: recruitment, intervention, and data collection. It is expected that the analysis of all data and the first results should be available in early-to-mid 2016.

Conclusions: An educational intervention based on therapeutic home advice and a reminder app has been developed by the authors with the intention that patients who have suffered stroke perform the ADL more easily and use their affected limbs more actively in the ADL. The use of reminders via mobile phone is proposed as an innovative tool to increase treatment adherence in this population.

Trial Registration: ClinicalTrials.gov NCT01980641; <https://clinicaltrials.gov/ct2/show/NCT01980641> (Archived by WebCite at <http://www.webcitation.org/6WRWFmY6U>).

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KEYWORDS

stroke; ADL; environment; patient adherence; mobile apps; mobile health

Introduction

Stroke is the third leading cause of death and the leading cause of long-term neurological disability in the world [1-3]. In Europe, 250 people per 100,000 suffer strokes each year, and this trend is worsening with time [1,4]. More than half of all patients who survive a stroke suffer a severe disability that causes limitations in their independent functioning and their performance of activities of daily living (ADL) [1,3-5]. The prevalence of stroke is around 2% in people over 20 years of age, increasing to 6 to 7% for those over 65. In men, 66.5% of strokes occur in people over 65 years old, while in women this percentage increases to 80.3% [6,7].

Researchers have examined the impact of stroke on patients who have suffered one and they have shown that cognitive, communication, and physical weakness combined with environmental changes frequently cause changes in roles, routines, and daily occupations [8-11].

Stroke patients often receive treatment from a multidisciplinary team, such as physiotherapy or occupational therapy, during their stay in hospital or in a rehabilitation service after home discharge [5,12-14]. There are even some cases in which stroke survivors receive aerobic and endurance training [15], strength, balance, and coordination training [16], a comprehensive geriatric intervention [17,18], or functional activity training [19] at home.

Another type of treatment is educational intervention, which is used in patients with different pathologies and even with professionals, thanks to its proven effectiveness [20-23]. Educational intervention combines didactic and interactive intervention [24], which combines the best choices for teaching new behaviors since it involves the active participation of the patient in learning [23]. The effectiveness of this intervention lies in the fact that patients synthesize and apply what they have learned, which is a reinforcement learning behavior [20,21]. In turn, the educational intervention can offer cost savings in the rehabilitation process because of the possible reduction in patient visits to their general practitioner, the emergency department, and/or specialists, as well as reduction in the use of drugs [25].

Some studies have shown the application of this type of intervention in people who have suffered a stroke as a means to reduce the risk of secondary stroke [26]. Educational intervention in this population remains unusual, however, despite being in great demand, due to the lack of information individuals often encounter in their rehabilitation process [26,27]. Therefore, in order to allow for continuity and applicability to the previous rehabilitation treatment received in the hospital, we propose an educational intervention at home for people who have suffered a stroke and who have been discharged to their homes in the 3 months prior to recruitment to the study. The therapist—using a tool for home therapeutic counselling—will perform an ergonomic assessment of the home and of the execution of the ADL by the participant. Subsequently, based on the items not presented in the tool, he or she will provide advice on the correct

or easiest way to perform ADL, on which adaptations they should make at home, and on what kind of technical assistance could be useful for them [28,29].

Patient satisfaction regarding information and knowledge about treatment are key to adherence to this therapy by patients with long-term diseases [30]. Nowadays, there are many types of interventions used to increase adherence to treatment, such as Web-based programs, video conferencing, or other means that are available due to technological advances [31,32].

Furthermore, mobile phones are increasingly being used in clinical practice to assess patients or for more precise tracking [32-35]. The development of mobile phone apps has favored diagnosis and early intervention in people who have suffered, or will suffer, a stroke [33-35]. Memory-aiding therapeutic apps have helped to improve the results of interventions for stroke patients as a result of the inclusion of the patients as an active part of the treatment [32].

Therefore, in this study we propose the development of a mobile phone app that acts as a daily reminder of the advice that was given to patients by the therapist during the educational intervention in their homes.

The aim of this study is that patients who have suffered stroke and have been discharged to their homes improve the performance of ADL in their home environments, following the restrictions caused by the stroke, after having been given advice by the therapist. A secondary aim is that these patients continue the treatment through a reminder app installed on their mobile phones (mHealth).

The hypothesis of this study is that patients who have suffered stroke will perform the ADL more easily and use their affected limbs more actively in the ADL after an educational intervention. The use of reminders via mobile phone is proposed as a tool to increase treatment adherence.

Methods

Design

This study is a clinical randomized controlled trial (RCT) and will be conducted following the CONSORT rules for reporting [36]. This trial has been registered with ClinicalTrials.gov (NCT01980641).

Participants

The total sample will consist of 80 adults who have suffered a stroke with moderate severity (score between 0 and 49 on the Barthel Index [37]), who have been discharged to their homes in the 3 months prior to recruitment to the study [28]. The sample will be taken from the Carlos Haya Hospital complex in Málaga, Spain.

Individuals with dementia or other severe cognitive impairment (scoring 0 to 17 in the Mini-Mental State Examination) will not be included [38].

Randomization

In stage 1, the sample will be divided into two groups of 40 participants each—experimental group and control group. The allocation and the randomization will be performed by a blinded researcher. The assignment of subjects to each group will be made through a system of sealed envelopes. Subsequently, for the pilot study in stage 2, we will create a group that will receive the app reminders on their mobile phones—the mobile phone group—and another group that will not receive the app reminder—the no mobile phone group. Group allocation will depend on whether the participant has a mobile phone and if its characteristics are adapted to the requirements of the study.

Educational Intervention

The therapist will go to each participant's home and perform an ergonomic assessment of the home. The therapist will also assess the execution of ADL by the participant using the home therapeutic advice for people who suffer stroke (HTAS) tool, which is a checklist of 60 items—the therapist will mark those items he valued as deficient. Later, with the experimental group, the therapist will mark on the participant's advice sheet those items that were rated negatively and will advise them on how to solve these shortcomings. With this advice, the therapist will educate participants on the correct or easiest way to perform their daily tasks, on which adaptations they should make at home, and on what kind of technical assistance could be useful for them. Previous studies on the impact of stroke in patients have demonstrated that cognitive, communication, and physical weakness combined with environmental changes frequently cause changes in roles, routines, and daily occupations [8-11].

In stage 2 of the study, the app will be installed on the mobile phones of participants in the mobile phone group, which will remind them of the advice previously offered by the therapist. The timing of reminders will differ for each participant depending on the amount of advice they received. However, in the 18 weeks of the app being used, each piece of advice will be given as a reminder three times. The mobile phone will beep once for each piece of advice and the participant must check

and mark the option indicating whether he has complied with the advice or not. Participants who will take part in the app intervention will have to answer at least 80% of the messages.

The app used in the study is called isoTimer (see Figure 1) and will be installed on participants' phones who have a mobile phone with Android OS 3.2 or higher. For correct use of the app, the Google Calendar app will also be installed through which educational advice will be implemented and synchronized on the day and time scheduled by the researcher.

Because of the complications that can occur in this population with the use of mobile phones, the app has been designed to open and start working automatically when the mobile phone is switched on. At no time does the participant have to open the app.

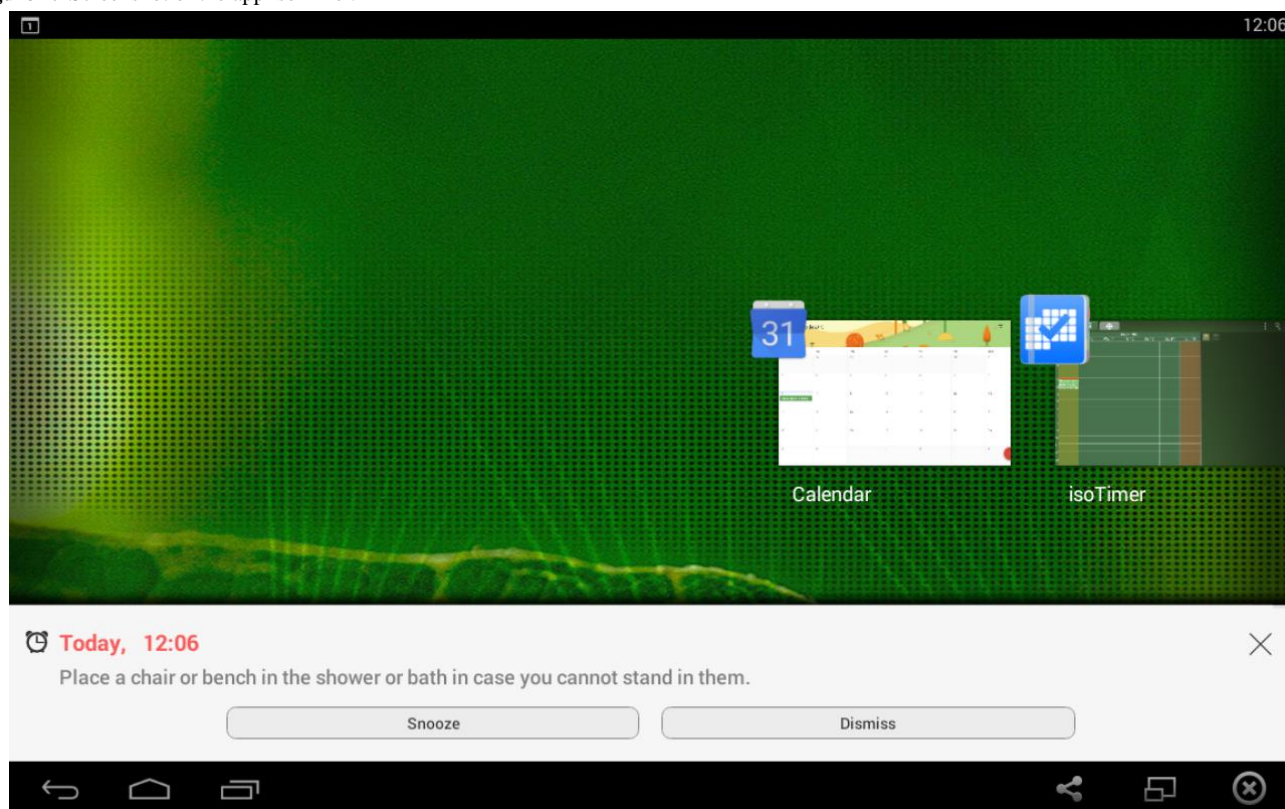
The app works as a reminder, so that the daily educational advice will appear on the screen and the participant must indicate whether the task has been carried out. These responses will be saved in the participants' mobile phones and then the researcher will download them to be added to the database.

Ethical Considerations

To carry out this study we will follow the guideline for Good Clinical Practice (GCP) from the International Conference on Harmonisation (ICH), thus guaranteeing protection of the rights, safety, and welfare of trial subjects in accordance with the principles of the Declaration of Helsinki. This will also guarantee the credibility of the clinical trial data.

Before any intervention, each participant and his/her family will be presented with an information sheet and an informed-consent form. This form will explain the study (the voluntary nature thereof), the protection of personal data in accordance with the Organic Law on Personal Data Protection 19/55, as well as their freedom to leave the study at any time they choose.

When the agreement is signed, a copy will be given to each participant, which they will hand in at the clinical trial.

Figure 1. Screenshot of the app isoTimer.

Outcome Measure

The outcome measure of this study will allow us to know and assess the level of patient dependency, cognitive ability, quality of life, social support, and physical condition. All of these factors will be measured by the Barthel Index, the Functional Independence Measure, the Mini-Mental State Examination, the Canadian Neurological Scale, the Stroke Impact Scale-16, the Trunk Control Test, the Modified Rankin Scale, the

Multidimensional Scale of Perceived Social Support, the Quality of Life Scale for Stroke, the Functional Reach Test, the Romberg Test, the Time Up and Go test, the Timed-Stands Test, a portable dynamometer, and a sociodemographic questionnaire (see [Table 1](#)).

In addition, visits to the emergency department, the general practitioner, and specialists after discharge from hospital to home, as well as taking drugs associated with stroke, will be controlled.

Table 1. Outcome measures of the study.

Test or scale (acronym), reference	Measure	Items, n	Statistical treatment, reference	Variable type
Barthel Index (BI) [39-41]	Level of dependence	10	$\kappa_w=.93$ (95% CI 0.90-0.96) random effects modeling [42,43]	Main
Functional Independence Measure (FIM) [39]	Level of dependence	18	ICC ^a =.124-.661 [44]	Secondary
Mini-Mental State Examination (MMSE) [38]	Cognitive disability	11	ICC=.69 [45]	Secondary
Canadian Neurological Scale (CNS) [46]	Cognitive and motor function	7	$\kappa=0.76$ [47]	Secondary
Stroke Impact Scale-16 (SIS-16) [48]	Quality of life	16	ICC=.70-.92 [49]	Secondary
Trunk Control Test (TCT) [50]	Trunk control	4	$\rho=.76$, $P<0.001$ [51]	Secondary
Modified Rankin Scale (MRS) [52]	Functional independence	1	Rater 1: $\kappa=.81$, .94 and Rater 2: $\kappa=.95$, .99 [53]	Secondary
Perceived Social Support Scale (MSPSS) [54,55]	Social support	12	$\rho=.72-.85$ [54]	Secondary
Quality of Life Scale for Stroke (ECVI-38) [56]	Quality of life	38	ICC=.81-.96 [56]	Secondary
Functional Reach Test (FRT) [57]	Stability	NA ^b	ICC=.90-.95 [58]	Secondary
Romberg Test (RT) [59]	Balance	NA	ICC=.84-.97 [60,61]	Secondary
Time Up and Go (TUG) [62]	Balance, mobility, and fall risk	NA	ICC=.96 [58]	Secondary
Portable dynamometer [63]	Strength in the upper limbs	NA	ICC=.98 [60]	Secondary
Timed-Stands Test (TST) [64]	Strength in the lower limbs	NA	ICC=.994 [65]	Secondary
Sociodemographic questionnaire	Sociodemographic data	25	NA	Secondary

^ainterclass correlation (ICC).

^bnot applicable (NA).

Procedure

Overview

This goal of this study is to implement an educational intervention at home for patients who have suffered a stroke, in order to optimize or improve their performance of ADL after discharge from the hospital to their homes. This intervention will be divided into two stages. In stage 1, assessments will be carried out for the experimental group and the control group, but educational advice will only be provided to the former. Stage 2 comprises a pilot program in which a reminder app will be installed on the mobile phones of some of the participants of the experimental group in order to increase treatment adherence.

Stage 1

Stage 1 will begin with the collection of the participants' demographic data through a questionnaire and by conducting various tests to measure primary and secondary outcome variables. Subsequently, the ergonomics of the home and the implementation of ADL from both the experimental group and the control group will be assessed using the HTAS tool, which was developed by the authors. For the development of the tool, a literature review was performed using the PubMed electronic database and by reviewing different practice guides about stroke. Subsequently, the HTAS tool was evaluated by a panel of

experts composed of occupational therapists, physiotherapists, nurses, caregivers, and patients.

Following the assessment of each participant's home and his or her performance of ADL, the therapist will provide the participants of the experimental group with a list of pieces of advice related to the HTAS tool items that were evaluated negatively. The advice will be aimed at changing the environment in which the participants execute the ADL. This may include facilitation in the execution of the ADL, promoting the active use of the affected side of the body in such execution, or to show them the most appropriate way of performing certain tasks according to their situation after the stroke.

The evaluation of the variables and the execution of the advised tasks will be carried out at participants' homes 2 and 4 weeks following the initial assessment. Researchers will analyze and compare the data obtained from the outcome variables of the experimental group and the control group to check whether the educational intervention was effective in patients who have suffered stroke and who have been discharged to their homes. If the hypothesis is confirmed, the educational intervention would be implemented in the control group.

Stage 2

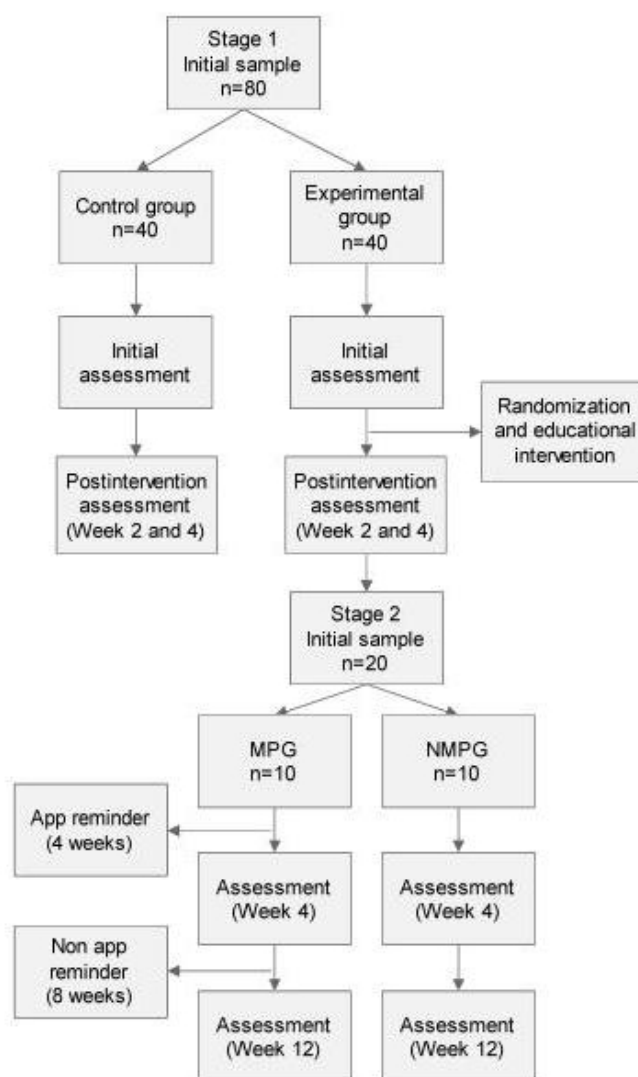
For the pilot study in stage 2, one group will receive the app reminders on their mobile phones—mobile phone group—and another group will not—no mobile phone group. Placement in

the first group depends on whether the participant has a mobile phone and if its characteristics are adapted to the requirements of the study. The app will provide the advice previously given by the therapist in the participants' homes. The timing of reminders will differ for each participant depending on the amount of advice given. However, in the 4 weeks of the app being used, each piece of advice will be given three times. The mobile phone will beep once for each piece of advice and the participant must check and mark the option indicating whether he has or has not complied with the advice. After this period,

the outcome variables will be analyzed in both groups to check whether there are differences between the two groups.

After 8 weeks, and after having removed the app from mobile phones of the mobile phone group, we will reanalyze the outcome variables. Will do this by testing both groups to see whether the mobile phone group participants have continued to perform the advised tasks provided by the therapist, and if differences still exist between them and the no mobile phone group. If so, a reminder system will be implemented in the no mobile phone group. Figure 2 shows the outline of the entire study protocol, including steps in stage 1 and stage 2.

Figure 2. Flowchart of the study protocol. MPG: mobile phone group, NMPG: no mobile phone group.



Statistical Analyses

Descriptive analyses will include mean, standard deviation, and 95% confidence intervals of the values for each variable. The normality of the variables will be performed using the Kolmogorov-Smirnov (KS) test. Preintervention values prior to each condition will be compared. A 2x2 mixed-model analysis of variance (ANOVA) with supplementation (mobile phone group or no mobile phone group) as the between-subjects variable, and time (pre- and postintervention) as the within-subjects variable will be used. Intergroup effect sizes

will be calculated (Cohen's *d*). An effect size <0.2 reflects a negligible difference, between ≥ 0.5 and ≤ 0.8 a moderate difference, and ≥ 0.8 a large difference. A *P* value $< .05$ will be considered statistically significant. Data will be analyzed using SPSS version 19.0.

Sample Size Calculation

A power analysis was conducted using the program G*Power 3.1. A priori, a sample of approximately 40 participants per group for the stage 1 intervention is needed to detect a significant difference (17.3 in the FIM [39]) between the

experimental group and the control group (effect size $d=0.59$, $\alpha=.05$, $\beta=.08$). The randomization will be performed by a blinded researcher.

Results

Currently, the study is in the recruitment phase and implementation of the intervention has begun. The authors anticipate that during 2015 the following processes should be completed: recruitment, intervention, and data collection. It is expected that the analysis of all data and the first results should be available in early-to-mid 2016.

Discussion

Implications of the Study

The aim of this study is that patients who suffer stroke and who have been discharged to their homes improve the performance of ADL in the home environment, in spite of the restrictions caused by the stroke, after advice given by the therapist. A secondary aim is that these patients continue the treatment through a reminder app installed on their mobile phones (isoTimer).

Some studies have analyzed the ergonomics of the workplace through a tool and other studies have carried out different kinds of treatments at home on people with stroke. Because of this, it is thought that an educational intervention at home with people who have suffered a stroke and who have been discharged to their homes could be an innovative and necessary study.

The use of a mobile phone reminder app is an innovative method because the mobile phone has been used with people who have suffered a stroke, but it has not been used before as a means of improving adherence to treatment at home with this population.

This method could result in advances in facilitating the continuity of treatment in this population once they return to their homes.

This study could be a breakthrough in the treatment of people who have suffered a stroke and who have been discharged to their homes, since during the first months the largest changes occur and it is essential to continue the rehabilitation treatment received at the hospital. The HTAS tool would allow a proper assessment of the home environment and the implementation of the ADL by the patient, bringing some useful advice that will guide them through the process of recovery of functional independence. Also, being able to have an app that reminds them of the advice provided by the therapist ensures that all patients who suffer a stroke and are discharged to their homes do not encounter barriers in the environment, and that they can advance their functional independence. Additionally, this continuity in the treatment without interruption and its early implementation would favor not only the recovery and rehabilitation of the patient, but could also result in cost savings in care services.

Conclusions

The aim of this project was that patients who have suffered a stroke and been discharged to their homes can continue with the rehabilitation treatment received at the hospital. This treatment should occur without interruption and in the shortest time possible in order for patients to achieve the highest possible level of functional independence, and so that their readaptation to the environment is optimal. To do this, there will be a therapist intervention using the HTAS tool and an app (isoTimer) that will communicate reminders of the advice. The potential effectiveness of this educational intervention lies in the active participation of the patient.

Authors' Contributions

AC-V contributed to the conception of this study. JAM-B, AC-V, and MG-S drafted the protocol and the manuscript. All the authors have given final approval of the version to be published.

Conflicts of Interest

None declared.

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Abbreviations

ADL: activities of daily living
ANOVA: analysis of variance
BI: Barthel Index
CNS: Canadian Neurological Scale
ECVI-38: Quality of Life Scale for Stroke
FIM: Functional Independence Measure
FRT: Functional Reach Test
GCP: Good Clinical Practice
HTAS: home therapeutic advice for people who suffer stroke
ICC: interclass correlation
ICH: International Conference on Harmonisation
KS: Kolmogorov-Smirnov
MMSE: Mini-Mental State Examination
MRS: Modified Rankin Scale
MSPSS: Perceived Social Support Scale
NA: not applicable
RCT: randomized controlled trial

RT: Romberg Test
SIS-16: Stroke Impact Scale-16
TCT: Trunk Control Test
TST: Timed-Stands Test
TUG: Time Up and Go

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Protocol

Scaled-Up Mobile Phone Intervention for HIV Care and Treatment: Protocol for a Facility Randomized Controlled Trial

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Abstract

Background: Adherence to prevention, care, and treatment recommendations among people living with HIV (PLHIV) is a critical challenge. Yet good clinical outcomes depend on consistent, high adherence to antiretroviral therapy (ART) regimens. Mobile phones offer a promising means to improve patient adherence and health outcomes. However, limited information exists on the impact that mobile phones for health (mHealth) programs have on ART adherence or the behavior change processes through which such interventions may improve patient health, particularly among ongoing clients enrolled in large public sector HIV service delivery programs and key populations such as men who have sex with men (MSM) and female sex workers (FSW).

Objective: Our aim is to evaluate an mHealth intervention where text message reminders are used as supportive tools for health providers and as motivators and reminders for ART clients to adhere to treatment and remain linked to care in Ghana. Using an implementation science framework, we seek to: (1) evaluate mHealth intervention effects on patient adherence and health outcomes, (2) examine the delivery of the mHealth intervention for improving HIV care and treatment, and (3) assess the cost-effectiveness of the mHealth intervention.

Methods: The 36-month study will use a facility cluster randomized controlled design (intervention vs standard of care) for evaluating the impact of mHealth on HIV care and treatment. Specifically, we will look at ART adherence, HIV viral load, retention in care, and condom use at 6 and 12-month follow-up. In addition, participant adoption and satisfaction with the program will be measured. This robust methodology will be complemented by qualitative interviews to obtain feedback on the motivational qualities of the program and benefits and challenges of delivery, especially for key populations. Cost-effectiveness will be assessed using incremental cost-effectiveness ratios, with health effects expressed in terms of viral load suppression and costs of resources used for the intervention.

Results: This study and protocol was fully funded, but it was terminated prior to review from ethics boards and study implementation.

Conclusions: This cluster-RCT would have provided insights into the health effects, motivational qualities, and cost-effectiveness of mHealth interventions for PLHIV in public sector settings. We are seeking funding from alternate sources to implement the trial.

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KEYWORDS

implementation science; mobile phones; mHealth; HIV; AIDS; HIV care and treatment; cluster-RCT; Ghana

Introduction

Background

Adherence to prevention, care, and treatment recommendations among people living with HIV (PLHIV) is a critical challenge facing HIV service delivery programs. Myriad personal, social, and systems level barriers influence adherence among PLHIV on antiretroviral therapy (ART). Difficulty managing treatment and forgetting to take medications or attend clinic appointments are common reasons for poor adherence [1-4]. Lack of social support, negative perceptions, poor communication with providers, and stigma and discrimination also may limit adherence [2,3]. In resource-poor settings, adherence challenges are amplified by structural and economic constraints such as residential dispersion that requires long travel times and has costs associated with travel and wage loss [3,4]. Key populations are disproportionately less likely to access and remain in care and treatment compared to the general population of PLHIV [5]. Good clinical outcomes depend on high adherence; consistent adherence to ART regimens is associated with reduced HIV RNA (viral load) levels, decreased transmission, higher CD4 cell counts, lower health care costs, and overall improved quality of life [6-9].

Mobile phones offer a promising means to improve patient adherence and health outcomes because they are private, portable, increasingly affordable, and nearly ubiquitous (88% use in Ghana [10]). Mobile phone interventions provide a means to address several of the key barriers to good adherence by providing reminders for care and a direct connection to health providers and facilities [11,12]. Research conducted in East Africa has shown that texting (short message service, SMS) reminders to ART clients' mobile phones improved adherence and health [13-15]. Due to favorable findings from mobile phones for health (mHealth) interventions, limited proven adherence and treatment support interventions [3,16,17], and the need for a combination of interventions to address the complexities of adherence, mHealth programs are rapidly being scaled up globally [18,19].

Justification for Study

Implementation research is needed to keep pace with mHealth program scale-up to provide guidance for optimal delivery and effectiveness of mHealth programs [3,18,20-22]. Although mobile phone reminders have been shown to improve medication adherence among new ART clients in a few health facilities, a trial conducted in one health facility in Cameroon with continuing ART clients did not improve adherence [21]. We have limited information about mHealth program effects on continuing ART clients and subpopulations in large-scale, public-sector HIV care and treatment programs where the majority of PLHIV in Ghana seek HIV care. Since women and key populations eg, female sex workers (FSW), and men who have sex with men (MSM), continue to be disproportionately affected by HIV, it is critical to assess effectiveness among these groups [3,5]. Moreover, the need for adherence support

may be greater among continuing ART clients as opposed to new ART clients, as adherence challenges grow over time [23,24]. The support provided by mHealth interventions may influence ART clients' adherence as well as retention in HIV care and treatment and adherence to other prevention and care directives such as use of condoms. Furthermore, there is little evidence about the motivational behavior change processes through which mHealth interventions improve patient health [25]. It is imperative to understand when, why, and how interventions work to develop a sound understanding of effectiveness to inform program scale-up [25,26]. Lastly, decision-makers and program implementers need mHealth cost-effectiveness data to guide resource allocation [14,27,28].

Study Objectives

The main study goal is to evaluate the impact, implementation, and cost-effectiveness of a mobile phone adherence support intervention delivered to patients on ART in large-scale public sector health services in Ghana, especially for women and key populations. The study has three objectives: (1) to evaluate mHealth intervention effects on patient adherence and health outcomes; (2) to examine the delivery of the mHealth intervention for improving HIV care and treatment; and (3) to assess the cost-effectiveness of the mHealth intervention.

Methods

Study Design

This study is a two-arm, facility randomized, open, controlled trial. Of the public-sector health facilities in Ghana that provide ART to PLHIV in conjunction with the National AIDS Control Program (NACP)/Ghana Health Services (GHS), 40 will be randomly and equally allocated to receive either the mHealth intervention or standard of care. Approximately 1600 PLHIV who have been on ART for at least 6 months and who own a mobile phone will be enrolled. Data collection will occur at baseline and 6 and 12 months post-enrollment. A subsample of women and intervention participants from key populations including MSM and FSW, and health care providers and managers at intervention facilities, will be randomly selected to complete qualitative interviews at follow-up.

Facility Eligibility and Recruitment

The study will be implemented in health facilities in five regions of Ghana that have sufficient numbers of people on ART in public sector facilities and are accessible to study staff for data collection and monitoring. Specifically, eligible facilities must have at least 150 patients enrolled on ART, follow the national Ministry of Health guidelines for ART care and treatment [29], be a NACP/GHS facility, and they must not be extremely difficult to access due to very remote location or poor infrastructure for reaching the facility. To maximize facility homogeneity while balancing representativeness of clinics and participants, facilities meeting eligibility criteria will be stratified by geography (urban and rural) and number of ART patients receiving services. Facilities then will be recruited for study

participation in proportion to their representation in the eligible facility population across strata until the target number of facilities is attained.

Participants

Eligibility

To be in the study, participants must be between 18-49 years old, currently receiving ART at public sector facilities, enrolled in ART for a minimum of 6 months, and own a mobile phone. They also must live near the study facility and plan on residing near it for 12 months following study enrollment. Study volunteers who are currently participating in another HIV adherence study or who were involved in the mHealth pilot intervention will be excluded.

Recruitment

Potential participants initially will be informed about the study by implementing partners at support groups and at the study clinics. In addition, peer educators who work with PLHIV will tell MSM and FSW about the study. Facility staff and clinicians also may apprise patients about the study. Interested PLHIV will be encouraged to speak with study staff at the facilities during predetermined study recruitment times; these times will be arranged during medication refill days or other times when substantive numbers of potential participants are likely to be in study facilities. Screening and enrollment will take place for interested volunteers in a private location in each health facility, where eligible participants will be enrolled until the target sample size is attained. Participants from intervention facilities will be enrolled into the mHealth intervention at enrollment. It is estimated that recruitment will take approximately 6 months to complete.

Informed Consent

Participation will require written informed consent. Informed consent will be administered in English or Twi, the local language.

Randomization

Once facilities are identified and agree to participate, they will be randomized within strata (urban/rural and number of ART patients) to the intervention or control group. Facility assignment will be revealed to field staff just prior to study initiation. Group assignment is needed before enrolling individuals and no blinding is possible. Eligible individual participants will receive the intervention or standard of care according to the assignment of the facility where they receive their HIV care and ART medication.

Intervention: LifeLine

The mobile phone intervention, termed LifeLine, was developed and piloted as one component of the United States Agency for International Development (USAID) Ghana project, Strengthening HIV/AIDS Partnerships with Evidence-based Results (SHARPER). SHARPER partners with 25 local non-governmental organizations (NGOs), the Ghana AIDS Commission, and the Ghana Health Service to increase healthy behaviors and access to HIV prevention and care services among MSM and FSW and their intimate partners, and PLHIV and

their partners. LifeLine is a one-way text messaging service; participants receive but do not respond to the messages via mobile phone. A local technological partner will provide support for the fully automated LifeLine program, including enrollment of LifeLine participants from mobile phone numbers provided by study staff.

The LifeLine intervention sends daily text message ART reminders at no cost to PLHIV upon enrollment into the program. The messages were developed with input from both PLHIV and members of key populations. Many different messages have been developed and will be rotated approximately every 3 months. Daily messages refer to "medication" rather than drugs or ART, and data from pilot testing showed high acceptability, recall, and sharing of messages. Sample LifeLine messages include:

Taking my medicine every day makes me stay healthy to work and take care of myself and family."

It is my life and I will make sure that nothing stops me from taking my medicine."

Good morning! How are you today? Please remember your medication. Stay blessed!"

Control

In the control condition, participants will receive usual care. This consists of the essential package of services specified by the Ministry of Health Guidelines for Antiretroviral Therapy in Ghana [29]. Services include ART adherence monitoring through self-report and pill counts, in-depth discussion of ART adherence at each treatment visit, regular CD4 testing, management of sexually transmitted infections (STIs), management of opportunistic infections, referrals and linkages within and outside the health system, and regular patient reports through the health information system. For patients who have been on ART for 6 months or more, regular visits are scheduled every 3 to 6 months unless there is an urgent health need, and CD4 testing is conducted twice per year.

Sample Size

We calculated that a sample size of 40 clinics with 40 completed participants per clinic on average for a total of 1600 PLHIV is needed to detect a 15% improvement in adherence at 12 months, with 84% power and a (two-tailed) significance level of 0.05. These calculations assume that, at baseline, 65% of enrolled participants will be defined as having good ART adherence according to national guidelines (>90% adherent in Ghana). We have assumed approximately 20% participant attrition over the life of the study and have increased participant recruitment targets accordingly (N=2000). These calculations assume an intra-class correlation coefficient (ICC) of 0.05 due to the enrollment of participants and randomization by facility. The correlation (stability) in self-reported adherence over time that occurs within both clinics and subjects is assumed to be .50.

Study Measures

Health Outcomes

Study health outcomes are ART adherence [23,30,31], viral load, retention in care [32,33], and condom use (Table 1).

Routine data collection for clinical care related to ART adherence and health outcomes and tracking already occurs in the public sector NACP/GHS health facilities. These data are collected electronically by trained Strategic Information/

Monitoring & Evaluation staff employed by each facility and supervised by the NACP/GHS. This will be augmented with a supplemental data collection form administered to all participants at enrollment and 6 and 12-month follow-ups.

Table 1. Overview of measures.

Measures	Indicators	Data source	M0	M6	M12
Health Outcomes					
ART adherence	Self-report in given time period; self-report via visual analog scale; pharmacy refills	Clinical care data; pharmacy records	X	X	X
Viral suppression	Undetectable plasma HIV viral load (<400 copies/ml)	Laboratory testing	X		X
Retention in care	Client tracking outcomes: stopped treatment, known to be dead, or lost to follow-up	Clinical care data		X	X
Condom use	Consistency of use and use at last sex with different partners (main, casual)	Clinical care data	X	X	X
Implementation Measures					
Health behaviors	Self-efficacy for taking ART; perceived social support for adherence; motivation for adherence; perceived quality and access to providers/facilities	Supplemental data collection	X	X	X
mHealth intervention adoption	Satisfaction with intervention; message receipt and recall; privacy and confidentiality concerns; message relevance and trust; message sharing; actions taken on receiving messages; use of additional mobile phone services	Supplemental data collection; qualitative interviews		X ^a	X ^a
Fidelity of intervention delivery	Messages sent on-time; messages received	Technology system logs; supplemental data collection		X ^a	X ^a
Provider perspectives	Benefits and challenges to intervention implementation; intervention impact on PLHIV quality of care; integration with health system	Qualitative interviews			X ^b
Costing Measures					
Costs of routine care	Training; additional staff time; travel for counselors; other	Intervention tracking tool; costing forms	X	X	X
Costs of intervention	Initial software and hardware/server costs; maintenance for software and server; maintenance for tech support; monthly reporting; SMS costs; message development	Intervention tracking tool; costing forms	X	X	X

^aMeasures administered in intervention facilities only.

^bProvider interviews will take place approximately nine months after intervention initiation in intervention facilities only.

Implementation Measures

This aspect of the study will use a theory-based evaluation approach to assess how and why the mHealth intervention works for PLHIV and key populations on ART [26]. The research will focus on how the mHealth intervention addresses behavioral, social, and cognitive change strategies. Study participants in both intervention and control groups will be asked about their motivation for good health and management of HIV disease in the supplemental data collection form. These health behavior constructs may influence the primary study outcomes, and they may mediate the impact of the mHealth intervention on these outcomes. In addition, to assess reasons for and barriers to mHealth intervention adoption, as well as consistency and timeliness of receipt of text messages, a few questions will be added to the supplemental data collection form for intervention

facilities only. Intervention fidelity also will be assessed through review of system logs from the technology provider to check for on-time and same-time of day delivery of text messages to intervention participants.

To explore implementation issues that may be unique for women and/or key populations living with HIV, qualitative in-depth interviews will further assess confidentiality and privacy concerns, message relevance and trust, and other program delivery and adoption issues, in addition to assessing opinions about the motivational aspects of the intervention. Interviews also will include questions about the social support function of mobile phones, probing on how the intervention may increase perceptions of social support from health care providers and PLHIV, as well as how social support may be increased by sharing of messages with family and friends. Finally, interviews will include questions about how participants' use of the

mHealth intervention may have affected their use of mobile phones for other information and services, particularly for women and key populations. A minimum of three interviews per intervention facility will be conducted.

The health care provider qualitative interviews will focus on benefits and challenges to implementing mHealth interventions in health facilities and with clients, as well as to integrating mHealth components into larger health systems in general. One health care provider and one manager will be interviewed in each facility.

Costing Measures

Costs will be assessed for implementing the standard of care in NACP/GHS facilities, as well as costs for implementing the LifeLine mHealth intervention. Information from NACP/GHS facility and SHARPER program records will be extracted to account for retrospective and prospective costs, detailed using an Intervention Tracking Tool (ITT) and accompanying prospective costing forms.

Analysis

Primary Analyses

Generalized estimating equations (GEE) will be applied to compare intervention and control arms on the key 6 and 12-month health outcomes. In order to adjust for variance in the outcomes at the facility-level, compound symmetric working correlation matrices will be used in all models. In order to maximize statistical power, all models will control for baseline measures of the outcomes. In addition, all models will include sex, stratification variables, and time on ART, as well as other covariates identified from the literature and to be specified in the final statistical analysis plan. Hypotheses will be tested at the 5% significance level for two-sided comparisons.

Mediation Analyses

In addition, we plan to explore the mediating effects of health behavior constructs such as self-efficacy for taking ART and using health services and perceived social support from health providers, PLHIV, and partners. In mediation analyses, we will estimate both the impact of the intervention on these factors as well as associations between these factors and the post intervention outcomes to partition any observed impacts of treatment into direct and indirect effects. The analytic approach will be based on path analyses using regression analyses or structural equation modeling.

Qualitative Analyses

A qualitative data software program, such as QSR Nvivo or QDA Miner, will be used to organize, code, and analyze all qualitative data. Inter-rater reliability checks will be conducted periodically during data coding and analysis, and quantitative coefficients such as Scott's Pi or Cohen's Kappa may be used to assess the extent of agreement between coders. Coded data will be analyzed for themes according to the study objectives and research questions. Data will be compared across women, men, and key populations (MSM and FSW) to identify similarities and differences in their reactions to and opinions about the mHealth intervention. Data from facility staff will be analyzed separately from intervention participant data.

Cost Effectiveness Analysis

To determine the incremental cost-effectiveness ratio (ICER) of LifeLine, we will relate incremental costs (the numerator) to health effects (the denominator). Specifically, the numerator for the ICER will be calculated as the additional costs associated with implementing the LifeLine program beyond the standard of care. The denominator for the ICER will be calculated from the change in proportion virally suppressed at 12-month follow-up in the LifeLine intervention group compared to the change in proportion virally suppressed in the standard of care group.

Sensitivity analyses will be conducted to model cost-effectiveness under different parameters, such as lower text message costs that may be negotiated with mobile network operators. A tornado diagram will be generated to visually represent the resulting sensitivity analyses to show the costs and savings associated with different scenarios. In addition, the World Health Organization (WHO) threshold for cost-effectiveness [34] of an ICER lower than three times gross domestic product per person will be considered in presenting results from cost-effectiveness analyses. Affordability also will be considered in evaluating cost effectiveness of the intervention; for example, intervention costs and the ICER will be compared to country expenditures on health.

Results

This study was funded through a competitive call for Implementation Science Research to Support Programs under the President's Emergency Plan for AIDS Relief (PEPFAR) Round 2. However, leading up to protocol review and approval, continued funding for the mHealth intervention under study became uncertain; as a result, there was not a guarantee that the intervention would remain active for the entire study period. Therefore, the funder and the study implementer made a mutual decision to terminate the study, and the study was terminated prior to ethics approval of the protocol. We are currently seeking funding from alternate sources to implement this study.

Discussion

Summary

To our knowledge, the current study would be the first clinical trial to examine the effects of mHealth for HIV prevention and care among PLHIV in a scaled-up public sector setting. Results from this study would inform development of guidelines for achieving improved clinical benefits and recommendations for mHealth service delivery, from the clinic to national and international policy levels. Findings also would contribute to understanding how mobile technology interventions motivate better health, as well as how they function when integrated into larger health systems. Furthermore, this study protocol may provide guidance to HIV and mHealth experts who are seeking to evaluate mobile phone programs for HIV prevention, care, and treatment. The protocol focuses on mHealth impact at the clinical, care, and behavioral levels; investigation of implementation issues unique to mHealth interventions; and

the costing component all are priorities for evidence generation in the area of mobile phones for health.

Limitations

There are a few study limitations worth noting. Supplementing routine data collection for ART clients with study-specific data collection reduces costs and participant burden; however, in collaboration with partners and facilities, great care will need to be taken to ensure high quality data, whether routine or study-specific, and across all time points. Self-reported adherence to ART has notable limitations, and we will complement self-reported data with objective measures from pharmacy, clinician, and laboratory data to provide a triangulated perspective on ART adherence. The health behavior constructs we will assess have rarely been evaluated in mobile phone interventions, but focus group data from LifeLine pilot participants suggests that the proposed constructs are impacted by mHealth programs. Finally, we will not be able to control external factors that may confound study results, such as medication supplies or health system challenges, civil or political

influences, or other health or technology programs occurring in study communities during the intervention period, although we will document these contextual factors to help with interpretation of findings.

Conclusions

This study is poised to make a substantive contribution to the evidence base for using mHealth strategies to improve HIV service delivery. Study results may advance the field of HIV service delivery by providing: appropriate and robust scientific methodologies for evaluating mHealth interventions for care and treatment; guidelines for achieving improved clinical benefits for specific populations (eg, women, key populations, time on ART) from mHealth reminders for care and treatment; recommendations (including cost-effectiveness) for service delivery programs and health systems that are planning or implementing mHealth interventions for care and treatment; and improved understanding of how mobile technology interventions motivate better health through use of behavioral, social, and cognitive strategies.

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Authors' Contributions

KL conceived the study and drafted the manuscript. KL, KG, and SS designed the trial. AL and SW contributed to trial design and study procedures. KG and SW developed the mHealth intervention. All authors read and approved the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ART: antiretroviral therapy
CD4: cluster of differentiation four
FSW: female sex worker
GEE: generalized estimating equations
GHS: Ghana Health Services
HIV: human immunodeficiency virus
ICC: intra-class correlation coefficient
ICER: incremental cost-effectiveness ratio
ITT: Intervention Tracking Tool
mHealth: mobile phones for health
MSM: men who have sex with men
NACP: National AIDS Control Program
PEPFAR: President's Emergency Plan for AIDS Relief
PLHIV: people living with HIV
RCT: randomized controlled trial
RNA: ribonucleic acid
SHARPER: Strengthening HIV/AIDS Partnerships with Evidence-based Results
SMS: short message service
STI: sexually transmitted infection
USAID: United States Agency for International Development
WHO: World Health Organization

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Protocol

The Mobile Insulin Titration Intervention (MITI) for Insulin Glargine Titration in an Urban, Low-Income Population: Randomized Controlled Trial Protocol

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Related Article:

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Abstract

Background: Patients on insulin glargine typically visit a clinician to obtain advice on how to adjust their insulin dose. These multiple clinic visits can be costly and time-consuming, particularly for low-income patients. It may be feasible to achieve insulin titration through text messages and phone calls with patients instead of face-to-face clinic visits.

Objective: The objectives of this study are to (1) evaluate if the Mobile Insulin Titration Intervention (MITI) is clinically effective by helping patients reach their optimal dose of insulin glargine, (2) determine if the intervention is feasible within the setting and population, (3) assess patient satisfaction with the intervention, and (4) measure the costs associated with this intervention.

Methods: This is a pilot study evaluating an approach to insulin titration using text messages and phone calls among patients with insulin-dependent type 2 diabetes in the outpatient medical clinic of Bellevue Hospital Center, a safety-net hospital in New York City. Patients will be randomized in a 1:1 ratio to either the MITI arm (texting/phone call intervention) or the usual-care arm (in-person clinic visits). Using a Web-based platform, weekday text messages will be sent to patients in the MITI arm, asking them to text back their fasting blood glucose values. In addition to daily reviews for alarm values, a clinician will rereview the texted values weekly, consult our physician-approved titration algorithm, and call the patients with advice on how to adjust their

insulin dose. The primary outcome will be whether or not a patient reaches his/her optimal dose of insulin glargine within 12 weeks.

Results: Recruitment for this study occurred between June 2013 and December 2014. We are continuing to collect intervention and follow-up data from our patients who are currently enrolled. The results of our data analysis are expected to be available in 2015.

Conclusions: This study explores the use of widely-available text messaging and voice technologies for insulin titration. We aim to show that remote insulin titration is clinically effective, feasible, satisfactory, and cost saving for low-income patients in a busy, urban clinic.

Trial Registration: Trial Registration: Clinicaltrials.gov NCT01879579; <http://clinicaltrials.gov/ct2/show/NCT01879579> (Archived by WebCite at <http://www.webcitation.org/6WUEgjZUO>).

(*JMIR Res Protoc* 2015;4(1):e31) doi:[10.2196/resprot.4206](https://doi.org/10.2196/resprot.4206)

KEYWORDS

patient care management; delivery of care; health care disparities; telemedicine; remote consultation

Introduction

Background

Diabetes disproportionately affects the poor and uninsured, who are more likely to suffer the severe health consequences of uncontrolled diabetes, including heart disease, death, stroke, blindness, renal failure, and nontraumatic lower limb amputations [1].

Diabetes care is quite complex. Patients often need to learn self-management (eg, monitoring home blood glucose), make multiple lifestyle changes (eg, diet, exercise), follow complex medication regimens, and attend multiple clinic appointments (eg, primary care providers, diabetic educators, specialists). In public hospitals and clinics that serve low-income populations, these appointment slots can be few and often occur during patients' work hours. Patients have to miss work, make arrangements for the children in their care, and arrange transportation to the clinic. These logistical and cost-related barriers to accessing clinic care contribute to the socioeconomic disparity in diabetes management [2,3,4,5].

Bellevue Hospital Center, located in New York City (NYC), primarily treats low-income, ethnically diverse patients [6]. The prevalence rate of diabetes in the hospital's Adult Primary Care Center (APCC) is 15%, compared to the rate of 10.5% in NYC and 9% in the US (hospital prevalence rate obtained from internal hospital database, HHC Patient Registry for Proactive Care) [6]. Many of these patients are advised to start insulin therapy, in accordance with the standard for diabetes care. Proper insulin treatment involves multiple steps, including the need for patients to communicate blood glucose values to a clinician who then adjusts the patient's insulin dose accordingly. Traditionally, this exchange of blood glucose data is achieved through face-to-face appointments with a clinician [7-11]. Given the many challenges low-income patients face attending frequent appointments, patients may struggle to have their insulin titrated regularly and the process of optimizing their dose is prolonged [9,12].

Mobile technology, especially mobile phones, may help alleviate the logistical barriers to care. Currently, 90% of US adults own a mobile phone, and 58% own mobile phones with advanced

operating systems (smartphones). While only 47% of low-income adults own an advanced mobile phone, 84% of low-income adults own any mobile phone (basic or advanced) [13]. Text messaging and voice calls are available on most basic mobile phones, making interventions using basic mobile phone technology a viable option for low-income populations.

Several studies have used text messaging to help patients manage their diabetes care, even among low-income populations [8,14-18]. Text messages have been used successfully to remind patients to carry out self-care (eg, monitoring home blood glucose levels) and to transmit this data to the clinician, thus ensuring that a home blood glucose log is available at the time of the next in-person visit. We also found studies where clinicians adjusted insulin doses remotely. In these studies, patients sent their blood glucose values to their clinicians by accessing the Internet. Clinicians could respond by uploading their advice via the Internet or through text message. These studies demonstrate the feasibility of the remote exchange of both blood glucose values and insulin dosage advice. However, they required patients to have access to the Internet and, in some cases, to navigate a website [8,17,19].

The Mobile Insulin Titration Intervention (MITI) incorporates the strengths of the studies above by using text messages as a prompt to remind patients to check their home blood glucose values and by allowing the remote exchange of actionable data, namely the receipt of the values and the transmission of titration advice. MITI builds upon the above studies by tailoring these interventions to low-income patients, requiring only texting capabilities to send the blood glucose values and a simple phone call to receive titration instructions. This intervention requires only a low-cost, basic-feature mobile phone, not an advanced mobile phone or Internet access, which our patients often do not have.

We designed the intervention to include both text messages and phone calls for insulin titration, rather than one or the other. Text messages act as a reminder to patients to check their blood glucose levels and can be automated to be sent to the patient at a given time of day. Text messaging also provides a simple and quick way for patients to send their blood glucose data to the clinician from any location, given their phones are able to send text messages. We included phone calls for the adjustment of

the insulin dose as a balanced approach between automated instructions (ie, insulin dosage sent via text, email, or Internet portal) and the personal nature of the in-person clinic appointment. Weekly phone calls give the patient an opportunity to discuss their treatment progress in real time with a clinician, while allowing the clinician to leave a voicemail with instructions if the patient is not available. This intervention is designed to alleviate the burden of in-person titration visits in a pragmatic manner, using basic technology available to our patient population.

Objectives

The objectives of this study are to (1) evaluate if MITI is clinically effective by helping patients reach their optimal dose of insulin glargine (defined in the *Outcome Measures* section), (2) determine if the intervention is feasible within the setting and population, (3) assess patient satisfaction with the intervention, and (4) measure the costs associated with this intervention.

Methods

Overview

The MITI study is a randomized controlled trial to evaluate a mobile phone intervention for insulin glargine titration. This trial has been registered at ClinicalTrials.gov (NCT01879579). We will recruit patients from Bellevue Hospital Center's Adult Primary Care Center who have type 2 diabetes and require insulin glargine titration. We will focus on glargine because it is the type of insulin used in our formulary. Using a parallel study design, patients will be randomized into either the MITI (intervention) arm or the usual-care (control) arm. Patients in the MITI arm will send their fasting blood glucose levels each weekday via text messages and have their insulin dose adjusted during phone calls with a diabetes nurse educator using a physician-approved algorithm. Patients in the usual-care arm will continue to receive their usual care, which includes scheduled clinic appointments to review daily blood glucose levels and to adjust their insulin dose. The primary outcome will be whether or not a patient reaches his/her optimal insulin glargine dose within 12 weeks.

Setting

Bellevue Hospital Center is a large tertiary care hospital within New York City's Health and Hospitals Corporation, the largest public hospital system in the United States and one of the largest safety-net providers. Bellevue Hospital's APCC cares for an ethnically diverse patient population, where 71% of the patients are nonwhite (41% Hispanic, 24% black, and 6% Asian). In the APCC, 76% of outpatient clinic visits are for patients who are either uninsured (31%) or have Medicaid (45%) [6]. Patients in this study will be recruited from the APCC, where the prevalence rate of diabetes is 15%.

Participants

We will recruit patients with diabetes who present to the Adult Primary Care Center. The inclusion criteria are as follows: (1) patients who are initiating insulin glargine treatment or require the titration of their existing insulin glargine dose, (2) English

or Spanish speaking, (3) most recent hemoglobin A1c (HbA1c) value is $\geq 8\%$, (4) able and willing to inject insulin, and (5) able and willing to provide informed consent. We will exclude patients who meet the following criteria: (1) on short-acting insulin, (2) on systemic glucocorticoids, (3) with sustained serum creatinine of ≥ 1.5 mg/dL for men and ≥ 1.4 mg/dL for women, (4) with documented hypoglycemia unawareness, and (5) diagnosed with type 1 diabetes.

Outcome Measures

The primary outcome will be whether or not a patient reaches his/her optimal insulin glargine dose within 12 weeks of enrolling in the study. Optimal insulin glargine dose is defined as the dose at which the patient has at least one fasting blood glucose value within the range of 80 to 130 mg/dL inclusive, or the maximum dose that can be safely administered to the patient. The research staff will record whether a patient has reached their optimal insulin dose at the time of the patient's weekly titration phone call (if in the MITI arm) or clinic appointment (if in the usual-care arm).

We hypothesize that the MITI arm will have a greater proportion of patients who reach their optimal insulin dose than the usual-care arm. Other clinical effectiveness outcomes include the time taken to reach optimal dose, the incidence of hypoglycemia, and the change in HbA1c levels between baseline and 3 months.

Feasibility measures include patients' text message response rate, ability of the diabetes nurse educator to reach patients for insulin titration, and the time spent by the diabetes nurse educator on the intervention.

We will measure patient treatment satisfaction at baseline and 3 months after study enrollment using the Diabetes Treatment Satisfaction Questionnaire. We will use an additional questionnaire—the "change" version of the Diabetes Treatment Satisfaction Questionnaire—to measure the change in the patient's treatment satisfaction between baseline and 3 months [20]. We will also use a semistructured interview to gather qualitative feedback from patients in the MITI arm. This will be administered when the patient has completed the intervention—by reaching their optimal insulin dose or when 12 weeks elapse.

We will collect data on the costs of insulin titration to compare the intervention to the established standard of care in the clinic. These outcomes include the time spent by patients traveling to the clinic, time spent in the waiting room prior to appointments, number and duration of insulin titration appointments, patient co-pays, and patient health care utilization (ie, the number of noninsulin-related medical clinic visits made at Bellevue during the 12-week study period).

Interventions

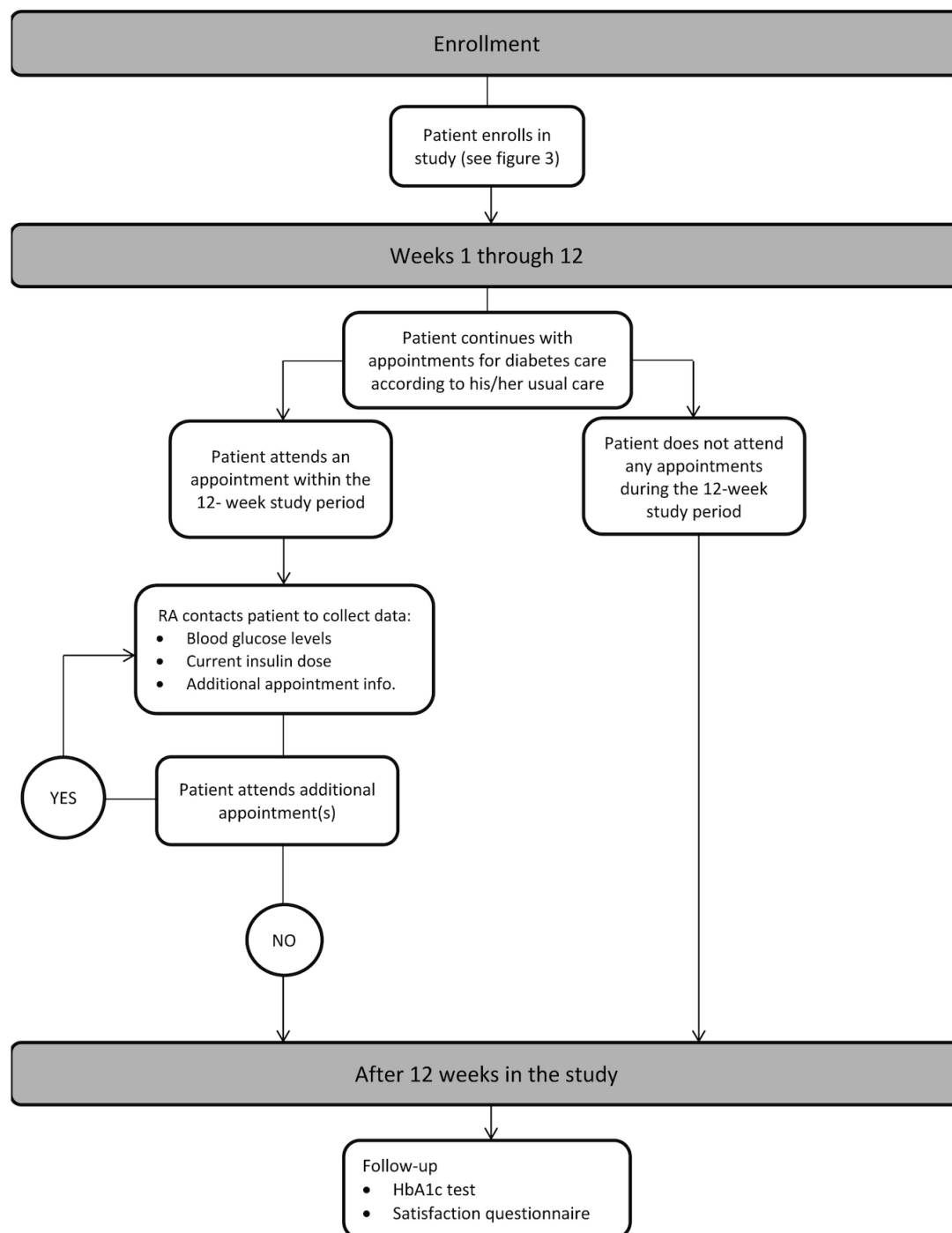
Usual-Care

Patients in the usual-care arm will continue with the treatment plan and appointments decided upon with their clinician prior to enrolling in the study (see Figure 1). According to the clinic's current practice, a clinician reviews the patient's fasting blood glucose log during appointments and titrates the insulin dose.

Our research assistant (RA) will collect data, such as fasting blood glucose readings, insulin dosage adjustments, and appointment duration, from patients after appointments, in-person or by phone, as well as appointment duration from

clinicians. These patients will continue to visit their primary care providers and have routine HbA1c tests according to the standard of care.

Figure 1. Usual-care flowchart.



Mobile Insulin Titration Intervention

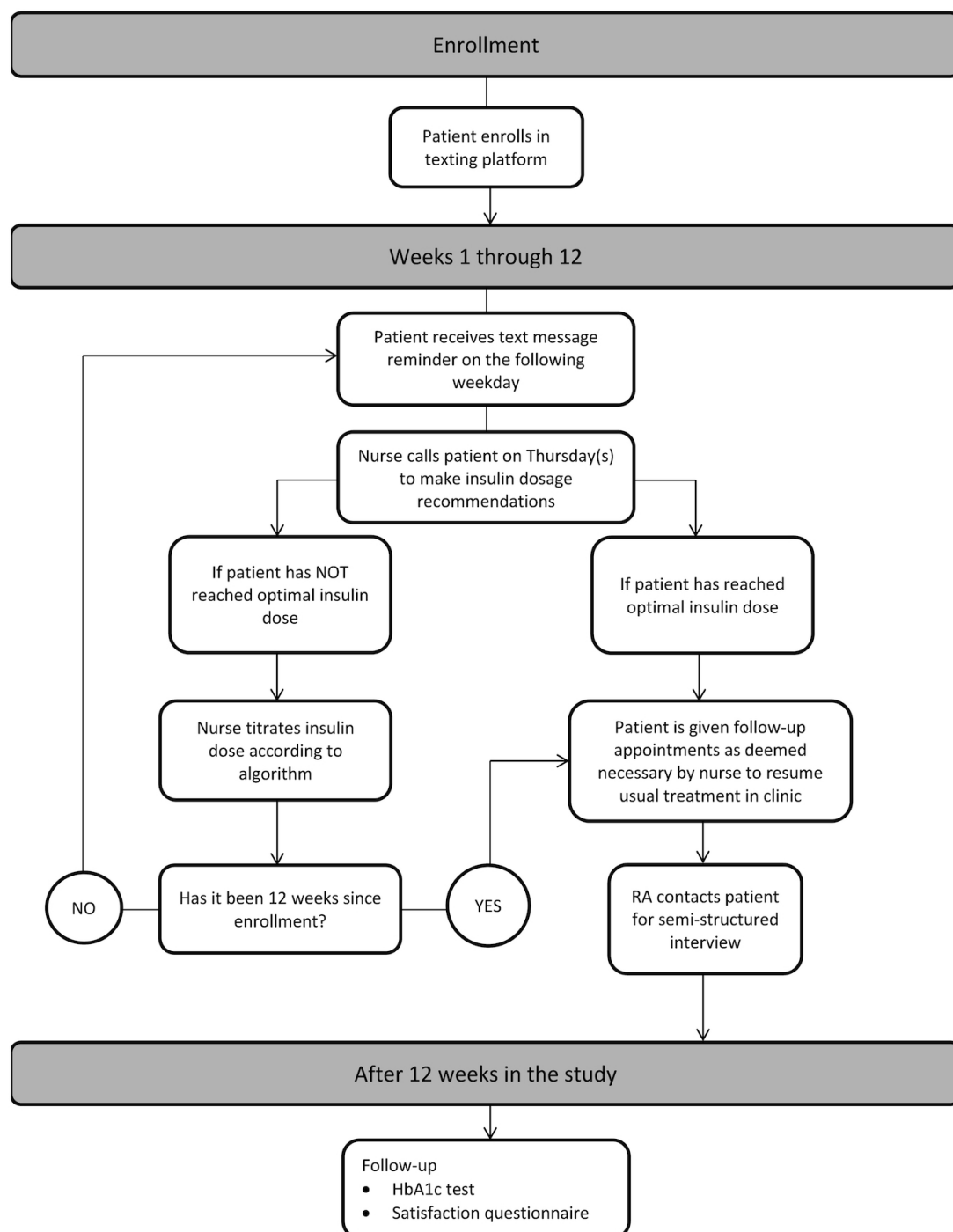
Patients in the MITI arm will sign up for a Web-based health management platform in the clinic with the assistance of the research staff. The platform allows patients and clinicians to communicate via text messaging. Patients will receive a text message each weekday from the platform requesting the patient's fasting blood glucose level for that day. The messages will be automatically delivered each morning at a time prespecified by

the patient, in either English or Spanish. Patients will respond via text message with their fasting blood glucose levels. Mobile phones can be provided to any patient who is otherwise eligible but does not have a mobile phone. It is implicit that a patient must be able to operate a mobile phone to participate in the study.

The diabetes nurse educator will check patients' responses on the secure Web portal each weekday and call any patient

reporting alarm values (ie, a blood glucose level <80 mg/dL or >400 mg/dL). Each Thursday afternoon, the diabetes nurse educator will call the patients to adjust their insulin dose according to a titration algorithm developed by physicians and nurses on the study team. The diabetes nurse educator may leave a voicemail with insulin titration instructions. If the patient cannot be contacted by phone, the diabetes nurse educator may call the patient's emergency contact upon her discretion. Another clinician may check text responses and make titration phone calls if the diabetes nurse educator is not available. If Thursday is a holiday, the titration calls can take place on another weekday.

This protocol of weekday text messages and weekly phone calls will continue for up to 12 weeks (see [Figure 2](#)), until the patient reaches their optimal insulin dose, or the patient chooses to withdraw from the study. Patients may attend appointments with their primary care provider during the intervention, but will not need to attend appointments specifically for diabetes management (eg, high HbA1c clinic or diabetes nurse educator appointments) within the primary care clinic. After completing the protocol, the patient will be transferred back to usual care in the clinic. The research team will arrange for follow-up appointments with the patient's primary care provider and, if appropriate, appointments with the diabetes nurse educator or high HbA1c clinic, so that the patient can resume their diabetes care through standard clinic visits.

Figure 2. Intervention (MITI) flowchart.

Follow-Up

Patients in both arms will be contacted by the RA at approximately 12 weeks in the study to remind them of their routine HbA1c test. The RA will also arrange to administer the Diabetes Treatment Satisfaction Questionnaire, either when the patient is present in the clinic for their blood test or via phone.

Implementation Challenges

During this pilot study, we refined our technological approach because our initial health management platform could not send text messages to prepaid mobile phones. Patients who had prepaid mobile phones either continued to attend in-person

clinic appointments for insulin titration or were provided a mobile phone to use for the duration of the study. We resolved this issue in 2014 when we switched to a different health management platform that could send text messages to any mobile phone.

Prior to May 2014, patients were stratified by whether the patient was initiating insulin therapy or having their existing insulin dose titrated, and by HbA1c level (8-11% or >11%). We removed the HbA1c stratification after finding that not all patients had an HbA1c value available in their medical record at the time of enrollment.

Intervention Standardization and Fidelity

To ensure that all patients receive the same level of care during the intervention, the diabetes nurse educator will use a script outlining what must be covered during an insulin titration phone call. The nurse will also use scripts to leave titration instructions via voicemail and for speaking with, and leaving voicemails for, the patient's emergency contact. These scripts were implemented in May 2014. The nurse can consult the principal investigator in real time if any event arises with a patient that is not outlined in the study protocol.

Sample Size (Power Analysis)

Our sample size is based on the hypothesis that the proportion of patients in the MITI group who reach their optimal insulin dose within 12 weeks will be significantly greater than the proportion of patients in the usual-care group who reach this goal. Based on the experience of clinicians treating our patient population at our study site, we expect that, at most, 50% of patients in the usual-care arm will reach their optimal insulin dose by 12 weeks. We expect at least 80% of patients in the MITI arm to reach this goal, since this arm will have weekly insulin titration phone calls, and frequent titration is associated with improved glycemic control [10,21,22]. Using Fisher's exact test with a 2-sided type I error rate of 5% to achieve at least 80% power, we need 44 subjects per group to detect a difference of 30% between 80% and 50%. Assuming a 10% drop-out rate by week 12, we need a total of 98 patients (49 per group).

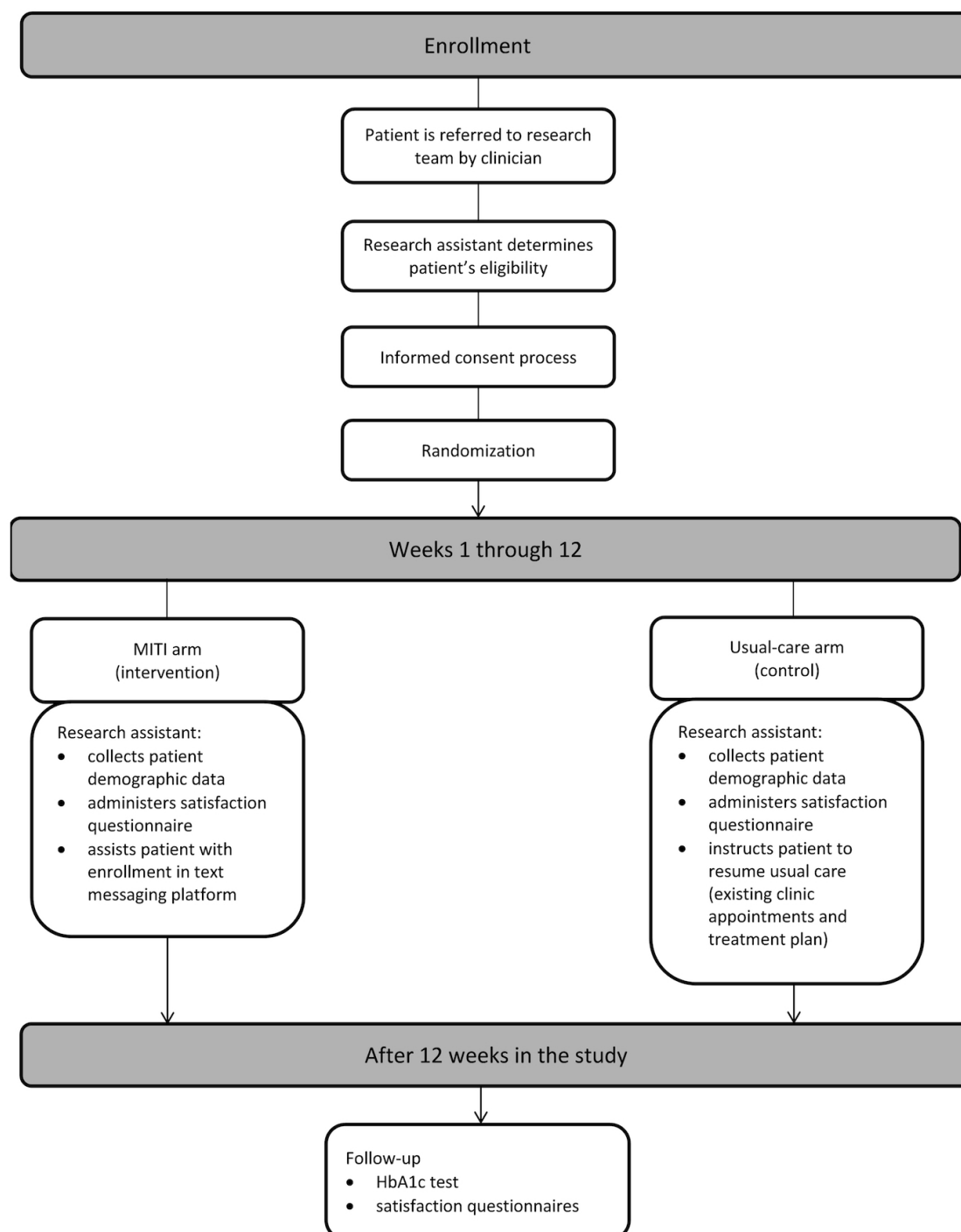
Recruitment, Randomization, and Retention

We will recruit patients from the Adult Primary Care Center. Clinicians can alert the research study staff of any patient who is interested in the study and may be eligible (see [Figure 3](#)).

The RA will also review the clinic's electronic medical records to identify patients that may be eligible for the study. The RA will screen the patient for eligibility, explain the study, and provide them with a consent form to read and sign in person at the Adult Primary Care Center. All patients must provide informed consent before participating in the study protocol.

Since patients will be randomized sequentially at the time they provide informed consent, we will use block randomization (block size of 4) to make sure the number of patients in each arm is approximately balanced at any time point during the study. Patients will be stratified by whether the patient is initiating insulin therapy or having their existing insulin dose titrated. The random allocation sequence will be computer-generated by a coinvestigator and concealed in presealed envelopes. The patient's arm assignment will be revealed to the patient and research team at the time of study enrollment by the RA. The research team and clinicians will not be blinded since the intervention requires that they alter the patient's treatment plan or, in the case of the usual-care arm, collect data from clinicians and patients regarding their appointments.

At the time of enrollment, patients will receive a US \$10 MetroCard to be used for travel to and from the clinic. Patients will receive a glucometer and a supply of test strips to ensure that they can test their blood glucose levels for the duration of the study. At approximately 12 weeks into the study, the research assistant will contact patients by phone to remind them to return to the clinic for their 3-month HbA1c blood test and complete the satisfaction questionnaire. Patients will receive an additional US \$10 MetroCard.

Figure 3. Enrollment flowchart.

Data Monitoring

A data and safety monitoring board is designated to meet quarterly, or sooner if necessary, to discuss any potential safety issues. In particular, the study team and the board will review any cases of hypoglycemia or hyperglycemia that occur among our patients (to assess the safety of our titration algorithm) and our ability to reach patients by phone (to ensure that our patients are being monitored regularly during the intervention).

Data Analysis

First, we will summarize all the baseline and follow-up measures using means and standard deviation (SD), medians and

interquartile range (IQR), or frequencies, and then compare them between the two arms. Second, we will test if baseline characteristics (eg, demographic measures and baseline HbA1c levels) are balanced between the two randomized arms. Third, to evaluate the intervention effects, we will use the chi-square test or Fisher's exact test for categorical outcomes (eg, whether or not a patient reaches optimal dose), Student's *t* test or Wilcoxon rank-sum test for continuous outcomes (eg, change in HbA1c levels, rate of hypoglycemia, scores on the Diabetes Treatment Satisfaction Questionnaire, number and duration of titration appointments, and patient health care utilization), and log-rank test for time to reach optimal dose. Fourth, we will

conduct multiple linear regression analyses for continuous outcomes and multiple logistic regression analyses for categorical outcomes to further evaluate the intervention effects, adjusting for some baseline characteristics and/or their interactions with the treatment assignment. At this stage, we will conduct multiple imputation to deal with the missing data problem. Finally, we will conduct descriptive analyses for other secondary outcomes, such as feasibility outcomes, patient travel time and waiting room time, and patient co-pays. We will also review the content of semistructured interviews to identify common themes in patient feedback.

Results

Recruitment for this study occurred between June 2013 and December 2014. We are continuing to collect intervention and follow-up data from our patients who are currently enrolled. The results of our data analysis are expected to be available in 2015.

Discussion

The MITI study builds upon lessons learned in previous interventions and presents an innovative approach to insulin

titration. It addresses the need for further research on mobile health interventions for diabetes and other chronic diseases. Research is especially needed in low-income populations who face numerous challenges in managing chronic illness.

The MITI study has a few limitations. We anticipate a small sample size for this study, which will limit our statistical power. We also have to consider volunteer bias, since those patients who choose to participate may not be representative of the population of patients we are seeking to treat (ie, those with type 2 diabetes in need of insulin titration).

While we use a strong study design (randomized controlled trial), our study is not blinded. Since our intervention directly affects the treatment our patients receive in the clinic, the patient's primary care provider and their other clinicians may become aware that their patient is participating in the study. In addition, those who are allocated to the usual-care arm will be contacted periodically by the research staff for data collection. While this data collection is necessary to measure certain outcomes for both study arms, we cannot rule out that patients may alter their behavior, since they are aware that their treatment progress is being monitored (ie, observer bias).

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Authors' Contributions

NL, AN, VM, KS, LSB, M-AE, YF, JC, and SN made significant contributions to the planning and design of the study. NL, AN, VM, and JC implemented the study in the Adult Primary Care Center. YF will conduct our data analysis.

Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-EHEALTH Checklist V1.6.2 [23].

[PDF File (Adobe PDF File), 82KB - [resprot_v4i1e31_app1.pdf](#)]

Multimedia Appendix 2

Insulin titration algorithm.

[PDF File (Adobe PDF File), 4KB - [resprot_v4i1e31_app2.pdf](#)]

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Abbreviations

APCC: Adult Primary Care Center

HbA1c: hemoglobin A1c

IQR: interquartile range

MITI: Mobile Insulin Titration Intervention

NCATS: National Center for the Advancement of Translational Science

NYC: New York City

NYU-HHC CTSI: New York University-Health and Hospitals Corporation Clinical and Translational Science Institute

RA: research assistant

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Protocol

Determinants of Weight Gain Prevention in Young Adult and Midlife Women: Study Design and Protocol of a Randomized Controlled Trial

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Abstract

Background: Treatment of overweight and obesity through body weight reduction has been monumentally ineffective as few individuals are able to sustain weight loss. Rather than treating weight gain once it has become problematic, prevention of weight gain over time may be more effective.

Objective: The aim of this research is to preclude the burden of adult obesity in women by identifying the determinants of weight gain prevention. The objective of this randomized controlled trial (RCT) is to compare a weight gain prevention intervention delivered by the registered dietitian versus counselor.

Methods: This is a 12-month parallel-arm weight gain prevention RCT designed to increase self-efficacy, self-regulation, outcome expectations and family and social support through the use of a nutrition education intervention in women, aged 18-45 years, from the Urbana-Champaign (Illinois, USA) area. Women have been randomized to registered dietitian, counselor or wait-list control groups (August 2014) and are undergoing weekly nutrition education sessions for four months, followed by monthly sessions for eight months (through August 2015). Outcome measures, including: (1) dietary intake, (2) physical activity, (3) anthropometric and blood pressure measurements, (4) biochemical markers of health, (5) eating behaviors and health perceptions, and (6) mediators of behavior change, were collected before the intervention began (baseline) and will be collected at 3, 6, 9, and 12 months of the study.

Results: In total, 87 women have been randomized to intervention groups, and 81 women have completed first week of the study. Results are expected in early 2016.

Conclusions: This RCT is one of the first to examine weight gain prevention in women across normal, overweight, and obese body mass index categories. Results of this research are expected to have application to evidence-based practice in weight gain prevention for women and possibly have implication for policy regarding decreasing the encumbrance of overweight and obesity in the United States.

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KEYWORDS

body weight; weight gain prevention; weight maintenance; women

Introduction

Adult Weight Management

Small weight gains over time, around 1-2 pounds per year [1,2], contribute to the development of overweight and obesity. Once established, obesity is difficult to treat [3], as reduction of excess body weight is rarely effective in the long term. Short-term weight loss can be achieved by a variety of methods, but few of these approaches are sustainable and effective in facilitating permanent weight loss [4-10]. On average, individuals adhere to weight loss programs for approximately six months [11]; following weight loss, most individuals regain half of the weight lost within one year, and return to baseline weight within 3-5 years [11-13]. Weight gain prevention, on the other hand, avoids the difficulties that may accompany weight loss and its maintenance and offers an alternative option for weight management.

To reduce disease risk and improve overall health, effective weight gain prevention is essential; however, few interventions have successfully examined weight gain prevention and little is known about the determinants of and strategies for preventing weight gain over the long term. Much of the existing research has focused on treatment of overweight and obesity through reduction of excess body weight [14,15] or prevention of weight regain following weight loss [16-20].

Weight Gain Prevention

In the first weight gain prevention trial, normal weight adults, aged 25-74 years, were randomized to an untreated control group or a treatment group that received monthly newsletters plus a financial incentive for weight maintenance for one year [21]. The treatment group experienced an average weight loss of 1 kg, which was significantly different from the control group; with the treatment effect being stronger in men than women [21]. Building upon the Pound of Prevention (POP) work, 3-year weight gain prevention in adults, aged 20-45 years, was investigated [22,23]. Participants were randomized to a no-contact control group or to one of two education groups that received nutrition education via monthly newsletters and semiannual nutrition and exercise classes. One education group received a lottery incentive for participation. Significant differences in weight gain between the control and education groups were not found, although weight-related behaviors did improve in participants receiving education [22,23].

The Shape Program was a medium-intensity behavioral intervention in overweight and class I obese premenopausal black women that included weekly self-monitoring, monthly counseling calls, tailored skills training and a YMCA gym membership and was compared to usual care that included newsletters covering general wellness topics every six months during the 18-month study [24]. After one year, weight loss was significantly greater in the intervention group; these changes were sustained at 18 months. No significant differences in waist circumference, blood pressure, glucose or lipid levels between the intervention and usual care groups were observed at any measurement point during the study [24]. Levine and colleagues [25] randomized normal weight and overweight women to a clinic-based group, a correspondence group or a control group

for 24 months. During three years, the intervention had no influence on weight gain in either group; however, age, dieting status, and feelings of hunger were found to be predictive of weight gain.

The Groningen Overweight and Lifestyle (GOAL) study examined weight gain prevention in overweight and obese men and women with hypertension and/or dyslipidemia in the Netherlands by comparing the effects of lifestyle counseling by a nurse practitioner to usual care from a general practitioner during a 1-year period [26]. No significant differences were observed in weight change between groups at one year or after three years [26,27]. Study of Novel Approaches to Weight Gain Prevention (SNAP) is the most recently published intervention [28]. Two novel self-regulation approaches to weight gain prevention—small consistent changes and large periodic changes—were compared to a minimal treatment control for an average of three years of follow-up. Results of this study have not yet been published [28]. Without complete knowledge of the determinants of and strategies for weight gain prevention, public health will remain at risk for complications and costs related to overweight and obesity. Weight gain prevention offers a primary strategy for weight management and obesity prevention [24,26].

Women who previously participated in a weight-loss intervention identified gender-specific life transitions and stressors, including pregnancy, post pregnancy, family responsibilities, health status changes, and aging as precipitators of weight gain [29]. Young adulthood and perimenopause appear to be critical intervals for weight gain [30-32]; therefore, weight gain prevention efforts should target these lifespan stages, specifically in women.

Aims and Objectives

The current study aims to identify determinants of weight gain prevention in young adult and midlife premenopausal women through a 1-year weight gain prevention intervention that includes nutrition education. We hypothesize that compared to a wait-list control group, women who participate in a weight gain prevention intervention designed to increase self-efficacy, self-regulation, outcome expectations, and family and social support will maintain current body weight during a 12-month period. It is further hypothesized that women in an intervention group led by registered dietitians will have less weight gain during 12 months compared to women in an intervention group led by counselors.

Methods

Recruitment, Screening, and Enrollment

Participants were recruited by word-of-mouth, electronic mail messages, and posted flyers from the University of Illinois campus and the Urbana-Champaign (IL, USA) communities. A flow diagram of response, screening, and randomization steps is displayed in Figure 1. A total of 330 women responded to recruitment methods, between June and August 2014. Of these, 266 women met prescreening criteria (appropriate age, body mass index [BMI], and desire to prevent weight gain) and received screening materials including a medical history form,

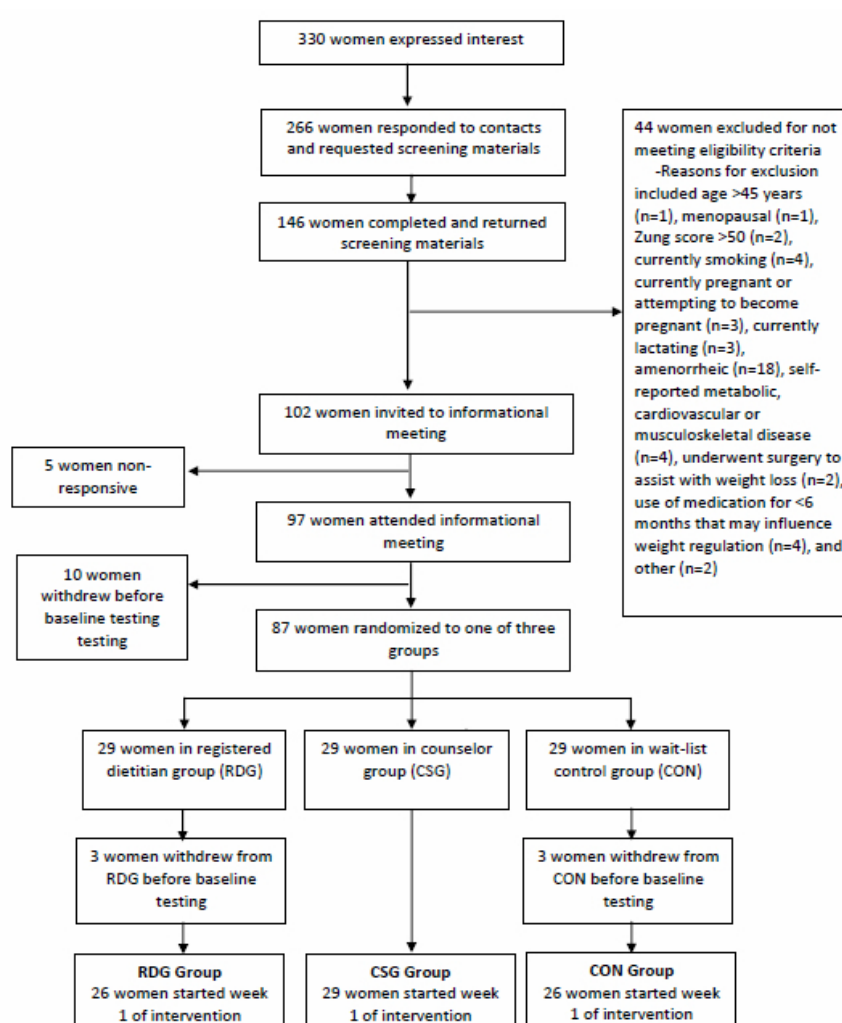
Zung Self-Rating Depression Scale/Status Inventory [33], and informed consent. A total of 146 women returned screening materials, which were reviewed by investigators. One hundred two women met eligibility criteria for participation, and 87 women were randomized, with 81 women completing baseline testing.

The current study included premenopausal women between the ages of 18-45 years with a BMI of $>18.5 \text{ kg/m}^2$. There were no additional criteria for body weight and BMI to ensure participation by women from a range of weight status categories. Further inclusion criteria included eumenorrhea (≥ 8 menstrual cycles/year), score of <50 on the Zung Self-Rating Depression Scale/Status Inventory [33], and no self-reported metabolic,

cardiovascular or musculoskeletal diseases or use of medications or supplements to manage a chronic health condition. Exclusion criteria included women who currently smoked, were pregnant or attempting to become pregnant or were currently lactating. Women using medications influencing weight regulation, such as steroid or thyroid hormones or oral contraceptives, were excluded if use was for <2 months before the start of the study. Gastric bypass surgery was also an exclusion criterion.

The Institutional Review Board (IRB) for the protection of human subjects at the University of Illinois at Urbana-Champaign (UIUC) approved the study protocol (UIUC IRB#14397). Each participant provided written informed consent before study participation.

Figure 1. Diagram of recruitment, enrollment and randomization of participants in a study examining weight gain prevention in young adult and midlife women.



Study Design

The current study is a 12-month parallel-arm weight gain prevention randomized controlled trial. After enrollment, women were randomized to one of three intervention groups: (1) weight gain prevention intervention delivered by a registered dietitian (RDG); (2) weight gain prevention intervention delivered by a counselor (CSG), or (3) wait-list control (CON) group. The RDG and CSG weight gain prevention interventions are identical in materials and content; the only difference is the credentialing

of the individuals leading the intervention. Women in the CON group receive no intervention; upon completion of the 12-month waiting period, these women will be randomized to the RDG group or CSG group and will receive the respective intervention for the next 12-month period.

Intervention

During the 1-year study, women randomized to the RDG and CSG groups will attend a total of 24, 1-hour nutrition education sessions that are based on effective weight-loss programs/plans

which address energy balance through sustainable diet, exercise, and behavior modifications [30,34-39]. These sessions will be held weekly for 16 weeks (months 1-4) and monthly thereafter (months 5-12) [30]. Vegetable consumption, planning ahead for food intake and portion control will be emphasized [34,35], and general nutrition information, eating away from home, food selection, food preparation, and recipe modification also will be addressed [34-37]. Other topics will include fitness and physical activity, culinary skills, breakfast consumption, healthy snacking and beverage choices, nutrient density, family menu planning, and grocery shopping. Problem solving, motivational concerns, and stress management will be encouraged [30,34-39]. Education sessions will relay constructs of the Social Cognitive Theory (SCT) [40].

Education sessions will follow a three-part format. Each session will begin with a brief review of information covered in the previous session and will address participant progress, including successes, challenges and questions. Next, the leader will deliver the nutrition education component of the session using an interactive group discussion format. Participants will be provided with handouts addressing food choices, dietary patterns, menu plans, and other information pertaining to the lesson. Finally, the content for the lesson will be summarized and participants will have a chance to ask questions, address concerns and set specific behavioral goals for the next session. Education sessions will be randomly selected for evaluation by a process observer who will rate the sessions based on investigator-established criteria.

Four registered dietitians will deliver the intervention to women in the RDG group. All women in the RDG group will equally interact with all four registered dietitians during the study. Four counselors will deliver the intervention to women in the CSG group, with these women having equal interaction with all four counselors across the study. The credentials of the professionals delivering the intervention will not be revealed to participants until after completion of the study. The registered dietitians are all female and have been practicing for <5 years. The counselors are all female and are graduate teaching assistants at UIUC in programs unrelated to nutrition or dietetics. Compliance will be defined as attendance of >85% of education sessions. If women are unable to attend an education session, virtual make-up sessions will be offered, along with a quiz. Completion and return of the quiz will indicate that the materials were studied and reviewed and that the participant was compliant.

Outcome Measures

Before the intervention (baseline), data on dietary intake, physical activity, anthropometric, and blood pressure measurements, biochemical markers of health, eating behaviors and health perceptions, and SCT mediators of behavioral change were collected. These outcome measures also will be obtained at 3, 6, 9 and 12 months.

Dietary Intake and Physical Activity Assessment

Participants were taught to accurately complete 4-day food records and the Stanford 7-Day Physical Activity Recall Scale [41]. To ensure accuracy in recording foods and beverage consumption, handouts containing examples of standard serving

sizes were provided. Participants recorded all food and beverages consumed for three non-consecutive weekdays and one weekend day before the baseline testing session [35]. Four-day food records will be analyzed using the Nutrition Data System for Research (NDSR) dietary analysis software (Nutrition Coordinating Center, Minneapolis, MN, USA) to estimate average daily dietary intake of total energy (kcal/day), carbohydrate (g/day), protein (g/day), fat (g/day), and fiber (g/day) in addition to intake by food groups (svgs/day).

For seven consecutive days before the baseline testing session, participants recorded the number of hours slept, spent in front of a television or computer screen, and engaged in moderate, hard, and very hard physical activity [35]. Participants wore accelerometers at the waist, wrist, or ankle during all waking hours for seven consecutive days while also recording physical activity to provide an objective assessment of energy expenditure. Approximately 70% of participants in each group wore accelerometers as they were not available for all individuals. Physical activity records will be analyzed by summing total hours of moderate, hard, and very hard activity and dividing by seven to estimate hours of physical activity per day. These records will be further analyzed by converting activities into metabolic equivalents (METs) (hr/d), which will be evaluated as light activity (1-3 METs), moderate activity (>3-6 METs), and vigorous activity (>6 METs) to estimate the number of calories expended per day. Accelerometry data will be analyzed using ActiLife 6.11 (ActiGraph, Pensacola, FL, USA) to estimate the number of calories expended per day, the MET rate per day, and the length of time (minutes) spent in sedentary, light, moderate, vigorous, and very vigorous activities.

Anthropometric and Blood Pressure Measurements

Baseline standing height (cm) was recorded to the nearest 0.1 cm using a calibrated scale-mounted stadiometer (Seca 700, Hanover, MD, USA). Body weight (kg) was measured using a calibrated scale (Tanita 410GS, Arlington Heights, IL, USA) to the nearest 0.1 kg. BMI (kg/m^2) was calculated using height and body weight measurements. A retractable measuring tape (Gulik II, Country Technology, Inc, Gay Mills, WI) was used to measure waist (cm) and hip (cm) circumferences, in duplicate, to the nearest 0.1 cm according to standard protocol [34]. Waist circumference was measured at the narrowest point of the waist, approximately one inch above the navel, and hip circumference was measured at the widest part of the buttocks [35]. Waist and hip circumference measurements were averaged to obtain a single value for each site; these values were used to calculate the waist:hip ratio. Fat mass (FM; kg) and body fat percentage (BF%) were measured using a Tanita scale (410GS).

Seated systolic and diastolic blood pressures (mm Hg) were measured by a trained study investigator using a standard sphygmomanometer (Baumanometer® Desk Model, Copiague, NY, USA) following a 5-minute rest period. Blood pressure measurements were taken in duplicate with a 2-3-minute rest period between readings; mean systolic arterial pressure values and diastolic arterial pressure values will be used in data analyses. Resting heart rate was also measured after the 5-minute rest period.

Biochemical Markers of Health

Venous blood samples (~30 mL) were collected by a trained phlebotomist between 7:00 to 9:30 AM after a 12-hour fast. Whole blood samples were processed and stored at -80 C. Serum will be analyzed for concentrations of insulin, glucose, total cholesterol, high-density lipoprotein-cholesterol (HDL-C), low-density lipoprotein-cholesterol (LDL-C), triacylglycerides (TG), leptin, adiponectin, and resistin.

Serum insulin ($\mu\text{U/mL}$) (LINCO Research, St Charles, MO, USA) will be measured using enzyme-linked immunosorbent assay (ELISA), and serum glucose (mg/dL) (Stanbio Labs, Boerne, TX, USA) will be measured by spectrophotometry. Total cholesterol (mg/dL), HDL-C (mg/dL) and TG (mg/dL) concentrations will be measured by spectrophotometry using the total cholesterol, HDL-C and TG kits, respectively (Stanbio Labs). Total cholesterol, HDL-C and TG concentrations will be used to calculate LDL-C concentration (mg/dL) using the equation: $\text{LDL-C} = \text{total cholesterol} - \text{HDL-C} - (\text{TG}/5)$ [42]. Serum leptin (ng/mL), adiponectin (ng/mL), and resistin (ng/mL) will be measured using ELISA (R&D Systems, Minneapolis, MN, USA). All serum samples for each biomarker will be analyzed in duplicate at corresponding study intervals. Intra- and inter-assay coefficients of variations (CV) are <15% for all kits.

Eating Behaviors, Health Perceptions, and SCT Mediators of Behavioral Change

Participants completed questionnaires designed to evaluate eating behaviors, health perceptions, perseverance, and SCT mediators. The Eating Inventory [43] will evaluate ratings of cognitive eating restraint, hunger, and disinhibition. The Short-Form 36 Health Survey (SF-36) [44] will assess self-reported health issues. Perseverance will be examined using the Short Grit Scale (Grit-S) [45], and an investigator-designed questionnaire will evaluate SCT mediators, including self-efficacy, outcome expectations, self-regulation, and social and family support. Standard scoring and interpretation methods will be used to evaluate all questionnaires [43-45].

Statistical Analysis

Baseline characteristics of study participants were characterized using descriptive statistics: mean (SD). Participants in the three intervention groups (Treatment) will participate in five data collection sessions at specified intervals (Time). The Shapiro-Wilk test for normality will be used to test for normality and homogeneity of variance within groups; data will be transformed if necessary. Body weight, BMI, waist : hip ratio,

FM, BF%, systolic and diastolic blood pressure, serum insulin, glucose, TC, HDL-C, LDL-C, TG, leptin, adiponectin, and resistin will be analyzed as dependent variables. Baseline variables that differ between groups will be included as covariates in the analysis. Dietary intake of macronutrients as estimated from 4-day food records, estimated energy expenditures, eating behaviors, health perceptions, and ratings of SCT mediators also will be compared among groups. A 3 x 5 (3 treatment groups x 5 time intervals) ANOVA with repeated measures on the time factor will be used to assess differences in outcomes within and between treatment groups over time. The group by time interaction will be examined for differences in time trend among intervention groups. Tukey pairwise comparisons will be used in conjunction with ANOVA to detect differences between treatment groups.

Some attrition is expected, as participants may be unable to comply with the intervention or may choose not to continue participation in the study. Participants who withdraw from the intervention will be asked to complete any remaining data collection sessions, and these data will be included in the statistical analyses (ie, intention-to-treat model). Data also will be analyzed using measurements only from those participants who complete all testing sessions. Statistical tests will be two-tailed with significance set at $P < .01$ to reduce the potential for Type I error. All statistical analyses will be conducted using Statistical Package for the Social Sciences (version 22.0, 2013, IBM Corp, Armonk, NY, USA).

Results

Eighty-one women completed baseline testing. Baseline descriptive characteristics of the sample are displayed in Tables 1 and 2. Overall, these women were highly educated, with a majority of participants having at least a 4-year college degree. The racial/ethnic breakdown was reflective of the larger population, with non-Hispanic whites representing the majority. Age range was 18-45 years, and BMI range was 18.5-49.6 kg/m^2 . On average, participants were overweight and normotensive. Participants have been recruited, enrolled, and randomized to one of the three intervention groups. Education sessions will continue through August 2015, and results are expected by early 2016.

After 8 weeks, the halfway point for weekly education sessions, 75 (93%) of the original sample remained in the study. For those randomized to the two intervention groups, 49 (89%) women were still enrolled.

Table 1. Baseline characteristics of women (n=81) participating in a 12-month weight gain prevention intervention and completing baseline testing.

Characteristic	All participants mean (SD)
Age (years)	31.4 (8.1)
Height (cm)	165.2 (5.9)
Weight (kg)	76.1 (19.0)
Body mass index (kg/m ²)	27.9 (6.8)
Waist circumference (cm)	83.3 (13.6)
Hip circumference (cm)	110.7 (14.6)
Waist: hip ratio	0.8 (0.1)
Body fat (%)	34.6 (9.1)
Fat mass (kg)	27.9 (14.2)
Fat free mass (kg)	48.2 (5.4)
Systolic blood pressure (mmHg)	106.2 (11.0)
Diastolic blood pressure (mmHg)	70.9 (9.9)
Resting heart rate (bpm)	65.8 (6.0)

Table 2. Demographic and education characteristics of all women (n=81) randomized to all groups.

Characteristic	All participants No (%)
Education	
High school graduate	2 (3)
Some college	15 (18)
2-year associate degree/graduate	2 (3)
4-year college degree/graduate	21 (26)
Some graduate school	8 (10)
Master's degree	27 (33)
Doctorate degree	6 (7)
Race/ethnicity	
White, non-Hispanic	53 (66)
Black, non-Hispanic	10 (12)
Asian	8 (10)
Non-white Hispanic or Latino	4 (5)
Other (including multiracial)	6 (7)
Total annual household income	
<\$15,000	7 (9)
\$15,000 - \$49,999	30 (37)
\$50,000 - \$99,999	25 (31)
>\$100,000 - \$199,999	18 (22)
No response	1 (1)

Discussion

Principal Findings

The importance of weight gain prevention and maintenance of current weight has recently been recognized by the American College of Sports Medicine [18] and Healthy People 2020 [46] as critical; yet, there are currently no treatment guidelines for weight gain prevention. The gap in the understanding of the determinants, facilitators, and barriers to weight gain prevention likely exists due to the limited number of studies addressing prospective weight changes in adulthood. Awareness and identification of the determinants of weight gain prevention are necessary in order to increase the practicality of weight gain prevention for managing obesity.

While it may seem counterintuitive to promote weight gain prevention in overweight and obese individuals rather than weight loss, weight gain prevention is relevant for individuals of all BMI categories [47]. Preventing weight gain over time offers the opportunity to slow the progression of overweight and obesity and to avoid further exacerbations related to excess body weight in individuals who are already overweight or obese [48]. Additionally, weight gain prevention may require less intensive treatment than that required to achieve weight loss [2], and may be more successful in the long term as it avoids the problems associated with weight loss and its maintenance [27]. Weight maintenance, regardless of whether an individual is normal weight, overweight or obese, may be more beneficial and practical than repeated, minimally successful weight-loss attempts. While modest weight losses of 5-10% of body weight have significant effects on risk factors of disease, these benefits may be ameliorated with weight regain. Even with weight loss, metabolically healthy obese individuals may not show improvement in health outcomes, and weight loss in these individuals may promote weight cycling, or periods of weight loss followed by weight gain, which may have detrimental effects on mental, metabolic, and psychological outcomes [48-52]. Further, the adverse effects associated with weight cycling may be as harmful as maintenance of a high “unhealthy” body weight [51]. However, a recent study by Mason and colleagues [53] found that weight cycling was not associated with negative metabolic outcomes and a history of weight cycling was not related to the ability to lose and successfully maintain weight in the long term.

In a recent qualitative study of women who completed a weight-loss intervention conducted by a registered dietitian, women perceived the registered dietitian to be a credible source of nutrition information and found lack of access to a registered dietitian following completion of the intervention to be a barrier to weight-loss maintenance [29]. As a credible source of nutrition information [37], registered dietitians have a specialized skill set to support and encourage sustainable behavior changes to achieve weight management. Registered dietitians are generally regarded as the experts in weight management, but no studies have compared registered dietitians to other health professionals in the delivery of weight management information. The current study will fill this scientific gap by testing the ability of the registered dietitian to

promote weight gain prevention as compared to an untrained professional. If registered dietitians are more effective in promoting weight gain prevention, these findings will support the notion that registered dietitians should be at the forefront in helping individuals attain successful weight management.

Women in the qualitative study [29] identified social support, basic nutrition education, accountability to others, self-motivation, mindfulness and awareness of food choices, planning ahead, portion control, and exercise as facilitators to weight loss and weight-loss maintenance while health status changes, environmental pressures, life transitions, absence of social support, lack of accountability, and internal factors were perceived as barriers. Additionally, women expressed their desire for continual contact with the registered dietitian as well as the group support offered by the education sessions [29].

Although there is no standardized definition of weight gain prevention or weight maintenance, a weight change of $\pm 3\%$ from baseline weight will be considered successful weight gain prevention. A 3% change criterion allows for normal day-to-day fluctuations that may result from measurement error, clothing, food consumption, and/or fluid balance [54].

Limitations

Results from this study will be limited in generalizability to premenopausal women. Future research should examine pre- and post-menopausal women, as these physiological changes appear to be other critical life stage intervals for weight gain. Weight gain prevention should also be examined exclusively in men, as determinants of and strategies for weight gain prevention may differ between men and women. Further, our results may be limited by the length of the study, as the current intervention is only for one year. Surveys, testing sessions or focus groups following completion of the intervention may be useful in order to garner more information about the feasibility of long-term weight gain prevention. There are limitations with using self-reported dietary intake and physical activity; however, participants have been taught to accurately complete food records, and accelerometry data will be used to validate written physical activity records. Finally, our intervention contains multiple components that address weight gain prevention, and the study design does not allow for examination of independent effects of the different elements of this weight gain prevention intervention. Investigator-designed surveys will be used to assist with determining the effects of individual intervention components.

Conclusions

The current study targets women who are at greater risk for weight gain compared to men; with the goal to help further the understanding of the determinants of weight gain prevention [29]. This study will fill a scientific gap in testing the ability of a registered dietitian to promote weight gain prevention as compared to another health professional that lacks formal nutrition and dietetics training. Although several studies have explored weight gain prevention with limited success, this may be the first study that targets young adult and midlife women of all weight status categories (normal weight, overweight, obese) and focuses on prospective weight gain prevention.

Results of this research will be expected to have implications for policy development and recommendations for decreasing the burden of overweight and obesity in the United States through weight gain prevention.

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Authors' Contributions

CJM and SMN-R contributed equally to the conceptual development, research design, and drafting of the manuscript. CJM was the lead investigator for data collection and analysis, to date. Both authors contributed equally to data interpretation and critical revision of the manuscript.

Conflicts of Interest

CJM discloses Graduate Research Fellowship funding from The Hershey Company. SMN-R discloses research funding from The Hershey Company; the Bell Institute of Health and Nutrition, General Mills, Inc; Dairy Research Institute; and the United States Department of Agriculture. Research funding provided to SMN-R is unrelated to the present study.

Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.2 [55].

[[PDF File \(Adobe PDF File\), 155KB - resprot_v4i1e36_app1.pdf](#)]

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Abbreviations

BF%: body fat percentage
BMI: body mass index
CON: control group
CSG: counselor group
CV: coefficients of variations
FM: fat mass

GOAL: Groningen Overweight and Lifestyle
Grit-S: Short Grit Scale
HDL-C: high-density lipoprotein cholesterol
IRB: Institutional Review Board
LDL-C: low-density lipoprotein cholesterol
MET: metabolic equivalent
NDSR: Nutrition Data System for Research
POP: Pound of Prevention
RDG: registered dietitian group
SCT: social cognitive theory
SF-36: Short-Form 36 Health Survey
SNAP: Study of Novel Approaches to Weight Gain Prevention
TG: triacylglycerides
UIUC: University of Illinois at Urbana-Champaign

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Protocol

Text Messaging to Improve Hypertension Medication Adherence in African Americans: BPMED Intervention Development and Study Protocol

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Abstract

Background: Hypertension (HTN) is a major public health concern in the United States, with almost 78 million Americans age 20 years and over suffering from the condition. Moreover, HTN is a key risk factor for health disease and stroke. African Americans disproportionately shoulder the burdens of HTN, with greater prevalence, disease severity, earlier onset, and more HTN-related complications than age-matched whites. Medication adherence for the treatment of HTN is poor, with estimates indicating that only about half of hypertensive patients are adherent to prescribed medication regimens. Although no single intervention for improving medication adherence has emerged as superior to others, text message medication reminders have the potential to help improve medication adherence in African Americans with uncontrolled HTN as mobile phone adoption is very high in this population.

Objective: The purpose of this two-phased study was to develop (Phase I) and test in a randomized controlled trial (RCT) (Phase II) a text message system, BPMED, to improve the quality of medication management through increasing medication adherence in African Americans with uncontrolled HTN.

Methods: In Phase I, we recruited 16 target end-users from a primary care clinic, to assist in the development of BPMED through participating in one of three focus groups. Focus groups sought to gain patient perspectives on HTN, medication adherence, mobile phone use, and the use of text messaging to support medication adherence. Potential intervention designs were presented to participants, and feedback on the designs was solicited. In Phase II, we conducted two pilot RCTs to determine the feasibility, acceptability, and preliminary efficacy of BPMED in primary care and emergency department settings. Both pilot studies recruited approximately 60 participants, who were randomized equally between usual care and the BPMED intervention.

Results: Although data collection is now complete, data analysis from the two pilot RCTs is still ongoing and results are expected in 2015.

Conclusions: This study was designed to determine preliminary feasibility and acceptability of our approach among African Americans with uncontrolled HTN in primary care and emergency department settings. Results from these studies are of great interest as little work has been done to document the use of text message medication reminders to improve HTN-related outcomes, particularly within underserved urban minorities.

Trial Registration: Clinicaltrials.gov NCT01465217; <https://clinicaltrials.gov/ct2/show/NCT01465217> (Archived by WebCite at <http://www.webcitation.org/6V0tto0lZ>).

KEYWORDS

mobile phone; text messaging; hypertension; blood pressure; African Americans; medication adherence; mobile health

Introduction

Background

Almost 78 million Americans age 20 years and over suffer from hypertension (HTN) [1], which is a key risk factor for health disease and stroke (the first and fourth leading causes of death in the United States, respectively) [2]. HTN is more prevalent among non-Hispanic blacks (42.0%) than non-Hispanic whites (28.8%) [3], a pattern that has persisted for 50 years [4,5]. Moreover, African Americans shoulder burdens of greater disease severity, with earlier onset and more HTN-related complications than age-matched whites [6].

Medication adherence for the treatment of HTN is poor, with estimates indicating that only about half of hypertensive patients are adherent to prescribed medication regimens [7,8]. To date, no single intervention for improving medication adherence has emerged as superior to others; however, those that include reminders have been shown to have positive effects on adherence and patient outcomes [9].

Mobile phones and text messages have become widely integrated into routine daily life and may offer a simple and non-labor intensive strategy for enhancing medication adherence. Work by Lawton et al suggests that the use of innovative approaches to medication management, such as text message interventions, may be useful at increasing medication adherence in adults [10]. Furthermore, the US Department of Health and Human Services recently published an environmental scan of the state of the science of text messaging to improve consumer health knowledge, behaviors, and outcomes, which reports that text messaging has been shown to increase treatment compliance, including medication adherence [11].

While African American adults use the Internet less frequently than whites (80% vs 87%) and have less access to home broadband (62% vs 74%), there are no significant differences in adoption of cellphones (92% and 90%) or smartphones (56% and 53%) [12], suggesting that mobile health (mHealth) is a viable strategy to reduce HTN-related disparities. Moreover, text messaging is the most common activity performed on a mobile phone among American adults, with 81% of mobile phone owners reporting that they text message [13].

Study Objective

The purpose of this two-phased study was to develop (Phase I) and test (Phase II) a text message system to improve the quality of medication management through increasing medication adherence in African Americans with uncontrolled HTN. Phase I was accomplished through user-centered design principles incorporating direct feedback from target end-users, and Phase II will be accomplished through the completion of two pilot randomized controlled trials (RCT) with patients recruited from primary care and emergency department (ED) settings (target of approximately 60 participants each). The RCT design of our

evaluation provides the opportunity to potentially determine if use of the intervention, BPMED, has an effect on primary and secondary outcome measures, compared to usual care controls, at 1-month follow-up.

Hypotheses

In our Phase II primary care pilot RCT, we hypothesize that individuals assigned to the text message intervention will have (1) a greater increase in medication adherence from baseline to 1-month follow-up as compared to individuals receiving usual care treatment, (2) a greater increase in medication adherence self-efficacy from baseline to 1-month follow-up as compared to individuals receiving usual care treatment, and (3) a greater reduction in systolic and diastolic blood pressure (SBP and DBP) from baseline to 1-month follow-up as compared to individuals receiving usual care treatment.

Because it is expected that not all participants in the ED pilot RCT will be undergoing active treatment for HTN at the time of enrollment, Hypotheses #1 and #2 will not be as salient in the ED trial due to lack of meaningful baseline adherence and medication self-efficacy measures.

Methods

Overview

The goal of this study was to develop and test an automated text message system to increase medication adherence among African Americans with uncontrolled HTN (using BPMED) and was designed in two parts. In Phase I, we recruited target end-users to participate in focus groups to gather target end-user feedback to be used in the design of the BPMED intervention. In Phase II, we initially sought to test the feasibility, acceptability, and preliminary efficacy of BPMED in a pilot RCT of uncontrolled hypertensive African Americans recruited from a primary care setting. The final protocol closely mirrored what was originally proposed to the funding agency (see [Multimedia Appendix 1](#) for original review summary statements). We subsequently received funding to conduct a parallel study to test the feasibility, acceptability, and preliminary efficacy of BPMED in a pilot RCT of a similar population recruited from an ED setting. Whittaker et al previously proposed a multi-step process for the development and evaluation of mHealth interventions, which included the following stages: conceptualizing, formative research, pretesting, pilot study, RCT, and qualitative follow-up [14]. In the development and evaluation of our own BPMED intervention, we utilized many of the same processes endorsed by Whittaker et al, and in the following sections, we delineate how our own process followed much of their already established process.

Intervention Development

Target End-User Recruitment

We approached the development of BPMED with user-centered design principles in mind. To gain user perspective on the design of BPMED, we conducted formative research, one of the several steps in mHealth intervention development and evaluation outlined by Whittaker et al [14], through focus groups that sought to gain patient perspectives on HTN, medication adherence, mobile phone use, and the use of text messaging to support medication adherence. We recruited target end-users to participate in one of three focus groups. These participants were recruited through targeted recruitment letters sent to primary care patients who met clinical eligibility requirements as identified in a retrospective chart review of electronic medical records of primary care patients at our recruitment site. This method was an efficient means of recruiting focus group participants, as it greatly accelerated participant recruitment and ensured that we were more likely to reach potential participants who were likely to meet our eligibility criteria. To be eligible for inclusion in our Phase I focus groups, participants had to meet the following eligibility criteria: self-identified African American, age ≥ 18 years, diagnosis of HTN based on International Classification of Diseases (ICD-9) codes in the medical record, had uncontrolled HTN on two successive clinic visits prior to screening (clinic SBP >140 mm Hg, DBP >90 mm Hg or SBP >130 , DBP >80 for those with diabetes or kidney disease) as documented in the medical record, taking at least one antihypertensive medication, own a mobile phone capable of receiving and sending text messages, ability to pay for and obtain HTN medications, and English speaking.

Focus Groups

Focus groups were conducted by the Wayne State University (WSU) Center for Urban Studies (CUS) and independent staff who were not directly involved in the study itself. Although study staff were present to introduce themselves, thank participants for their participation, and to explain the purpose of the study, all study staff excused themselves from the room prior to the start of the focus groups, and all focus group facilitation and moderation was conducted by trained WSU CUS staff members. To control for any potential effect that the race of our focus group moderators had on the outcome of the focus groups, the CUS staff members conducting the focus groups were African American females. At the outset, instead of written informed consent, all participants were given an information sheet that explained the purpose of the study, participation expectations, risks, benefits, and compensation. Prior to the focus groups, all participants were provided a meal and were asked to fill out a survey assessing demographics, medication adherence (using the Morisky Medication Adherence Scale; MMAS) [15], and mobile phone use.

After the completion of the survey, all focus groups were conducted using the same structured focus group script that was broken down into three separate parts. In the first part, facilitators explained the purpose of the study and all procedures for the focus groups, including participant expectations, focus group guidelines, and study compensation. In the second part, focus group members discussed HTN, medication regimens,

medication adherence, and reasons for medication non-adherence. Finally, focus group participants were asked about mobile phones and text message use, and feedback was solicited regarding participant perceptions of using text messages for three different potential intervention functions: (1) to enable participant self-reporting of medication adherence, (2) to provide medication reminders, and (3) to receive educational information pertaining to HTN. In addition, participants were asked to identify what additional features would be useful in a text messaging program to increase medication adherence, as well as to identify potential problems that may be encountered by using text messaging for this purpose. The focus group protocol included prompts to solicit participant feedback on messaging frequency and content. Each of the three focus groups lasted approximately 90 minutes. At the conclusion of the focus groups, participants were given a US \$25 cash incentive. In total, 16 individuals participated in one of three focus groups ($n=6$, $n=4$, and $n=6$, respectively). All methods were approved by the Wayne State University Institutional Review Board (#0410810B3E).

Data Analysis

During the focus groups, a CUS staff member served as the focus group moderator, while a second CUS staff member served as a dedicated note taker, capturing detailed notes on participant responses, and audio recording the focus groups for later review. After the focus groups, the two CUS staff members reviewed the audio recordings and supplemented the detailed notes with direct quotations and any opinions expressed by focus group participants that were not captured in the original notes. The CUS staff members also analyzed the notes and recordings for themes pertaining to HTN and medication adherence, as well as mobile phone and text message use. CUS staff also noted whenever consensus or majority opinions were expressed by focus group members related to potential BPMED functionality. Finally, all suggestions for possible BPMED functionality were prioritized by study staff according to participant majority consensus and ultimate feasibility of implementation. All survey data collected prior to the focus groups were analyzed with descriptive statistics in STATA 11.0.

Focus Group Sample

Focus group participants were primarily female (87.5%, 14/16) and ranged in age from 34–67 years (mean 50.8, SD 9.6). All participants had at least a general education development (GED) or high school diploma. Despite the level of education of our sample, annual combined household incomes for the previous year were quite low with 31.3% (5/16) earning less than US \$10,000, and 25.0% (4/16) earning between \$10,000 and \$19,999. In terms of mobile phone use, 100.0% (16/16) of focus group participants reported that they carried their mobile phone all day, every day, and had the ability to send and receive text messages. Regarding mobile phone plans, 66.7% (10/15) of participants reported that they had their mobile phone plans for 1 year or more, and 62.5% (10/16) report that unlimited text messaging was included in their mobile phone plan. Only 6.3% (1/16) report that they had used a prepaid mobile phone. Although text messaging capabilities were pervasive, only 56.3% (9/16) reported that they used text messaging daily. See

[Table 1](#) for a complete breakdown of focus group participant characteristics.

The complexity of antihypertensive medication regimens varied within our sample as 56.3% (9/16) of participants reported taking one antihypertensive medication, 12.5% (2/16) taking two medications, and 31.3% (5/16) reported taking three or more different medications. Based on MMAS scores, the majority of our sample were considered to have low medication adherence (62.5%, 10/16), while 18.8% (3/16) were medium and 18.8% (3/16) were high adherers.

Focus Group Findings

Based on the themes that emerged from our three focus groups, it was clear that participants did not always take their medications as prescribed, with participants stating: “I have to think about it: did I take that medicine? I’m afraid I’ll take a double dose, so I say ‘well, forget it’ ” and “I try to take my medication every day...The dosing is really easy, but I might take it later, like two or three hours later”.

Reasons for not taking medications as prescribed varied, but simply forgetting to take their meds was cited by the majority of focus group participants as the primary reason for medication non-adherence. In addition, participants also mentioned issues related to fears of doubling up, stopping medications when HTN

symptoms subsided, and undesirable side effects as reasons for non-adherence. Participants reported developing their own tricks for remembering to take medications, such as “Every time Steve Harvey [is on], I know it’s time to take my blood pressure medicine”. Participants overwhelmingly supported the use of text messaging, citing beliefs such as: “That’s the way people talk now” and “In this day and age, everybody texts...[You are going to] automatically look, just to see who it is”.

In addition, the vast majority of participants thought that text message reminders would be helpful in improving medication adherence. Specifically, participants requested the ability to customize the frequency and timing of medication reminders each day. In addition, focus group participants indicated a preference for receiving educational text messages with information on topics such as nutrition and HTN symptoms, although a few expressed concerns about costs associated with receiving additional text messages. Although there was great support for receiving text message reminders for medication adherence, participants were adamant that they did not want to use text messaging for self-monitoring their adherence back to the study team. As our initial conceptualization of our intervention was based on the Theory of Self-Regulation and relied heavily on participant self-monitoring, this was key information to inform the development of BPMED.

Table 1. Focus group participant characteristics (n=16, except where indicated).

Characteristic	n (%)
Age, mean (SD)	50.8 (9.6)
Gender	
Female	14 (87.5)
Male	2 (12.5)
Highest level of education^a	
High school diploma or GED	8 (50.0)
Some college	4 (25.0)
Bachelors degree	3 (18.8)
Graduate degree	1 (6.3)
Marital status^a	
Single, never married	6 (37.5)
Married	1 (6.3)
Divorced	7 (43.8)
Widowed	2 (12.5)
Annual household income, US\$	
<10,000	5 (31.3)
10,000-19,999	4 (25.0)
20,000-39,999	3 (18.8)
40,000-59,999	2 (12.5)
≥60,000	2 (12.5)
Employment status^a	
Part time	4 (25.0)
Full time	3 (18.8)
Retired	2 (12.5)
On disability	3 (18.8)
Laid off / unemployed	4 (25.0)
Mobile phone plan is prepaid (requires phone cards)^a	
Yes	1 (6.3)
No	15 (93.8)
Length of current mobile phone plan ownership^b	
<1 month	0 (0.0)
1-3 months	2 (13.3)
4-6 months	1 (6.7)
7-12 months	2 (13.3)
>1 year	10 (66.7)
Who pays for mobile phone^c	
Self	10 (76.9)
Spouse	0 (0.0)
Family member other than spouse	1 (7.7)
Friend	2 (15.4)
Frequency of text message use^a	

Characteristic	n (%)
Never	3 (18.8)
A few times per month	3 (18.8)
A few times per week	1 (6.3)
Daily	9 (56.3)
Does mobile phone plan include text messaging ^a	
Yes, unlimited text messaging is included in plan	10 (62.5)
Yes, a limited number of text messages are included in mobile phone plan	3 (18.8)
No	2 (12.5)
Don't know	1 (6.3)

^aSum total does not equal 100% due to rounding error.

^bn=15.

^cn=13.

BPMED Intervention Design

Based on focus group participant feedback, we developed our 1-month intervention to provide automated text message medication reminders that would be sent to participants at the time of their choosing. Because we did not have access to all participant therapeutic regimens as documented in their medical records, we had to rely on participant self-reports of dosing regimens. Moreover, as dosing times vary between participants, sending daily reminders at times that participants were not taking their medications was considered not useful. As such, we allowed participants to set the number of text message reminders they wished to receive each day, as well as timing of the messages, to suit their needs.

In addition to medication reminders, eight educational messages (two/week) were developed and added to the intervention. These educational messages were based on HTN management recommendations from the American Heart Association and were focused on topics of smoking cessation, the importance of limiting dietary sodium, coping with stress, nutrition, weight reduction, limiting alcohol use, and physical activity. A weekly satisfaction question asking participants to rate their satisfaction with the BPMED intervention was also added. Finally, there were several study-related text messages that were used to enroll participants into BPMED, set up medication reminders, and remind participants to schedule their 1-month follow-up data collection appointment (see [Table 2](#) for a complete listing of all text messages included in BPMED). All text messages were pretested by content experts with experience working in our target community. Pretesting, another step endorsed by

Whittaker et al in mHealth intervention design and evaluation [14], helped to ensure that our messages were accurate, clear, and appropriately tailored to our target population.

BPMED utilized a double opt-in architecture. First, study staff enrolled each participant in an online participant management system with their name, phone number, and participant identification. As a part of this enrollment process, participants were required to read a statement that further clarified expectations for involvement in the study, as well as the number of text messages participants could expect to send/receive as a part of their participation. Directions for how to opt-out of the text message intervention were also provided. Once participants read the statement and checked a box indicating that they agreed, participants received an automated text message asking to confirm the participants' desire to enroll in the text message intervention. After agreeing a second time to use the text message intervention, participants were fully enrolled and were instructed on how to set medication reminders.

Although we had initially intended to ground our work with text messaging in a Theory of Self-Regulation framework, as previously mentioned, formative research revealed that target users were adamantly opposed to using text messaging to self-monitor their medication adherence. With our shift toward providing simple text message medication reminders, BPMED became more closely aligned with a Health Belief Model framework with medication reminders serving as cues to action, and educational messaging serving to increase participant perceived benefits of behavior change and self-efficacy, as well as reduce perceived barriers to behavior change.

Table 2. Text messages included in BPMED by type.

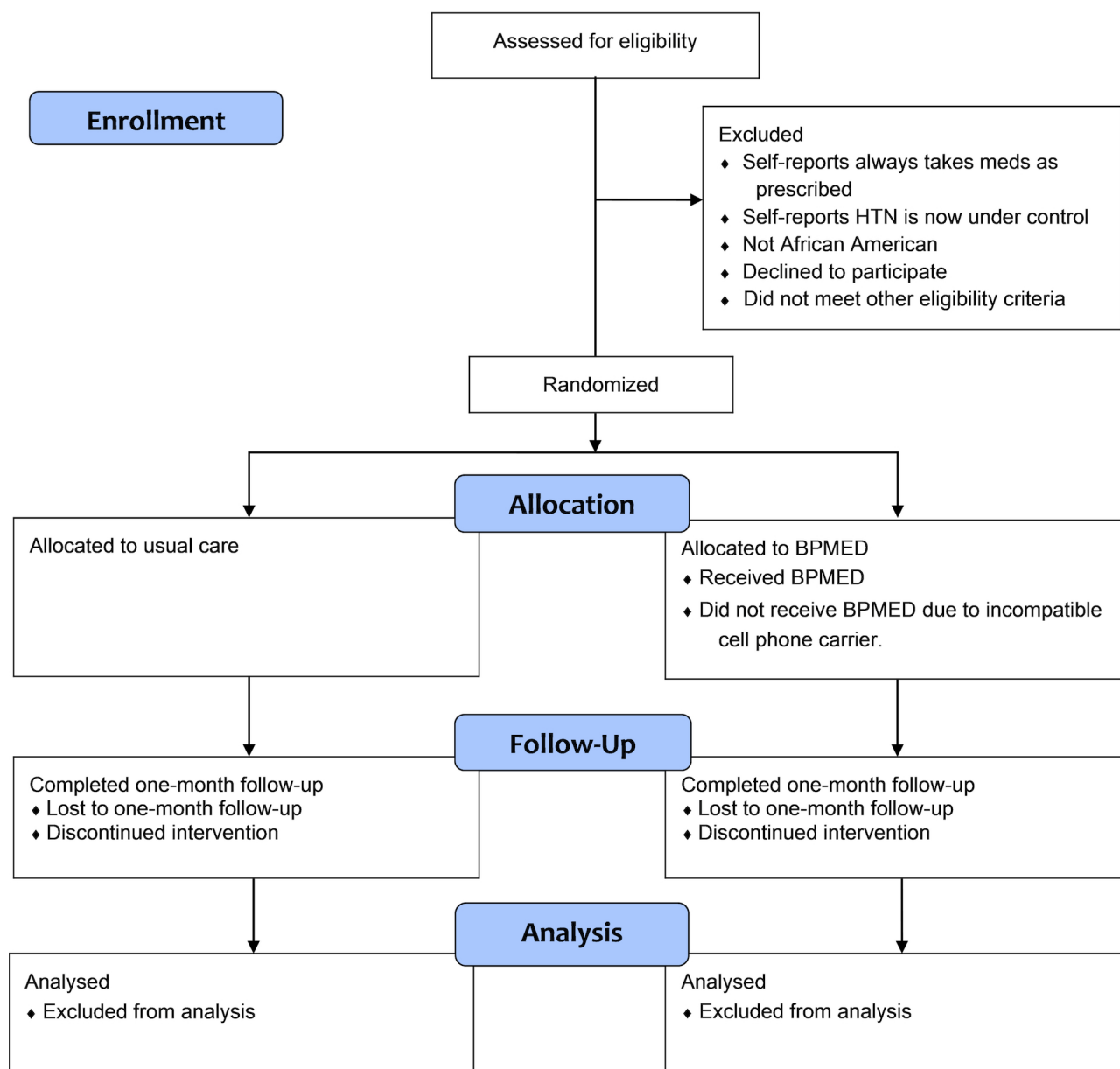
Type of message	Content of message	Day of intervention that message was sent
Medication reminder	BPMED: Hello [first name], this is your [reminder time] reminder to take your medication. Please don't forget!	Sent daily at times specified by participant
Educational	BPMED: The DASH diet works! Eat foods rich in whole grains, fruits, vegetables, and low-fat dairy, while limiting saturated fat and cholesterol.	3
	BPMED: Physical activity lowers blood pressure. Aim for 30 minutes each day over small chunks or all at once. Try a 30 min brisk walk or three 10 min walks!	6
	BPMED: Smoking can increase blood pressure. If you are a smoker and want help quitting, call 1-800-QUITNOW or talk to your doctor.	10
	BPMED: Foods high in sodium (salt) can increase blood pressure. Try to limit your sodium intake to 1500 mg/day, including what is in and what is added to food.	13
	BPMED: Did you know that 30 minutes of moderate physical activity can help make your blood pressure medications work more effectively and help you feel better?	17
	BPMED: To manage your blood pressure, limit your alcohol consumption to no more than two drinks per day for men and no more than one drink per day for women.	20
	BPMED: To help reduce sodium intake, use spices instead of salt in cooking and at the table. Flavor foods with herbs, citrus, vinegar, or salt-free blends.	24
	BPMED: Did you know that blood pressure rises as body weight increases? Losing even 10 pounds can lower blood pressure and your risk of chronic disease.	27
Satisfaction assessment	BPMED: We would like your feedback [first name]. From 1-10 (with 10 being best), how satisfied are you with the program? Reply BPMED RESPONSE [number of intervention week] and your rating.	7, 14, 21, 28
Study-related	BPMED: You've chosen to receive text message medication reminders. If you wish to proceed text BPMED AGREE FIRSTNAME LASTNAME to 37717. Standard message rates apply.	0 (baseline)
	BPMED: [first name], thanks for participating in this study. To begin, please text BPMED START FIRSTNAME LASTNAME to 37717.	0 (baseline)
	BPMED: Thanks for participating! Once you set up your reminders, you will start receiving them tomorrow and will continue to get them for one month.	0 (baseline)
	BPMED: To set up reminders, text BPMED TIME and the times you want to get texts, ie BPMED TIME 9am 5am 730pm, to 37717. Please mind the spacing.	0 (baseline)
	BPMED: Thanks [first name]. You've chosen to receive reminders at [reminder time 1] [reminder time 2]...	Whenever participant requests a new reminder
	BPMED: Hello [first name]. If you have not yet set up your one month follow-up appointment, please give us a call at 313-577-4107 to do so.	26
	BPMED: Thank you for your study participation. Today is your last day of reminders.	30

Phase II Pilot Randomized Controlled Trials

Trial Design

In Phase II, we sought to conduct two 1-month pilot RCTs with patients recruited from primary care and ED settings. These trials sought to enroll approximately 60 participants each, who were randomized equally to receive either usual care or the BPMED intervention (see [Figure 1](#) for participant flow through

the trials). We chose these specific settings to reflect the way patients in our community engage with the health care system and to assess potential scalability of our intervention to real world clinical practice. Although Whittaker et al advocates the use of non-randomized pilot tests in the development and evaluation of mHealth interventions [14], we chose to use an RCT design of BPMED compared to usual care control so that we may be able to determine potential intervention effects on primary and secondary outcome measures at 1-month follow-up.

Figure 1. Participant flow through BPMED trials.

Human Subjects Protections

The methods utilized in the two pilot RCTs were approved by the Wayne State University Institutional Review Board (#0410810B3E).

Participant Recruitment

To enlist participants for the primary care pilot RCT, a combination of recruitment methods were used including targeted recruitment letters mailed directly to potentially eligible participants who met clinical eligibility requirements as identified through retrospective records analysis of electronic medical records, recruitment posters displayed in primary care clinic exam rooms, and direct provider referral. Interested, potentially eligible participants were screened via phone, and those who met inclusion criteria were scheduled for a baseline data collection visit. Potential participants who previously

participated in the Phase I focus groups were not excluded from participation in the pilot RCTs. To recruit participants for the ED pilot RCT, patients meeting clinical eligibility criteria were identified initially through real-time monitoring of the ED tracking board by trained research assistants. Recruitment, screening, and enrollment were conducted onsite in the Detroit Receiving Hospital ED and typically occurred directly after patient discharge from the ED.

Inclusion/Exclusion Criteria

To be eligible to participate, participants were required to self-identify as African American, be at least 18 years of age, have a diagnosis of HTN based on ICD-9 codes documented in the medical record, own a mobile phone capable of receiving and sending text messages, and be English speaking. Additional inclusion criteria specific to the primary care pilot included having uncontrolled HTN on two successive clinic visits prior

to screening (clinic SBP >140 mm Hg, DBP >90 mm Hg or SBP >130, DBP >80 for those with diabetes or kidney disease) as documented in the medical record, and be taking at least one antihypertensive medication. Additional inclusion criteria specific to the ED pilot included having elevated blood pressure on successive measurements. Exclusion criteria included reporting strict adherence to medication regimens, receiving hemodialysis, plans to move >50 miles from the recruitment site within the next 3 months, diagnosis of resistant HTN documented in the medical record, plans to terminate mobile phone contract during the next month, compliance risk, and/or other major health problems that would make participation in this study difficult.

Intervention

All trial participants were fully informed about the risks and benefits of participating in this study, and written informed consent was obtained from all participants. Prior to randomization, all participants completed a baseline survey assessing demographics, mobile phone use, medication adherence, and medication adherence self-efficacy, as well as having their blood pressure taken. Primary care patients had been previously instructed to bring all antihypertensive medications with them to the baseline data collection visit so that pill counts could be taken to be used as an additional measure of medication adherence. In the ED trial, given that many participants were not currently taking medications to treat their HTN, all ED trial participants were given a 35-day supply of an appropriate antihypertensive medication. After completing all baseline measures, participants were block-randomized with a 1:1 ratio to either the usual care control or BPMED intervention group. Intervention group participants were then enrolled in BPMED and trained on how to use the program. All participants, regardless of trial assignment, were asked to come back for a 1-month follow-up visit where medication adherence, medication adherence self-efficacy, and blood pressure measures were assessed. In addition, intervention group participants completed a brief BPMED satisfaction questionnaire and open-ended interview at 1-month follow-up. This qualitative follow-up among intervention group participants post trial is advocated by Whittaker et al in the development and evaluation of mHealth interventions [14]. All participants received US \$25 at the conclusion of baseline and 1-month follow-up data collection visits, for a possible total of US \$50/participant. Any participant who indicated that text messaging was not included in their mobile phone plan was reimbursed US \$0.20/text message sent or received as a part of their participation in this study. Finally, parking expenses were covered for primary care trial participants.

Outcomes

Medication adherence was the primary outcome of interest in this study and was measured using the MMAS [15], pill counts, and an additional self-report of medication adherence. For the primary care trial, medication adherence change from baseline to 1-month follow-up was of particular interest. In the ED pilot, adherence at follow-up was the primary outcome of interest due to the fact that some participants were not taking an antihypertensive medication at baseline. Secondary outcome

measures of interest included medication adherence self-efficacy as measured by the Medication Adherence Self-Efficacy Scale [16], blood pressure, and participant satisfaction with BPMED. We also conducted post-trial qualitative interviews and questionnaires to assess BPMED participant perceptions of the program. In addition to participant outcomes, logs of unintended system down time will be analyzed to understand whether participant reminders were sent as expected.

Trial Statistical Methods

Descriptive statistics will be used to describe participant characteristics and intervention satisfaction at follow-up. Categorical data will be displayed as frequency and percentages, and where appropriate, chi-square tests will be used for comparison. Continuous variables such as medication adherence, medication adherence self-efficacy, and blood pressure will be expressed as mean (standard deviation), and means will be compared using two-tailed unpaired independent samples *t* tests. Regression models, controlling for variables such as gender, age, and other potentially important confounders, will be used to predict improvements in primary and secondary outcomes. All statistical analysis will be carried out using STATA version 12.0.

Results

Data collection from both pilots is now complete, and results from these pilots are expected to be published in early 2015.

Discussion

Principal Findings

This paper outlines the methodology of a two-phased study designed to develop (Phase I) and test (Phase II) the feasibility, acceptability, and preliminary efficacy of text message medication reminders to improve medication adherence in African Americans with uncontrolled HTN. Through the completion of the two pilot RCTs, we seek to add to the growing evidence base of mobile phone-based mHealth approaches for chronic disease self-management. With a rigorous study design, we hope to advance the field of mHealth beyond single group quasi-experimental research designs. Moreover, we hope to demonstrate the feasibility and acceptability of our approach among an urban African American population that suffers from considerable HTN-related health disparities and is often overlooked as a good candidate for technology-based behavior change interventions.

Limitations

Perhaps the largest limitation to this study is our reliance on a short-term 1-month follow-up. This 1-month follow-up period was chosen for several reasons. First of all, this study was designed as a pilot project and was primarily concerned with showing feasibility and acceptability of our approach, with secondary emphasis on demonstrating preliminary efficacy. In addition, our 1-month follow-up period was chosen out of an initial concern of the stability of mobile phone numbers in this population.

Another limitation to our approach is our dependence on small sample sizes. To address this, depending on the differences in results of our two pilots, we will consider pooling the results if appropriate. We also acknowledge a lack of health care provider feedback in the design of BPMED and that many members of the care team, including physicians, nurses, and pharmacists, may have valuable insight to provide in the development of this sort of intervention. Given that this is a consumer-facing intervention that could be used independent of an established patient-provider relationship, we made the conscious decision to focus exclusively on the patient perspective in our design, but we do understand that additional provider feedback from a variety of care team members may have improved our ultimate design.

Finally, the lack of additional rigorous objective measures of medication adherence, such as the use of electronic pill bottles or other objective devices, may weaken our primary outcome measure. The decision not to use such devices was made out of budgetary necessity. Future work should seek to use more rigorous measures of medication adherence.

Comparison With Prior Work

The evidence supporting long-term efficacy of text message medication reminders is largely missing from the literature [11], and the evidence supporting short-term efficacy has been mixed. Improvements in medication adherence as a result of receiving text message reminders have been demonstrated for adherence to antiretroviral therapy (ART) for people living with HIV/AIDS [17], as well unspecified medication regimens [18], and a variety of conditions and treatments, including type 2 diabetes [19], glaucoma [20], schizophrenia [21], and asthma [22]. However, other studies focused on text message reminders for acne

medications [23] and oral contraceptives [24] have found no effect. A recent systematic review of text message reminders for health services by Kannisto et al [25] identified 60 studies that met inclusion criteria. Of those, 63% were focused on studies that utilized text message reminders for medication or treatment, whereas the other 37% were focused on clinical appointment reminders. Kannisto et al report that 77% of studies report improved outcomes on primary outcome measures of interest. Despite largely positive data suggesting the efficacy of the use of text message reminders for health care services, the authors acknowledge that more well-conducted studies are still needed to build the evidence base for this approach [25].

Although several studies have investigated the use of text message medication reminders for a variety of diseases, conditions, and therapeutic regimens, little work has been done to study this approach within the context of HTN. Moreover, few studies have been published to date that focus on the use of this approach within an urban, African American population. This trial protocol marks one of the first RCTs testing the efficacy of text message medication reminders on medication adherence among hypertensive African American participants.

Conclusions

This study was designed to determine preliminary feasibility and acceptability of our approach in a cohort of African Americans with uncontrolled HTN in primary care and ED settings. Through our 1-month pilot RCTs, we also expect to demonstrate preliminary efficacy of BPMED to provide support for further exploration of the use of text message medication reminders to improve HTN-related outcomes in underserved urban minorities.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Initial summary statements from AHRQ.

[PDF File (Adobe PDF File), 37KB - [resprot_v3i4e82_app1.pdf](#)]

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Abbreviations

ART: antiretroviral therapy
CUS: Center for Urban Studies
DBP: diastolic blood pressure
ED: emergency department
HTN: hypertension
ICD-9: International Classification of Diseases version 9
mHealth: mobile health
MMAS: Morisky Medication Adherence Scale
RCT: randomized controlled trial
SBP: systolic blood pressure
WSU: Wayne State University

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Protocol

A Fully Automated Diabetes Prevention Program, Alive-PD: Program Design and Randomized Controlled Trial Protocol

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Abstract

Background: In the United States, 86 million adults have pre-diabetes. Evidence-based interventions that are both cost effective and widely scalable are needed to prevent diabetes.

Objective: Our goal was to develop a fully automated diabetes prevention program and determine its effectiveness in a randomized controlled trial.

Methods: Subjects with verified pre-diabetes were recruited to participate in a trial of the effectiveness of Alive-PD, a newly developed, 1-year, fully automated behavior change program delivered by email and Web. The program involves weekly tailored goal-setting, team-based and individual challenges, gamification, and other opportunities for interaction. An accompanying mobile phone app supports goal-setting and activity planning. For the trial, participants were randomized by computer algorithm to start the program immediately or after a 6-month delay. The primary outcome measures are change in HbA1c and fasting glucose from baseline to 6 months. The secondary outcome measures are change in HbA1c, glucose, lipids, body mass index (BMI), weight, waist circumference, and blood pressure at 3, 6, 9, and 12 months. Randomization and delivery of the intervention are independent of clinic staff, who are blinded to treatment assignment. Outcomes will be evaluated for the intention-to-treat and per-protocol populations.

Results: A total of 340 subjects with pre-diabetes were randomized to the intervention (n=164) or delayed-entry control group (n=176). Baseline characteristics were as follows: mean age 55 (SD 8.9); mean BMI 31.1 (SD 4.3); male 68.5%; mean fasting glucose 109.9 (SD 8.4) mg/dL; and mean HbA1c 5.6 (SD 0.3)%. Data collection and analysis are in progress. We hypothesize that participants in the intervention group will achieve statistically significant reductions in fasting glucose and HbA1c as compared to the control group at 6 months post baseline.

Conclusions: The randomized trial will provide rigorous evidence regarding the efficacy of this Web- and Internet-based program in reducing or preventing progression of glycemic markers and indirectly in preventing progression to diabetes.

Trial Registration: ClinicalTrials.gov NCT01479062; <http://clinicaltrials.gov/show/NCT01479062> (Archived by WebCite at <http://www.webcitation.org/6U8ODy1vo>).

(*JMIR Res Protoc* 2015;4(1):e3) doi:[10.2196/resprot.4046](https://doi.org/10.2196/resprot.4046)

KEYWORDS

prediabetes; insulin resistance; diabetes; prevention; obesity; physical activity; internet; world wide web; blood glucose; metabolic syndrome

Introduction

In the United States, 86 million adults, more than one-third of the population, have pre-diabetes [1]. It has been estimated that over half will eventually progress to type 2 diabetes [2] unless they make changes to their dietary and physical activity behaviors. Therefore, there is an urgent need to reach large numbers of individuals with pre-diabetes with strategies to help them produce long-term behavioral changes and weight management.

Previous interventions intended to prevent diabetes have incorporated various levels and combinations of lifestyle coaching, in-person interaction, and technology-enhanced tools. These various models differ in reach, cost, and effectiveness. Intensive personal and group coaching can produce medically significant changes in those persons with pre-diabetes who choose to participate, as demonstrated by the Diabetes Prevention Program (DPP) [3]. While efficacious, such interventions are costly [4] and challenging to implement [5].

Adaptations of the DPP model in community settings [5-7] that rely on group meetings and frequent in-person contact require substantial organizational skills and professional or semi-professional implementation [8]. Equally important is the reluctance of many, even those quite highly motivated, to dedicate the time to attend a series of onsite meetings. Costs remain substantial [4,8] and effectiveness modest [5,9-11].

Given the well-established transience of weight loss for most people, interventions that can produce robust establishment of new habits and that also permit long-term reinforcement and support in the future are called for. Internet-delivered applications, if proven sufficiently effective, could meet a substantial part of that need. A number of such efforts have been described [9,12-16]. A meta-analysis [9] found that among electronic media-assisted programs, there was a statistically significant but modest mean weight loss of 4.2% body weight. However, often such programs rely on some form of contribution by human counselors in addition to the technological component, which substantially increases cost and will prevent the large economies of scale that a fully automated system would provide.

Fully automated technological approaches have been found to improve diet and/or physical activity behaviors [17,18]. Alive!, which forms the basis of the diabetes prevention program described here, was shown in a randomized trial to produce significant improvements in physical activity and diet [19,20]. However, fully automated or nearly fully automated programs have been studied only rarely for effectiveness on weight loss [12], and almost not at all for diabetes prevention.

To address the need for a diabetes prevention program that can reach thousands or millions of pre-diabetics with an evidence-based intervention, we designed the Alive-PreventDiabetes (Alive-PD) program. Alive-PD is a newly developed, fully automated, 1-year behavior change program to prevent the progression of pre-diabetes to diabetes. Like its precursor program [19,20], it emphasizes lasting lifestyle change in diet and physical activity, which can lead to

improvements in blood sugar and weight. It is a stand-alone intervention, although it can also be used to supplement clinician recommendations or to provide long-term support following pre-diabetes classes. This paper describes the Alive-PD program and describes the protocol of the randomized trial currently under way to evaluate its efficacy.

Methods

Study Design Overview

The Alive-PD study is a randomized parallel-group controlled trial of the Alive-PD program versus a 6-month-delayed control group among participants with pre-diabetes. The primary outcome measures are change in hemoglobin A1c (HbA1c) and fasting glucose after 6 months. After the study began, the follow-up period was extended to 12 months for both arms. We hypothesize that those in the intervention group will achieve statistically significantly greater reductions in fasting glucose and HbA1c than a delayed-entry control group at 6 months post baseline and that the intervention group will retain a statistically significant change at 1 year. Clinic assessments and laboratory data are collected at 3, 6, 9, and 12 months. The trial is ongoing.

This randomized clinical trial is being conducted in collaboration with the Palo Alto Medical Foundation Research Institute (PAMFRI). The study design and materials were approved by the Institutional Review Boards of NutritionQuest and of the Palo Alto Medical Foundation (PAMF). See [Multimedia Appendix 1](#) for the CONSORT-EHEALTH checklist [21].

Participant Eligibility Criteria

Participants were recruited from a primary care health center of PAMF, a community-based multi-specialty group practice in northern California. We used the following inclusion criteria for participation: primary care patients with pre-diabetes, age 30-69 years old, BMI ≥ 27 (BMI > 25 for Asian race/ethnic subgroups only), fasting glucose measure in the pre-diabetic range (100-125 mg/dL) or HbA1c in the pre-diabetic range (5.7-6.4%) or physician diagnosis of pre-diabetes, HbA1c $\geq 5.3\%$ and fasting glucose ≥ 95 mg/dL (added after study under way), a visit to PAMF primary care department within the past 5 years, access to email and Internet, and able to read and understand English. Those meeting the following exclusion criteria were not eligible: presence of medical conditions contraindicating gradual adoption of moderate physical activity, current use of diabetes medications or weight loss medications, currently pregnant or planning to become pregnant during the period of the study, currently doing more than 150 minutes/week of moderate/vigorous physical activity *and* currently on a low-carbohydrate diet (by self-report), and current participation in another clinical trial.

Procedures

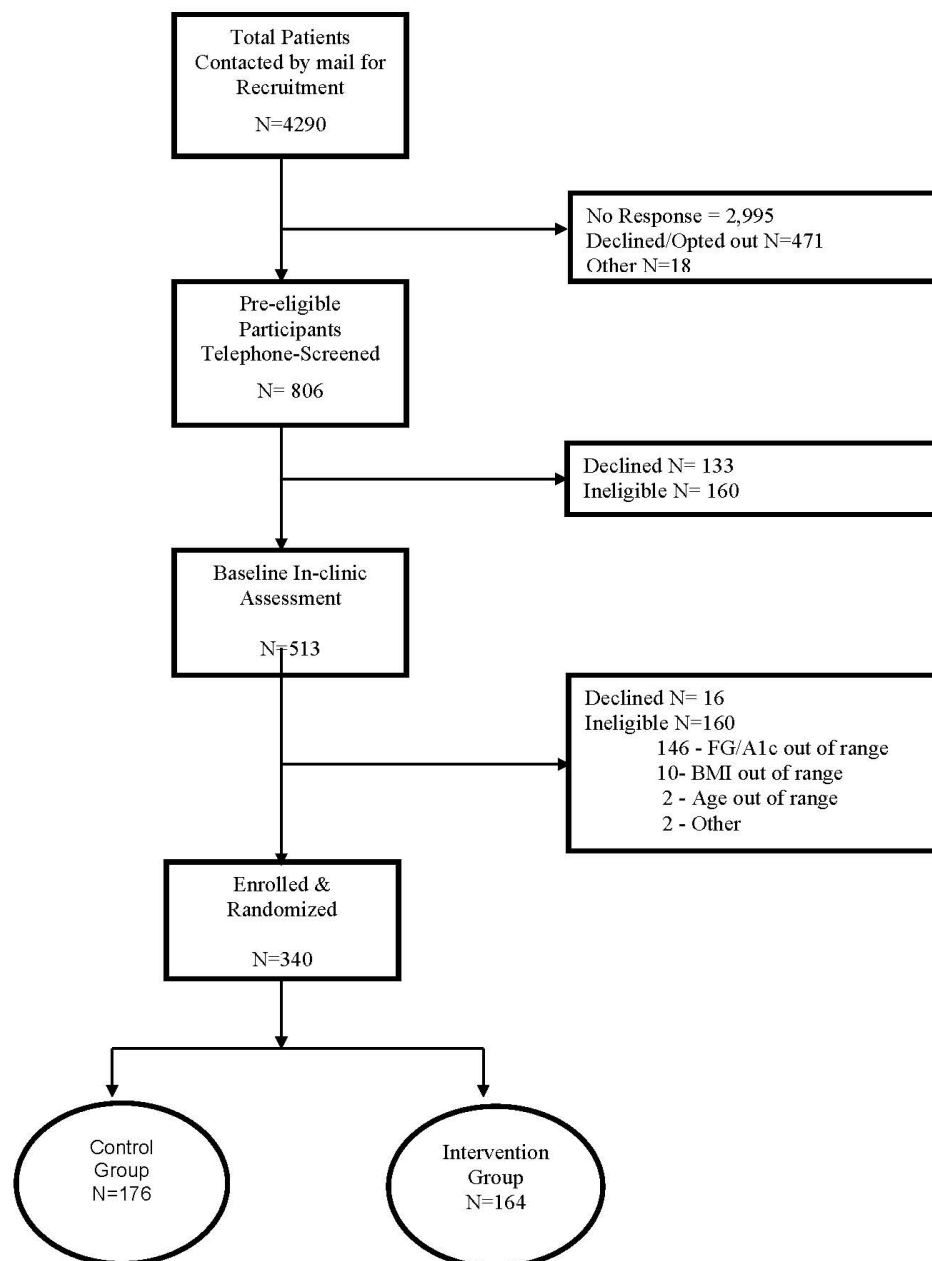
Recruitment and Screening Process

Potential participants were pre-screened and identified through an electronic health records (EHR) query using broad eligibility criteria of a recent glucose or HbA1c within the pre-diabetes range, in addition to other demographic criteria ([Figure 1](#)). In addition to the EHR query, posters were placed in the lobby of

the PAMF clinics. Study invitation letters were mailed to potentially eligible participants, with phone follow-up to explain the study, conduct further eligibility assessment, and invite participation. Those who remained eligible and were interested in participating were invited to attend the baseline visit at the

PAMF Research Institute for confirmation of eligibility based on point-of-care laboratory testing for glucose and HbA1c. Subjects were enrolled in the study between February and June 2014.

Figure 1. Flowchart of participant screening, recruitment, and randomization.



Baseline Assessment and Clinic Visit

At the baseline clinic visit, HbA1c, fasting glucose, total and high-density lipoprotein (HDL) cholesterol, triglycerides, and low-density lipoprotein (LDL) by calculation were assessed through point-of-care whole blood samples (Siemens DCA Vantage point-of-care analyzer [22] and Alere Cholestech LDX point-of-care analyzer [23] respectively). In addition to meeting other eligibility criteria, subjects were deemed eligible if either HbA1c and/or fasting glucose fell within the pre-diabetic range, and neither measure reached the diabetic range. A number of

subjects who were eligible by one measure were found to have quite low HbA1c or fasting glucose; a further restriction, HbA1c $\geq 5.3\%$ and glucose ≥ 95 , was added after the study had begun. Prospective participants with one measure in the diabetes range and the other in the pre-diabetes range were deemed provisionally eligible pending physician review and verification of pre-diabetes status. Signed informed consent was obtained.

Other biometric measures included blood pressure, height, weight, and waist circumference, measured according to the procedures recommended by the Airlie Conference. In addition, a baseline questionnaire was administered, assessing medication

use, adverse events and participation in activities relevant to weight loss, diet, and physical activity. With separate consent, a blood sample was obtained by FTA (Flinders Technology Associates) card for future research on genetic analysis of the intervention's efficacy and disease progression.

Once enrolled and confirmed eligible, subjects received brief (5-10 minutes) instruction that they were at risk for developing diabetes and that increased physical activity as well as changes in their dietary behaviors could help prevent progression to diabetes. Research staff assisted participants in signing into an account for the Alive-PD Web-based program, to confirm to the Alive-PD system that they had completed the informed consent and to provide their email address and password to the system. All subsequent communications from and interactions with the electronic Alive-PD program took place outside of the clinic.

Subsequent Clinic Visits

At 3, 6, 9, and 12 months, the same biometric and questionnaire measures are repeated. An adverse events questionnaire is also administered at each follow-up.

Randomization and Blinding

After the baseline clinic visit and the initial account set-up, randomization and delivery of the intervention is conducted electronically by the Alive-PD program, completely independent of clinic staff. After leaving the clinic, participants are sent an introductory email from the automated Alive-PD system, with further information and questionnaires. These and all further online interactions are done at a time and place of the participants' choosing. An online baseline questionnaire is required, to provide demographic and BMI information required for randomization and to provide brief eating habits and physical activity data for baseline comparison of intervention and control groups. Participants are randomized by computer algorithm, with blocked stratified randomization to achieve balance on sex, BMI (above/below 35), and race/ethnicity (white non-Hispanic, other). Participants are informed by the system by email about whether they have been randomized to begin

the program immediately or after a 6-month delay. Those in the delayed group receive no further contact until a reminder to complete a 3-month and 6-month online follow-up questionnaire. Those randomized to begin immediately receive a more extensive diet and activity questionnaire.

Reimbursement

Participants are reimbursed for attending the clinic and providing the biometric outcome data. They receive a US \$25 gift card at the 3-month clinic visit and a US \$50 gift card at the 6-month clinic visit. If they re-consent to participate in the study extension, they receive a US \$25 gift card at the 9-month clinic visit and a US \$50 gift card at the 12-month clinic visit.

Intervention

Overview

Alive-PD is a fully automated intervention, with no human coaching or advice. It is delivered via an individualized website and interactive emails and is supplemented by a mobile app and automated phone and print modules. Participants complete a diet and physical activity assessment online at baseline, followed by immediate automated individualized feedback. They also complete an activity planning tool to guide improvements in aerobic activity. Participants then engage in a program of weekly tailored goal setting and tracking over the next 6 months and every other week for the subsequent 6 months. Participants work simultaneously on dietary and physical activity behaviors. Targeted behavior changes include increasing physical activity, decreasing added sugars and some starchy carbohydrates, decreasing saturated and trans fats, increasing fruit and vegetable consumption, and achieving modest weight loss or weight maintenance. Participants are invited (but not required) to choose a long-term weight loss target of 5%, 7%, or 10% of body weight. Changes in food type and reduction in portion size are emphasized as a means of reducing calorie intake, rather than specific calorie targets or counting. The focus throughout is on the objective of lowering hemoglobin A1c and preventing diabetes. See [Figure 2](#) and [Multimedia Appendix 2](#) for screenshots and other information.

Figure 2. Alive-PD personal home page. Users are taken here when they choose goals in the weekly email. Or they may go here directly at any time -- for example, to log, check or send messages, get automated coaching. Further down the page are infographics and quizzes. If they hadn't yet chosen or reported on goals this week, the home page would show the week's suggested goals to choose, and request a report on last week's goals.



Features of the Alive-PD Program and Website

The program begins with an online baseline questionnaire that assesses the individual's intake of added sugars, carbohydrates, saturated and trans fats, fruits and vegetables, and time spent in moderate and vigorous intensity activity, walking, sedentary activities and strength training. Questionnaire content is tailored to the participant's reported ethnic dietary habits. Analysis occurs with each response, allowing for continuous and relevant feedback on the individual's reported diet and activity, in relation to national guidelines and type 2 diabetes risk factors. The questionnaire responses provide the basis for tailoring specific goals and tips for changes in diet, physical activity, and weight control that the program will recommend to the participant throughout the program. Questions on lifestyle, diet, and physical activity preferences, and psychosocial characteristics form the basis of additional tailoring.

Weekly tailored goal setting is one of the key behavioral features of Alive-PD. In addition to long-term goal setting, individually relevant small-step goals are suggested weekly, developed by an algorithm that draws from the participant's questionnaire responses, the participant-constructed activity plan, and from an extensive database of potential goals. For example, participants with added sugar intake above the recommended level are offered weekly goals targeting the individual's own

reported sources of added sugars. The goal recommendation algorithm adjusts in response to past performance.

The system suggests to participants that they select one eating habits goal and one physical activity goal from among those suggested each week. However, they may select any number of goals and/or may write their own goals each week. The program also prompts them each week to report on their success at the previous week's goals. The number and type of successful goals is tracked for the respondent. Mid-week reminders about the goals chosen that week serve to keep the participant engaged and the overall objective salient. Participants who have not responded by mid-week by choosing a goal are reminded by email and/or mobile phone of their self-reported motivations for joining the program and are encouraged again to commit to 1-2 goals for the remainder of the week.

An interactive activity planning tool forms the basis of physical activity goal setting. Alive-PD automatically creates a recommended activity plan based on a participant's measured activity level, but the participant may edit the plan at any time. The default target is 150 minutes per week, but those already achieving that level may aim higher. As participants interact with each setting, their activity plan is instantly recomputed and drawn onscreen. Their saved plan guides the tailored aerobic activity goals recommended to the participant each week.

Two weekly Health Notes, developed by Certified Diabetes Educators and behavioral experts, provide health information. Topics include subjects such as the role of diet and physical activity in preventing diabetes and other chronic diseases, physical activity guidelines, dietary sources of saturated fat and sugars, portion control, and behavioral strategies including self-monitoring, mindfulness, stress reduction, and sleep. Each Health Note includes a quiz, and participants may rate the Health Note and share it on social media. Delivery of the Health Notes may be tailored to the ethnicity of the participant.

The program promotes social support through a team system, which allows participants to send messages to each other with either a pre-drafted motivational message or a personalized message of support. The system also encourages participants to elicit the support of their personal social network. Participants may invite friends and family to the program, and those who accept receive weekly emails from the system, which include the Health Notes the participant is reading that week and a function to send a message to the participant's Alive-PD inbox.

Other features include a Daily Tracker to log weight, activity, and dietary intake, with automatic graphing over time; an automated coaching tool to help participants overcome common barriers; weekly infographics that reinforce core messages of the program; downloadable worksheets; and links to external resources.

Program engagement strategies combine intrinsic and extrinsic motivators, with individual and optional team aspects and software gamification features. At the individual level, interaction with central components of the intervention is incentivized using a points system. Participants are awarded points for the following behaviors: setting and reporting goals; successfully accomplishing goals; reading Health Notes and taking the related quizzes; logging body weight, activity, or dietary intake; and sending support messages to other Alive-PD participants. Points can be redeemed for modest monetary rewards or may be contributed to a pooled donation to the American Diabetes Association. At the team level, teams compete for small monetary rewards based on the greatest average HbA1c reduction in each 3-month period.

Automated Phone and Print

The content of these Alive-PD modules was developed by nutrition and physical activity professionals, through collaboration with Stanford and Brown University experts. With these technologies, individually tailored print and phone messages are delivered automatically by computer algorithm. They make use of the participant's baseline responses to factors such as barriers and motivations for behavior change, participant real-time dropout or adherence status, and ongoing participant reports on success at goals undertaken in the Alive-PD program. Individually tailored printed materials are sent monthly. Automated individually tailored phone coaching is delivered every 2 weeks via Interactive Voice Response technology (IVR). Participant responses to the IVR questions are recorded in the system and used to inform subsequent IVR interactions. Both phone and print are entirely automated and require no real-time professional or semiprofessional input.

Alive-PD Mobile App

Alive-PD includes an Android and iPhone app that extends some of the program functionality to the participant's mobile phone. The app allows participants to select Alive-PD weekly goals, report on accomplishment of previous goals, and set calendar reminders. The program also reinforces selected goals via push notifications and coaxes potential dropouts to engage with the program. The mobile phone app was introduced after approximately a quarter of subjects had begun the trial, at which time its availability was announced to all participants.

Online Assessment of Non-Physiologic Outcomes

Physiologic outcomes, which are the primary outcomes, are assessed by anthropometric or biometric measures in the clinic, as stated above. Other outcomes are assessed by self-administered questionnaire or through automated capture of use metrics. These include factors such as number of weeks in which a goal was chosen, number of goals chosen, number of goals achieved, number of team support messages sent, and number of quizzes answered. Changes in physical activity and eating habits are assessed by online modified Block questionnaire. Satisfaction with the program is also assessed by online questionnaire.

Theoretical Basis

Alive-PD's intervention strategies are based on principles derived from several models and bodies of behavior change research. The basic objective, derived from learning theory and other habit formation research [24-26] is to have participants gradually incorporate new eating and physical activity behaviors into their daily lives until the behaviors are both habitual and substantial enough to reduce diabetes risk. A focus on small, achievable, personally relevant goals provides continued reward from accomplishing those goals.

Strategies and features of the program are consistent with several other bodies of research, including models centering on cues and triggers [27,28], social cognitive theory [29,30], and the theory of planned behavior [31]. Concepts from behavioral economics [28,32] underlie suggestions for making desired behaviors more convenient and undesired behaviors less convenient. In addition, strategies have been influenced by research on willpower showing the neurophysiological limits of sustained cognitive control for behaviors like dieting [33]. Several empirically validated positive psychology methods [34,35] promote increased resilience and optimism, helpful when undertaking major changes. Techniques based on mindfulness research [36,37] can provide support in the face of cravings. The program's continuing flow of information on the consequences of diabetes, the ability to reduce one's risk and skills for doing so is consistent with the health belief model [38]. Promotion of social support through the messaging system, teams, and inclusion of real-world friends and family can provide reinforcement of desirable changes, buffering of stress, and continuing engagement. Further maximizing of engagement through elements such as gamification provides continuing salience of issues around health, nutrition, and physical activity. In sum, techniques consistent with a variety of theories and

models provide support for individual differences and for individuals at different times, as they gradually adopt new habits.

Measures and Data Collection

The primary outcome of Alive-PD is change in HbA1c and fasting glucose at 6 months from baseline, assessed through point-of-care whole blood samples (see Baseline Assessment and Clinic Visit, above). Secondary endpoints are clinic-measured changes in other biometric measures (weight, waist circumference, lipids and other metabolic syndrome factors, and blood pressure). We will examine retention of changes at 12 months in a pre-post analysis. In addition, we will examine self-reported behavior changes in eating and physical activity.

Statistical Analysis

Sample Size

Sample size was estimated using data from Davis et al [39], who conducted a dietary intervention in patients with diabetes. They reported standard deviations for change in HbA1c of 0.9-1.4% for one arm of the study. With an SD of 1.4 and an alpha of .05, a final sample of 268 participants would provide 80% power to detect a minimum detectable difference in change for HbA1c of 0.48. We planned to enroll 314 persons to achieve a completed sample of 268 after a 15% dropout rate.

Data Analysis

The primary approach for analyses of treatment effects on glycemic markers (HbA1c and glucose) and other biometric markers will be on the intention-to-treat population. Variables missing at follow-up will be imputed using a maximum likelihood approach. We will also repeat analyses on the per-protocol population, in which effects will be assessed among those providing follow-up biometric data and in relation to the

participants' degree of interaction with the program. Outcomes will be analyzed using linear regression models. Change in the outcome measures (HbA1c, glucose, or weight) will be included in regression models as the dependent variable, and treatment group will be included as the primary predictor variable (intervention vs delayed control). The baseline value of the outcome measure of interest will be included as a covariate. Normality, interaction, and potential confounding will also be investigated, and potential confounders will be included as appropriate. We will also examine the proportion of participants who achieve and retain categories of body weight loss, and the proportion who move from pre-diabetic to normal HbA1c. These binary outcomes will be modeled in logistic regression models with an approach similar to that described for linear regressions. Clinic staff obtaining the biometric measurements are blinded to treatment group and data analysis is conducted on masked data.

Results

Enrollment and Baseline Characteristics

A total of 349 participants completed the Informed Consent, and 340 completed the baseline online questionnaire and were randomized to Alive-PD or 6-month delayed control. The 9 participants who did not complete the baseline questionnaire did not differ in age, sex, race, BMI, or lipids, but did have a significantly lower fasting glucose but higher HbA1c (data not shown).

Baseline characteristics are shown in Table 1. The large proportion of males (68.5%, 233/340) is notable, and quite the opposite of what is commonly seen in health studies. It is also notable that only 45% of the sample were in the pre-diabetic range by HbA1c and that the mean HbA1c is in the normal range.

Table 1. Baseline demographics and clinical characteristics.

Variable	Category	All (n=340)	Control (n=176)	Intervention (n=164)	<i>P</i> ^a
Age, years, mean (SD)		55.0 (8.9)	54.8 (9.1)	55.1 (8.8)	.77
Female, n (%)		107 (31.5)	54 (30.7)	53 (32.2)	.75
Race/ethnicity, n (%)^b					.38
	White	204 (60.0)	104 (59.1)	100 (61.0)	
	Black	7 (2.1)	1 (0.6)	6 (3.7)	
	Asian	63 (18.5)	36 (20.4)	27 (16.5)	
	Hispanic	16 (4.7)	9 (5.1)	7 (4.3)	
	Other	8 (2.3)	5 (2.8)	3 (1.8)	
	Not reported	42 (12.4)	21 (11.9)	21 (12.8)	
Blood pressure, mmHg, mean (SD)					
	Systolic	130.4 (14.7)	130.4 (14.5)	130.4 (15.0)	.99
	Diastolic	82.3 (8.4)	82.6 (8.6)	82.0 (8.1)	.45
Weight, lbs, mean (SD)		204.8 (34.8)	205.6 (36.5)	203.9 (32.9)	.64
BMI, kg/m ² , mean (SD)		31.1 (4.3)	31.2 (4.3)	31.1 (4.4)	.86
Waist circumference, cm, mean (SD)		102.8 (10.8)	103.1 (11.2)	102.5 (10.4)	.59
Glucose, mg/dL, mean (SD)		109.9 (8.4)	109.0 (8.3)	110.2 (8.6)	.52
HbA1c, %, mean (SD)		5.6 (0.3)	5.6 (0.3)	5.6 (0.3)	.94
Total cholesterol, mg/dL, mean (SD)		191.5 (31.7)	191.9 (33.0)	191.2 (30.2)	.83
LDL cholesterol, mg/dL ^c , mean (SD)		116.0 (27.6)	116.5 (27.9)	115.5 (27.3)	.72
HDL cholesterol, mg/dL ^c , mean (SD)		47.3 (14.0)	46.5 (13.0)	47.8 (14.5)	.40
Triglycerides, mg/dL ^c , mean (SD)		144.6 (73.7)	148.2 (68.8)	139.4 (67.3)	.24

^aSignificance of difference between intervention and control.

^bNative American/Alaskan, Native Hawaiian/Pacific Islander, reported as multiple races or "other". Ethnicity from EHR.

^cFor LDL: Control, n=172, Intervention, n=161; for HDL: Control, n=176, Intervention, n=162; for triglycerides: Control, n=174, Intervention, n=162; for waist circumference: Control, n=175, Intervention, n=163.

Preliminary Outcome Results

Preliminary data on treatment-control differences indicate a statistically significant treatment effect on HbA1c, fasting glucose, and body weight (data reported elsewhere). These significant treatment effects were seen despite the fact that the control group achieved a statistically significant ($P<.01$) reduction in HbA1c and weight.

Preliminary Participation, Retention Results

Dropout rate (defined as permanently declining to attend further clinic visits) as of the 3-month clinic visit is 5.9% (20/340). Also as of the 3-month time point, 78% of the intervention group were still participating actively in the online program, by choosing or reporting on a goal, logging weight or activity, answering a quiz, or sending a message to team members via the online messaging system.

Discussion

Summary

The Alive-PD program is one of very few interventions designed as a fully automated algorithm-driven program for persons at risk of developing diabetes. If proven effective in the randomized trial described here, it could reach many of the 86 million US pre-diabetics with an evidence-based behavior-change intervention. In addition, the delivery of the program is highly configurable and can be readily adapted for other medical conditions or for populations with other eating and activity behaviors. Alive-PD will be commercially available.

Limitations

We will not have the duration or sample size to have a diabetes incidence endpoint. However, we do have the power to assess efficacy for glycemic control and weight loss. Furthermore, the fact that the study is restricted to participants with email and Internet access is a limitation. However, as of August 2011, 92% of American adults used email and the Internet, including 93% of whites, 87% of African Americans, and 88% of

Hispanics, and over 50% had a mobile phone. Finally, we recognize that wholly automated interactions, without person-to-person contact, can be limiting for many. However, such a system can reach large numbers at a much lower cost than systems requiring interaction with human coaches. Even modest changes on a proportion of the very large target population could result in major benefits in cost savings and disease prevention. If only 5% of the 86 million Americans with pre-diabetes were reached with an effective automated intervention program, and as few as one-third of them succeeded

in maintaining or reducing their pre-diabetic status, that would mean more than 1 million Americans with reduced risk of type 2 diabetes and billions of dollars saved in health care costs.

Conclusions

Alive-PD is a multi-channel automated intervention to prevent diabetes by lowering or preventing the increase in HbA1c and glucose. If proven effective, Alive-PD would demonstrate how a preventative intervention can be provided with wide reach, high fidelity, and low cost for persons with pre-diabetes.

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Authors' Contributions

GB obtained funding and led the study. TB, CB, GB, and HC designed and implemented the Alive-PD program. DH conducted and led the systems engineering. KA led the sub-award to PAMFRI, RR was co-investigator of the PAMFRI sub-award, and both conducted the recruitment, biological measurements, and clinic-based data collection. LP facilitated the establishment of the sub-award. GB, CB, TB, RR, KA, and LP contributed to the drafting of the manuscript.

Conflicts of Interest

CB, TB, and GB are co-owners of NutritionQuest, which developed the Alive-PD program.

Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.1 [21].

[PDF File (Adobe PDF File), 948KB - [resprot_v4i1e3_app1.pdf](#)]

Multimedia Appendix 2

Screenshots, Medicine 2.0 2014 talk, Gladys Block.

[PPT File (Microsoft PowerPoint Presentation), 4MB - [resprot_v4i1e3_app2.ppt](#)]

Multimedia Appendix 3

NIH reviewers' comments.

[PDF File (Adobe PDF File), 77KB - [resprot_v4i1e3_app3.PDF](#)]

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Abbreviations

EHR: electronic health records
HDL: high-density lipoprotein
IVR: Interactive Voice Response
LDL: low-density lipoprotein
PAMF: Palo Alto Medical Foundation
PAMFRI: Palo Alto Medical Foundation Research Institute
RCT: randomized controlled trial

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Protocol

Internet-Based Implementation of Non-Pharmacological Interventions of the "People Getting a Grip on Arthritis" Educational Program: An International Online Knowledge Translation Randomized Controlled Trial Design Protocol

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Abstract

Background: Rheumatoid arthritis (RA) affects 2.1% of the Australian population (1.5% males; 2.6% females), with the highest prevalence from ages 55 to over 75 years (4.4-6.1%). In Canada, RA affects approximately 0.9% of adults, and within 30 years that is expected to increase to 1.3%. With an aging population and a greater number of individuals with modifiable risk factors for chronic diseases, such as arthritis, there is an urgent need for co-care management of arthritic conditions. The increasing trend and present shifts in the health services and policy sectors suggest that digital information delivery is becoming more prominent. Therefore, it is necessary to further investigate the use of online resources for RA information delivery.

Objective: The objective is to examine the effect of implementing an online program provided to patients with RA, the People Getting a Grip on Arthritis for RA (PGrip-RA) program, using information communication technologies (ie, Facebook and emails) in combination with arthritis health care professional support and electronic educational pamphlets. We believe this can serve as a useful and economical method of knowledge translation (KT).

Methods: This KT randomized controlled trial will use a prospective randomized open-label blinded-endpoint design to compare four different intervention approaches of the PGrip-RA program to a control group receiving general electronic educational pamphlets self-management in RA via email. Depending on group allocation, links to the Arthritis Society PGrip-RA material will be provided either through Facebook or by email. One group will receive feedback online from trained health care professionals. The intervention period is 6 weeks. Participants will have access to the Internet-based material after the completion of the baseline questionnaires until the final follow-up questionnaire at 6 months. We will invite 396 patients from Canadian and Australian Arthritis Consumers' Associations to participate using online recruitment.

Results: This study will build on a pilot study using Facebook, which revealed promising effects of knowledge acquisition/integration of the evidence-based self-management PGrip educational program.

Conclusions: The use of online techniques to disseminate knowledge provides an opportunity to reduce health care costs by facilitating self-management of people with arthritis. Study design strengths include the incorporation of randomization and allocation concealment to ensure internal validity. To avoid intergroup contamination, the Facebook group page security settings will be set to "closed", thus allowing only invited participants to access it. Study limitations include the lack of participant blinding due to the characteristics of this KT randomized controlled trial and a potential bias of recruiting patients only online, though this was proven effective in the previous pilot study.

Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12614000397617; <http://www.anzctr.org.au/TrialSearch.aspx> (Archived by WebCite at <http://www.webcitation.org/6PrP0kQf8>).

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KEYWORDS

rheumatoid arthritis; technology; knowledge translation; clinical trial; social media

Introduction

Overview

With an aging population and a greater number of individuals with modifiable risk factors for chronic diseases such as arthritis, there is an urgent need for co-care management of arthritic conditions (pharmacological as well as non-pharmacological management). Given that there is no cure for rheumatoid arthritis (RA), patients need ready access to effective self-management programs to optimize their quality of life and reduce the burden on the limited number of health care professionals in both Canadian and Australian health systems, especially in rural locations [1,2]. RA affects 2.1% of the Australian population (1.5% males, 2.6% females), with the highest prevalence from 55-75 years (4.4-6.1%). By 2032, the number of Australians with RA is projected to increase by 40% to 0.7 million [3]. Rheumatoid arthritis affects approximately 0.9% of Canadian adults, and within 30 years it will increase to 1.3% [4]. RA is a significant source of disability and economic burden for individuals and health systems [3,5]. Allowing patients with RA to have easy access to effective self-management programs will increase patient self-efficacy, optimize their quality of life (QOL), and reduce the burden on the limited number of health care professionals in both Canadian and Australian health systems, especially in rural locations [1,2,6].

Internet-Based Health Behavior Change Programs

In general, traditional face-to-face self-management patient education programs, such as didactic lecture, videotape on RA-related information, one-to-one teaching, group education (cognitive-behavioral), and booklet or workbook are effective

in the management of RA [7,8]. However, innovative low-cost and effective methods for disseminating self-management programs to a large proportion of individuals are necessary given the increasing burden caused by physical inactivity and chronic disease [9,10]. One of the growing trends today in health care delivery includes online services and information delivered or enhanced through the Internet and related information communication technologies (ICT) [11,12]. Internet-delivered interventions have been shown to produce small, but significant improvements in health behavioral changes among the general adult population [13], with a potential for having powerful implications for those with arthritis [14]. Evidence shows that patients are beginning to rely on the Internet more frequently than their physicians as a source of health information; however, they still wish to discuss Internet-based health information with their health providers [15,16]. Current recommendations for future evaluation of the implementation of evidence-based self-management programs through online interventions [6,17-21] state that the following have not been adequately evaluated: cost effectiveness, the comparative effectiveness of different online knowledge translation (KT) strategies, and which components of complex interventions provide the greatest benefit.

One ICT method that has not been well explored in rehabilitation is social media, such as Facebook, Google+, Twitter, and LinkedIn. Although social media sites are attractive for disseminating public health messages, they remain underused by health care professionals despite their low cost and wide reach [16]. A recent systematic review [13] had nine of the 10 included studies considering the efficacy of interventions, such as online health social network websites (n=2), research health

social network websites (n=3), and multi-component interventions delivered in part via pre-existing popular online social network websites (Facebook: n=4 and Twitter: n=1). This systematic review revealed significant improvements in outcome measures related to health behavior change (effect sizes ranging from -0.05 (95% CI -0.45 to 0.35) to 0.84 (95% CI 0.49-1.19) [13]. Facebook has also been shown to be a successful tool for recruiting and communicating with a research team, even in a multinational context [22]. It provides a readily accessible portal for patients and health care professionals to share their experiences of investigation, diagnosis, and management of disease [23]. In addition, Facebook has been the medium for a learning strategy, which included external experts and thought leaders, providing professional communication via social media [24]. Facebook has not been used to deliver an effective self-management strategy in arthritis according to existing published protocols and studies using social media and ICT as a KT strategy [21,25-33].

This complex randomized controlled trial (RCT) will identify which component of various patient education approaches delivered through different ICT methods is an important catalyst for stronger effect sizes and sustainable results compared to the control condition.

People Getting a Grip on Arthritis (PGrip) is an evidence-based educational program [34] that is based on the Ottawa Panel guidelines [34-36]. It consists of education about numerous effective non-pharmacological self-management interventions for arthritis to improve health behavioral changes such as self-efficacy [37]. PGrip has been adapted by primary care providers and translated into lay words for patients to improve arthritis care in the community. The proposed PGrip-RA program will provide updated material. For the purpose of the proposed study, the PGrip program will be made available to participants via a direct Uniform Resource Locator (URL) link to the Facebook webpage (see Figure 1) and/or The Arthritis Society (TAS) PGrip webpage via email [38].

The proposed RCT will examine the effectiveness of Facebook as a KT strategy to deliver effective self-management interventions (with or without the participation of health care professionals). The protocol builds on a pilot project by proposing a larger-scale RCT that involves health care professionals and electronic dissemination of the self-management guidelines and broadening the study to include an international site.

Figure 1. Screen caption of the Facebook group page for People Getting a Grip (PGrip) on arthritis.



Hypothesis and Objective

The general hypothesis is that an online program provided to patients with RA using Facebook in combination with arthritis health care professional support and electronic educational

pamphlets can serve as a useful and economical method for KT. The primary research questions presented in [Textbox 1](#) will be addressed to explore the effect of each component of the multifaceted complex KT intervention. The secondary questions are shown in [Textbox 2](#).

Textbox 1. Primary clinical and KT research questions.

Primary clinical research questions

1. Is “PGrip-RA TAS website URL link via Facebook Plus” (Group E) more effective for self-managing pain (first dimension: clinical effect) compared with the control (Group A: general electronic educational pamphlets only [No PGrip] via e-mail [No Facebook]) at 6-month follow-up ([Figures 2 & 3](#))?
2. Is “PGrip-RA TAS website URL link via Facebook” (Group D) more effective for self-managing pain (first dimension: clinical effect) compared with the control (Group A) at 6-month follow-up ([Figures 2 & 3](#))?
3. Is “PGrip-RA TAS website URL link via email” (Group C) more effective for self-managing pain (first dimension: clinical effect) compared with the control (Group A) at 6-month follow-up ([Figures 2 & 3](#))?
4. Is “PGrip-RA workbook via email” (Group B) more effective for self-managing pain (first dimension: clinical effect) compared with the control (Group A) at 6-month follow-up ([Figures 2 & 3](#))?

Primary KT research questions

1. Is “PGrip-RA TAS website URL link via Facebook Plus” (Group E) more usable (second dimension: technology/ICT effect) compared with the control (Group A) at 6-month follow-up ([Figures 2 & 3](#))?
2. Is “PGrip-RA TAS website URL link via Facebook” (Group D) more usable (second dimension: technology/ICT effect) compared with the control (Group A) at 6-month follow-up ([Figures 2 & 3](#))?
3. Is “PGrip-RA TAS website URL link via email” (Group C) more usable (second dimension: technology/ICT effect) compared with the control (Group A) at 6-month follow-up ([Figures 2 & 3](#))?
4. Is “PGrip-RA workbook via email” (Group B) more usable (second dimension: technology/ICT effect) compared with the control (Group A) at 6-month follow-up ([Figures 2 & 3](#))?

Textbox 2. Secondary research questions.

A. Secondary clinical, economic, and KT outcome measures:

The group compared for the primary outcomes ([Textbox 1](#)) will also be assessed for the secondary outcomes at 6-month follow-up.

B. Improvement in outcome measures:

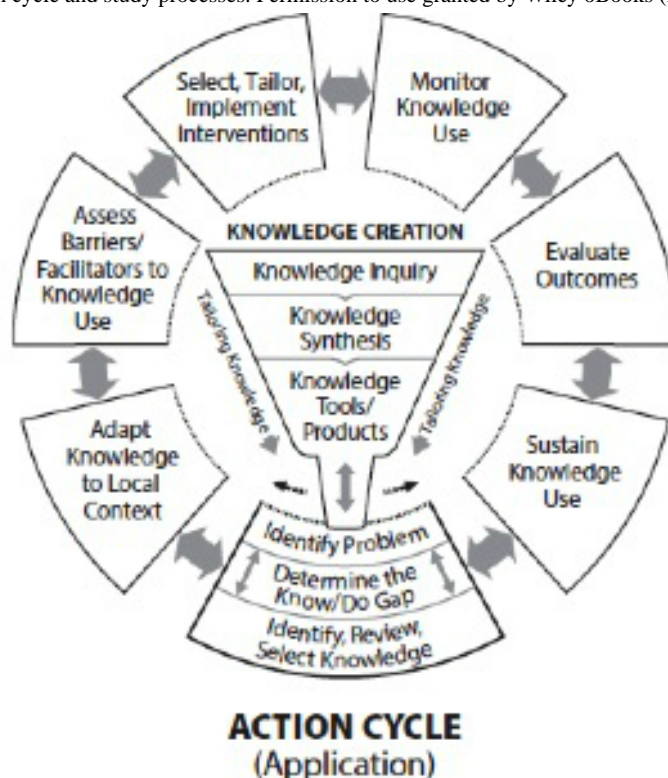
Changes in all primary and secondary outcomes will be assessed over time (baseline, 6 weeks, 3 months, and 6 months) for each study group comparison ([Textbox 1](#)).

C. Comparison of specific treatment study groups:

All primary and secondary outcome measures at 6-month follow-up and changes over time (baseline, 6 weeks, 3 months, and 6 months) will be compared between study groups as follows:

1. “PGrip-RA TAS website URL link via Facebook Plus” (Group E) compared with “PGrip-RA TAS website URL link via Facebook” (Group D).
2. “PGrip-RA TAS website URL link via Facebook” (Group D) compared with “PGrip-RA TAS website URL link via email” (Group C).
3. “PGrip-RA TAS website URL link via email” (Group C) compared with “PGrip-RA workbook via email” (Group B).
4. “PGrip-RA workbook via email” (Group B) compared with the control (Group A).

Figure 2. The Knowledge-To-Action cycle and study processes. Permission to use granted by Wiley oBooks (license number: 3340791020769).



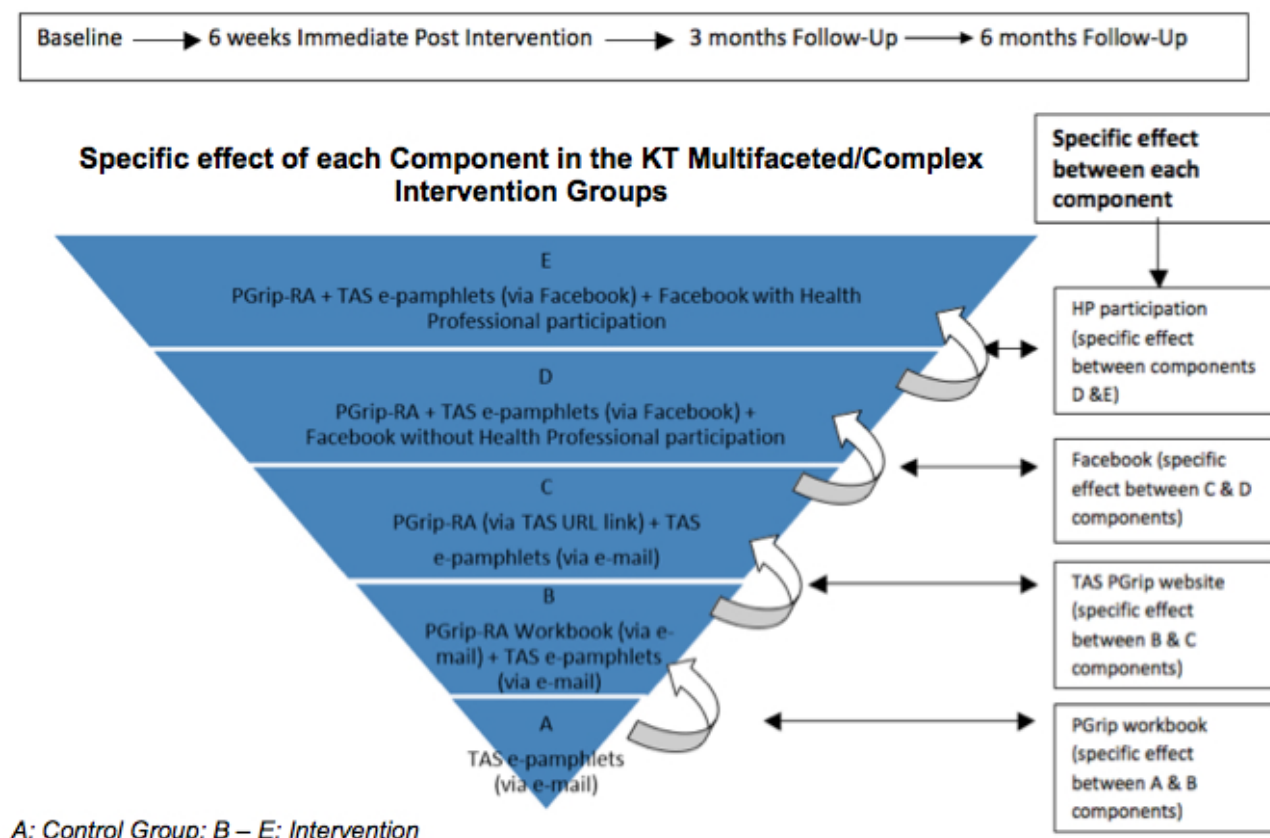
Methods

This study will be guided by the milestones of the Knowledge-To-Action (KTA) framework (Figure 2) [39]. The objective of the first dimension is to examine the effect of the implementation of the PGrip-RA program on clinical and economic outcomes (ie, clinical and economic effects). The objective of the second dimension is to examine the effect of the usability of ICT (ie, Facebook and emails) as KT strategies to implement the evidence-based PGrip-RA self-management educational program (ie, technology/ICT effect).

Study Design

The methodology used in the proposed study is in concordance with the CONSORT-EHEALTH checklist [40] (see Multimedia Appendix 1). We plan to perform an RCT that will assess five different intervention groups each receiving the PGrip-RA program delivered by different methods (Figure 3). The total intervention period is 6 weeks. Participants will have access to the online material after the completion of the baseline questionnaires up until the final follow-up questionnaire at 6 months.

This KT RCT will use a prospective randomized open-label blinded-endpoint (PROBE) design [41]. The PROBE design was selected given the nature of the study, which means the interventions, the participants, and the research coordinator administering the program will be unblinded. A blinded independent assessor will be trained to assess the online self-reported questionnaires given at the baseline, 6-week post-intervention, and at 3-month and 6-month follow-up to reduce detection bias. Investigators will be blinded to intervention assignment throughout the study period. With training and standard operating procedures, it is anticipated that any performance bias due to unblinding will be minimized. In addition, the study will use a complex intervention design, as we will be using a multifaceted intervention consisting of several educational components. In order to evaluate the effectiveness of the complex intervention, the Medical Research Council (MRC) methodological framework will be used [42]. The following key elements from the MRC framework have been accomplished: development through PGrip based on the Ottawa Panel guidelines; and feasibility and piloting, with the conduction of a previous pilot study. The evaluation and implementation elements must be completed in the proposed RCT (Figure 2); all elements will be guided by the KTA framework [39,42].

Figure 3. Specific effect of each component in the Knowledge Translation multifaceted/complex intervention groups.

Recruitment

Overview

Using online methods, we plan to recruit 396 people with RA from Arthritis Consumers' Associations across Australia and Canada. Recruitment methods include an advertisement on the Facebook page of the Arthritis Associations (eg, TAS, Arthritis and Arthritis Consumers' Associations' electronic newsletter websites and other health-related websites. Potential participants will register to a universal email address and will be invited to complete an online eligibility/admission questionnaire to ensure that they meet the study's selection criteria prior to randomization. The admission questionnaire includes information on demographics, comorbidities, comorbidities, medication intake, years of experience with ICT, expressed preference for ICT, and self-reported RA [14]. An online invitation letter with informed consent will be sent to the eligible study participants by email. Once informed consent is obtained at pre-admission, participants will be invited to complete an online baseline questionnaire. This recruitment method was approved by the University of Ottawa research ethics board for a previous pilot project using Facebook [14,43]. The recruitment process was shown to be successful in this pilot as approximately 100 participants were recruited in just over 1 month.

Feasibility

We anticipate similar compliance rates as in our pilot study [14]. Only 1% (1/97) of participants did not complete the baseline questionnaire, and 20% (17/97) did not complete the

final 3-month follow-up questionnaire. Based on data from our pilot study [14], only 2 participants out of 99 dropped out of the study. Participants were considered dropouts if they indicated that they no longer wanted to participate in the study. The sample size has been adjusted accordingly for the proposed study.

Inclusion Criteria

Participants must fulfill the following criteria: (1) between 18-75 years old, (2) diagnosed with RA, (3) reside in Canada or Australia, (4) no serious comorbidities or chronic disease (eg, cancer or other illness) judged by the patient or study physician to make participation in this study inadvisable, (5) use RA-specific medications that are not expected to change during the study period, (6) self-report as inactive (30 minutes of moderate physical activity, 5 times or less per week) or not using physical interventions or agents other than prescribed medication, (7) no concurrent face-to-face consultation with a health care provider other than general practitioners or rheumatologists for RA for the recruitment period and the duration of the study, (8) capable of using and accessing the Internet weekly and a functioning email account during the study duration (6 months) (no Facebook account required, since a Facebook group page will be created specifically for this RCT), (9) free from contraindications to exercise without supervision established by the revised version of the physical activity (PA) readiness questionnaire [44], (10) able to communicate in English, (11) be a new participant (ie, not having participated in either of the two previous PGrip pilot studies), and (12) willing to sign informed consent.

Participant Allocation

Participants will be randomly assigned PGrip-RA to one of the two Facebook intervention groups (Groups E and D), via email only groups (Groups C and B), or the No PGrip control group (Group A) based on a sequence of computer-generated random numbers using a blocking factor (randomly varying between 4 and 6). After the potential participant registers online the PGrip Gmail account, they will be contacted by the research coordinator and their eligibility confirmed. If eligible and consenting, the participant will then be randomly allocated to one of the five study groups (Group A, B, C, D, or E) using the central randomization scheme. The research assistant, who is not involved in data collection, will contact the research study Methods Center data manager. Prior to running the randomization program, the data manager will document the participant’s initials (first and last) and date of birth (month and year). After running the program, the data manager will document the intervention assignment with the participant information, assign a study identification number (ID) and then inform the research assistant of the assignment and participant ID. This process will help ensure concealment of allocation. After randomization, the participant will be informed through email of their group assignment. Participants in the interventions groups (Groups E and D) will receive specific confidential information for login purposes.

Intervention

Overview

There will be five study groups (Figure 3) in the proposed complex RCT. The PGrip evidence-based self-management educational program intervention will be provided online (via email or Facebook) for 6 weeks (Table 1). More details about intervention and control conditions are provided using the TIDieR checklist and guide [45] in the trial registry version. Similar online methods were used in the previous pilot study [14]. This study was approved by the University of Ottawa Ethics Committee (certificate number: H11-12-10).

PGrip-RA TAS Website Link via Facebook Plus (Group E)

Participants in the Facebook Plus group (Group E) will have access to a Facebook group page, which will present the PGrip-RA online program. Using the material from the previous pilot study [14], the PGrip-RA online Facebook page will include YouTube video presentations of various effective RA self-management intervention strategies based on the Ottawa Panel guidelines [34,35]. Similar to the PGrip pilot study [14,43], YouTube videos will include narrated PowerPoint presentations with simplified, concise instructions on how to perform/apply each self-management intervention and case studies illustrating their appropriateness and relevance. In addition, YouTube video presentations of practical sessions including a health care professional describing step-by-step instructions while performing the evidence-based intervention will also be posted on each Facebook group page. Participants will have the opportunity to share their unique perspective on living with arthritis and how they plan to integrate the effective self-management interventions into their daily lives by posting comments on the “wall” of the Facebook group page. Participants will take part in three separate self-management online modules, each over the course of 2 weeks, consisting of (1) physical activity interventions, (2) wrist orthotics and foot insoles interventions, and (3) transcutaneous electrical nerve stimulation (TENS) interventions. A group of three trained health care professionals with at least 1 year of clinical experience with individuals with RA will represent three professions (physiotherapy, occupational therapy, and kinesiology). An advertisement will be posted on the Arthritis Health Profession Association (AHPA) website. An interview will be performed based on their clinical experience, expertise, and ICT abilities. A general orientation on the nature and relevance of these three effective interventions will be provided. They will also be asked to read the comments and questions that participants write to each other on the “wall” and will give feedback to the participants on a weekly basis to fulfill the participants’ needs (Table 1).

Table 1. Facebook Plus (Group E) module including health care professionals.

Module (6 weeks total)	Moderator
Physical activity (PA) interventions (2 weeks)	Physiotherapist #1 and kinesiologist #1 (English)
Wrist orthotics and foot insoles interventions (2 weeks)	Occupational therapist #1 (English)
TENS interventions (2 weeks)	Physiotherapist #1 (same as PA) (English)

The health care professionals will participate in a half-day workshop at the University of Ottawa prior to the study, where they will receive training and information on evidence-based practice and the selected self-management interventions [46-52]. Training will consist of Ottawa Panel guidelines, PGrip-RA material using PowerPoint presentations and videos, and frequently asked questions from the pilot study [14]. One physiotherapist and one kinesiologist will be responsible for the physical activity module. An occupational therapist will cover the module with wrist orthotics and foot insoles. The same physiotherapist will also cover the TENS module. During each 2-week module, the respective health care professional(s) will

monitor the Facebook page on three separate days (Monday, Wednesday, and Friday for 4 hours each day), review all of the participants’ written comments, and provide feedback (Figure 3). Health care professionals involved in Group E will help Group E participants set goals for self-management interventions offered in PGrip-RA. Goal setting will not be required for the participants in the four other groups. However, study participants in Group E will record their physical activities and participation in PGrip interventions using the 7-day Physical Activity Readiness (PAR) calendar [53] included in electronic logbooks (e-logbooks) during the 6 weeks of the intervention and at 3-month and 6-month follow-up. Goal attainment and

intervention adherence will be measured in Group E by comparing individual records with what is recommended for each intervention in the PGrip program.

AHPA has agreed to recruit health care professionals with expertise in arthritis/RA on their website and newsletters. In addition, participants will be provided with TAS educational pamphlets on self-management interventions for RA (general information) by posting URL links for each on the Facebook page. The TAS educational e-pamphlets on general self-management interventions for RA will include (1) Rheumatoid Arthritis: Know your options [54] and (2) Physical Activity & Arthritis [55].

PGrip-RA TAS Website Link via Facebook (Group D)

Similar to Group E, participants in the Facebook group (Group D) will have access to a Facebook group page (separate from Group E, without the participation of health care professionals) and will participate in the three self-management modules. All participants in Group D will also be provided with TAS educational pamphlets on general self-management interventions for RA by posting a URL link for each on the Facebook page.

PGrip-RA TAS Website Link via Email (No Facebook) (Group C)

A third online intervention group (Group C) will consist of individuals being emailed (once for the entire duration of the study) a URL link to access the TAS PGrip-RA website. This website will contain the same educational information that will be provided in the Facebook groups. Individuals in this group will not have access to the two Facebook group pages and will not interact with each other or the health care professionals through written messages. Participants will also be provided with TAS educational pamphlets on general self-management interventions for RA.

PGrip-RA Workbook via Email (No Facebook) (Group B)

A fourth group will be emailed (once for the entire duration of the study) a workbook of similar quality with the content of the online PGrip-RA program in a Portable Document Format (PDF) file and the URL links of the electronic TAS educational pamphlets on general self-management interventions for RA. They will not have any access to the health care professionals, any of the Facebook group pages, or the online version of PGrip-RA.

Control With TAS Electronic Educational Pamphlets Only (No PGrip-RA) via Email (No Facebook) (Group A)

In order to avoid intergroup contamination, participants in the control group will only be emailed (once for the entire duration of the study) the URL links of the electronic TAS educational pamphlets on general self-management interventions for RA. They will not have any access to the health care professionals, the PGrip-RA material (online or PDF workbook), or any of the Facebook group pages.

Outcome Measures

Overview

The outcome measures will be measured immediately after the PGrip intervention (6 weeks) and at 3-month and 6-month follow-up to determine when the intervention becomes effective and whether effects are maintained (retention effect) (Tables 2-4 and Figure 3).

A 6-month follow-up will be considered as the primary endpoint and is supported by previous studies [25,37,56] that have found significant benefits for self-efficacy of an online, as well as a face-to-face arthritis self-management program. The PGrip evidence-based self-management educational program intervention will be provided online (email or Facebook) during the 6-week duration. This length application is justified and in concordance with existing effective arthritis self-management interventions [37,57]. We will measure immediately after the PGrip intervention and also 3 months later [58] as secondary outcome measures and to see when it becomes effective and when the effects are maintained (retention effect).

There are two theoretically based dimensions refining the KTA framework concepts for Monitoring Knowledge Use and Evaluated Outcomes (Tables 2-4; [14,53,59-71]). The first dimension is to examine the effect of the implementation of the PGrip-RA program on clinical and economic outcome measures. The Hypothesized Model of Effects of Self-Efficacy-Enhancing Interventions for People with Chronic Diseases (HMESE) (Figure 4) [59] is adapted from the Self-Efficacy and Social Cognitive Theory developed by Bandura [72] and by Lorig [60] for arthritis and chronic disease assessment purposes [60,72]. The second dimension is to examine the effect of the usability of Facebook and emails as KT strategies to implement the evidence-based PGrip-RA educational program. This will be measured by the Diffusion of Innovation Model (DIM) [61] and more specifically the Technology Acceptance Model (TAM) (Figure 5) [62].

Table 2. Assessment schedule and additional outcome measures.

Assessment	Admission	Baseline	6 weeks post intervention	3-month follow-up	6-month follow-up
Informed consent (pre-admission)	X				
Demographics	X				
Self-reported diagnosis of RA	X				
Physical Activity Readiness Questionnaire (PAR-Q) [44]	X				
Self-efficacy to manage pain		X	X	X	X
Prior knowledge of self-management programs (SMPs)		X			
Attained knowledge of SMPs			X	X	X
Intention to use SMPs			X		
Actual use of SMPs				X	X
Self-efficacy (function)		X	X	X	X
Quality of life (EQ-5D) [63]		X	X	X	X
Health resource utilization		X	X	X	X
Usability with online learning		X	X	X	X
Self-reported pain (visual analogue scale)		X	X	X	X
e-logbook (daily) using 7-day Physical Activity Recall (PAR) calendar (Facebook Plus /Group E only)		X	X	X	X
7-day PAR (periodic) [53]		X	X	X	X
Long-term goal attainment scaling (Facebook Plus /Group E only)			X	X	X

Table 3. Outcome measures according to selected measurement frameworks: KTA monitoring knowledge use.

Concept	Theory-based	Operationalization	Time period	Dimension
Knowledge acquisition (Secondary outcome measure for first dimension)	DIM [61]; TAM [62]	Questionnaire developed in pilot study	Baseline & 6 weeks	PGrip-RA: clinical dimension
Intention to use (Secondary outcome measure for first dimension)	DIM [61]; TAM [62]	Questionnaire developed in pilot study; goal setting for Facebook Plus /Group E only	6 weeks, bi-weekly during 6 weeks, 3-month and 6-month follow-up	PGrip-RA: clinical dimension; Facebook or email ^a ; technology/ICT dimension

^aFacebook or email: KT dimension using ICT.

Table 4. Outcome measures according to selected measurement frameworks: KTA evaluated outcomes.

Concept	Theory-based	Operationalization/ Instrumentation	Time period	Dimension
Self-efficacy (pain) (Primary outcome measure for first dimension)	DIM [61]; HMESE [59]	Arthritis self-efficacy (pain management subscale)	Baseline, 6 weeks, 3-month and 6-month follow-up	PGrip-RA: clinical dimension
Actual use (Secondary outcome measure for first dimension)	DIM [61]; TAM [62]; HMESE [59]	Questionnaire developed in previous pilot study [14]; 7-day physical activity readiness (PAR) calendar [53] and changes report [65] (periodic) for the previous week e-logbooks & Long-Term Goal Attainment [64] (Facebook Plus /Group E only) # log in # hits; Facebook intensity scale [66]	3-month and 6-month follow-up	PGrip-RA: clinical dimension Facebook or email ^a : Technology/ICT dimension
Better clinical outcome measures: pain, quality of life, self-efficacy (function), motivation, social (Secondary outcome measures for first dimension)	DIM [61]; HMESE [59]	Pain intensity [67]; arthritis self-efficacy (function management/other symptom subscale) [60]; Euro QoL: EQ-5D-5L [63], mobility, self-care, pain, anxiety/depression	Baseline, 6 weeks, 3-month and 6-month follow-up	PGrip-RA: clinical dimension
Interventions adherence (Secondary outcome measures for first dimension)	DIM [61]; HMESE [59]	7 day-PAR [53] (periodic) questionnaire to measure what was their typical physical activity level and other PGrip interventions just for the previous week) e-logbooks (daily) & Long-Term Goal Attainment [64] (Facebook Plus /Group E only)	Baseline, 6 weeks, 3-month and 6-month follow-up 6 weeks, 3-month and 6-month follow-up	PGrip-RA: clinical dimension
Usability (Primary outcome measure for second dimension)	DIM [61]; TAM [62]	System Usability Scale [68]; adapted TAM 2 Scale [69]	Baseline, 6 weeks, 3-month and 6-month follow-up	Facebook or email ^a : technology/ICT dimension
Better health economic outcome measures: Decreased health care costs and utilization (Secondary outcome measure for first dimension)	DIM [61]; HMESE [59]	Health Resource Utilization questionnaire [70]; quality adjusted life years (QALY) [71]	Baseline, 3-month and 6-month follow-up	PGrip-RA, Facebook or email ^a : economic dimension

^aFacebook or email: KT dimension using ICT.

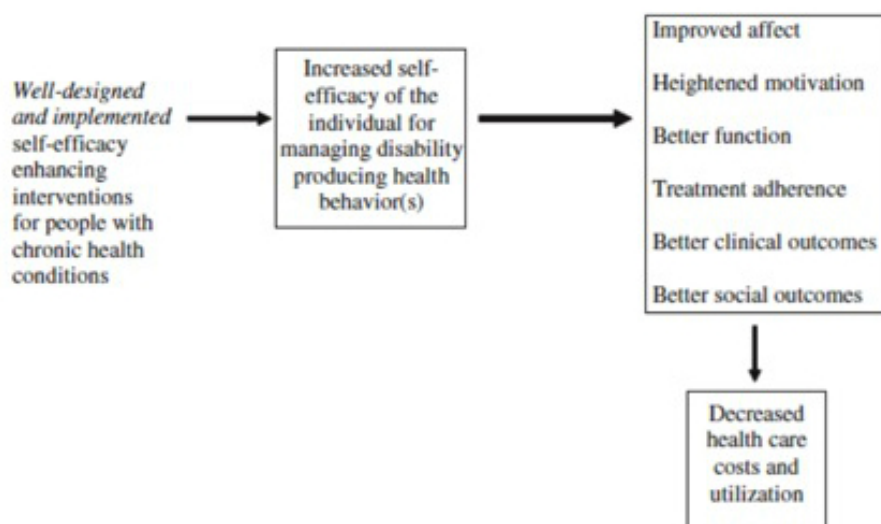
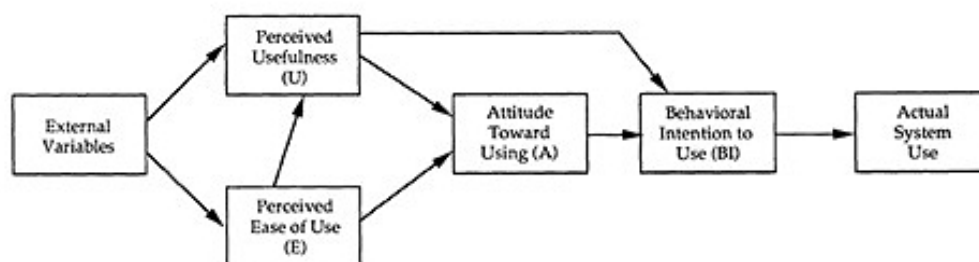
Figure 4. Hypothesized model of effects of self-efficacy-enhancing interventions for people with chronic diseases. Permission to use granted by SAGE Publications (license number: 3340780145743).

Figure 5. Technology Acceptance Model. Reprinted by permission. Copyright [1989] INFORMS. Fred D. Davis, Richard P. Bagozzi, Paul R. Warshaw (1989) User Acceptance of Computer Technology: A Comparison of Two Theoretical Models. Management Science 35(8):982-1003, the Institute for Operations Research and the Management Sciences, 5521 Research Park Drive, Suite 200, Catonsville, Maryland 21228, USA.



Self-Efficacy to Manage Pain Related to KTA Evaluate Outcomes (Primary Outcome Measure: Clinical Effect, First Dimension)

Self-efficacy is one's belief and confidence to perform a given behavior, such as exercise [56-60,72]. Self-efficacy was chosen as the primary outcome measure, as the self-management interventions consist of various activities to improve symptoms associated with RA, principally pain. The measurement of self-efficacy will therefore capture the effectiveness of all interventions regardless of the specific type of self-management strategy. The Stanford Arthritis Self-Efficacy Scale (ASES), a valid tool with an internal consistency reliability of 0.94 [60], will be used to assess participants' self-efficacy (Tables 2 and 4). The subscales of the ASES tool (self-efficacy to improve function and other symptoms) will be used for secondary outcome measures. The internal consistency reliability of the pain scale is 0.75 with a test-retest reliability of 0.87, while the internal consistency reliability of the pain scale is 0.87 with a test-retest reliability of 0.90 [60].

Usability With ICT Related to KTA Evaluate Outcomes [Primary Outcome Measure: Technology/ICT Effect, Second Dimension]

Participants in all groups will be assessed according to their level of usability with their respective ICT KT strategy (ie, Facebook or email). The System Usability Scale (SUS) instrument (Tables 2 and 4), an empirically validated tool [68], as well as the adapted technology acceptance model (TAM) 2 scale [69], will be used to measure participants' usability perception at baseline, 6 weeks immediate post-intervention, and 3-month and 6-month follow-ups (Tables 2 and 4).

Knowledge Acquisition, Related to KTA Monitoring Knowledge (Secondary Outcome Measure)

Knowledge acquisition will be measured by questionnaires used in the previous pilot study [14]. Participants' pre-program knowledge of the self-management interventions will be assessed at baseline, and post-program knowledge will be measured at 6 weeks immediate post intervention (Tables 2 and 3). Participants will be asked to complete a series of questions using a Likert scale to determine which self-management strategy options are effective for treating RA. Knowledge acquisition related to ICT use will also be performed. Examples of how "knowledge use" and "intended use" were operationalized are presented in Table 3.

Intention to Use the PGrip Self-Management Interventions (Secondary Outcome Measure)

Intention to use the PGrip-RA self-management interventions will be measured via questionnaires used (Tables 2 and 3) in the previous pilot study [14]. Study participants in Group E will be asked to set goals bi-weekly regarding any self-management interventions offered by PGrip-RA with the guidance of a health care professional (Group E).

Actual Use of the PGrip Self-Management Interventions and ICT Related to KTA Evaluate Outcomes (Secondary Outcome Measure)

Actual use of the PGrip-RA self-management interventions will be measured by questionnaires used (Tables 2 and 4) in the two pilot studies [14,73]. The number of views of the YouTube videos and the number of comments and postings (Facebook or emails) will be recorded. Furthermore, the Facebook Intensity Scale will be used to measure participants' overall engagement in Facebook for groups E and D only [66]. PGrip-RA program adherence will be measured with the actual use questionnaire [14] and also by calculating the proportion of the number of intervention sessions performed divided by the number of sessions prescribed (eg, walking program 3 times a week as recommended in the Ottawa Panel guidelines [34,35]) and recorded in the participants' online logbooks. A logbook used in a previous RCT [65], will be filled out daily online (e-logbook: as exploratory outcome measure) using the validated 7-day PAR calendar [53,74] during the study duration by study participants in Group E and a bi-weekly questionnaire on potential changes in PA, medication intake, habits, and adverse events. The calendar proposed by the 7-day PAR [53] incorporated in the e-logbooks (Tables 2 and 4) will be used as a self-report questionnaire to calculate the number of intervention sessions each participant will attend each week.

However, the periodic online 7-day PAR questionnaire [53] (Tables 2 and 4) will be performed by all the study participants of the five study groups (A-E) at baseline, 6 weeks post intervention, and 3-and 6-month follow-up to measure their typical physical activity level only for the previous week. The 7-day PAR will also be adapted to record prescribed numbers of application sessions of other physical interventions (eg, physical activity, TENS) to be optimally effective according to the Ottawa Panel guidelines [34,35]. Actual individual recordings in the 7-day PAR calendar will be compared with PGrip-RA intervention recommendations using the long-term

goal attainment scale [64]. Long-term goal attainment scaling is a validated tool that will measure (as an exploratory outcome measure) participants' long-term goal attainment levels (Tables 2 and 4) in Group E only. It includes five goal attainment levels: (1) -2 (much worse than expected), (2) -1 (somewhat less than expected), (3) 0 (expected level), (4) +1 (somewhat better than expected), and (5) +2 (much better than expected) [64].

Self-Efficacy to Improve Function Related to KTA Evaluate Outcomes (Secondary Outcome Measures)

The self-efficacy function subscale of the ASES will be used to measure participants' self-efficacy to improve their functional status (Tables 2 and 4). The internal consistency reliability of this scale is 0.90 with a test-retest reliability of 0.85 (Tables 2 and 4) [60].

Quality of Life Related to KTA Evaluate Outcomes (Secondary Outcome Measure)

Quality of life will be assessed using the EuroQoL Index (EQ-5D-5L) [63] (Tables 2 and 4). It is the most commonly used and extensively validated measure of health-related quality of life [72]. It includes five domains: (1) mobility, (2) self-care, (3) usual activities, (4) pain/discomfort, and (5) anxiety/depression. The scoring system has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems [72]. The EQ-5D-5L is an integral component of the economic analysis detailed later (Tables 2 and 4). QOL will be measured at baseline, 6 weeks, 3-month, and 6-month follow-up.

Self-Reported Pain (Secondary Outcome Measure)

Study participants' self-reported assessment of pain intensity will be recorded at baseline, 6 weeks, 3 month, and 6 month follow-up on an online 100-millimeter (mm) visual analogue scale (Tables 2 and 4), where 0 mm represents no pain and 100 mm maximal pain (Tables 2 and 4) [67].

Economic Outcomes (Secondary Outcome Measures) and Analysis

These outcomes are described in the Economic Evaluation section.

Measurement Frequency

Four different measurement sessions will be conducted throughout this RCT for each participant in all five groups (Table 2 and Figure 3). All measurements will be performed through the use of online questionnaires and will take 45 minutes to complete. Online questionnaires will be developed using an online survey tool "Fluid Survey", which is a Canadian and confidential database. The online questionnaire is in accordance with the CHERRIES checklist [75] and will be made accessible to participants in Groups E and D on the Facebook pages using a URL link to access each online questionnaire on each group page. Participants in Groups C, B, and A will be emailed the same URL link to access the questionnaires. Using the "wall" on the Facebook page for Groups E and D, our research team will provide updates and reminders to all participants regarding deadlines to complete questionnaires. As an incentive and to reduce the number of participant dropouts, the participants will

receive a CAN \$30 gift certificate for each completed questionnaire and a personalized certificate of participation. Prior to obtaining participants' mailing addresses, participants will be asked to give their consent to provide this personal information in order to receive the gift certificate.

Statistical Analysis

Overview

Data analysis will be performed using SPSS 21 and will be conducted on an intention-to-treat basis using multiple imputation for missing data. Descriptive statistics such as proportions, means, and standard deviation will be used to summarize baseline variables across the five study groups (Groups A-E) (Figure 3). Baseline characteristics will be assessed to ensure there are no differences among the study groups.

For the primary research questions (Textbox 1), an analysis of variance (ANOVA) will be conducted to compare groups B-E to A on the primary clinical outcome measure (ie, self-efficacy to manage pain using ASES) and primary KT outcome measure (ie, usability using SUS) at 6-month follow-up. In particular, Dunnett's multiparameter test will compare groups B-E individually to group A on the primary outcome measure. If clinically important differences in baseline variables are found, the interventions will be compared adjusting for these baseline variables using multiple regression and similar multiparameter tests will be conducted.

For the secondary outcome measures (secondary research questions A) (Textbox 2), the same analysis strategy considered for the primary outcome measures will be followed.

Furthermore, for the change over time from baseline, 6 weeks, 3 months, and 6 months for the primary and secondary outcome measures (secondary research questions B) (Textbox 2), a two-way repeated measures ANOVA will be conducted involving the within factor time (0, 6 weeks, 3 months, 6 months) and between factor (study group), following a similar strategy as outlined above for the primary outcome measures.

In order to assess the importance of the different components making up the interventions for Groups B-E (secondary research questions C) (Textbox 2), an ANOVA will be conducted and a posterior test using Tukey's honest significance difference test will compare Group E to D, Group D to C, Group C to B, and Group B to A. This analysis will be considered for all outcomes. In addition, the outcomes will be compared from baseline to 6 weeks immediate post intervention, and 3-month and 6-month follow-up using a two-way ANOVA with the between factor as the study groups (Groups A-E) and the within factor as time (baseline, 6 weeks, 3 months, and 6 months).

The cost-effectiveness analysis is described in the economic evaluation section below. Further, the number of visits per page will be monitored using Facebook's group page tracking tool, and qualitative information will be collected from comments and posts on the Facebook group page wall. This qualitative data will be analyzed using a generalized content analysis approach [76].

In addition to multiple imputation for missingness, general repeated measures likelihood methods will be considered when repeated observations are available, in order to provide an assessment of the robustness of the missingness estimation.

Sample Size Calculations

The sample size is based on the number of observations needed to compare self-efficacy to manage pain (ie, primary clinical outcome measure) and usability (primary KT outcome measure) at 6-month follow-up. In the psychometrics paper for the Stanford Arthritis Self-Management Study [60], the standard deviation of the self-efficacy to manage pain subscale of the ASES for the control group was found to be 1.79. A small effect size of 0.15 in pain self-efficacy (and similarly for usability measured by SUS [14]) was identified by the investigators as being a minimal clinically important effect size to identify. The spread in the means across the study groups is formally represented by the standard deviation of the group means (Figure 6) [77]. To detect an effect size of 0.15, the size of the variation in the means as represented by their standard deviation is 0.90, given the common standard deviation within a group measured with the self-efficacy in pain scale of the ASES of 1.79

(difference in means (.15) (1.79)=0.90). Given the self-efficacy to manage for the control group [60] of 4.82, the hypothesized means being compared for the five study groups are 4.82, 5.09, 5.36, 5.63, and 5.90. In a one-way ANOVA study, a sample size of 63 is needed for each of the five groups whose means are to be compared. The total sample of 315 subjects achieves 80% power to detect an effect size of 0.15 in the differences among the means versus the alternative of equal means using an *F* test with a 0.025 significance level (0.025 selected since there are two primary outcome measures).

With the given sample size of 63 per group, we will be able to detect an effect size of 0.21 in the SUS scale for usability. This small effect size was deemed acceptable by the study investigators. This effect size is based on a standard deviation of 3.1 from the pilot study, 80% power, 0.025 significance level, and the sample size of 63 derived for the primary clinical outcome.

To account for a potential loss to follow-up, the sample size has been adjusted to accommodate a 20% loss which is typical of the losses in similar past studies, that is, $63(1-.2)=79$ per group, and in total 396.

Figure 6. Sample size formula.

$$\sigma_m = \sqrt{\frac{\sum_i^5 = 1(m_i - \bar{m})^2}{5}}$$

Economic Evaluation (Secondary Outcome Measure: Economic Effect, First Dimension)

The economic analysis will be a cost-utility analysis where we will compare the costs of the five comparative groups related to their health service utilization over the 6-month period. In order to facilitate the economic analysis, estimates of total costs for each participant will be assessed at baseline and at 6-month follow-up. These will be obtained from each participant to attain an estimate over the duration of this RCT. Finally, these participant-level costs will be analyzed to obtain estimates of average costs for each of the five alternatives considered within this RCT. Estimates of resource use (over the previous 6 months) will be obtained from a health resource utilization questionnaire at baseline and 6 months included in the online questionnaires. The questionnaire will provide information on participant's use of family physician visits, specialist visits, prescription drug use, and other related health care resource use. The questionnaire will be a modified version of one we have used in a previous study [65]. Each health and community resource will have a unit cost applied to it. The weighted sum of resource use will be used to estimate the total cost. Resource costs for hospitalization will be obtained from the Ontario Case Costing Initiative [78]. For health care professional consultation and

specific procedures, costs will be obtained from the provincial fee schedule [79]. Costs for outpatient medication will be obtained from the provincial drug formulary [80]. Utility values derived from the EQ-5D-5L responses (Tables 2 and 4) will be used to estimate QALYs for the 6-month period adjusting for baseline utility. The economic analysis will compare the incremental cost per QALY gained by each intervention group (Groups B-E) compared to the control (Group A) at 6-month follow-up. In order to estimate and adjust for the uncertainty of the incremental cost and effectiveness, probabilistic analysis will be conducted using non-parametric bootstrapping [81].

Results

This proposed RCT builds on a previous pre-post pilot study using Facebook [14], which revealed promising effects of knowledge acquisition/integration of the evidence-based self-management PGrip educational program.

Discussion

Strengths and Limitations

The proposed KT international study is a rigorous RCT using the PROBE design with a low-cost online intervention. The

major strength of this study design is that it will use ICT to deliver information to people with RA that is both accessible and interactive. The design will be able to overcome the barriers of geographical distance between the two study sites (Canada and Australia) and resolve other disparities in care. Making use of the rapid increases in eHealth will appeal to consumers who are already consulting online sources for self-management [9,10,13,14]. Assessments will include a range of outcome measures from self-efficacy to usability to health economics. Furthermore, the study design is sustainable, easily modifiable, low-cost, and is in alignment with current primary care and chronic disease management reforms.

However, blinding participants is impossible in this type of study, as is generally the case with physical rehabilitation RCTs [82]. We recognize that the results of this study will likely be generalizable only to individuals with RA who are computer literate and have Internet access. Furthermore, we are also aware of the potential bias of recruiting patients only online, though this was efficient in the previous pilot study [14].

Self-reported diagnosis is also a limitation of this project. Since it is an online project, the investigators cannot request participants to send via email a confirmed medical diagnosis, for ethical and confidentiality issues. However, to minimize the potential misclassification bias, a specific question about confirmed diagnosis of RA will be included in the admission questionnaire delivered through the online survey tool "Fluid Survey", which is a confidential database. This specific question will precisely describe the symptoms and criteria of RA.

Another limitation involves the timeframe of the intervention, as they will not be assessed for adherence in the long term beyond the 6-month follow-up. There is an increased risk of Type-1 error due to the presence of multiple outcomes (ie, multicollinearity).

Challenges and Potential Solutions

The national implementation of the PGrip pilot study [14] previously identified challenges to the uptake of the best evidence for RA due to varying perceptions about facilitators and barriers in adopting effective self-management interventions for RA. These barriers will be considered by the research team

developing the program. The PGrip educational program will be built into the format, delivery, and content of all online learning modules. An additional challenge will be adapting the hands-on portions of the program (interactions with patients and faculty, exercise demonstrations, assistive devices demonstrations) to an online environment. Videos will be one strategy used to address these issues as well as linking participants with local resources to provide another means of reinforcing the learning. Creating a peer support network might be another approach. These strategies will be considered by the team in the planning process, since the members provide expertise in this area.

Another challenge is with the recruitment of participants and convincing them that using Facebook will be secure. This could be solved by providing a statement on the informed consent form indicating that their information will remain confidential. Since this will be a long study, it will be difficult to maintain adherence, and participants not in Group E will have less motivation to set goals independently and complete their e-logbooks during the retention phase after the first 6 weeks. Videos may serve as a reminder of how to optimally perform the interventions so participants will be encouraged and have a desire to continue with the intervention. Those who are in Group E will receive reminders to set goals and complete their e-logbooks, and periodic online questionnaires could also help remind all participants to continue with the intervention. Seasonal challenges could make it more difficult for participants in Canada to remain self-motivated, so adjustments in the commencement of the study to avoid the winter months (ie, starting at the end of March and continuing until late September) is a potential solution.

After the completion of this RCT, the People Getting a Grip on Rheumatoid Arthritis (PGrip-RA) program on the arthritis.ca website can be disseminated, for instance, through the Facebook page of The Arthritis Society (Canada) as well as that of Arthritis and Osteoporosis (Australia) for a broader group of arthritic individuals, especially for use in rural or underserved areas. The use of social media as a method to disseminate self-management programs is novel and has a high potential to be a method to increase access to information for individuals with arthritis, particularly in rural or underserved areas.

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LB conceptualized the design of the whole proposal for the KT study, the PGrip program, the KT intervention, and conceptualized and conducted the pilot study in Canada. GAW contributed to methods, sample size calculation, and statistical analysis. SB conceptualized the PGrip program, the KT intervention, and conceptualized and conducted the pilot study in Canada. KB, AB, KTA, and SC conceptualized the design for the KT intervention. CS and DS conceptualized the design for the KT intervention and conceptualized and conducted the pilot study in Australia. JK, RT, ME, LL, GDA, LC, MB, CS, AP, PR, and SP conceptualized the KT intervention and conceptualized and conducted the pilot study in Canada. RA conceptualized the frameworks in communication sciences and the KT intervention. DC contributed to methods and statistical analysis for the health economics aspect.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.2 [40].

[PDF File (Adobe PDF File), 1007KB - [resprot_v4i1e19_app1.pdf](#)]

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Abbreviations

AHPA: Arthritis Health Profession Association

ANOVA: analysis of variance

ASES: Stanford Arthritis Self-Efficacy Scale

EQ-5D-5L: EuroQoL Index

HMESE: Hypothesized Model of Effects of Self-Efficacy-Enhancing Interventions for People With Chronic Diseases

ICT: information communication technologies

ID: identification number
KT: knowledge translation
KTA: knowledge-to-action
MRC: Medical Research Council
OA: osteoarthritis
PA: physical activity
PAR: physical activity readiness
PAR-Q: Physical Activity Readiness Questionnaire
PGrip: People Getting a Grip on Arthritis
QALY: quality-adjusted life year
QOL: quality of life
RA: rheumatoid arthritis
RCT: randomized control trial
SMP: self-management program
SUS: System Usability Scale
TAM: Technology Acceptance Model
TAS: The Arthritis Society
TENS: transcutaneous electrical nerve stimulation

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Protocol

Impact of the Mobile HealthPROMISE Platform on the Quality of Care and Quality of Life in Patients With Inflammatory Bowel Disease: Study Protocol of a Pragmatic Randomized Controlled Trial

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Abstract

Background: Inflammatory bowel disease (IBD) is a chronic condition of the bowel that affects over 1 million people in the United States. The recurring nature of disease makes IBD patients ideal candidates for patient-engaged care that is centered on enhanced self-management and improved doctor-patient communication. In IBD, optimal approaches to management vary for patients with different phenotypes and extent of disease and past surgical history. Hence, a single quality metric cannot define a heterogeneous disease such as IBD, unlike hypertension and diabetes. A more comprehensive assessment may be provided by complementing traditional quality metrics with measures of the patient's quality of life (QOL) through an application like HealthPROMISE.

Objective: The objective of this pragmatic randomized controlled trial is to determine the impact of the HealthPROMISE app in improving outcomes (quality of care [QOC], QOL, patient adherence, disease control, and resource utilization) as compared to a patient education app. Our hypothesis is that a patient-centric self-monitoring and collaborative decision support platform will lead to sustainable improvement in overall QOL for IBD patients.

Methods: Participants will be recruited during face-to-face visits and randomized to either an interventional (ie, HealthPROMISE) or control (ie, education app). Patients in the HealthPROMISE arm will be able to update their information and receive disease summary, quality metrics, and a graph showing the trend of QOL (SIBDQ) scores and resource utilization over time. Providers will use the data for collaborative decision making and quality improvement interventions at the point of care. Patients in the control arm will enter data at baseline, during office visits, and at the end of the study but will not receive any decision support (trend of QOL, alert, or dashboard views).

Results: Enrollment in the trial will be starting in first quarter of 2015. It is intended that up to 300 patients with IBD will be recruited into the study (with 1:1 allocation ratio). The primary endpoint is number of quality indicators met in HealthPROMISE versus control arm. Secondary endpoints include decrease in number of emergency visits due to IBD, decrease in number of hospitalization due to IBD, change in generic QOL score from baseline, proportion of patients in each group who meet all eligible outpatient quality metrics, and proportion of patients in disease control in each group. In addition, we plan to conduct protocol

analysis of intervention patients with adequate HealthPROMISE utilization (more than 6 log-ins with data entry from week 0 through week 52) achieving above mentioned primary and secondary endpoints.

Conclusions: HealthPROMISE is a unique cloud-based patient-reported outcome (PRO) and decision support tool that empowers both patients and providers. Patients track their QOL and symptoms, and providers can use the visual data in real time (integrated with electronic health records [EHRs]) to provide better care to their entire patient population. Using pragmatic trial design, we hope to show that IBD patients who participate in their own care and share in decision making have appreciably improved outcomes when compared to patients who do not.

Trial Registration: ClinicalTrials.gov NCT02322307; <https://clinicaltrials.gov/ct2/show/NCT02322307> (Archived by WebCite at <http://www.webcitation.org/6W8PoYThr>).

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KEYWORDS

medical informatics; patient reported outcome; mHealth; engagement

Introduction

Background

Inflammatory bowel disease (IBD) is a chronic condition of the bowel that affects over 1 million people in the United States [1]. Although the incidence of IBD is rising, the precise cause of the disease remains unknown. Medical treatment for IBD has improved significantly in recent years; however, current efforts are largely ameliorative rather than curative. As a result, IBD patients have to cope with a lifelong condition in which there are commonly remissions and relapses. This makes IBD patients the ideal candidates to target for improved self-management when it comes to care.

While diseases such as hypertension and diabetes render themselves well to quality improvement efforts because of standardized indicators such as blood pressure and hemoglobin A1C respectively, a single quality-of-care (QOC) metric cannot define a heterogeneous disease such as IBD, where optimal approaches to manage patients differ between different phenotypes. Furthermore, IBD profoundly affects patients not only physically but also in social, professional, and emotional activities [1,2]. Overall well-being of IBD patients cannot be achieved if these dimensions are not improved [3-6]. Unfortunately, most of the currently proposed quality improvement initiatives in IBD are process measures and do

not include quality of life (QOL) or clinically meaningful outcomes such as clinical remission or hospitalizations that matter most to patients and their state of health [7].

Chronic diseases affect almost 1 out of every 2 Americans and produce a significant burden on US health care [8,9]. Meaningful health system quality improvement warrants patient-provider interaction focused on QOC and QOL in chronic diseases like IBD [10,11]. For health care teams, the question remains: how do we better engage patients without placing increased time constraints on health care staff? Based on pilot work, we believe that patients are as eager as physicians, if not more, to improve their QOL and care, and involving them as partners to improve care can bring remarkable efficiency to current quality improvement efforts [3].

Objectives

HealthPROMISE [12] is a unique cloud-based PRO (patient-reported outcome) and decision support platform developed at Sinai AppLab, Icahn School of Medicine at Mount Sinai [13]. Patients track their QOL and symptoms, and providers can use the visual data in real time (integrated with electronic health records [EHRs]) to provide better care to their entire patient population (Figures 1 and 2). HealthPROMISE addresses unique challenges to improving quality and outcomes for patients with a chronic disease like IBD.

Figure 1. Quality of life measure.

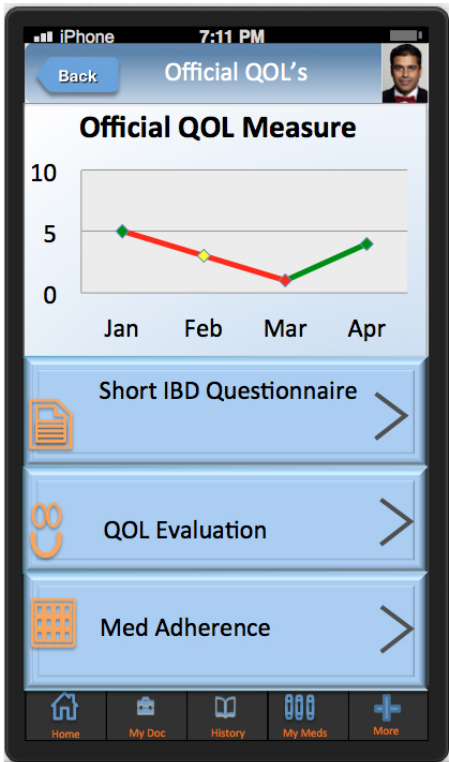
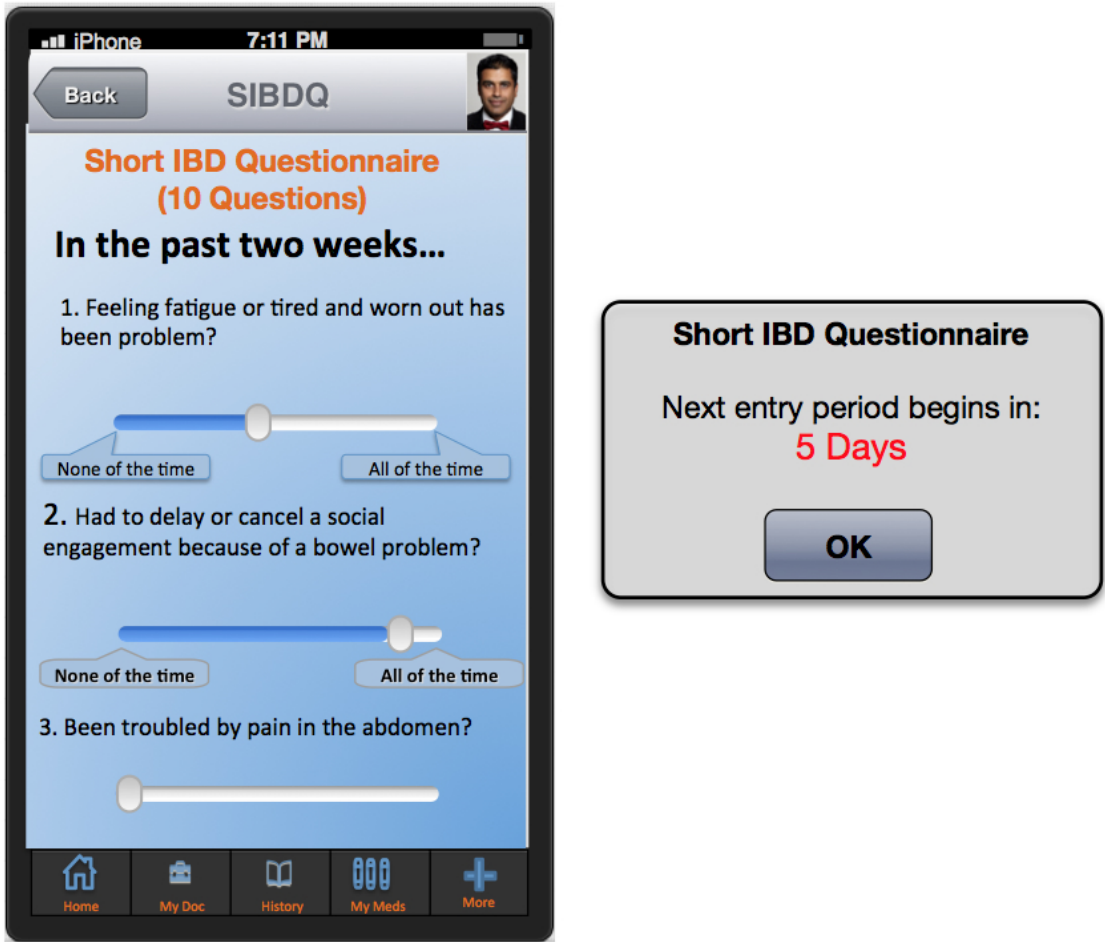


Figure 2. Short Inflammatory Bowel Disease Questionnaire.

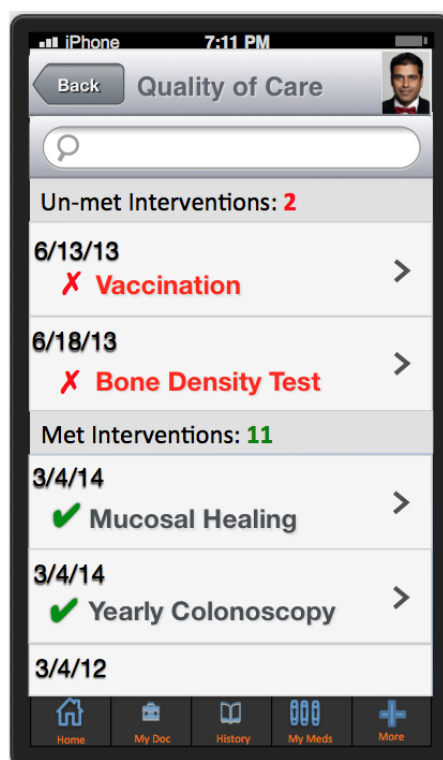


Adopting a Broader Definition of Quality

A more comprehensive assessment may be provided by complementing the QOL with quality of care metrics (Figure 3). QOL has been defined as “a global measure of patient’s perceptions, illness experience, and functional status that incorporates social, cultural, psychological, and disease-related factors” [14]. QOL metrics can be used to inform outcomes in clinical encounters, monitor population health, and as end points in clinical trials [14]. National Institutes of Health (NIH) Patient

Reported Outcomes Measurement Information System [15] and more recently Project Health Design [16] have provided valuable insights into generic measurements for QOL. To address this challenge, we have previously defined a set of comprehensive quality indicators for IBD patients through analyzing different focus groups to study what factors patients assess and value when defining “quality” in terms of living with IBD and the treatment of IBD. Additionally, through semi-structured interviews and Delphi panel sessions with 15 providers, provider input on QOC was recorded.

Figure 3. Quality of care.



Decreasing the Burden of Measuring Quality

Quality improvement efforts so far have shown that measuring even limited QOC metrics carries a prohibitively high administrative and cost burden. The estimated costs from the Institute for Healthcare Improvement quality improvement initiative for either congestive heart failure or diabetes ranged from \$81,000 to \$148,000 per organization [17]. Chen and Bates have shown that total reported costs for inpatient quality improvement for a hospital ranged from \$2 million to \$21 million, with the majority of costs attributed to collecting and reporting quality metrics for national organizations [18]. This burden of measuring quality is likely to increase exponentially when multiple QOC metrics are included in quality measurement. To address this challenge, patient- and physician-provided indicators were incorporated into a mobile health strategy platform, HealthPROMISE, that allows patients to record and self-report their QOL and treatment with regards to their IBD.

Improving the Effectiveness of Quality Improvement Initiatives

Currently, there is no well-accepted national model for quality improvement. Most of the quality improvement projects to date involve some kind of data abstraction from the clinical encounters that is fed into a registry to allow benchmarking, risk adjustment, and quality reporting. This cycle takes anywhere from a few weeks to a few months and happens long after the patient has left the health care facility. Patients are not involved in measuring or improving quality. Thus, an important patient-physician “productive interaction” opportunity to improve outcomes at the point of care is missed [19]. In HealthPROMISE, patients track symptoms and QOL before office visits and in waiting rooms, thus allowing meaningful discussion about QOC to take place during office visits (Figures 1 and 2).

The aim of this research protocol is to evaluate the patient-centric Web- and mobile-based application, HealthPROMISE, where IBD patients longitudinally measure their QOC and QOL metrics and physicians use this information for collaborative decision making and improving patient

outcomes. Our hypothesis is that a patient-centric self-monitoring and collaborative decision support platform will lead to sustainable improvement in overall QOL for IBD patients.

Methods

Study Design

This is a phase III, single-center, pragmatic randomized controlled trial (RCT) to evaluate if a patient-centric self-monitoring and collaborative decision support platform will lead to sustainable improvement in overall QOL for IBD patients. It is intended that 300 patients with IBD will be

recruited into the study (allocation ratio 1:1; [Figure 4](#)). After meeting all the inclusion criteria with no exclusions, patient is asked to complete a tablet-based screening questionnaire at the end of which patient is randomized at the point of care to intervention or control arm. Patients in the control arm will receive an IBD education app PIN whereas the intervention arm will receive HealthPROMISE app PIN ([Figure 3](#)). Intervention patients enter their data once every 2 weeks and this data is then made visible to providers using a Web-based dashboard integrated with the EHR ([Figures 4](#) and [5](#)). Intervention and control apps will be provided free of charge to patients, and patients will be given \$25 after completing initial and end of study questionnaires.

Figure 4. Point of care recruitment and randomization.

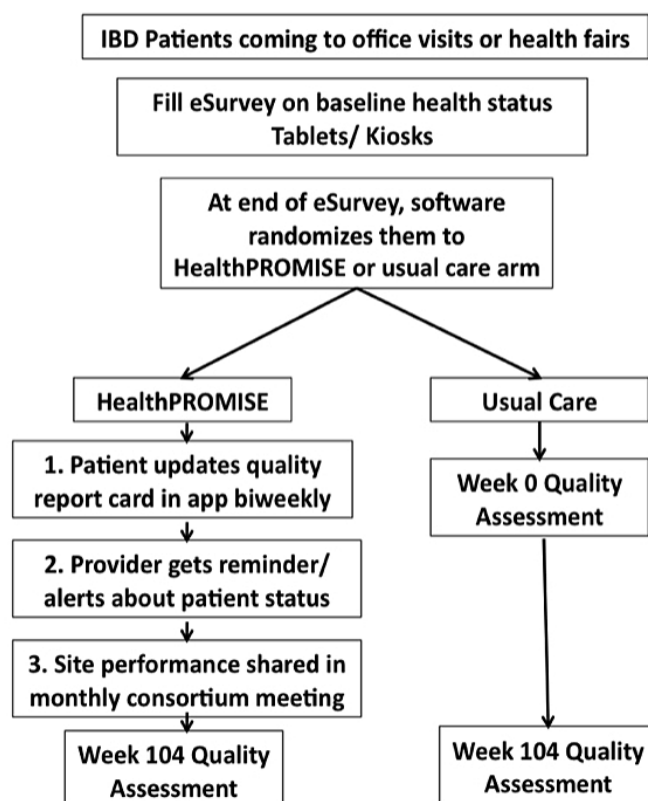
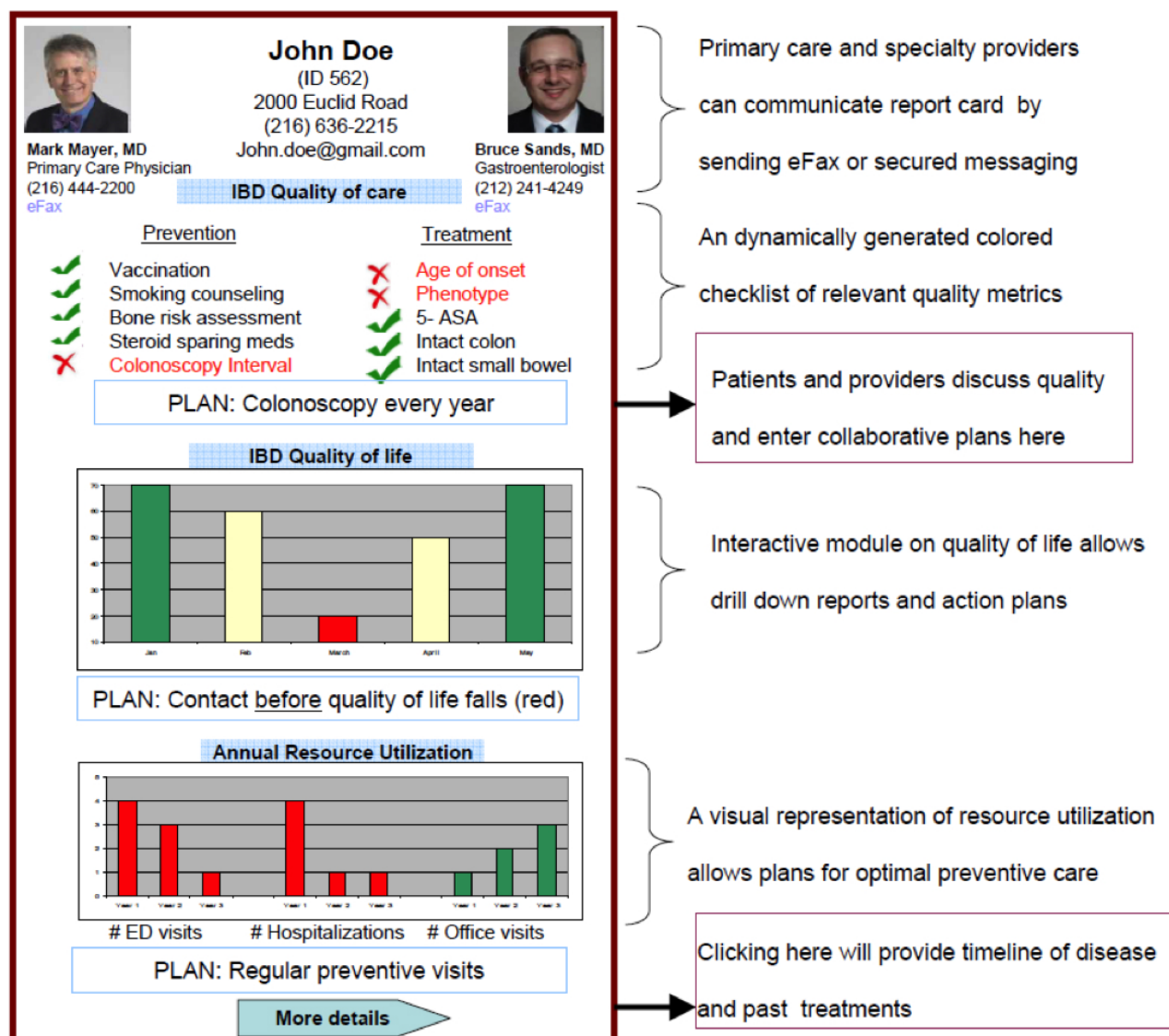


Figure 5. Shows initial mock-up of app.

Study Population

Patients will be recruited at outpatient and inpatient facilities in an academic center through informational paper and electronic flyers. Once enrolled, patients will receive a walkthrough of the app, which includes access to a training video. The provider dashboard will also have access to the training video. Eligible patients will be 18 years or older, have a mobile phone or access to the Internet at home, and be able to complete a Web-based questionnaire in English. Exclusion criteria include the inability to communicate with the investigators and comply with the study requirements, presence of short bowel syndrome or stoma,

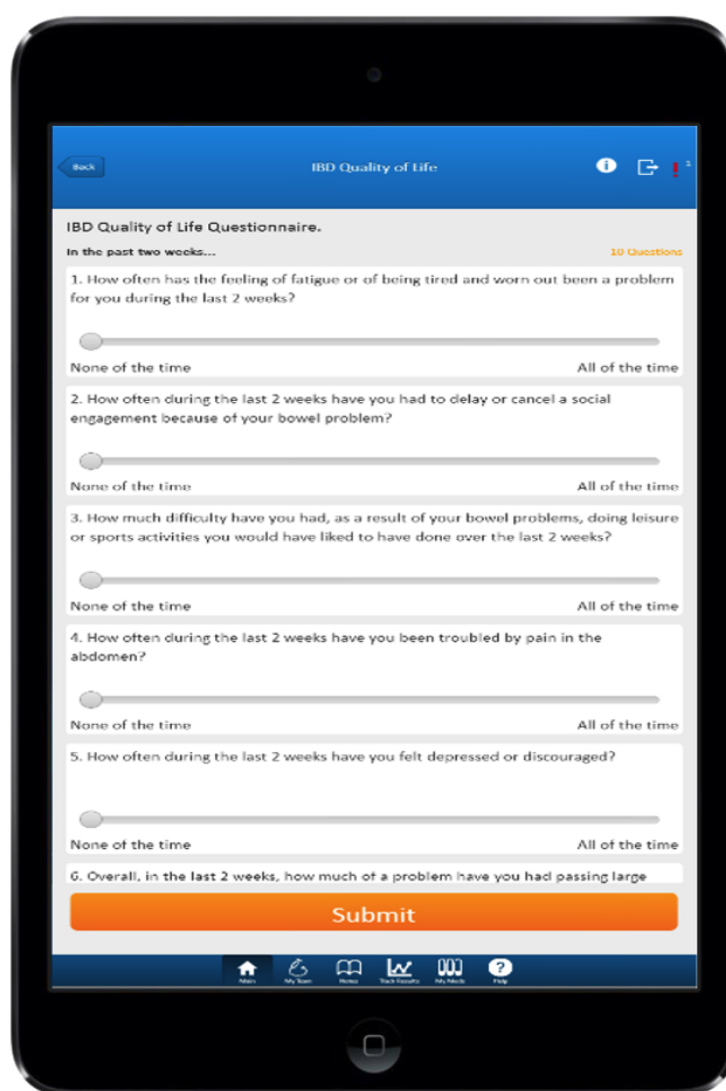
and presence of a condition or disease that, in the opinion of the investigators, may make it difficult for the patient to use the HealthPROMISE app, including, but not limited to, advanced dementia.

Study Instruments

Overview

A combination of different questionnaires (eg, SIBDQ), symptom updates, and quality indicators relevant for evaluating patient status will be the data collected during this study through the HealthPROMISE app (Figure 6).

Figure 6. Shows completed app.



Disease Specific Quality of Life Questionnaire

The Short Inflammatory Bowel Disease Questionnaire (SIBDQ) [20] is a validated and reliable tool to measure health-related QOL in adult patients with IBD. The questionnaire consists of 10 questions scored in four domains: bowel symptoms, emotional health, systemic systems, and social function. The SIBDQ is a respected QOL questionnaire used extensively in academic research and clinical trials. Study patients in the control arm and interventional arm will complete an SIBDQ as part of a survey to objectively measure QOL at baseline and at exit (52 weeks or 104 weeks). Additionally, patients in the intervention arm will be asked to complete the SIBDQ every 2 weeks; this will be used to classify patients as having “good control,” “fair control,” or “poor control.”

General Quality of Life Questionnaire

EQ-5D is a standardized instrument for measuring generic QOL [21]. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status. EQ-5D is primarily designed for self-completion by respondents. It is cognitively simple and

takes only a few minutes to complete. It is generally recognized that a change of 0.5 points (on a scale of 1-7) is the minimal clinically important difference (MCID), consistent with moderate effect size. Patients in the intervention arm will be asked to complete the EQ-5D every 2 weeks.

Other Instruments

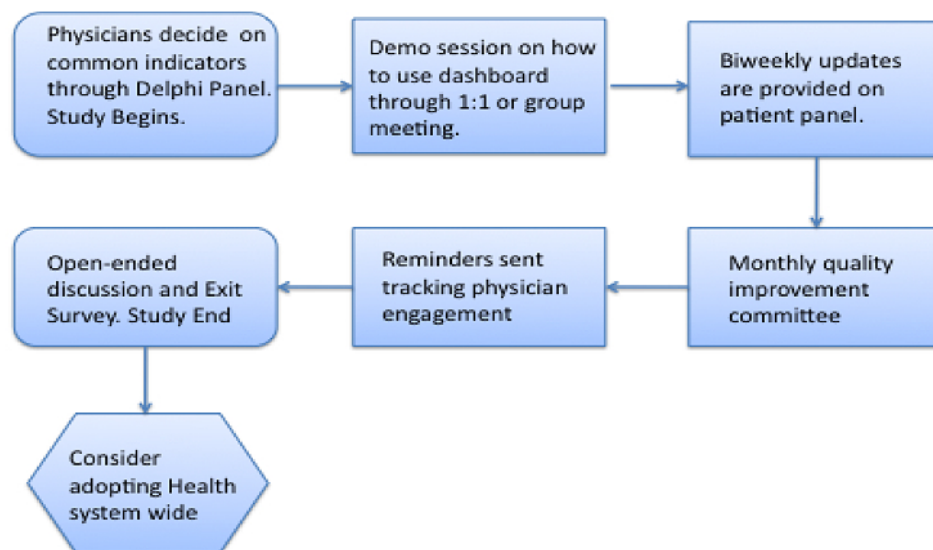
eHEALS is an 8-item measure of eHealth literacy developed to measure consumers’ combined knowledge, comfort, and perceived skills at finding, evaluating, and applying electronic health information to health problems [22]. This instrument has been psychometrically validated and its score positively correlated with intention to use personal health records. Patient Activation Measure (PAM-13) will be used to measure patient activation and engagement with health [23]. eHEALS and PAM-13 will be completed by patients in both arms during entry and exit surveys only.

Quality indicators are included from a list of indicators published by national societies and finalized through a Delphi panel of IBD providers [24,25]. These will be updated every three months

by either providers or patients, along with hospitalization and emergency department visit information (Figure 7).

Utilization will be assessed through log-in, page views, health information updates, and response to alerts and reminders.

Figure 7. Provider workflow on app dashboard.



Results

Outcome Measures

All outcome data (Textbox 1) will be collected online. Additionally, we will conduct subgroup analysis of patients with poor disease control at week 0 (SIBDQ \leq 30) and in those with high patient-reported anxiety, depression, or stress

achieving primary and secondary endpoints. We will assess change in inflammatory markers, endoscopic scores, and additional quality metrics in each group and determine predictors of HealthPROMISE and control app utilization and its impact on other primary and secondary end-points. Consistent with the pragmatic nature of the trial, study progress will be assessed throughout and effort will be optimized to better engage providers and patients (Table 1).

Textbox 1. Primary and secondary endpoints.

Primary endpoint

- Number of quality indicators met in HealthPROMISE versus control arm

Secondary endpoints

- Decrease in number of emergency visits due to IBD
- Decrease in number of hospitalization due to IBD
- Change in generic QOL score (EQ-5D) from baseline
- Proportion of patients in each group who meet all eligible outpatient quality metrics
- Proportion of patients in disease control in each group
- Emergency visits in each group
- Hospitalizations in each group
- General QOL scores in each group
- Per protocol analysis of intervention patients with adequate HealthPROMISE use (more than 6 log-ins with data entry from week 0 through week 52) achieving above mentioned primary and secondary endpoints

Table 1. Evaluation metrics for HealthPROMISE progress

Metric	Target Group	Goal / Timeline
Process		
Number of providers trained	Investigators	10 in 2 months
Number of patients enrolled	Participants	300 in 6 months
Recruitment and training of key personnel	Coordinator	1 in 3 months
Patient utilization of HealthPROMISE	Participants	Ongoing
Provider utilization of HealthPROMISE	Providers	Ongoing
Response to alert within 2 business days	Providers	>90%
Outcome		
Improvement in quality of care metrics	Provider, Center	Quarterly reports
Improvement in quality of life	Provider, Center	Quarterly reports
Readmission rate in two arms	Provider, Center	Quarterly reports

Statistical Analysis Plan

Overview

We will use SAS 9.2 (SAS Institute, Inc) to calculate frequencies and percentages for categorical factors and means with standard deviations and/or percentiles for continuous factors. Pearson's chi-square tests will be used for primary outcome (number of quality indicators met in HealthPROMISE vs control arm) and secondary outcomes. We will calculate percentage score for each patient at baseline and at week 104 ([number of quality metrics met/quality metrics eligible]*100). Change in the percentage score from baseline to week 104 will be aggregated for each arm to calculate percentage-point improvement in quality metric, similar to the strategy by Cebul et al [26].

Analysis of covariance (ANCOVA) will be performed to assess differences in the area under the curve of QOL scores while adjusting for baseline QOL score. To assess the association between patient and practice characteristics and achievement of eligible quality metrics, we will use multivariable analyses. Since the data will be hierarchically structured, with patients clustered within physicians and metrics clustered within patients, we will construct multilevel, generalized, linear mixed models with random effects to determine predictors of quality care, similar to the strategy used by Kanwal et al [27]. Independent variables will include demographic characteristics (age, gender), education and income level, race and ethnicity, computer usage, eHealth literacy scores, clinical characteristics (comorbidities, phenotype, disease severity), and provider characteristics (gender, age, site of practice, years of practice, presence of nurse practitioner).

Interim Analysis

Interim analysis will be performed once 150 patients are followed up for week 52. If primary outcome is met by that time, all patients will be offered HealthPROMISE app and followed for the additional 52 weeks.

Sample Size Justification

Study endpoints will be primarily assessed using intention-to-treat (ITT) analysis; however, per-protocol analysis

will also be performed. The study is to be powered such that there is a >80% probability of demonstrating a difference with a P value ($P = .05$) using a two-tailed t test.

We assume that 128 out of 150 subjects (85%) in the intervention arm will meet all quality indicators (primary outcome) and expect that this percentage will be at least 15% lower in the control arm. A sample size of 95 patients will be needed in each arm to achieve at least 80% power to detect the difference with a 5% one-sided significance level.

Accounting for an estimated 30% attrition rate, we will require a total of 250 IBD patients to be enrolled in the study. Since some patients may agree to enroll but not download the app or use the PIN, we will recruit a total of 300 patients in the study.

For secondary outcomes related to QOL, the control arm is not a placebo arm and physicians are free to initiate any therapy based on patients' symptoms. Hence, we will assess the difference in proportion of patients achieving MCID in the HealthPROMISE arm versus control arm in the study. Using the distribution-based approach, an effect size of 0.5 SD is the closest estimate for determining MCID for SIBDQ and EQ-5D. Assuming that 20% more patients in HealthPROMISE arm will achieve MCID than in the control arm, the sample size of 250 patients will have 88% power to detect the difference with a 5% one-sided significance level and an estimated 30% attrition rate.

Discussion

Principal Findings

This pragmatic trial will help us study if a patient-centric self-monitoring and collaborative disease management app and dashboard can lead to improvement in care provided to IBD patients. Our hypothesis is that IBD patients using the HealthPROMISE platform will have significant improvement in QOC metrics, QOL, and resource utilization by the end of the 2-year study period when compared to IBD patients in the control arm (using a health education app alone).

Future Direction and Sustainability

HealthPROMISE can be a sustainable platform in the long run because it is patient-centric, device and disease agnostic, and not dependent on proprietary EHRs. As most of the data is entered by patients, the cost of running, supporting, and sustaining HealthPROMISE is very low compared to traditional disease registries. HealthPROMISE has a rapid form generator capability to allow it to be customized for other chronic diseases. Additionally, the decision support that generates alerts and dashboard reports is within the stand-alone HealthPROMISE app and not dependent on proprietary EHRs. We aim to integrate HealthPROMISE with personal health records, partner with

national societies, and support through consortia so it can become a new standard of quality care for IBD and other chronic diseases.

Conclusion

HealthPROMISE is a unique cloud-based PRO and decision support tool that empowers both patients and providers. Patients track their QOL and symptoms, and providers can use the visual data in real time (integrated with EHRs) to provide better care to their entire patient population. Using pragmatic trial design, we hope to show that IBD patients who participate in their own care and share in decision making have appreciably improved outcomes when compared to patients who do not [28,29].

Acknowledgments

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Conflicts of Interest

The app was developed in-house at Sinai AppLab.

Multimedia Appendix 1

Initial critique of the proposal before it got funded in second attempt.

[[PDF File \(Adobe PDF File\), 198KB - resprot_v4i1e23_app1.pdf](#)]

Multimedia Appendix 2

Informed consent form.

[[PDF File \(Adobe PDF File\), 184KB - resprot_v4i1e23_app2.pdf](#)]

Multimedia Appendix 3

CONSORT-EHEALTH checklist V1.6.2 [30].

[[PDF File \(Adobe PDF File\), 977KB - resprot_v4i1e23_app3.pdf](#)]

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Abbreviations

IBD: inflammatory bowel disease
QOL: quality of life
QOC: quality of care
PRO: patient-reported outcome
EHR: electronic health records

NIH: National Institutes of Health

RCT: randomized controlled trial

SIBDQ: Short Inflammatory Bowel Disease Questionnaire

MCID: minimal clinically important difference

PAM: patient activation measure

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Protocol

An Integrated Web-Based Mental Health Intervention of Assessment-Referral-Care to Reduce Stress, Anxiety, and Depression in Hospitalized Pregnant Women With Medically High-Risk Pregnancies: A Feasibility Study Protocol of Hospital-Based Implementation

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Abstract

Background: At prevalence rates of up to 40%, rates of depression and anxiety among women with medically complex pregnancies are 3 times greater than those in community-based samples of pregnant women. However, mental health care is not a component of routine hospital-based antenatal care for medically high-risk pregnant women.

Objective: The purpose of this study is to evaluate the effectiveness and feasibility of the hospital-based implementation of a Web-based integrated mental health intervention comprising psychosocial assessment, referral, and cognitive behavioral therapy (CBT) for antenatal inpatients.

Methods: This study is a quasi-experimental design. Pregnant women are eligible to participate if they are (1) <37 weeks gestation, (2) admitted to the antenatal inpatient unit for >72 hours, (3) able to speak and read English or be willing to use a translation service to assist with completion of the questionnaires and intervention, (4) able to complete follow-up email questionnaires, (5) >16 years of age, and (6) not actively suicidal. Women admitted to the unit for induction (eg, <72-hour length of stay) are excluded. A minimum sample of 54 women will be recruited from the antenatal high-risk unit of a large, urban tertiary care hospital. All women will complete a Web-based psychosocial assessment and 6 Web-based CBT modules. Results of the psychosocial assessment will be used by a Web-based clinical decision support system to generate a clinical risk score and clinician prompts to provide recommendations for the best treatment and referral options. The primary outcome is self-reported prenatal depression, anxiety, and stress symptoms at 6-8 weeks postrecruitment. Secondary outcomes are postpartum depression, anxiety, and stress symptoms; self-efficacy; mastery; self-esteem; sleep; relationship quality; coping; resilience; Apgar score; gestational age; birth weight; maternal-infant attachment; infant behavior and development; parenting stress/competence at 3-months postpartum; and intervention cost-effectiveness, efficiency, feasibility, and acceptability. All women will complete email questionnaires at 6-8 weeks postrecruitment and 3-months postpartum. Qualitative interviews with 10-15 health care providers and 15-30 women will provide data on feasibility and acceptability of the intervention.

Results: The study was funded in September, 2014 and ethics was approved in November, 2014. Subject recruitment will begin January, 2015 and results are expected in December, 2015. Results of this study will determine (1) the effectiveness of an integrated Web-based prenatal mental health intervention on maternal and infant outcomes and (2) the feasibility of implementation of the intervention on a high-risk antenatal unit.

Conclusions: This study will provide evidence and guidance regarding the implementation of a Web-based mental health program into routine hospital-based care for women with medically high-risk pregnancies.

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KEYWORDS

Web-based; screening; cognitive behavior therapy; pregnancy; depression; anxiety; psychological stress; quasi-experimental studies

Introduction

Background

Depression, anxiety, and stress are among the most common morbidities in pregnancy [1-3]; at prevalences of 14% to 25%, they rival the rates of prenatal medical complications such as gestational diabetes [4] and hypertension [5]. Without early intervention, up to 70% of those with prenatal depression or anxiety [6] experience chronic symptoms that extend through the postnatal [2,7,8] and early childhood periods [9-11]. Indeed, recent systematic reviews of pregnancy cohort studies examining early life determinants of adverse child outcomes suggest that prenatal mental illness is one of the main predictors of suboptimal child mental health and development [12,13].

Few studies have explored mental health rates and needs in women hospitalized with high-risk pregnancies. Available research suggests that these women represent a vulnerable group with rates of anxiety and depression up to 40%—more than 3 times greater than those reported in community-based samples of pregnant women [14-16]. Despite high prevalence of symptoms of anxiety and depression, a recent study reported low treatment rates (5%) among high-risk pregnant women despite their inpatient status [15]. In this same study, 77% of women expressed the desire for weekly in-hospital group psychotherapy [15], highlighting the need for regular mental health support. Thus, there is a need to address the mental health needs of hospitalized pregnant women with a low-resource, sustainable approach that can be embedded into routine hospital care.

Major Impediments to the Delivery of Prenatal Mental Health Care

Barriers to the delivery of prenatal mental health care are ubiquitous across community- and hospital-based settings. In the absence of routine, standardized screening as a component of prenatal care, prenatal mental illness is underdetected and undertreated. Less than one-third of women with depression and anxiety are detected by obstetrical providers [17] and fewer than 20% of women screened as positive follow-up on a referral [18] or engage in treatment [19]. Thus, although there is general consensus about the value of mental health care among prenatal care providers [20-23] and this is supported by international and professional organizations [24-26], serious system-related barriers deter the incorporation of mental health screening, referral, and treatment into the practice of routine prenatal care.

Providers cite lack of time, skills (including screening tool selection and use), and established referral systems as the most prominent barriers [27]. To add to this challenge, although pregnant women report high acceptability of provider-initiated mental health screening [28-30], the vast majority express discomfort with self-initiating discussions related to mental health concerns with their health care provider due to stigma, not wanting to take antidepressants, and not understanding whether their symptoms are outside the range of “normal” within the context of pregnancy [31-33].

Evidence-Based Strategies for Improving Perinatal Mental Health Care

Overview

A growing body of evidence based on depression care in the general population suggests that 2 key strategies for reducing barriers to mental health care are (1) employing models of integrated mental health care and (2) Web-based delivery of mental health care. Both of these strategies have high utility for the perinatal period.

Integrated Perinatal Mental Health Care

Mental health care is a 3-stage process involving screening, referral, and treatment. Barriers encountered at any of the 3 stages can impede women from achieving treatment success [18]. An integrated approach that seamlessly links mental health screening results to a defined referral process and treatment is a more clinically and cost-effective means for managing depression and anxiety by optimizing treatment accessibility, completion, and response [15,34-36]. Among the few studies that have evaluated the effectiveness and feasibility of models of postnatal depression care with some level of integration [37-42], integrated care results in increased screening and treatment rates with improved clinical outcomes (eg, reduction of postpartum depression). However, only 1 study to date is evaluating an integrated model of prenatal screening, referral, and treatment (trial in progress) [43].

Web-Based Delivery of Mental Health Care

Web-Based Psychosocial Assessment

Web-based psychosocial assessment can address barriers related to limited time; thus, it is a feasible option for high-paced clinical settings. It offers a standardized approach to assessment, can be adapted for use in populations with low literacy through the addition of audio or video components, can be linked with

electronic medical record systems [35,44,45], and is preferred by some patients because it offers an anonymity that an in-person assessment cannot achieve. [45-47]. Pregnant and postnatal women report that Web-based screening is acceptable for sensitive issues, including intimate partner violence [48,49] and mental health [45,50]. Because mental health assessment alone cannot directly improve symptoms [51] or promote treatment engagement [43,52], it must be linked to a defined referral system.

Web-Based Clinical Decision Support Systems

Web-based clinical decision support systems promote evidence-based, personalized care by generating ideal treatment and referral options based on a patient's risk profile [35]. They can be highly beneficial in prenatal mental health care because many perinatal care providers cite lack of knowledge as a barrier to treating mental health problems directly and lack of established linkages with psychological or psychiatric services as a barrier to referral [18].

Web-Based Cognitive Behavioral Therapy

Group-based cognitive behavioral therapy (CBT) is an effective intervention for reducing postpartum depression [53-57], but its accessibility is limited by expense and prolonged wait times that extend beyond the prenatal period [58]. Web-based CBT is clinically and cost-effective [59-62], accessible [59], and recommended as a primary therapy for mild and moderate depression [24,63]. Given that a major concern with psychological therapies is nonadherence, a benefit of Web-based CBT is its lower attrition rates (20%) compared to group-based CBT (40%-50%) [10,34,64]. Early evidence suggests that Web-based CBT is effective for reducing postnatal depression [34]. However, to our knowledge only 1 in-progress trial is evaluating Web-based CBT during pregnancy [43]. With clear potential benefits due to low cost, high accessibility, and greater treatment adherence [34], there is a need to determine the effectiveness and acceptability of Web-based CBT in high-risk antenatal inpatients.

Purpose of the Study and Research Questions

This study is an extension of an in-progress community-based randomized controlled trial (RCT), the Integrated Maternal Psychosocial Assessment to Care Trial (IMPACT) [43], which is evaluating the clinical- and cost-effectiveness of a Web-based mental health care intervention in primary care settings. Initiated by the recruiting hospital, the current study evaluates both the effectiveness of the Web-based mental health intervention in high-risk antenatal inpatients and the feasibility of its integration into the hospital setting. As such, this study is distinguished from the IMPACT trial in its focus on determining the intervention effectiveness in an underserved group—high-risk antenatal patients—and the assessment of the full implementation of the Web-based intervention into hospital-based antenatal care. Specific research questions are:

1. What is the effectiveness of the integrated mental health intervention on (1) the prevalence and severity of prenatal depression, anxiety, and stress in antenatal inpatients and (2) the prevalence and severity of postnatal depression,

anxiety, and stress at 3-months postpartum compared to preintervention?

2. What is the acceptability and feasibility of the intervention for women?
3. What is the logistical and economic feasibility of implementing the integrated mental health intervention as a component of routine hospital-based antenatal care? What is needed to improve the clinical utility of the intervention in the hospital setting?

The Intervention

Rationale, Development, and Pilot Testing of the Intervention

The intervention was developed to address the need for prenatal mental health care in systems where assessment, referral, and treatment are not components of routine prenatal care. It was designed to (1) target the needs of pregnant women, recognizing that sources of anxiety and depression are unique among pregnant women; (2) overcome the most prominent barriers cited by women and health care providers regarding prenatal mental health screening and care (eg, lack of time, lack of knowledge regarding type and interpretation of screening tools, lack of linkages with mental health resources) [18,27,32,65]; and (3) provide an integrated system of assessment, referral, and treatment that would optimize the flow for providers and women from assessment to treatment. Developed by the Healthy Outcomes of Pregnancy and Postpartum Experiences (HOPE) Research Team for a pilot RCT (Integrated Maternal Psychosocial Assessment to Care Trial-Pilot; ClinicalTrials.gov identifier: NCT01901796) [43], the usability of the intervention was tested in a group of 8 pregnant women recruited from a survey-based study on views of prenatal mental health screening conducted by our team. Based on recommendations for the evaluation of health information systems [64,66,67], a research assistant met with participants individually in March 2013 and instructed them to “think aloud” as they interacted with the Web-based psychosocial assessment and CBT modules to describe their ease of use, esthetics, program capability, navigability, and content. Interviews were taped and transcribed verbatim and transcripts were reviewed by the research team to identify women's recommendations. Minor changes were made to the CBT modules based on participants' recommendations, primarily involving clarification of directions for exercises. Recruitment for the pilot trial will be completed by December 2014.

Description of the Intervention

The integrated mental health intervention is a Web-based intervention that is available through a password-protected Web link on a bedside computer terminal. The intervention consists of 3 components: (1) psychosocial assessment, (2) a clinical decision support system that uses results of the psychosocial assessment to generate a clinical risk score with a clinician prompt that guides the provider on the best referral/treatment approaches for that woman, and (3) CBT. Given the potential enhancement of treatment outcomes in Web-based CBT supplemented by supportive coaching [41], a nontherapeutic coach is assigned to each woman. The role of the coach is to (1) discuss psychosocial assessment results, discuss referral

options, and set-up referrals; (2) contact women weekly via text-based messaging to encourage completion of the CBT modules and follow-up questionnaires; and (3) address general program or technical questions.

Psychosocial Assessment

On recruitment, women complete a single Web-based psychosocial assessment that combines a standardized screening tool (Edinburgh Postnatal Depression Scale, EPDS) to evaluate depression and anxiety symptoms in the past week with a holistic assessment of psychosocial risk factors, including mental health history, substance use, and interpersonal violence (Antenatal Risk Questionnaire, ANRQ-R) [3,28]. The ANRQ-R was designed to be embedded within an integrated system of assessment-referral-care to identify psychosocial risk factors associated with poor mental health outcomes in pregnant women. Both instruments can be completed in less than 10 minutes. The ANRQ-R has high levels of acceptability and satisfactory psychometric properties (sensitivity 0.62; specificity 0.64) [3,28], comparable to other commonly used self-report depression/anxiety tools. The EPDS is a widely used 10-item self-report depression scale used to detect depression symptoms during the previous 7 days [68]. Psychometrically validated for use in pregnant and postpartum women [69], testing revealed sound psychometric properties (sensitivity 86.7%; specificity 78%; positive predictive value 74%, $\alpha=.87$) [68].

Web-Based Clinical Decision Support Systems

Using the EPDS and ANRQ-R scores, a Web-based decision algorithm automatically generates a clinical risk score that is linked to a clinician prompt describing the best referrals for that particular woman. Once women complete the EPDS and ANRQ, 1 of 10 clinical risk scores is calculated automatically based on the severity of symptoms and combination of risk factors (risk 1 highest to risk 10 lowest). As soon as women submit their data, they are transmitted to the Faculty of Medicine and

Dentistry server. The clinical risk score and clinician prompt are then viewed by the coach who telephones each woman to discuss results of the psychosocial assessment and referral options and provides information on accessing the password-protected CBT modules. The decision support system was built for the pilot RCT [43] and has been pilot tested and refined. By way of example, for women who have mild or moderate symptoms of anxiety, stress, or depression, the Web-based CBT is the choice treatment. For women with severe symptoms, the clinical prompt would recommend Web-based CBT plus referral to a psychiatrist.

Web-Based Cognitive Behavioral Therapy Program

Women access the 6-module Web-based CBT program through a password-protected link. Two [70] to 6 [34] Web-based CBT sessions have been found to effectively reduce depression symptoms, and a recent feasibility study of Web-based CBT in postpartum women demonstrated completion rates of 87% in the 6-module program [34]. The topics of the modules are (1) taking stock; (2) identifying and labeling emotional health concerns; (3) changing distorted thinking; (4) understanding and changing actions, responses, and behavior; (5) relaxation; and (6) developing and maintaining a plan (Figures 1 and 2). Each module has interactive assignments that women complete. Each assignment has 1 to 4 options and women select the 1 (or more) that best suits their needs (Figure 2). Completion of the exercises is required before progression in the modules can occur. The modules use pregnancy-relevant scenarios and these are used as the basis of examples in the assignments. The Web-based delivery allows women to set their own pace by completing the modules at a time and location that is most convenient and ensures standardization of the intervention. Women access the modules using a username and password, and content that women provide in the assignments is accessible only by them.

Figure 1. Screenshot of the introduction to the Web-based CBT module.

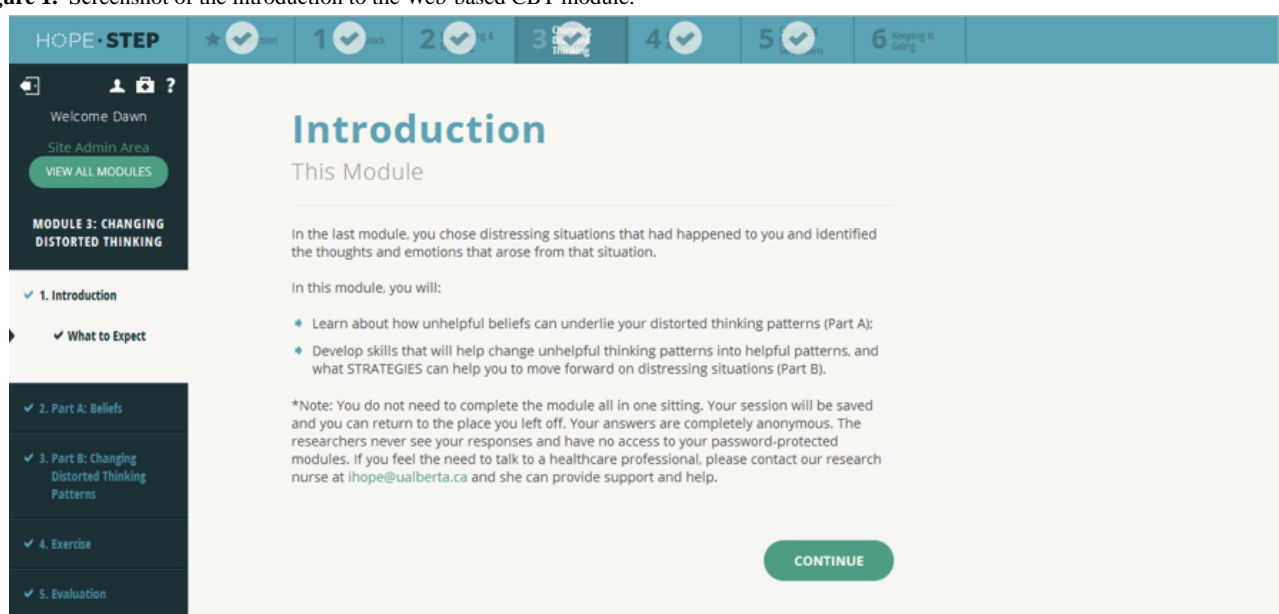
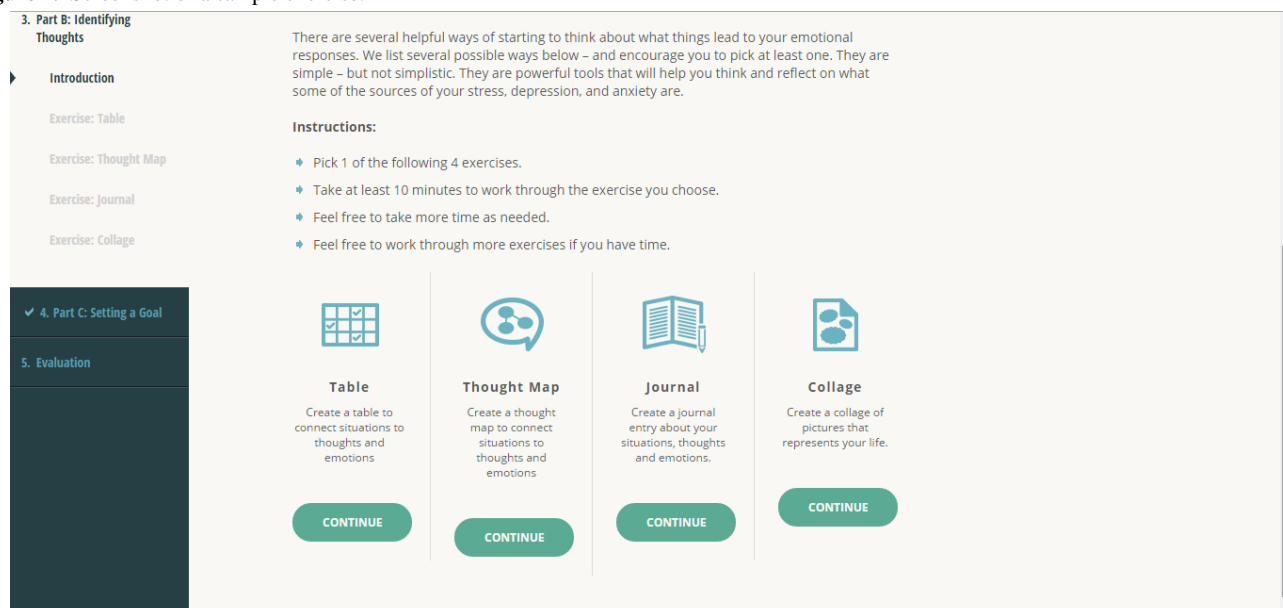


Figure 2. Screenshot of a sample exercise.

Methods

Study Design

The proposed study is a before-after quasi-experimental design with a qualitative component. Because women in the antenatal unit interact frequently, it was not possible to avoid the contamination that would occur in a RCT. The study has 2 phases: (1) phase 1—the before-after study designed to evaluate the clinical- and cost-effectiveness of the integrated psychosocial assessment-referral-CBT intervention and (2) phase 2—a qualitative descriptive component designed to assess the utility, usability, feasibility, and acceptability of the intervention.

Phase 1: Before-After Study

Setting and Recruitment Procedures

Recruitment will take place on a 24-bed antenatal inpatient unit at a tertiary care hospital in a large, urban Canadian city (Edmonton, Alberta). The hospital has more than 6500 annual births and draws patients from the northern half of the province to serve an ethnically and sociodemographically diverse population. The average length of stay on the unit is 5.5 days and the most common admission diagnoses are preterm labor, placenta previa, and hypertension.

Participant Eligibility and Recruitment Procedures

Pregnant women are eligible to participate if they are (1) <37 weeks gestation, (2) admitted to the antenatal inpatient unit for >72 hours, (3) able to speak and read English or be willing to use a translation service to assist with completion of the questionnaires and intervention, (4) able to complete follow-up email questionnaires, (5) aged >16 years, and (6) are not actively suicidal. Women admitted to the unit for induction (eg, <72-hour length of stay) are excluded.

Eligible women will be approached on admission by a research assistant who will describe the study and administer informed consent. Following consent, participants will complete a Web-based baseline questionnaire, which begins with the EPDS.

Question 10 of the EPDS asks women about self-harm. For women who answer question 10 affirmatively, 4 additional questions pop-up to discriminate between suicidal ideation (ie, thinking about suicide with no plans) and active suicidality (ie, thinking about suicide with plans):

1. In the past week, have you sometimes felt hopeless about the future?
2. In the past week, have you sometimes wished you were dead?
3. In the past week, have you sometimes thought of ending your life?
4. If yes, is there anything that would stop you from acting on these thoughts of ending your life?

An affirmative response to any of these 4 questions would constitute active suicidality (=risk 1) and study exclusion. In this case, a computer message appears thanking the woman for her study participation and an email is sent to the research assistant immediately. Our safety protocol requires the research assistant to immediately inform unit nurses, who will arrange contact with hospital-based reproductive mental health services.

Women who remain eligible for the study following the EPDS completion will be permitted to continue with the baseline questionnaire for completion of the ANRQ-R and remaining baseline components. On submission, the data are securely stored in RedCap in the Faculty of Medicine and Dentistry at the University of Alberta. An automatic email informs the coach of the new participant. The coach accesses the woman's psychosocial assessment results, the clinical risk score, and the clinician prompt in RedCap, and telephones the woman to discuss her results, referral options if applicable, and instructions for accessing the Web-based CBT. All coach contact is documented in a coach's log in RedCap. One coach will be assigned to the recruitment site to ensure consistency across contacts.

Coach Training and Support

The coach will participate in a primary investigator-led 8-hour training course that addresses the structure of each of the 3 components of the intervention, study protocols (including arranging referrals), safety protocols, interpretation of assessment tools, approaches for describing assessment results, and managing follow-up. Processes are compiled in a Coach's Guide that is provided during training. Didactic and scenario-based practice sessions will be used during the course. Weekly meetings with the primary investigator and monthly meetings with the broader research team will be used for troubleshooting and refinement of recruitment processes.

Sample Size Estimation and Feasibility

The sample size calculation is based on the primary outcome of symptoms of depression, anxiety, and stress as measured by the depression, anxiety, and stress subscales of the 21-item Depression Anxiety Stress Scale-21 (DASS21) [71]. We calculated the sample size required to test the minimum clinically important difference in each subscale and selected the highest 1 for the final sample size. Based on DASS21 data collected as part of Australia's national perinatal mental health initiative, standard deviations for the depression, anxiety, and stress subscales in pregnant women are 5.4, 10.2, and 8.6 [72]. To determine the minimal clinically important difference, we used Milgrom et al's [55] approach for calculating the difference in scores on each subscale that would shift a woman 1 level of severity—the minimal, reasonable expectation for an effective therapy. For example, the DASS21 manual “categorizes” women as having normal, mild, moderate, severe, and extremely severe symptoms of depression, anxiety, and stress [71]. To shift women from midrange moderate to mild severity on the depression, anxiety, and stress subscales would require a reduction of 4 points in each subscale. Therefore, based on the sample size formula for paired *t* tests (2-tailed) at a significance level of 5% (1.96), a power of 80% (.84), a minimal clinically important difference of 4 points, and standard deviations of 5.4, 10.2, and 8.6 for the depression, anxiety, and stress subscales, respectively, the number of women required to detect a statistically significant difference in pre- and posttest scores would be 17 for depression symptom changes, 54 for anxiety, and 39 for stress. Therefore, based on the highest number of women needed, 54 women are required to complete full data for this study. Accounting for a participation rate of 50% based on previous studies of CBT in pregnant women [73], a conservative attrition rate of 25% based on previous studies of prenatal CBT [34,64], and a 5% loss to follow-up, 98 women

would need to be invited to participate in the study to achieve the final sample size. Given the estimated number of 20 new admissions per month, the duration of recruitment is anticipated to be 5 months.

Definition and Measurement of Outcomes

Primary Outcome

The primary outcome is the presence and severity of prenatal depression, anxiety, and stress symptoms at 6-8 weeks post-recruitment as measured by the DASS21 [71]. The DASS21 has been widely used and psychometrically tested, and it distinguishes well between symptoms of depression, anxiety, and stress in clinical and nonclinical populations [66,71,74]. It is used in clinical settings to screen pregnant and postpartum women for presence and severity of current symptoms of depression, anxiety, and stress [72,75]. The DASS21 has good psychometric properties with Cronbach alphas of .91, .80, and .84, respectively, for the depression, anxiety, and stress subscales [66]. High correlations with other standardized depression, stress, and anxiety measures (eg, Beck Depression Inventory, State-Trait Anxiety) and clinical assessments demonstrate its validity [76,77].

The presence of symptoms of prenatal depression, anxiety, and stress is measured as the proportion of women scoring above established DASS21 cut-offs (>10, >8, and >15, respectively) [71]. Severity of symptoms is measured by the mean depression, anxiety, and stress scores. Ranges of scores corresponding to symptom severity levels of normal, mild, moderate, and severe are also well established through psychometric testing: depression (normal: 0-9; mild: 10-13; moderate: 14-20; severe: >21), anxiety (normal: 0-7; mild: 8-9; moderate: 10-14; severe: >15), and stress (normal: 0-14; mild: 15-18; moderate: 19-25; severe: >26) [71].

Secondary Outcomes

The secondary clinical outcomes are presence and severity of symptoms of postpartum depression, anxiety, and stress [71]; prenatal and postnatal self-efficacy [78], social support [79], sense of mastery [80], self-esteem [81], sleep [82,83], relationship quality [10,84], coping [85], and resilience [86]; 5-minute Apgar score; gestational age; birth weight; maternal-infant attachment [87]; infant behavior [88]; infant development [86,89]; and parenting stress/competence [90,91]. These outcomes were selected because of their association with maternal depression, anxiety, and stress and their potential modifiability by the intervention. Table 1 presents the primary and secondary clinical outcomes.

Table 1. Measures (primary and secondary clinical outcomes; other) and timeline for phase 1 of the quasi-experimental study.

Measures	Timeline of assessments		
	Baseline	6-8 weeks	3-months postpartum
Primary clinical outcome			
Prenatal depression, anxiety, stress symptoms (Depression Anxiety Stress Scale, DASS21) presence (% above cut-off point) and severity (mean score, SD)	X	X	
Intervention component			
Psychosocial assessment (Antenatal Risk Questionnaire-Revised, ANRQ-R; includes substance use and violence)	X		
Depression (Edinburgh Postnatal Depression Scale, EPDS)	X	X	X
Secondary clinical outcome			
Postnatal depression, anxiety, stress symptoms (Depression Anxiety Stress Scale, DASS21) presence (% above cut-off point) and severity (mean score, SD)			X
Social support (Interpersonal Support Evaluation List, ISEL)	X	X	X
ANRQ-R acceptability	X		
Mastery (Pearlin's Mastery Scale)	X	X	X
Self-efficacy (Generalized Self-Efficacy Scale)	X	X	X
Self-esteem [81]	X	X	X
Resilience (Connor-Davidson Resilience Scale)	X	X	X
Sleep (Pittsburgh Sleep Quality Index)	X	X	X
Parenting competence (Parenting Sense of Competence Scale, PSCS; subscales Efficacy, Interest, Satisfaction)			X
Parenting stress (Parental Stress Scale)			X
Relationship quality and adjustment (Dyadic Adjustment Scale, DAS-7)	X	X	X
Coping (Brief Cope)	X	X	X
Maternal-infant attachment [87]			X
Infant behavior (Infant Behavior Questionnaire)			X
Infant development (Ages and Stages Questionnaire, 3rd edition, ASQ-3; The Baby Pediatric Symptom Checklist for Social/Emotional Screening)			X
Birthweight (medical record)			X
Gestational age (medical record)			X
5-minute Apgar score (medical record)			X
Other			
Feeding method (medical record; parent report); neonatal/infant health (medical record; parent report) (Parent report from All Our Babies birth cohort study ^a)			X
Demographics (education, income, maternal age at recruitment, ethnicity; items from Maternity Experiences Survey, MES ^b)	X		
Obstetric and medical history (parity, chronic and pregnancy complications, type of delivery, weight at pre-pregnancy, delivery, 6 weeks postpartum) (self-report items from MES; medical record)	X		X
Mental health history (history of depression, anxiety, stress; age of onset of previous episodes of mental health problems) (items from MES)	X		
Pharmacologic therapy for depression/anxiety (past; current) (items from Canadian Community Health Survey, CCHS)	X	X	X

^a The All Our Babies Birth Cohort study is a pregnancy birth cohort in Alberta, Canada. Details of the study methodology and design have been previously published [92].

^b The Maternity Experiences Survey (MES) is a national survey designed and administered by the Public Health Agency of Canada and Statistics Canada [93].

Secondary process outcomes related to the overall feasibility of the intervention focus on its cost-effectiveness, efficiency, utility, usability, and acceptability (Table 2). We will evaluate the intervention feasibility from both the patients' and providers'

perspectives using both quantitative (phase 1) and qualitative (phase 2) approaches. These data will be used to refine the intervention components to optimize their implementation into the hospital setting.

Table 2. Measures of secondary process outcomes.

Secondary process outcomes	Baseline	6-8 weeks	3 months postpartum
Phase 1: quasi-experimental study			
Cost-effectiveness			
Women's health service use, medication use (self-report and medical record)	X	X	X
Women's quality of life (For economic analysis-SF-12,SF-6D to calculate QALY)	X	X	X
Costs related to hospital-based implementation (eg, computer access; time to manage referrals)			X
Efficiency of intervention (% of women with psychosocial assessment, referral, and care; self-report and medical record)	X	X	X
Utility of intervention (1 question asked at the end of each CBT exercise: "This exercise was useful to me" with 4 response options of I strongly agree, I somewhat agree, I somewhat disagree, I strongly disagree; 1 question asked at the end of each CBT module: "The information in this module was useful to me" with same response options)	X	X	
Usability of intervention (1 question asked at the end of each CBT exercise: "This exercise was clear and easy to understand" with response options; 2 questions asked at the end of each module: "The information in this module was clear and easy to understand" and "It was easy to work through the module [for example, it was easy for me to get from 1 part to the other, easy to find what I needed]" with same response options)	X	X	
Acceptability			
Web-based psychosocial assessment (1 question at end of completing ANRQ-R: "I would recommend a Web-based approach to asking about emotional health to a pregnant friend" with 4 response options of I strongly agree, I somewhat agree, I somewhat disagree, I strongly disagree)	X		
CBT (1 question at end of each CBT module: "I would recommend this module to a pregnant friend who was struggling with stress, depression, or anxiety" with 4 response options of I strongly agree, I somewhat agree, I somewhat disagree, I strongly disagree)	X	X	
Overall assessment (2 open-ended questions at the end of every CBT module: "The thing I liked most about this module was..." and "The thing I liked least about this module was...")	X	X	
Phase 2: qualitative descriptive study			
Efficiency (providers' views of the efficiency of the intervention in facilitating referrals and care; women's views on access to timely care)			X
Utility (providers' views on the usefulness of the intervention in promoting mental health assessment, providing guidance on referral/treatment; aiding referral process; women's views of how useful the modules were in meeting their needs)			X
Usability (women's views of how easy/difficult the modules were to navigate)			X
Feasibility (providers' views of feasibility of the integrated intervention in their setting; women's views of the feasibility of doing the modules; Google Analytics such as % women accessing CBT within 2 weeks postassessment; % women accessing each CBT module within 1-2 weeks; % completion of all 6 CBT modules; % completion of CBT modules within 8 weeks)			X
Acceptability (providers' views; women's views)			X

Data Collection

Procedures

The 3 data collection points for all study participants are recruitment (pretest), 6-8 weeks postenrollment (posttest), and 3 months postpartum (Table 1). On recruitment, all consent and

baseline data are completed on a link available on each patient's bedside computer terminal. Follow-up questionnaires will be completed online. Participants will receive an email with a password and link to the Web-based questionnaire. Retention will be enhanced using Dillman's approach [94] in which women who have not completed the questionnaires within 1

week will receive automated email/mobile phone reminders at 1, 3, 7, 10, and 14 weeks by RedCap. We will track reasons for nonadherence (eg, lost to follow-up).

Data Management

No data are stored on the bedside computers; when women submit their information, it is sent to a secure server housed in the Faculty of Medicine and Dentistry's Data Centre (University of Alberta). Data transfer between the computer and server is encrypted. Follow-up questionnaires will be distributed and submitted via email that is also encrypted. All processes involving electronic data capture and storage are managed by the Women's and Children's Health Research Institute Informatics Core at the University of Alberta. Once recruitment has been completed, the Informatics Core will transfer data to the Health Research Data Repository at University of Alberta. The Repository is a secure, interactive environment offering storage and interactive platforms for data analysis. Electronic data will be stored for 5 years at the Data Centre and then deleted. Research team members requiring direct access to data will complete a confidentiality orientation by the Repository Manager.

Adherence, Fidelity, and Concomitant Care

Adherence to the intervention will be tracked through Google Analytics and analytics designed for this study (eg, number modules completed, length of time to complete modules, etc). As part of the qualitative descriptive component, we will seek women's opinions about aspects of the psychosocial assessment that were challenging and features of the CBT modules that affected their ability, need, or desire to complete them. To improve adherence, the coach will send weekly text messages to women describing the importance of regular progress through the module exercises, the benefit of completing all modules, and encouragement when modules are completed. In addition, an automatic email or text message reminder will be generated if women have been inactive on the site for more than 2 weeks. The Web-based format of the intervention preserves its fidelity (ie, consistency in its components and delivery) and thus enhances external validity. To account for cointervention, follow-up questionnaires will ask women to disclose any pharmacological or nonpharmacological therapy that they have begun and this additional intervention will be accounted for in the analyses.

Ethics Considerations

The study protocol was approved by the Human Research Ethics Board at the University of Alberta. Following electronic consent, all women receive an emailed copy of the Participant Information Letter and Consent.

Safety Protocol

Several strategies ensure women's safety throughout the study. Mental health crisis contact information is described on a sidebar of the CBT modules, along with a statement encouraging women to contact their coach if they feel their mental health is deteriorating. The coach will contact women within 24 hours using a defined algorithm to guide decisions regarding help or referral that is recommended.

At the end of each CBT module, women will complete question 10 of the EPDS to assess self-harm thoughts over the past week. An affirmative response will generate an automatic message with crisis contact information for the woman's immediate use and an email sent to the coach. The coach will contact the woman within 24 hours to assess whether the woman is receiving help from a health care provider. A 4% affirmative response rate to question 10 of the EPDS has been reported [14]. The coach will document all interactions in the coach's log.

Analyses

Effectiveness of Intervention

We will use descriptive data (frequencies and 95% CIs; means and SDs) for sample description. We will assess differences in pre- and posttest means using paired *t* tests and proportions using McNemar tests. We will generate multivariable logistic regression models to identify predictors of intervention success, reporting relative risks and 95% CIs. Multivariable regression models will be built using variables that are associated with outcomes at $P < .10$ on unadjusted analyses. Primary analyses will use a type I error of 5% as a criterion for statistical significance, whereas a more stringent alpha of .01 will be used for secondary outcomes to account for multiple testing. Because women will be starting the intervention at different points in pregnancy, we will control for gestation. We will conduct exploratory analyses using stratified analyses to explore differences of intervention effect by (1) number CBT modules completed, (2) antidepressant or use of nonpharmacological therapy, (3) severity of DASS21 scores, (4) participant characteristics, (5) mental health history, and (6) gestational age. We do not plan to do imputation of missing data because we anticipate that the Web-based questionnaires with required fields will result in a low percentage of missing data.

Efficiency, Utility, Usability, and Acceptability of Intervention

In addition to assessing efficiency, utility, usability, and acceptability of the intervention through qualitative interviews (phase 2), we will use descriptive statistics (frequencies, proportions, means, SDs) to describe the efficiency of the intervention (eg, percentage of women with psychosocial assessment, referral, and care pretest vs posttest) and women's perceptions of the intervention's utility (eg, rated usefulness of exercises and information), usability (eg, ease of exercises and module), and acceptability (completion rates, willingness to recommend intervention to a friend).

Cost-Effectiveness of Hospital-Based Intervention

The economic evaluation will be a within-study cost-effectiveness analysis comparing the intervention with usual hospital-based mental health care. The analysis will assess costs associated with the delivery of the intervention (eg, cost of equipment, salary of coach) and subsequent service utilization by study participants. Direct health care utilization will be extracted from patient records. Data related to health and social care utilization will be collected from the medical record and self-reported by women (including SF-12). The primary outcome measure for the cost-effectiveness analysis will be the Quality

Adjusted Life Year (QALY). Utilities for the construction of QALYs will be obtained from the SF-12 data using the SF-6D algorithm [95]. Because the time horizon for the analysis is less than 12 months, discounting will not be required [96]. We will report the incremental cost per QALY gained for the intervention compared to usual prenatal care. Uncertainty in the expected costs and outcomes for the integrated intervention and usual prenatal care will be characterized using the nonparametric bootstrap. The results of the bootstrap analysis will be used to construct scatterplots on the cost-effectiveness plane and cost-effectiveness acceptability curves showing the probability that the integrated intervention is a cost-effective use of health care resources for a range of values of health.

Phase 2: Qualitative Descriptive Study to Assess Overall Feasibility of the Intervention

Design and Rationale

Phase 2 is a qualitative descriptive study with a primary aim of assessing women's and health care providers' views on efficiency, utility, usability, feasibility, and acceptability of the intervention. Phase 2 is a critical component to support further refinement of the intervention that will optimize its feasibility for women and providers, and enhance women's engagement and adherence [58].

Participant Eligibility and Recruitment

All women and health care providers working at the study site are eligible for participation in phase 2. Purposeful sampling will be used to maximize variability in the sample, ensuring that a broad range of views and demographics are represented [97]. We plan to interview 15-20 women and 10-15 providers (eg, unit staff, executive director, managers, reproductive mental health service staff, physicians) with the final sample size established by data saturation. Given the importance of understanding factors contributing to attrition, we will also interview women who do not complete all CBT modules. To capture these women, a statement at the end of each of the final 3 CBT modules will invite women to participate in a follow-up interview. Selection of the affirmative response will generate an automatic email to the research coordinator for follow-up. Posters and staff meetings will be used to invite unit staff members to participate in a follow-up interview.

Data Collection and Management

We will conduct individual face-to-face or telephone-based interviews. Semistructured interview guides will be used [97]

to ask participants their views on the efficiency, utility, usability, feasibility, and acceptability, as well as its strengths, suggestions for improvement, components that were effective/not effective, and the benefits that they experienced. The anticipated length of the interviews is 30 minutes. They will be digitally recorded and transcribed verbatim. Transcribed interviews and digital files will be stored in the Health Research Data Repository (University of Alberta) and stored for 5 years. All data will be anonymized for publication.

Analysis

We will use standard qualitative content analysis approaches for thematic analysis [97]. Two members of the team experienced in qualitative analysis will independently code the first 2 or 3 transcripts and engage in discussion to reach consensus on a draft coding scheme. This coding scheme will be used to code 2 additional transcripts with revisions made as necessary. Subsequent transcripts will be coded by 1 team member. Analysis will occur concurrently with data collection to allow further exploration and clarification of emergent ideas, and data collection will continue until data saturation [98].

Results

The study was funded in September, 2014 and ethics was approved in November, 2014. Subject recruitment will begin January, 2015 and results are expected in December, 2015. Results of this study will determine (1) the effectiveness of an integrated Web-based prenatal mental health intervention on maternal and infant outcomes and (2) the feasibility of implementation of the intervention on a high-risk antenatal unit.

Discussion

Results of this feasibility study will guide the refinement of the 3 components of the Web-based mental health intervention and full integration in the hospital setting. In this study, the research coach plays the role of coach/case manager in that she maintains regular supportive contact with participants, reviews women's psychosocial assessment results and debriefs them, and organizes referrals as well as linkage to the Web-based CBT program. The next steps would involve hospital-based personnel adopting this role and integration of the Web-based assessment and clinical decision support system into the electronic medical record.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Decision letter (grant review - CIHR).

[[PDF File \(Adobe PDF File\), 326KB - resprot_v4i1e9_app1.pdf](#)]

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Abbreviations

CBT: cognitive behavioral therapy
DASS21: 21-item Depression Anxiety Stress Scale
EPDS: Edinburgh Postnatal Depression Scale
HOPE: Healthy Outcomes of Pregnancy and Postpartum Experiences
MES: Maternity Experiences Survey
QALY: Quality Adjusted Life Year
RCT: randomized controlled trial

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Protocol

Implementation and Evaluation of a Wiki Involving Multiple Stakeholders Including Patients in the Promotion of Best Practices in Trauma Care: The WikiTrauma Interrupted Time Series Protocol

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Abstract

Background: Trauma is the most common cause of mortality among people between the ages of 1 and 45 years, costing Canadians 19.8 billion dollars a year (2004 data), yet half of all patients with major traumatic injuries do not receive evidence-based care, and significant regional variation in the quality of care across Canada exists. Accordingly, our goal is to lead a research project in which stakeholders themselves will adapt evidence-based trauma care knowledge tools to their own varied institutional contexts and cultures. We will do this by developing and assessing the combined impact of WikiTrauma, a free collaborative database of clinical decision support tools, and Wiki101, a training course teaching participants how to use WikiTrauma. WikiTrauma has the potential to ensure that all stakeholders (eg, patients, clinicians, and decision makers) can all contribute to, and benefit from, evidence-based clinical knowledge about trauma care that is tailored to their own needs and clinical setting.

Objective: Our main objective will be to study the combined effect of WikiTrauma and Wiki101 on the quality of care in four trauma centers in Quebec.

Methods: First, we will pilot-test the wiki with potential users to create a version ready to test in practice. A rapid, iterative prototyping process with 15 health professionals from nonparticipating centers will allow us to identify and resolve usability issues prior to finalizing the definitive version for the interrupted time series. Second, we will conduct an interrupted time series to measure the impact of our combined intervention on the quality of care in four trauma centers that will be selected—one level I, one level II, and two level III centers. Participants will be health care professionals working in the selected trauma centers. Also, five patient representatives will be recruited to participate in the creation of knowledge tools destined for their use (eg, handouts). All participants will be invited to complete the Wiki101 training and then use, and contribute to, WikiTrauma for 12 months. The primary outcome will be the change over time of a validated, composite, performance indicator score based on 15 process performance indicators found in the Quebec Trauma Registry.

Results: This project was funded in November 2014 by the Canadian Medical Protective Association. We expect to start this trial in early 2015 and preliminary results should be available in June 2016. Two trauma centers have already agreed to participate and two more will be recruited in the next months.

Conclusions: We expect that this study will add important and unique evidence about the effectiveness, safety, and cost savings of using collaborative platforms to adapt knowledge implementation tools across jurisdictions.

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KEYWORDS

interrupted time series; wiki; quality improvement; knowledge translation; trauma care; stakeholder engagement; adapting knowledge tools

Introduction

The Research Question

What Is the Problem to Be Addressed?

Injuries represent a major health and economic burden for Canadians. They are the most common cause of mortality for people between the ages of 1 and 45 years [1], costing Canadians 19.8 billion dollars in 2004 in direct and indirect costs [2,3]. Up to half of all patients with major traumatic injuries do not receive evidence-based recommended care [4-8]. A recent study conducted in partnership with the Institut national d'excellence en santé et services sociaux (INESSS) and funded by the Canadian Health Services Research Foundation [5] determined that many trauma practices in Quebec's trauma centers are substandard because they underuse proven therapies [4,5]. Studies in several other countries have identified adverse events, including death, that occur in trauma centers because of their failure to adopt best practices [9-13]. Aside from underusing proven therapies, there is also evidence of overuse of diagnostic procedures with known side effects, such as full-body computerized tomography (CT) scanning that exposes patients to unnecessary ionizing radiation that may increase the risk of cancer [14,15]. An estimated one million children every year in the US are unnecessarily imaged with CT [16].

Promoting best practices in trauma care has become an urgent and strategic investment for the health of Canadians and others [17,18]. Unfortunately, the implementation of best practices in the chaotic, acute trauma care environment is a difficult task because of three main factors, which are (1) macroenvironmental (eg, lack of financial resources), (2) organizational (eg, unclear definition of responsibilities within trauma team), and (3) professional (eg, resistance to clinical guidelines) [19]. Studying strategies used to implement best practices in trauma care, the Commonwealth Fund study [19] identified that trauma systems needed better knowledge management and coordination of care through well-implemented guidelines (ie, recommendations about what to do), protocols (ie, detailed procedures for how to administer care), and pathways (ie, frameworks for organizing who administers care and why). Moreover, these tools must be flexible and responsive to individual patients and to accumulating bodies of evidence. Many different health organizations have, therefore, started using wikis to manage knowledge and coordinate care [20-28]. Increasingly popular among health professionals [29-32], wikis are websites based on a novel technology that allow people to view and edit the website's content, with viewing and editing privileges determined by different levels of access. Wikipedia—the best-known wiki—has 365 million visitors per month, is the sixth-most popular website in the world and its medical articles,

available in 271 languages, are viewed about 150 million times per month [33].

In partnership with our team of researchers, the INESSS in Quebec is exploring how wikis could be used to improve the delivery of care to trauma patients. The INESSS oversees the quality of trauma care in the province of Quebec, Canada. It is also the accreditation body that designates different trauma center levels. This organization has expressed the need to explore wikis as a solution to improve the quality of care in trauma. To this end, we have conducted a scoping review that found that wikis could be effective in supporting the implementation of best practices in health care [34-39]. We also conducted a survey that identified that trauma professionals are willing to use wikis and that they share many positive beliefs about using them [40]. Specifically, wikis could serve as centralized knowledge management systems helping clinicians and decision makers coordinate the implementation of best practices by collaboratively building knowledge translation (KT) tools (eg, guidelines, protocols, pathways, and patient decision aids) that meet their needs [41-45] and monitor their use using novel Web metrics [46,47]. Wikis' other interesting features included their low cost [40,48-51], their broad and global availability [33], their adaptability to local practices, and their capacity to empower stakeholders [52-54]. Wikis were perceived to facilitate the sharing and updating of KT tools by different professionals and to help clinicians working in rural areas where access to specialized care is limited [55,56].

Building on these results, we held a meeting funded by the Canadian Institutes of Health Research (CIHR) in May 2014 in partnership with the INESSS, the Trauma Association of Canada, and the Royal College of Physicians and Surgeons of Canada to plan a study to evaluate WikiTrauma (see Figure 1), a wiki we created to promote best practices in trauma care. At this planning meeting we decided to study its implementation in a limited number of Quebec trauma centers as a first trial for this novel intervention. We also decided to create Wiki101 (see Figure 2), a theory-based continuing professional development (CPD) program, that will train participants at the selected trauma centers to use WikiTrauma effectively and safely in order to create and share different types of KT tools (eg, care protocols, order sets, and patient decision aids).

Thus, in partnership with the INESSS and in collaboration with our other WikiTrauma partners, we propose an interrupted time series to measure the combined effect of Wiki101 and WikiTrauma on the quality of trauma care in four trauma centers in Quebec. We also propose to conduct a mixed-methods process evaluation in parallel with this trial to explore possible causal mechanisms about how our combined intervention succeeds—or fails—to lead to improved quality of trauma care.

Figure 1. Screenshot of WikiTrauma order set.

Post-intubation ventilator settings Updated Nov 4, 2014, 12:49 PM

WikiTrauma.ca

Wiki order sets >
Post-intubation ventilator settings

Ventilation modes

It is essential to calculate the ideal weight of the patient (all calculations of tidal volume must be done with the IDEAL WEIGHT and not the ACTUAL weight).

The IDEAL WEIGHT is calculated using the measured size of the patient and the patient's gender.

☐ Enter the size of the patient here: _____ cm

☐ Men: Ideal Body Weight (kg) = $50 + (0.91 \times (\text{height in cm} - 152.4))$ = _____

☐ Women: Ideal Body Weight (kg) = $45.5 + (0.91 \times (\text{height in cm} - 152.4))$ = _____

NB: With the C2 fan Hamilton Medical, just simply measure the size of the patient and enter into the ventilator settings. The ventilator's computer will calculate the ideal weight according to the formula.

Checklist for choosing the PEEP

FIO ₂	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1.0
PEEP	5	5-8	8-10	10	10-14	14	14	15

NB: Remember that you can lower the PEEP = 0 to 3 if the patient is hypovolemic and hypotensive to promote venous return pending the complete volume resuscitation.

☐ Patient with normal lung compliance (these are the majority of intoxicated patients, isolated head trauma, coma)

Three possible modes

☐ VAC: Volume Assist/ Controlled
Tidal volume (V_T) (suggestion 8-10 cc / kg): _____

Figure 2. Screenshot of Wiki101 training program.

Wiki101: An Introduction to creating and using wiki decision tools Updated Oct 30, 2013, 6:48 PM

WikiTrauma.ca

Home >
Wiki101: An Introduction to creating and using wiki decision tools

This web page will serve as an introduction for students enrolled in the *Wiki101* CPD program.

Wiki101 will teach health professionals how to use *WikiTrauma*.

Its overall aim will be to address the main barriers and potential negative impacts related to using wikis identified in the following publication: <http://www.jmir.org/2012/2/e49/>

Specific objectives:

1. [Learn how to use evidence-based reminders \(eg. care protocols, treatment algorithms and order sets\) found in WikiTrauma.](#)
2. [Learn how to share evidence-based reminders within WikiTrauma](#) (using GRADE)
3. [Learn how to collaboratively write new evidence-based reminders within WikiTrauma](#)
4. [Learn how to update old reminders within WikiTrauma with the latest evidence](#) (using GRADE)
5. [Learn how to adapt reminders to local contexts](#) (using the APAPTE framework)

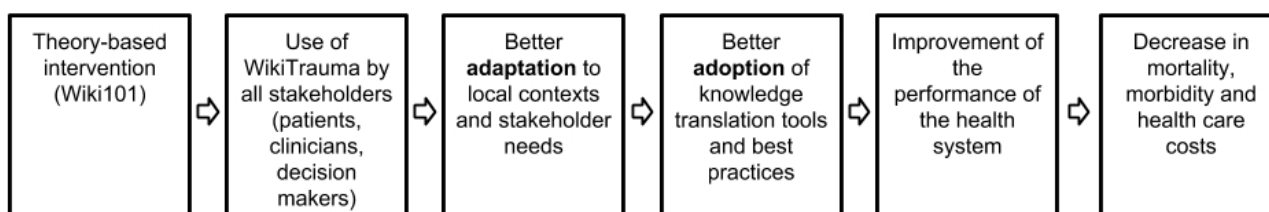
As a general introduction here are a series of videos introducing participants to the concept of wikis, Google sites wikis and wikis adapted to the sharing of reminders in the context of trauma care.

This page contains a series of YouTube Tutorials on how to use the Google Sites wiki application.

What Are the Principal Research Questions to Be Addressed?

Ultimately, we seek to test our hypothesis that our theory-based intervention (Wiki101) in combination with the use of

WikiTrauma will result in better adoption of best practices in trauma care in Canada (see the conceptual framework in [Figure 3](#)), safer care (ie, fewer complications), improved patient outcomes, and less costly care.

Figure 3. Conceptual framework underlying the proposed mechanism of action for the intervention.

Why Is This Project Needed Now?

Getting new evidence into health care practice is a slow and challenging process [57-65]. There is an ongoing and urgent need to find effective and low-cost methods of promoting best practices in all areas of health care [65-67] and, particularly, into interprofessional settings such as trauma care [17,68-72]. Recognizing that wikis capitalize on the free and open access to information, scientists, opinion leaders, and patient advocates have called for more research to determine whether wikis can equip decision-making constituencies to improve the delivery of health care [33,73], decrease its cost [49,74], and improve access to knowledge within developing countries [33,75-77]. Moreover, wikis are increasingly being used in health care by different academic institutions [32,41,78-81], health organizations [20,22,25,82,83], and health professionals [84-86] to share and disseminate information. As well, the principal knowledge user involved in our project (INESSS) is planning to use a wiki to promote best practices in trauma care, but would like to have more evidence about their use. Our CIHR-funded scoping review [34] confirmed that wikis have tremendous potential for improving the delivery of health care, but that a rigorous prospective trial to evaluate their effectiveness at implementing best practices is outstanding. Both our review and our survey identified an important need to test a theory-based approach addressing the main barriers that are preventing wikis from widely benefiting our health care system. The barriers most frequently mentioned, in order of frequency, were unfamiliarity with wikis, time constraints, lack of self-efficacy (ie, belief in one's competence to use a wiki), and lack of access to a useful wiki containing reliable information for bedside decision making. For these reasons, we have designed WikiTrauma—a wiki promoting best practices—and Wiki101—a theory-based intervention—to maximize the potential benefits, to address the main barriers, and prevent any potential negative impacts of using a wiki to promote best practices in trauma care. In summary, there is sufficient evidence to support the conduct of this prospective interrupted time series for testing our novel intervention, which will combine a wiki to promote best practices in trauma care and a theory-based implementation strategy designed to maximize its benefit. This trial will inform our knowledge users about the impact of the combined effect of WikiTrauma and Wiki101 on the implementation of best practices in trauma care.

Best Practices in Trauma Care

Barriers to Implementing Best Practices in Trauma Care

Various aspects of trauma care can impede best practices [13]. Trauma professionals must often make quick decisions, mostly based on intuitive reasoning [87], which is fast, impulsive, effortless, and reflexive. While this serves trauma care well, it is also prone to error. Reminders (eg, care protocols) are knowledge tools [88] that improve intuitive decision making [87]. A recent systematic review indicated that noncomputerized reminders had the potential to improve practices in critical care [70]. Computerized reminders and clinical decision support systems, which were excluded from the previous review, offer different KT opportunities in trauma centers' hectic environments [89-91].

Systematic Reviews About Computerized Decision Support Systems and Barriers to Their Adoption

Systematic reviews indicate that computer-based reminders are effective interventions for fostering best practices in a variety of clinical areas [26,92-100], including in acute care [89]. Such reminders range from simple prescribing alerts to more sophisticated computer systems that support decision making. This said, health professionals have rejected many computer-based reminder systems on the grounds that they are slow, incompatible with work processes, unable to adapt to local practices, difficult to access, and/or are costly to implement [90,91,101-105]. Finding innovative ways to involve end users in designing, implementing, and evaluating reminder systems is key to increasing their use and their impact on health outcomes. Novel collaborative applications like wikis offer an easy and inexpensive solution [31].

Theoretical Framework Supporting the Use of Wikis as a Driver for Change in Health Systems

According to behavior-change theories, self-efficacy—roughly defined as an individual's belief in his/her own competence—is one of the most important cognitive determinants of behavior [106-109]. By involving health professionals in sharing, updating, and creating practical reminders, wikis—highly accessible, interactive vehicles of communication—have the potential to increase professionals' self-efficacy in using reminders [29,30,74].

Rising Use of Wikis in the Health Care System

Studies have found that 70% of junior physicians (mostly residents) use Wikipedia weekly [84], that 50-70% of physicians use it as a source of information in providing care [33], and that 35% of pharmacists refer to it for drug information [85]. Different large health care organizations (eg, Canadian Agency for Drugs and Technologies in Health [110-112], US National Institutes of Health [20,113], The Cochrane Collaboration [22], World Health Organization [83], and several universities [32,41,78-81,114]) are exploring the use of wikis and/or Wikipedia for different purposes. There is a rising use of wikis in health care and, consequently, increased potential safety risks involved with using nonvalidated information for the care of patients. Therefore, we believe there is an urgent need to evaluate the positive benefits wikis could provide in improving the quality of care, while limiting the potential negative effects. We intend to do this by conducting a rigorous and well-planned prospective trial in the controlled setting of a closed wiki (WikiTrauma) managed by strong central leadership (INESSS).

Objectives

Our main objective will be to study the combined effect of WikiTrauma and Wiki101 on the quality of care in four trauma centers in Quebec using an interrupted time series design. Our secondary objectives will be (1) to evaluate the impact of our intervention on mortality, rate of complications, length of stay, and the Functional Independence Measure (FIM), (2) to evaluate participants' opinions about the combined intervention—Wiki101 and WikiTrauma, (3) to evaluate the quality of the different knowledge tools developed in

WikiTrauma, and (4) to estimate the costs saved by sharing the different knowledge tools within WikiTrauma.

Methods

Pilot-Testing of WikiTrauma and Wiki101 Before the Prospective Trial

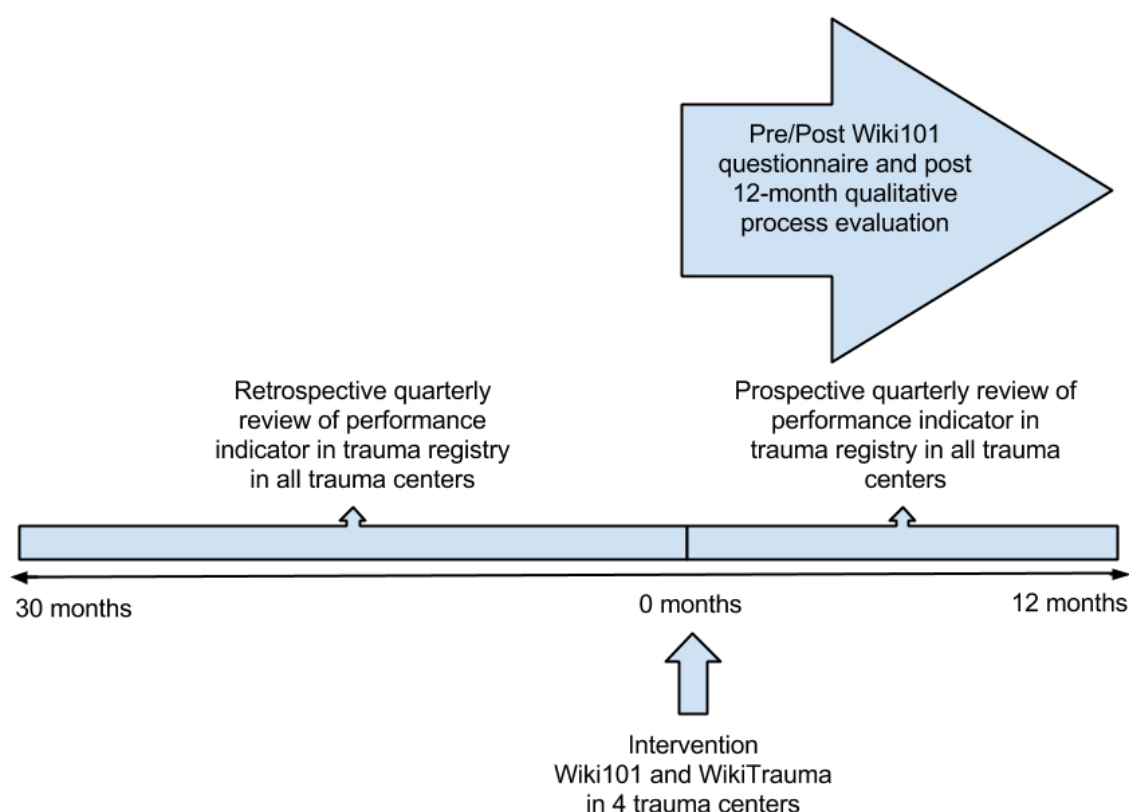
In consultation with two human factors specialists (HW, ST) and using the versions of WikiTrauma and Wiki101 developed at the planning meeting, we will further refine WikiTrauma and Wiki101 by employing user-centered design methods focused on our users' needs [115,116]. A rapid, iterative prototyping process with 15 health professionals from nonparticipating centers will allow us to efficiently identify and resolve usability issues prior to finalizing the definitive version of WikiTrauma and Wiki101 for the interrupted time series [117,118].

What Is the Proposed Trial Design?

This study will be an interrupted time series with a parallel, theory-based process evaluation alongside the trial (see [Figure 4](#)

4). In the context of quality improvement, the interrupted time series is a simple but powerful tool used for evaluating the impact of a quality improvement program [119]. Our time series—repeated observations of the quality of care collected over time—will be divided into two segments. The first segment will comprise 10 retrospective, quarterly measurements of the quality of care measured before our intervention (a period of 30 months), and the second segment will be four prospective, quarterly quality of care measurements after our intervention (12 months). There are 57 adult-designated trauma centers of varying levels in Quebec—three level I, 26 level II, and 28 level III trauma centers. Four trauma centers will be selected in Université Laval's trauma network. We already identified one level I trauma center and a level II trauma center as participants. We will recruit two level III centers to complete our targeted sample of participating centers. Participants will not be blinded to their study assignment, however, all analyses will be blinded. The control group will comprise all of the 53 remaining adult trauma centers in the province.

Figure 4. Diagram representing the interrupted times series design.



What Are the Planned Trial Interventions?

Experimental Group

Participants from trauma centers assigned to the experimental group will receive a password to access and complete the Wiki101 course and to use WikiTrauma. They will receive three reminders at 2-week intervals to complete Wiki101. Before and after each Wiki101 course, participants will be administered a validated questionnaire to measure changes in opinion and

beliefs about using WikiTrauma. Questionnaires will also be repeated after the prospective 12-month period. After each course, participants will also receive a 2-week reminder about skills taught during the course.

Control Group

Participants in the control group will receive an email promoting access to the regular INESSS webpage and will also receive

three reminders at 2-week intervals to access the website. They will not have access to view or edit WikiTrauma.

Management of WikiTrauma During the Trial

For the purpose of this trial, to monitor its use, and ensure its quality, access to WikiTrauma will be protected by password.

Quality of Information Monitoring

Since the wiki content can be constantly changed by the participants, the quality of information and the strength of evidence will be assessed weekly by a medical expert (JL) and monthly by the steering committee using a standardized evaluation form. This committee will edit any serious deviations from recognized standards of care and will flag controversial topics to stimulate discussion within the wiki community.

What Are the Proposed Practical Arrangements for Allocating Participants to Trial Groups?

All professionals and decision makers working in the four participating trauma centers will be eligible to participate. With the help of the local leaders on the trauma committee, we will recruit as many clinicians (eg, physicians, nurses, respiratory therapists, and pharmacists) and decision makers (eg, heads of Emergency Department, Surgery Department, and Critical Care Department) as possible. All participating trauma committees will also be asked to designate five patient representatives to take part in the construction of various tools designed for their use (eg, decision aids and patient handouts). In each center, we will present the project to the local representatives of each trauma committee. We will provide a hands-on Wiki101 session to all the members of the local trauma committee and the five patient representatives, who will then become the local leaders able to teach their colleagues how to access the wiki and contribute to its content. An online version of Wiki101 will be available to all clinicians and patient representatives for future consultation.

What Are the Proposed Methods for Protecting Against Sources of Bias?

Although blinding of the participants and randomization are not feasible in this small trial, we will mobilize all efforts to minimize any other sources of bias. All data collectors (medical archivists) will be blinded to the allocation group. Throughout our study, we will prevent contamination by protecting Wiki101 and WikiTrauma by password and note any potential competing intervention. We will also identify any professional working in more than one participating trauma center to consider the impact of this potential source of bias. Wiki101 will be a standardized online training program. We will encourage all participants to complete all 12 months of the study. To minimize a potential Hawthorne effect, our control group will receive an invitation to consult the INESSS website at the beginning of the study. Moreover, our proposed study design of an interrupted time series provides the advantage of controlling for secular trends in the data.

What Are the Planned Inclusion/Exclusion Criteria?

Inclusion Criteria

We will select four trauma centers—one level I, one level II, and two level III trauma centers. The two level III centers will be identified by the authors based on their willingness to participate and collaborate with the other trauma centers for the 12-month project. At the individual level, study participants must be decision makers (eg, trauma program coordinators) or health care professionals (eg, emergency physicians, critical care physicians, trauma surgeons, nurses, respiratory therapists, physiotherapists, or pharmacists). Patient representatives will be selected without any restrictions or limitations with regard to their qualifications. These patient representatives could also be caregivers to existing trauma patients. Health care professional students and trainees (eg, residents, medical students, and nursing students) will have the same access to WikiTrauma and Wiki101 as fully certified professionals.

Exclusion Criteria

At the cluster level, a trauma center will not be eligible to participate if more than 50% of the members of the local trauma committee refuse to participate. Reasons for exclusion or refusal to participate will be documented. Pediatric trauma centers will be excluded.

What Is the Proposed Duration of the Treatment Period?

Wiki101 will take 3 hours to complete for each participant and they will have access to use Wiki101 and WikiTrauma for 12 months.

What Is the Proposed Frequency and Duration of Follow-Up?

Aside from our pre- and post-Wiki101 questionnaire and the 2-week reminder after completing Wiki101, we will only administer a final questionnaire after the 12-month treatment period.

What Are the Proposed Primary and Secondary Outcome Measures?

The primary outcome measure will be the change over time in a validated, composite performance indicator score based on 15 process performance indicators found in the Quebec Trauma Registry [4]. The secondary outcome measures will be rates of complications, length of stay, mortality, and the FIM. These will also be found in the Quebec Trauma Registry. Other secondary outcome measures will be the following: (1) intention to use WikiTrauma and the sociocognitive determinants of this intention, (2) the self-reported use of WikiTrauma in clinical practice, (3) the actual frequency of WikiTrauma use—number of visits, length of visits, number of visitors, and number of unique visitors, (4) the quality of information contained within WikiTrauma, (5) the frequency of content modifications—number of visitors having modified content, number of pages modified, number of new pages created, and number of pages having generated an edit war, (6) participants' comments about what worked and improvements suggested, (7) the estimated annual cost of maintaining WikiTrauma, (8)

the cost of delivering Wiki101, (9) the estimated cost of creating new knowledge-decision tools, and (10) the estimated cost of updating old knowledge-decision tools.

How Will the Outcome Measures Be Measured at Follow-Up?

We will measure quarterly composite performance scores from the Quebec Trauma Registry for all 57 adult trauma centers. Data in the Quebec Trauma Registry is routinely collected in all Quebec trauma centers every 3 months. The composite performance score is calculated as the average of 15 other indicators routinely collected in the Quebec Trauma Registry [4]. This score has good discrimination, construct validity, criterion predictive validity, and forecasting properties [120]. Mortality rates, complication rates (for delirium, pneumonia, and deep venous thrombosis), length of stay, and FIM will also be measured on a quarterly basis for all 57 trauma centers from routinely collected data in the Quebec Trauma Registry. The intention to use WikiTrauma will be measured by a validated questionnaire [40]. The actual wiki use and the frequency of content modification will be measured on a quarterly basis using a Google Analytics account linked to WikiTrauma.

Safety Monitoring and Quality Assurance

Since participants can change wiki content, the quality of information and the strength of evidence will be assessed weekly by an INESSS medical expert, and monthly by the scientific committee using a standardized evaluation form. This committee will edit any serious deviations from recognized standards of care and will flag controversial topics to stimulate discussion within the wiki community. The quality of different KT tools will be evaluated using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) methodology for grading quality of evidence and strength of recommendations [121]. To estimate the amount of supervision that was needed by the medical supervisor at INESSS, we will document the number of pages modified and created, and the number of edit wars. In order to ensure that only high-quality and officially approved knowledge tools will be used in clinical practice, wiki pages that are not approved for clinical use by local trauma committees will be color-coded in RED with a warning message to say that the page is currently under construction. Pages that are approved by local trauma committees will be color-coded in GREEN for use only in the trauma center that approved the page. To estimate activity that was generated by our wiki and the amount of supervision that was needed during this trial by the medical supervisor at INESSS, we will study the wiki's revision history page to document the number of visitors having modified the content, the number of pages modified, the number of new pages created, and the number of pages having generated an edit war [122] on a quarterly basis. An edit war will be defined as more than three reverts by a single editor on a single page within a 24-hour period. An edit that undoes other editors' actions will count as a revert. All cases of potential patient harm reported by any quality assurance committee or participant will be described and declared.

Sample Size

As a rule of thumb for an interrupted time series, 10 measurement points before and 10 measurements after an intervention provides 80% power to detect a change in level of 5 standard deviations (of the predata) only if the autocorrelation is greater than .4 (ie, extent to which data collected close together in time are correlated with each other) [123]. In our case, we will be able to measure 10 measurement points before (30 months), but the period of observation after our intervention will be limited to 12 months—4 quarters is equal to 4 measurement points. This will decrease our power, but we are currently applying for funding from other sources to collect data for a total of 32 postintervention months (10 quarters).

Data Analysis

Segmented regression will be used to measure, statistically, the changes in level and slope in the postintervention period compared to the preintervention period [119]. Thus, we will present a regression model with different intercept and slope coefficients for the pre- and postintervention time periods. We will compare the changes in quality of care measured at our four intervention trauma centers to the changes in quality of care measured at the other 53 trauma centers where no experimental intervention occurred. During the implementation period of WikiTrauma, we will continue to measure the impact on the quality of care. However, we will only proceed to compare the change in slope in the postintervention period once WikiTrauma has been fully implemented. We will use a Durbin-Watson test to verify the presence of autocorrelation and use an autoregressive error model to correct for this serial correlation.

Qualitative Content Analysis

We plan to enlist two researchers experienced in qualitative content analysis who will review participants' written questionnaire answers to identify the barriers in using our intervention. They will also try to understand how our combined intervention succeeded—or failed—to lead to improved quality of trauma care. When consensus between the two reviewers is not possible, a third reviewer will be consulted.

Study Duration

This project is planned to last 18 months. We have planned 3 months to implement the trial, including ethics approval in the four designated trauma centers and for delivering Wiki101 to the four local trauma committees. We will analyze all retrospective data obtained from the Quebec Trauma Registry in the first 3 months of our study and every 3 months thereafter for a total of 12 months. The last 3 months will be used to prepare our datasets, conduct our various analyses, and write our final report.

Ethical Considerations

We will apply for ethical approval to conduct this trial in all four participating trauma centers. All participants will be asked to consent before accessing the wiki for the first time and before any questionnaire administration. Local trauma committees will be consulted and we will obtain approval and support from each trauma center's chief executive officer. Patient participants will

also be asked to complete a consent form before participating in any phase of this trial.

A legal disclaimer will also be posted on the wiki site asking participants to always use their clinical judgement first. Clinical judgement should never be replaced by any information found in a protocol based in WikiTrauma. In addition, clinicians should only use the wiki pages that have been approved by their local trauma committee.

All personal information on study participants will remain anonymous and we will not publish the names of any of the participating trauma centers. All sensitive information will be kept in a locked filing cabinet at the principal investigator's (PI) research center or in a password-protected computer at the research center.

Results

This project was funded in November 2014 by the Canadian Medical Protective Association. We expect to start this trial in early 2015 and preliminary results should be available in June 2016. Two trauma centers have already agreed to participate and two more will be recruited in the next months.

Discussion

We expect that this study will yield important and unique evidence about the effectiveness, safety, and cost savings of

using collaborative platforms to adapt knowledge-implementation tools across jurisdictions. A recent scoping review had not identified any prospective studies analyzing the impact of a wiki intervention on the quality of care in any field of health care [34]. Thus, to the best of our knowledge, this will be the first interrupted time series evaluating the impact of a wiki on the implementation of best practices in trauma care. Patient safety science will gain from this project because we will investigate how WikiTrauma can help standardize care across our trauma system. This will be done by providing a unique collaborative tool that allows centers to learn from others in the implementation of evidence-based knowledge translation tools (eg, care protocols, order sets, and patient decision aids). WikiTrauma will also offer a unique knowledge-management platform to support the central leadership provided by provincial decision makers, such as the Institut national d'excellence en santé et services sociaux. This study will also provide a new platform for effective local collaboration between professionals, decision makers, and patients. Public- and patient-involvement programs will gain insight about using wikis to engage patients and the public in the implementation of best practices. Interprofessional education and quality-improvement programs will also learn about how these novel platforms can support collaboration and coordination in the implementation of novel best practices.

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Conflicts of Interest

Christian Chabot works for Telus Health. Telus Health offers many different health information technology solutions, including electronic medical records. Telus has not had any role in influencing the content of this protocol. None of the other authors have received any honorariums for the conduct of this trial from Telus. Richard Grenier works for Thales Canada as Director of Research and Technology. Thales has provided in-kind financial support for the development of the wiki, but has not had any role in influencing the content of this protocol. None of the other authors have received any honorariums for the conduct of this trial from Thales.

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Abbreviations

CHAU: Centre hospitalier affilié universitaire
CHU: Centre hospitalier universitaire
CIHR: Canadian Institutes of Health Research
CPD: continuing professional development
CSSS: Centre de santé et services sociaux
CT: computerized tomography
FIM: Functional Independence Measure
GRADE: Grading of Recommendations, Assessment, Development and Evaluation
INESSS: Institut national d'excellence en santé et services sociaux
KT: knowledge translation
PI: principal investigator

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Protocol

Optimizing Inter-Professional Communications in Surgery: Protocol for a Mixed-Methods Exploratory Study

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Abstract

Background: Effective nurse-physician communication is critical to delivering high quality patient care. Interprofessional communication between surgical nurses and surgeons, often through the use of pagers, is currently characterized by information gaps and interprofessional tensions, both sources of workflow interruption, potential medical error, impaired educational experience, and job satisfaction.

Objective: This study aims to define current patterns of, and understand enablers and barriers to interprofessional communication in general surgery, in order to optimize the use of communication technologies, teamwork, provider satisfaction, and quality and safety of patient care.

Methods: We will use a mixed-methods multiphasic approach. In phase 1, a quantitative and content analysis of alpha-numeric pages (ANP) received by general surgery residents will be conducted to develop a paging taxonomy. Frequency, timing (on-call vs regular duty hours), and interval between pages will be described using a 4-week sample of pages. Results will be compared between pages sent to junior and senior residents. Finally, using an inductive analysis, two independent assessors will classify ANP thematically. In Phase 2, a qualitative constructivist approach will explore stakeholders' experiences with interprofessional communication, including paging, through interviews and shadowing of 40 residents and 40 nurses at two institutions. Finally, a survey will be developed, tested, and administered to all general surgery nurses and residents at the same two institutions, to evaluate their attitudes about the effectiveness and quality of interprofessional communication, and assess their satisfaction.

Results: Describing the profile of current pages is the first step towards identifying areas and root causes of IPC inefficiency. This study will identify key contextual barriers to surgical nurse-house staff communication, and existing interprofessional knowledge and practice gaps.

Conclusions: Our findings will inform the design of a guideline and tailored intervention to improve IPC in order to ensure high quality patient care, optimal educational experience, and provider satisfaction.

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KEYWORDS

communication; interprofessional; pager; resident; nurse; education; patient safety

Introduction

Background

Interprofessional Communication Challenges

Effective interprofessional communication (IPC) is associated with greater patient safety, quality of care, and provider satisfaction. Ineffective nurse-physician communication has been linked to medication errors, patient injuries, and patient deaths [1]. Despite advances in clinical communication technologies designed to facilitate communication, there is limited evidence suggesting that any have led to improvements in the ability of health professionals to communicate effectively [2]. Communication systems designed for interprofessional use are not always optimal from the perspectives of the different providers who use them. For instance, the introduction of alphanumeric paging in surgery has been reported to pose a number of problems with communication from surgeons' perspectives, including insufficient content in a page and limited indication of the degree of urgency [3]. In addition, communication between nurses and physicians is inherently challenged by profession-specific communication styles and norms which create barriers to interprofessional care [4]. An abundance of research indicates a range of barriers to nurse-physician communication, which are embedded in professional cultures and power dynamics [5].

In contrast to other areas of inpatient care, direct face-to-face communication between nursing and surgical staff is challenged by the need for house staff presence in the operating room, in the emergency department, and attending to off-service patients. At this time, paging remains the primary mode of electronic communication between surgical nurses and house staff. Because of a lack of consensus guidelines for sending and responding to a page, nurses' decision to page surgeons for patient care, and surgeons' responses rely on each professional's judgment. Tension and communication breakdown between nurses and surgeons can arise when either party perceives a problem with a paged communication.

Impact of Inefficient Communication

Both nurses and surgeons have indicated that the current IPC model based on paging is a source of workflow interruption, particularly when sending or receiving pages seems incessant by either party [6,7]. Such paging systems are indeed disruptive for all health professionals [8]; during peak periods of the day, pages are received by general surgery house staff as often as every 6 to 12 minutes [9]. Of these frequent pages, up to 50% result in patient care interruption, including 19% interrupting direct patient contact [6,10,11]. Previous assessments of paging patterns revealed that 34% of pages received by residents were judged to require a response within one hour and result in change in patient care. Improving communication patterns and reducing unnecessary pages could result in 42% fewer interruptions in patient care [12].

Such workflow interruptions have been reported as detrimental for patient care. A direct observation study of ward nurses indicated that each interruption during medication administration and procedures is associated with a 13% increase in clinical errors [13]. Disruption of clinical work has also been related to more frequent surgical errors, with teamwork and communication failures identified as main predictors of these errors [14].

Negative impacts of inadequate paging systems have also been noted for educational experience of residents [15]. Up to 35% of residents' time is filled with activities without perceived educational value, including responding to unnecessary pages, and residents have expressed the wish to improve the efficiency of paging communications to reduce work interruptions that contribute to medical errors, stress, and fatigue [15-17]. Impaired nurses' job satisfaction due to inefficient paging communication has also been observed [18].

Need for in-Depth Assessment

Suboptimal use of the paging system, either through inappropriate activation/nonactivation of a page or inappropriate response to a page, leads to work interruption, communication gaps, and provider frustrations. Efforts to improve the quantity and quality of paging communications are ongoing but are challenged by poor understanding of barriers to effective IPC. A comprehensive understanding of the nature of interprofessional collaboration and communication in general surgery, including use of the existing paging system and other modes of communication, is needed to inform the development of meaningful and effective solutions to optimize interprofessional care delivered by nurses and surgeons.

Study Purpose

We plan to describe the current paging communication system in general surgery, and to explore barriers and enablers to effective use of paging in order to optimize interprofessional collaboration, provider satisfaction, and quality and safety of patient care. This study will be carried out with the following objectives: (1) to develop a paging taxonomy, by describing the urgency and content of pages sent on a general surgery service; and (2) to explore current patterns of communication between general surgery nurses and house staff, and compare them between two institutions.

Methods

Study Setting

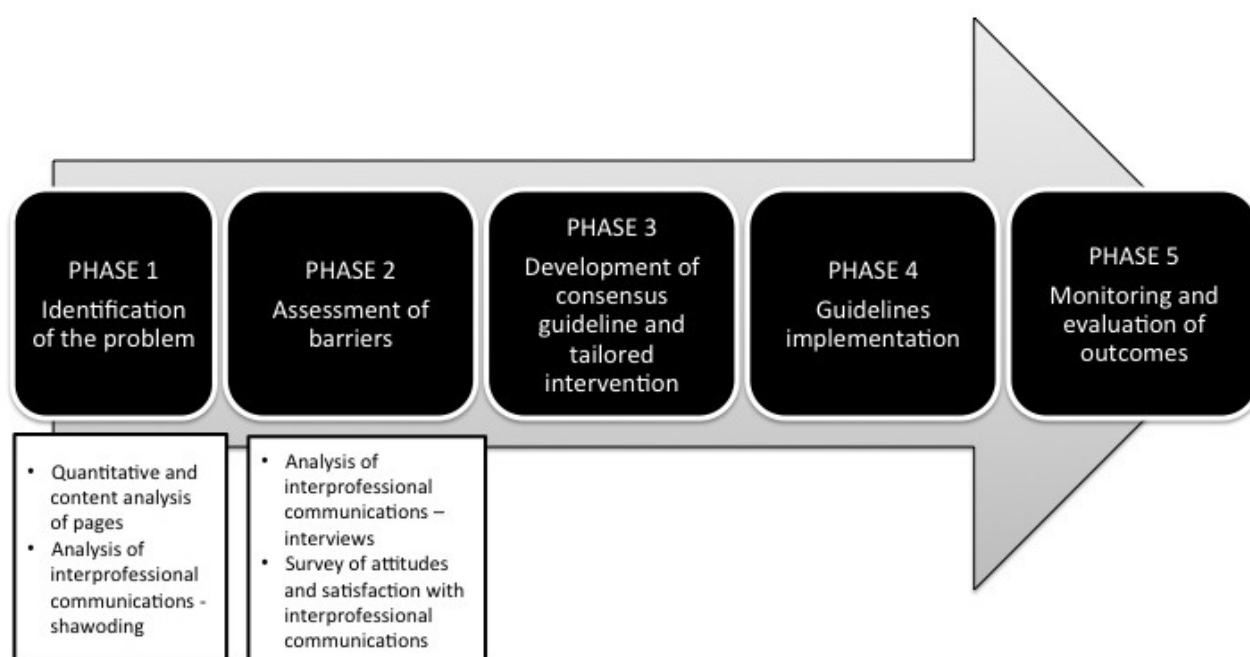
This study is the first part of an ongoing initiative to develop, implement, and evaluate a guideline and tailored strategy to enhance IPC, in order to optimize the delivery of timely high quality patient care. The outline of this initiative is based on the Knowledge-to-Action framework, with the current study aiming at identifying the problem at hand and addressing barriers to implement solutions, before future efforts are dedicated to development and implementation of a larger, tailored intervention, and evaluation of its outcomes (Figure 1). The

Sunnybrook Health Science Centre (SHSC) Research Ethics Board has approved this study (REB 044-2014).

This study will be carried out at SHSC and Saint-Michael's Hospital (SMH) in Toronto, Ontario. SHSC is a large academic institution including a tertiary level 1 Trauma Centre and the sixth largest cancer center in North America. SMH is a large tertiary institution that also includes a level 1 trauma center. general surgery house staff covers surgical oncology, vascular

surgery, acute care surgery, and trauma surgery services. In-house on-call teams include a junior resident, a senior resident, and a trauma team leader. All general surgery house staff are provided by the institution with an alphanumeric pager device associated with a unique messaging ID. Alphanumeric pages (ANP) are sent using an online tool on the hospital's intranet through which health care professionals can type and deliver their own messages.

Figure 1. Outline of an initiative to improve interprofessional communication in general surgery.



Adapted from: CIHR Knowledge-to-Action cycle - http://www.cihr-irsc.gc.ca/e/documents/kt_in_health_care_chapter_3.1_e.pdf

Quantitative and Content Analysis of Pages

We will conduct a retrospective quantitative content analysis of pages received by residents on general surgery services at SHSC.

All pages received by residents on the general surgery service at SHSC during four consecutive weeks will be included in the study. Residents on service during this period will be identified through the hospital's administrative records. Pages will be abstracted electronically from the pages database maintained by the Department of Information and Telecommunication, using the unique messaging ID of each resident. Based on previous exploratory analyses, we estimate that approximately 3000 pages will be retrieved.

The information retrieved will include date, time, receiver characteristics, origin (call-back number), and complete alphanumeric message for each page. Level of training of receivers will be inputted using the general surgery administrative list for the time period considered. The data will be anonymized and inputted into a spreadsheet for analysis.

The primary outcome will be the communication priority of pages based on required page-to-intervention time, divided into immediate (0-5 minutes), high (5-30 minutes), medium (30-120

minutes), and low priority (more than 120 minutes), as adapted from the institutional Escalation of Care Policy ([Multimedia Appendix 1](#)). Two independent physician assessors will code pages based on perceived priority. Disagreements will be solved by consensus or by a third physician if consensus cannot be reached.

Secondary outcomes will include number, timing, and interval of pages. Number of pages will be computed as number of pages per resident per day and number of pages per day for the whole group of residents. Timing will consist of subdivision of pages into the following time periods: on-call (week days 5:00 pm to 7:00 am, and weekends/holidays 7:00 am to 7:00 pm), and regular duty (week days 7:00 am to 5:00 pm). Interval will be defined as time (minutes) between two pages.

We will finally proceed with content analysis of the ANP using an inductive process by two independent assessors.

We will conduct a descriptive analysis using mean with standard deviation or median with interquartile range for continuous variable, proportions with 95% confidence intervals for categorical variables. Communication priority, number, timing, interval, and content of pages will be compared between pages sent to junior (postgraduate years 1 to 2) versus senior (postgraduate years 3 to 7) trainees, using chi-square test for

categorical data and students t test for continuous data. Inter-rater agreement between physician and nurse assessors for communication priority will be computed using a weighted kappa score [19]. All P values less than .05 will be considered statistically significant.

We will perform a multivariate analysis to identify factors associated with immediate/high communication priority of pages using logistic regression modeling, including variables of page timing, origin, receiver, and content category. Using the Wald chi-square test, any variable with a P value less than .05 will be considered a significant predictor of emergent/urgent pages.

Exploration of Interprofessional Collaboration and Communication: a Comparative Case Study

In phase 2, we will explore general surgery nurses and house staff perspectives and experiences with regard to activating, receiving and responding to pages, and compare both groups' opinions on when, why, and how paging should be used for communication. We will also compare the perspectives and experiences of nurses and house staff across two divisions of general surgery at the university (SHSC and SMH).

We will use a qualitative constructivist approach [20] to understand providers' perspectives and experiences with interprofessional communication. This approach, rooted in the interpretivist paradigm [21], assumes that multiple viewpoints are operating in the construction of providers' experiences and understandings of interprofessional communication and collaborative care. This approach aims to disentangle and explore these experiences and viewpoints accepting each as valid and true.

A theoretical sampling approach will be used. Nursing team leaders and nurses providing direct patient care will be recruited. We will recruit nurses of varying years of experience to capture the potential range of perspectives among more seasoned and junior nurses, and residents in different years of training (juniors/seniors). A total of 10 nurses and 10 residents will be recruited for interviews at each site, and an additional 10 nurses and 10 residents will be recruited for shadowing at each site.

Semistructured interviews and shadowing techniques will be used to understand nurses' and residents' perspectives and experiences with paging in general surgery. For nurses, the interviews will explore their perspectives on interprofessional communication, the effectiveness of the current paging system, the types of patient care situations for which paging is important, and the challenges faced when using paging to communicate with surgeons. Residents' interviews will explore their perspectives on interprofessional communication, the effectiveness of the current paging system, types of patient care situations for which paging is appropriate, and current challenges faced with receiving and responding to pages from the general surgery ward. Questions will elicit each professional's positive and negative experiences with paging and ideas for optimizing the use of this system and interprofessional communication more broadly. Interviews will be conducted by an experienced qualitative researcher for approximately 30 minutes (Multimedia Appendix 2: Interview Guide), audiorecorded, and transcribed.

Nurses and residents will be individually shadowed by a trained observer. Shadowing will take place at varying times during the day and overnight, to capture the range of patient care activities and clinical scenarios in which nurses page surgeons and residents receive pages. During shadowing sessions, the observer will take handwritten notes to document communication as it pertains to nurses and surgeons' collaborative patient care. These notes will be transcribed into documents comprising reconstructed reflective field notes [22]. All field notes will be anonymized and no identifiable patient information will be recorded. Shadowing sessions will last 2-3 hours each.

Analysis of interview and shadowing data will be inductive and iterative. We will use emerging themes to generate questions for participants as the project progresses, by transcribing, reading, coding, and comparing data in cyclical fashion, identifying recurring themes and ideas as well as disconfirming cases. A constant validity check will be used to guide data interpretation. This entails identifying and exploring participants' opposing perspectives and ideas, member-checking (ie, asking participants to confirm data), searching for negative evidence, searching for alternative explanations, and theorizing negative cases.

Data from nurse and surgeon interviews and shadowing will be triangulated to produce a holistic description and analytic interpretation of nurse-surgeon paging and response experiences. A comparative analysis of perspectives and experiences of nurses and house staff between the two sites will be conducted.

Survey of Attitudes and Satisfaction With Interprofessional Communications

We will conduct a survey to explore attitudes about the effectiveness and quality of communication, and assess the overall satisfaction with paging as a means of communication and the reasons for satisfaction or dissatisfaction. The survey will allow for confirmation or of the conclusions drawn from, by assessing perceptions of a larger number of professionals. It will also investigate further potential new hypotheses or information that will emerge from the quantitative analysis.

The survey will be distributed to all general surgery nurses and residents working at SHSC, including those who will have participated in the interviews and shadowing assessments. Potential participants will be identified through the SHSC Department of Nursing and Division of General Surgery. We estimate that 50 nurses and 15 residents will be surveyed.

A group of experts will identify important domains and specific issues within those domains to be addressed in the survey, highlighting those most pertinent interprofessional communications. Items will initially be generated without restriction through inductive analysis by the experts, informed by the results from the previous quantitative, content, interviews, and shadowing analyses. The generated items will then be grouped into domains. Finally, the list of items will be reduced to eliminate redundancy and keep only the most relevant items. To this end, the experts will be asked to rate the relevancy of each item on a 1 to 5 Likert scale [23]. Closed questions using 4 to 5 level Likert scales will be constructed to assess the

perceptions of respondents. In addition, we will solicit feedback on fifteen actual verbatim pages selected by the group of experts, with an effort to well represent the range of urgency and subject matter. Scales will be used for respondents to rate each page for clarity, urgency, overall amount of time within which a call-back should occur, and overall amount of time within which medical intervention should occur. Respondents will also have an opportunity to provide brief comments on the pages via an open-ended question.

To assess the clarity and interpretation of the questionnaire, it will be pretested among four residents and four nurses. They will be asked to provide feedback about the flow, clarity, and ease of administration of the questionnaire. The expert group will evaluate face validity, clarity, and comprehensiveness through a clinical sensibility analysis [23]. The questionnaire will be revised accordingly.

The survey will be self-administered through a Web-based platform (Fluidsurveys, Chide.it Inc, Ottawa, Canada). Each potential respondent will receive an individual invitation to complete the survey, through their institutional email address. Electronic reminders will be sent 3 and 6 weeks after the initial invite. Gift certificates will be drawn among all respondents, as an incentive to improve response rate.

We will first perform a descriptive analysis of completed questionnaires. Responses will be reported using proportions (n/N, %), and median with inter-quartile range for scale responses. Responses from nurses and house staff will be compared using the chi-square or ANOVA test. Comparison between responses obtained at the two sites will be compared using stratified chi-square and ANOVA. Regression analyses will be conducted, including the site as a covariable. All *P* values less than .05 will be considered statistically significant.

Discussion

Few studies have investigated the profile of pages to surgical services. Describing the profile of pages is the first step towards

identifying areas of inefficiency within the hospital, thereby allowing for the improvement of both the quality of patient care as well as the educational experience of all general surgery residents.

Qualitative methods have proven to be well-suited to uncovering the root causes of what are oftentimes deeply embedded contextual barriers to quality improvement and safety implementation [24]. The comparative design of the qualitative and survey analyses will allow for comparison and contrast of the contexts in which certain interprofessional communication practices, such as paging, are favorable or detrimental to quality patient care. Our mixed methods approach will provide important insights to the type and quality of interprofessional communication and collaboration within general surgery. This issue is important from a broad systems perspective as the results from this study will ultimately lead to the discovery of key contextual barriers to nurse-surgeon communication. It will identify existing interprofessional knowledge and practice gaps, and it will inform the design of improvement efforts to address them.

In order to highlight contextual barriers and facilitators to optimal interprofessional communication and to generate input and buy-in for addressing these barriers, our findings will be disseminated at the organizational level and through nursing teams and surgery rounds. Additionally, results from this study will inform the development of a tailored consensus guideline and communication protocol for general surgery, aimed at improving interprofessional communications. Institutional executives, program leaders, and managers who are part of the research team will support implementation of this protocol, which will ensure successful translation of our findings into practice. Results of this strategy will be evaluated 2 years after completion of its implementation using the same mixed-methods approach to quantitative and qualitative appraisal of interprofessional communication, and comparing it with the current results in a before-and-after design.

Conflicts of Interest

Julie Hallet is Chief Administrative Fellow for the Surgical Oncology training program at the University of Toronto. Trevor Hall is a Patient Safety and Emergency Preparedness Leader at SHSC. Najma Ahmed is Program Director of the General Surgery training program at the University of Toronto. Andy J Smith is Executive Vice-President at SHSC. Avery B Nathens is Surgeon in Chief at SHSC. Natalie G Coburn is Head of the Division of General Surgery at SHSC. Other authors declare that they have no competing interests.

Multimedia Appendix 1

Assessment of Pages Communication Priority based on the Institutional Escalation Response Time Clinical Practice Guideline (Sunnybrook Health Sciences Centre).

[PDF File (Adobe PDF File), 5KB - [resprot_v4i1e8_app1.pdf](#)]

Multimedia Appendix 2

Sample Interview Guides (not exhaustive).

[PDF File (Adobe PDF File), 3KB - [resprot_v4i1e8_app2.pdf](#)]

Multimedia Appendix 3

Funding agency letter confirming funding.

[[PDF File \(Adobe PDF File\), 114KB - resprot_v4i1e8_app3.pdf](#)]

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Abbreviations

ANP: alphanumeric page

IPC: interprofessional communication

SHSC: Sunnybrook Health Sciences Centre

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Protocol

Web-Based Telemonitoring and Delivery of Caregiver Support for Patients With Parkinson Disease After Deep Brain Stimulation: Protocol

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Abstract

Background: The increasing number of patients, the high costs of management, and the chronic progress of the disease that prevents patients from performing even simple daily activities make Parkinson disease (PD) a complex pathology with a high impact on society. In particular, patients implanted with deep brain stimulation (DBS) electrodes face a highly fragile stabilization period, requiring specific support at home. However, DBS patients are followed usually by untrained personnel (caregivers or family), without specific care pathways and supporting systems.

Objective: This project aims to (1) create a reference consensus guideline and a shared requirements set for the homecare and monitoring of DBS patients, (2) define a set of biomarkers that provides alarms to caregivers for continuous home monitoring, and (3) implement an information system architecture allowing communication between health care professionals and caregivers and improving the quality of care for DBS patients.

Methods: The definitions of the consensus care pathway and of caregiver needs will be obtained by analyzing the current practices for patient follow-up through focus groups and structured interviews involving health care professionals, patients, and caregivers. The results of this analysis will be represented in a formal graphical model of the process of DBS patient care at home. To define the neurophysiological biomarkers to be used to raise alarms during the monitoring process, neurosignals will be acquired from DBS electrodes through a new experimental system that records while DBS is turned ON and transmits signals by radiofrequency. Motor, cognitive, and behavioral protocols will be used to study possible feedback/alarms to be provided by the system. Finally, a set of mobile apps to support the caregiver at home in managing and monitoring the patient will be developed and tested in the community of caregivers that participated in the focus groups. The set of developed apps will be connected to the already existing WebBioBank Web-based platform allowing health care professionals to manage patient electronic health records and neurophysiological signals. New modules in the WebBioBank platform will be implemented to allow integration and data exchange with mobile health apps.

Results: The results of this project will provide a novel approach to long-term evaluation of patients with chronic, severe conditions in the homecare environment, based on caregiver empowerment and tailored applications developed according to consensus care pathways established by clinicians.

Conclusions: The creation of a direct communication channel between health care professionals and caregivers can benefit large communities of patients and would represent a scalable experience in integrating data and information coming from a clinical setting to those in home monitoring.

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KEYWORDS

telemedicine; deep brain stimulation; Parkinson disease; delivery of health care, integrated; mobile applications

Introduction

Background

Parkinson disease (PD) is a common neurodegenerative disorder affecting about 1% of the population over the age of 60 years [1]. PD is typically characterized by motor symptoms; however the clinical spectrum of the disease is more extensive, covering a wide range of nonmotor symptoms including cognitive and behavioral changes, sleep disorders, autonomic dysfunctions, sensory symptoms, and fatigue [2,3]. The surgical treatment of PD was reintroduced in the late 1990s with the advent of subthalamic deep brain stimulation (DBS) [4,5], and this is now an established treatment for PD patients [6-9].

Follow-up studies in PD show that after DBS surgery, motor function and performance during daily living activities improve for up to 5 to 10 years, although the initial benefit in part progressively deteriorates [10] and patients still experience clinical fluctuations that prevent them from performing simple daily activities [11]. In addition, immediately after surgery PD patients face a highly fragile stabilization period, in which parameters are set and patients and families get used to the new situation introduced with DBS.

The long-term outcome of DBS depends on the development of unresponsive PD disturbances related to disease progression that should be properly monitored to allow early recognition and treatment [9].

Long-term PD disability involves motor and nonmotor symptoms that worsen in time. Cognitive impairment and dementia have a higher prevalence in older patients [12,13]. Dementia and hallucinations predict nursing home placement and seem to double the mortality risk especially in older PD patients [14]. Another common, bothersome nonmotor symptom is the onset of lower urinary tract symptoms [15]. Up to 68% of PD patients fall every year, with approximately 50% falling repeatedly [16]. Cognitive behavioral education and exercise training were suggested to be effective in reducing the risk of falls [17,18]. Pain affects 29% to 85% of PD patients who experience various types of pain that may fluctuate with motor symptoms as “nonmotor fluctuations” [19]; the pain improves after DBS [20].

PD progression often leads to hospitalization [21]. The most frequent causes for admission are falls, pneumonia, urinary tract infections, reduced mobility, psychiatric disorders, and mental status changes [22]. PD progression in DBS patients is

monitored in scheduled follow-up clinical visits (once or twice a year) when the neurologist takes an instantaneous picture of the patient's condition that cannot completely reflect the daily condition. At home, patients rely on a family caregiver, who is usually not trained to deal with PD progression and DBS. Often, the reference center is far from the patient's house.

Research carried out in the last 15 years shows that recordings of neuronal activity (local field potentials [LFPs]) from the implanted electrodes provide information related to the patient's state [23-34]. LFPs correlate with motor and nonmotor PD symptoms and were recently proposed as a feedback variable for new DBS systems able to adapt stimulation parameters to the patient's state [11]. Provided that the new generation of DBS stimulators will allow LFP recordings during stimulation [11], it is likely that the analysis of neuronal activity in DBS patients can be integrated into monitoring systems to provide feedback and alarms.

These observations suggest that monitoring DBS patients more closely and continuously might be crucial to ensure a better quality of life. The use of telemedicine for monitoring PD patients has attracted a lot of attention [35-38], but no technology has been developed to support the continuous monitoring of DBS patients at home, including neurophysiological monitoring, together with an effective empowerment tool for caregivers.

Objectives

Consensus Guideline and Requirements Set

The reference guideline will be developed by the multiprofessional team responsible for the patient's care (neurologist, neurophysiologist, nurse, psychologist, physiotherapist, speech therapist) via modeling and defining the clinical care pathway of the DBS PD patient at home. In addition, the team will work with associates of the patient to establish a shared set of needs of the caregiver and patient community for the optimal management of patients with PD undergoing DBS at home.

Neurophysiological Biomarkers

Neurophysiological biomarkers provided by the neuronal signals recorded from deep brain electrodes can be used to directly monitor the patient's state at home. Motor, cognitive, and behavioral protocols will be used to study possible feedback/alarms to be provided by the system. These biomarkers will ground the future management of DBS PD patients at home, with the implanted stimulators being part of a system, already

available as an experimental device, that will be able to record from DBS electrodes while stimulating.

Information System Architecture

The architecture of the information system will be created to meet the specific needs of caregivers at home by integrating the clinical care pathway of the patient in order to provide a caregiver support system connected to and sharing information with the electronic health record of the patient. The platform will be able to manage neurosignals analysis and provide alerts related to changes in biomarkers underlying changes in the patient's state. The architecture will hence be specific for home telemonitoring of DBS PD patients and empowerment of caregivers and include educational material, a direct communication channel with the specialist, and operative instructions for the recognition and management of simple alert symptoms.

Methods

Defining and Modeling the Process of Homecare Monitoring for DBS Patients

To achieve the definition of the consensus care pathway for PD patients with DBS implant and establish a shared set of caregiver needs, we will analyze the current management practices by involving neurologists and psychologists (maximum 15) from the DBS Study Group of the Italian Neurological Society (Società Italiana di Neurologia) and organizing a focus group dedicated to homecare management of patients. The focus group will draft a consensus clinical care pathway that will be validated by a larger group of at least 30 PD experts.

We will then prepare structured interviews for patients and caregivers to establish their main needs while at home, and we will interview patients and caregivers recruited through the Associazione Italiana Parkinson and directly through the Movement Disorders Ambulatory of both the Borgoroma Hospital and the Fondazione IRCCS Ca'Granda Ospedale Maggiore Policlinico. The expected number of patients and caregivers to be interviewed is 50.

Finally, we will involve 10 to 15 patients, together with their caregivers and reference neurologists, in a focus group dedicated to the definition of the main needs and requirements for home monitoring support systems starting from the results of the interviews.

After having completed the needs analysis for both health care professionals and patients and families, we will model through a graphical language (Unified Modeling Language [UML]) the care pathway of the PD patients with DBS at home, according to the clinical care pathway and the patient and caregiver needs.

UML is a widely used visual language for specifying, visualizing, constructing, and documenting the artifacts of

software systems, as well as for business modeling and other nonsoftware applications [39,40]. A UML model is composed of diagrams modeling the static and dynamic behaviors of the system/process. The UML modeling approach is based on the decomposition of a complex system into many different objects representing the subjects/objects related through hierarchical and functional relationships and specified through properties. The methods available to each object represent all the actions that the object exposes or receives. The methods available map all the existing interactions between objects in the system. This decomposed and simplified structure allows the introduction of a formal representation and supports the verification of its validity.

Defining Neurophysiological Biomarkers

To define neurophysiological biomarkers (Table 1) providing feedback on the patient's state, we will record LFPs from 30 patients affected by PD and implanted with subthalamic nucleus DBS electrodes through a new experimental system that records LFPs while DBS is ON [41] and transmits signals by radiofrequency to a recording system (Figure 1). Recordings will take place 2 to 3 days after the surgery for electrode implantation and will record continuously for 3 hours. All of the experimental sessions will be videorecorded to allow further offline reassessment of the patient's state by an experienced neurologist in order to detect motor fluctuations and other symptoms that may require feedback to the caregiver or to the reference neurologist.

LFPs will be bipolarly recorded through DBS electrodes (Medtronic 3389) implanted in the subthalamic nucleus. The DBS electrode has four cylindrical contacts (0, 1, 2, and 3 beginning from the most caudal). Two contacts will be used for recording and one for DBS delivery. LFPs will be recorded through a new system (aDBS, Newronika srl) that allows LFP recording with DBS ON [41]; control of DBS parameters, manual and automatic, through ad hoc algorithms; and radiofrequency transmission of recorded signals.

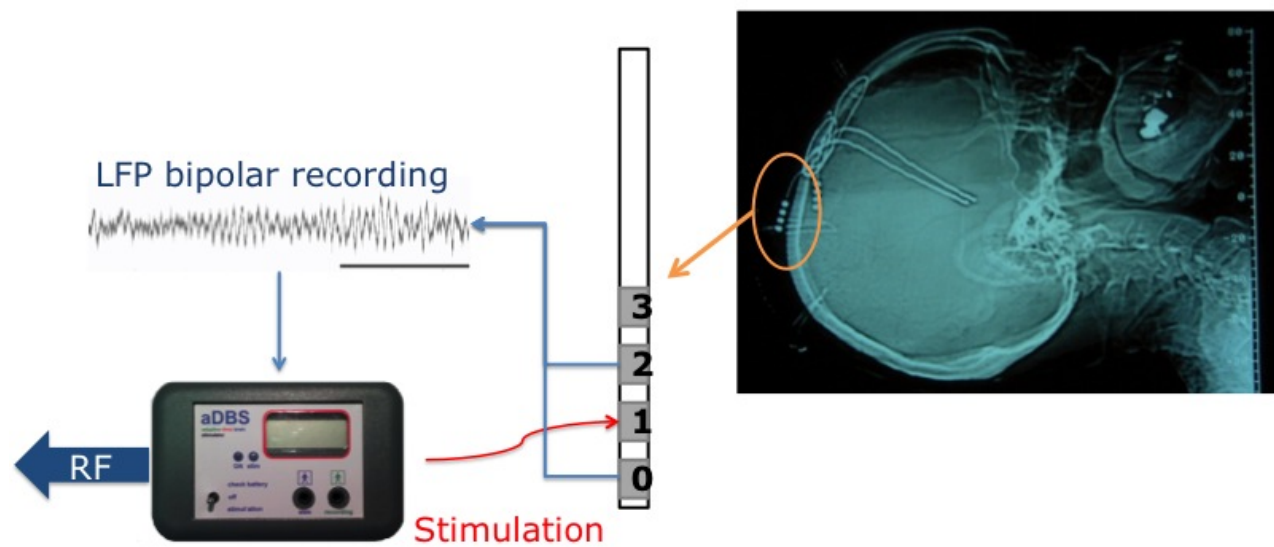
LFP analysis will be conducted offline with ad hoc programs stored on the WebBioBank system for clinical data collection. These Matlab-based programs allow signal preprocessing and analysis and were previously used for other LFP analyses [25,26,28,33].

Because LFPs represent the activity of large populations of neurons, the analysis will be carried out in the frequency domain. Spectral analysis (power spectrum), cross-spectral analysis (coherence), parametric and nonparametric time-frequency analysis, and bispectral analysis (bicoherence) will be applied to extract biomarkers. Parametric and nonparametric tests will be used to evaluate the intrasubjective changes of LFP biomarkers in different conditions and during different tasks.

Table 1. Protocols for defining neurophysiological biomarkers.

LFP recording	DBS
After 12 hours withdrawal of antiparkinsonian therapy:	
Rest (with the patient lying in an armchair or on a bed)	Off
Rest (with the patient lying in an armchair or on a bed)	On
Movement (during self-paced repetitive movement of one arm/leg, during cued movements of the limbs, and during spontaneous walking around the room)	Off
Movement (during self-paced repetitive movement of one arm/leg, during cued movements of the limbs, and during spontaneous walking around the room)	On
Emotional and decision-making tasks (during an emotional task—patient will be shown pictures/movies that elicit emotional response—and during a decision-making task—patient must choose an answer to moral and neutral questions)	Off
Emotional and decision-making tasks (during an emotional task—patient will be shown pictures/movies that elicit emotional response—and during a decision-making task—patient must choose an answer to moral and neutral questions)	On
After the administration of a clinically effective dose of levodopa:	
Rest (with the patient lying in an armchair or on a bed)	Off
Rest (with the patient lying in an armchair or on a bed)	On
Movement (during self-paced repetitive movement of one arm/leg, during cued movements of the limbs, and during spontaneous walking around the room)	Off
Movement (during self-paced repetitive movement of one arm/leg, during cued movements of the limbs, and during spontaneous walking around the room)	On
Emotional and decision-making tasks (during an emotional task—patient will be shown pictures/movies that elicit emotional response—and during a decision-making task—patient must choose an answer to moral and neutral questions)	Off
Emotional and decision-making tasks (during an emotional task—patient will be shown pictures/movies that elicit emotional response—and during a decision-making task—patient must choose an answer to moral and neutral questions)	On

Figure 1. LFPs are recorded bipolarly from the DBS electrodes while the stimulation is turned ON through the aDBS device that also allows DBS parameter change and radiofrequency transmission of the recorded signals.



Defining the Architecture of the Integrated Telecare System

The implementation of the system architecture will be based on the extension of the already-existing WebBioBank system for the management of electronic health records (EHR) of PD patients with DBS electrode implants, integrated with signal

analysis [42]. The system will be extended with a set of mobile apps to support the caregiver in managing and monitoring the patient at home.

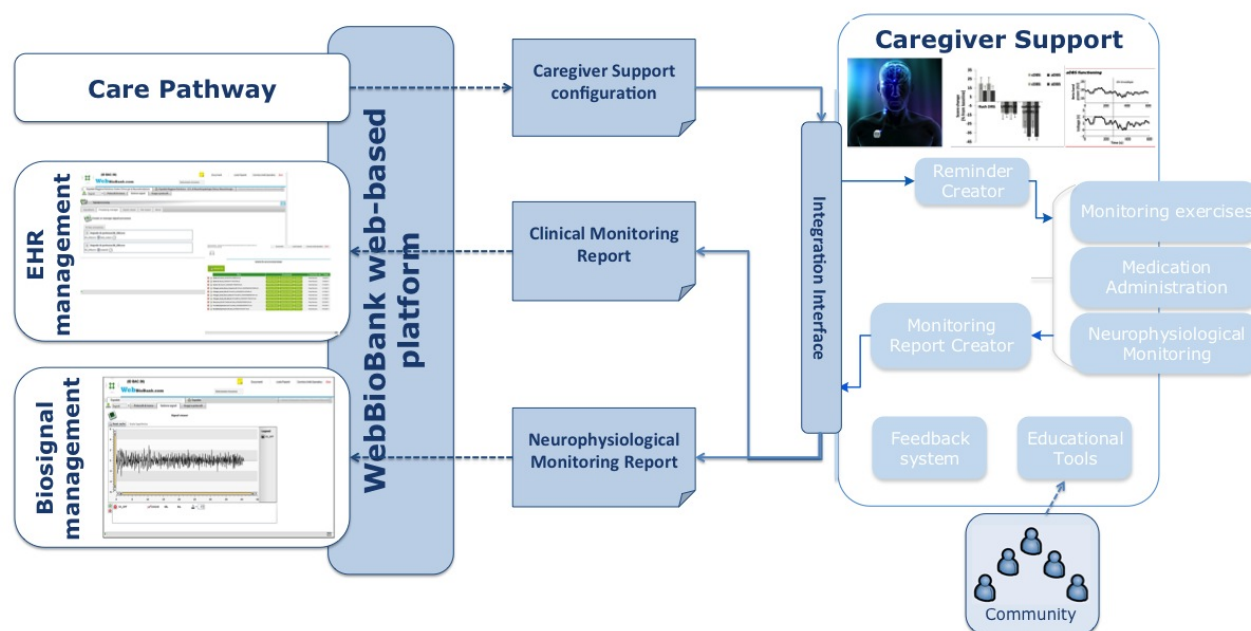
The architecture will consist of two modules, Care Pathway and Caregiver Support, which are both connected to the WebBioBank Web-based platform (Figure 2). The Care Pathway

module will be a part of the WebBioBank EHR system and will be devoted to supporting the continuous monitoring of the disease progression and updating of home treatments, customized for each patient. The Caregiver Support module will be designed to provide the tools and information the patient and caregiver need for the proper implementation of the Care Pathway, according to the needs and requirements defined in the first phase of the project. A set of mobile apps will be made available to patients and caregivers to support symptom

interpretation, emergency management, and routine daily activities and allow information exchange with the reference neurologist. A mobile device, such as a tablet, will be provided to patients who do not have a personal one.

The system will be implemented and preliminary tested (alpha test) on the same patients involved in the focus groups previously described. System validation will be not part of this project.

Figure 2. Expected architecture of the prototype system. The WebBioBank Web-based platform supports the information exchange between the Care Pathway module that defines the configuration of the homecare monitoring/treatments and the Caregiver Support module, a mobile app dedicated to the caregiver.



Results

The project is supported by preliminary observations showing that PD patient and caregiver associations are already active in asking for more effective communication with their care team and reliable education sources for the management of patients in homecare. Also, our previous studies show that neurophysiological signals from DBS electrodes provide information on PD motor and nonmotor symptoms [11,34], and we have already implemented a platform for the management and analysis of biopotentials recorded from DBS electrodes, integrated with WebBioBank [42].

We expect at the end of the project to obtain a reference consensus guideline and a shared requirements set for the home monitoring and care of patients with PD treated with DBS that, combined with the set of biomarkers that will provide alarms/feedback to caregivers and health care professionals regarding the patient's state, will constitute the implementation of continuous home monitoring for DBS patients. The implementation of a prototype information system architecture allowing communication between health care professionals and caregivers will support the improvement of the quality of care for PD patients treated with DBS.

Discussion

Patients with PD undergoing DBS face a highly fragile stabilization period and require specific support at home. At present, no system for DBS home monitoring is available. Our project, introducing effective direct and continuous monitoring of patients at home, would help not only to assess PD progression but also to make the patients and their families central actors in the care process.

More specifically, the definition of consensus care pathways for patient home monitoring, the definition of neurophysiological biomarkers from signals recorded through DBS electrode, and the in-depth analysis of caregiver needs will ground the development of supporting tools and telemonitoring of DBS PD patients at home. Properly integrated with patient EHRs, these tools will improve the quality of life for DBS PD patients by supporting caregivers, optimizing patient continuous monitoring, and providing alerts to professionals and caregivers about disease worsening or reprogramming needs.

The project results will contribute to the integration of the caregiver role in the care pathway of the patient through a direct communication channel between health care professionals and caregivers by means of an enhanced and easily accessible mobile

app system for DBS patient home monitoring. In the project, we will also address the issue of ongoing support to caregivers through dedicated apps facilitating their education and interaction with local resources. Also, the definitions by clinicians of consensus care pathways and personalized care plans may produce better resource management for the national health care service and may improve, in terms of effectiveness

and efficiency, the management of this costly neurodegenerative chronic disease.

The experience in integrating data and information coming from a clinical setting to those in home monitoring can be scalable to other conditions involving patients with chronic diseases in the homecare environment, and tailored apps can be developed according to consensus care pathways established by clinicians.

Conflicts of Interest

SM, AP, SB, LR, and FC are founders and shareholders of Newronika Srl, a spin-off company of the Fondazione IRCCS Ca'Granda Ospedale Maggiore Policlinico and the University of Milan.

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Abbreviations

PD: Parkinson disease
DBS: deep brain stimulation
LFP: local field potential
UML: Unified Modeling Language
EHR: electronic health record

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Protocol

Working With Parents to Prevent Childhood Obesity: Protocol for a Primary Care-Based eHealth Study

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Abstract

Background: Parents play a central role in preventing childhood obesity. There is a need for innovative, scalable, and evidence-based interventions designed to enhance parents' motivation to support and sustain healthy lifestyle behaviors in their children, which can facilitate obesity prevention.

Objective: (1) Develop an online screening, brief intervention, and referral to treatment (SBIRT) eHealth tool to enhance parents' concern for, and motivation to, support children's healthy lifestyle behaviors, (2) refine the SBIRT eHealth tool by assessing end-user acceptability, satisfaction, and usability through focus groups, and (3) determine feasibility and preliminary effectiveness of the refined SBIRT eHealth tool through a randomized controlled trial.

Methods: This is a three-phase, multi-method study that includes SBIRT eHealth tool development (Phase I), refinement (Phase II), and testing (Phase III). Phase I: Theoretical underpinnings of the SBIRT tool, entitled the Resource Information Program for Parents on Lifestyle and Education (RIPPLE), will be informed by concepts applied within existing interventions, and content will be based on literature regarding healthy lifestyle behaviors in children. The SBIRT platform will be developed in partnership between our research team and a third-party intervention development company. Phase II: Focus groups with parents, as well as health care professionals, researchers, and trainees in pediatrics (n=30), will explore intervention-related perceptions and preferences. Qualitative data from the focus groups will inform refinements to the aesthetics, content, structure, and function of the SBIRT. Phase III: Parents (n=200) of children—boys and girls, 5 to 17 years old—will be recruited from a primary care pediatric clinic while they await their children's clinical appointment. Parents will be randomly assigned to one of five groups—four intervention groups and one control group—as they complete the SBIRT. The randomization function is built into the tool. Parents will complete the eHealth SBIRT using a tablet that will be connected to the Internet. Subsequently, parents will be contacted via email at 1-month follow-up to assess (1) change in concern for, and motivation to, support children's dietary and physical activity

behaviors (primary outcome), and (2) use of online resources and referrals to health services for obesity prevention (secondary outcome).

Results: This research was successfully funded and received ethics approval. Development of the SBIRT started in summer 2012, and we expect all study-related activities to be completed by fall 2016.

Conclusions: The proposed research is timely and applies a novel, technology-based application designed to enhance parents concern for, and motivation to, support children's healthy lifestyle behaviors and encourage use of online resources and community services for childhood obesity prevention. Overall, this research builds on a foundation of evidence supporting the application of SBIRTs to encourage or "nudge" individuals to make healthy lifestyle choices. Findings from Phase III of this project will directly inform a cluster randomized controlled trial to study the effectiveness of our intervention across multiple primary care-based settings.

Trial Registration: ClinicalTrials.gov NCT02330588; <http://clinicaltrials.gov/ct2/show/NCT02330588> (Archived by WebCite at <http://www.webcitation.org/6WyUOeRlr>).

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KEYWORDS

body weight; Canada; child; childhood obesity; Internet; parents; prevention; primary health care

Introduction

Childhood obesity is an urgent public health issue. Approximately one-third of Canadian children are overweight or obese [1], a proportion that has doubled over the past 25 years [2]. Pessimistically, the impact of most interventions for managing childhood obesity has been modest to date [3], a point that highlights the need for innovative strategies that are designed to prevent unhealthy weight gain among healthy-weight children (ie, primary prevention) *and* manage excess weight among children with overweight and obesity (ie, secondary prevention). To optimize the effectiveness of such approaches, parents need to play a central role. Specifically, parents set the stage for children's healthy lifestyle behaviors by fostering a supportive home environment, role-modelling healthy lifestyle habits, and monitoring and reinforcing children's behaviors [4,5]. Paradoxically, some parents do not perceive their children's excess weight as a health concern [6], a perception that may be influenced by parents' inability to accurately recognize obesity in their children [7]. Among parents who have an accurate perception of their child's weight status (eg, their child meets clinical criteria for obesity *and* parents perceive their child to be obese), only 50 to 60% initiate and sustain healthy lifestyle changes [8]. These results suggest that interventions that attempt to correct parents' inaccurate perceptions of their children's weight status *and* enhance their concern for, and motivation to, support children's healthy lifestyle behaviors may be useful.

Obesity is a common health issue, so interventions to prevent obesity need to be accessible, affordable, and scalable in order to reach a large target audience. The widespread use and availability of the Internet highlights its potential value as a vehicle to deliver obesity prevention interventions [9]—eHealth (electronic health) and mHealth (mobile health) interventions are contemporary terms used to describe health care services and practices that are supported by electronic infrastructure. The benefits of these types of interventions include their ability to offer immediate and tailored feedback, cost-effectiveness, and potential for widespread reach [10]. Web-based interventions may specifically enhance health services by (1)

removing social barriers and providing anonymity [11], (2) overcoming limited availability of obesity-related health services [12], and (3) compensating for low confidence and skill levels reported by health care providers [13,14]. Systematic reviews have reinforced such advantages for Web-based interventions for both children [11,15] and parents [16], reporting statistically and clinically meaningful improvements in obesity-related outcomes and lifestyle behaviors.

To date, the majority of online interventions to address obesity-related behaviors have applied time-intensive (eg, online programs up to 52 weeks in length [17]) and resource-intensive (eg, online interventions with additional in-person components [18]) models, suggesting there is value in examining the application of brief and novel online strategies for the prevention of obesity in children [19,20]. One such strategy includes screening, brief intervention, and referral to treatment (SBIRT) approaches, which are time-limited and include an initial screening step followed by the delivery of a short intervention, usually within a 10 to 20 minute period, with options to refer users to treatment and other supportive resources. Fundamental to SBIRTs is the feedback, responsibility, advice, menu options, empathy, and self-efficacy (FRAMES) model [21], which (1) personalizes feedback to communicate unique health outcomes and positive behavior change to the participant, (2) emphasizes personal responsibility for behavior change, (3) provides advice on how to initiate and sustain change(s), (4) creates a menu of change options, (5) expresses empathy, and (6) emphasizes self-efficacy for change. Historically, SBIRTs have been used to address preventable health concerns (eg, alcoholism, cannabis use) and studies have shown this approach can exert a positive influence on intention to change behaviors as well as behavior change itself [22,23]. SBIRTs are particularly well-suited for obesity prevention in primary care, as providers often have frequent opportunities to interact with families, but limited time and resources to do so. Furthermore, because primary care represents most families' first point of contact with the health care system [24], the provision of preventative health services, particularly for the primary prevention of chronic diseases, is proactive, efficient, and cost-effective. As well, families tend to access primary care-based health services throughout the life

course, so it represents a suitable environment to capture longitudinal data.

With these issues in mind, we hypothesize that an online SBIRT targeting parents will increase their awareness of their children's weight status and enhance parents' concern for, and motivation to, support their children's healthy lifestyle behaviors. The program will have a prevention approach designed to benefit parents with children from across the body weight continuum. Specifically, our SBIRT will encourage parents of children with healthy weights to seek resources to eat healthfully and be physically active to maintain their children's weight status. It will also guide parents of children with unhealthy weights to access information and health services to improve their children's weight status and associated health risks. Our three-phase, multi-method study includes the following objectives:

1. Develop an online SBIRT tool designed to raise parents' awareness of their children's weight status and lifestyle behaviors.
2. Refine the SBIRT tool by assessing acceptability, satisfaction, and usability using focus groups with pediatric health care professionals, researchers, and parents.
3. Determine the feasibility (pilot-testing) and impact (pragmatic trial) of the intervention through a randomized controlled trial (RCT) design, which will include administering our SBIRT to a sample of parents and collecting data at baseline and 1-month postintervention to assess (1) changes in parents' concern for, and motivation to, support children's dietary and physical activity behaviors—primary outcome—and (2) families' use of resources and health services for the prevention of childhood obesity—secondary outcome.

Methods

Study Design

This study includes intervention development (Phase I), refinement (Phase II), and testing (Phase III). Such a design is appropriate when a number of research-related parameters (eg, adverse events, cost-effectiveness, feasibility, power calculation for sample size) remain unknown [25].

Study Setting

This study is being conducted in the primary care setting and will be performed in the waiting room while parents and children await their upcoming pediatrician appointment. Specifically, we are working in partnership with colleagues who lead the Edmonton Oliver Primary Care Network (PCN), one of more than 40 PCNs in the province. In Alberta, PCNs were developed by our provincial health system to enhance and coordinate health services delivery in primary care. They include family physicians, a multidisciplinary team of health care professionals, decision makers, and administrators, all of whom work collaboratively to address the needs of the local patient population. This setting represents a suitable venue to address the primary and secondary prevention of childhood obesity because (1) PCNs are often families' first point of contact with the health care system, (2) the goals and priorities of PCNs are

aligned with primary and secondary prevention of chronic diseases, and (3) patients typically access health care services at PCNs throughout their lives, which represents an excellent setting to maintain contact with, and collect information from, families over an extended period [24,26].

Phase I: Development

Our SBIRT tool, which we have titled the Resource Information Program for Parents on Lifestyle and Education (RIPPLE), will be developed in partnership with Evolution Health (EH), a Web-based intervention development company based in Toronto, Ontario [27]. Content in the SBIRT will be incorporated from current literature on children's healthy lifestyle behaviors, including dietary, physical activity, and sedentary behavior habits, as seen in Slater et al [28] and a review by Steinbeck [29]. Theoretical underpinnings of the SBIRT will be informed by concepts used in existing interventions, for example, the Norm Activation Model [30]. Consistent with the Health Belief Model [31], the SBIRT will be designed to act as a *cue to action*, in which the intervention will prompt parents to initiate and sustain healthy lifestyle changes for their children. Specifically, the SBIRT will act as a trigger by creating a discrepancy between parents' perceptions of their children's dietary and physical activity habits and either *normative* or *injunctive* feedback—parents will receive either *normative* feedback on how their child relates to reference norms drawn from the Canadian pediatric population for eating [32] and physical activity [33], or *injunctive* feedback, which includes national recommendations [34]. By providing parents with two types of feedback, we will determine if injunctive or normative feedback is more salient for parents in the context of supporting their children's healthy lifestyle behaviors.

Based on SBIRTs previously developed by Evolution Health [35,36], our SBIRT will *screen* children's weight status, which will include sharing this information with parents, as well as deliver a *brief intervention* to parents related to their children's lifestyle behaviors, and provide *referrals to treatment* and other supportive resources for parents. Specifically, the guided user interface (GUI) within the online program will include the following steps:

1. Data input. Children's height (cm) and weight (kg) will be measured by the study-designated research assistant (RA) using a wall-mounted electronic stadiometer and an electronic medical scale. The RA will enter this data into the iPad program and then pass the iPad to the parent.
2. Screening. Parents will receive objective, personalized feedback both numerically, based on their children's body mass index percentile, and visually, using a healthy weight ruler [37].
3. Brief theory-driven intervention. Parents will be randomly assigned to an intervention group, where they will complete one of four brief questionnaire-based interventions, or to the control group, *Heads Up!* The latter includes information on children's lifestyle behaviors only. Two interventions will include nutrition-based questions—*Eat It!*—and two interventions will include physical activity-based questions—*Move It!* In each of the interventions, parents will receive either *normative* or *injunctive* feedback. Between-group

differences in primary and secondary outcomes will be assessed to determine the differential impact of the intervention across the five groups of parents.

4. Toolkit. Parents will be presented with a menu of online resources and community services to choose from.

5. Theory-based measurement. To understand how the SBIRT works to influence parents' intentions, a brief questionnaire has been adopted from Campbell et al [38] and will assess parents' concern for, and motivation to, support children's dietary and physical activity behaviors.

6. Tailored report. Parents will receive a personalized report that will include their children's weight status, their responses to the intervention questions as well as the feedback they received, and the resources and services they selected from the toolkit.

To measure changes in primary (ie, parental concern for, and motivation to, support changes in children's lifestyle behaviors) and secondary outcomes variables (ie, families' use of resources and health services), parents will be contacted at 1-month follow-up to complete the same theory-based measurements they completed at baseline and a brief questionnaire to assess their use and/or intention to use the suggested resources and community services. By design, the SBIRT will require parents to indicate their preferred mode of contact for receiving the 1-month follow-up measure and questionnaire (eg, mail, telephone, email), which is designed to optimize participant retention.

Phase II: Refinement

Following intervention development, focus groups with parents of children aged 5 to 17 years, along with pediatric-focused health care professionals (ie, primary, secondary, and/or tertiary providers with experience in childhood obesity prevention and management), health services administrators, and researchers (ie, faculty and trainees in the field of pediatrics and obesity) will be used to assess acceptability, satisfaction, and usability of the SBIRT tool. Parents will be recruited via word of mouth at the local university where the research is being conducted—a minimum of 10 parents will be recruited in order to gain an adequate representation of the caregiver perspective. Consistent with reports regarding the difficulties in organizing and running focus groups with specific populations [39,40], mechanisms to obtain parents' perspectives (eg, one-on-one individual interviews) will be used if necessary. Using the recruitment technique of snowball sampling, health care providers, administrators, and researchers (n=20-25) will be purposefully sampled for demographic variation in participant groups (eg, disciplinary orientation, experience). This estimated sample size is consistent with methodological recommendations [41] and similar previous investigations [42,43], which will enable us to attain a high level of data saturation.

In a private room, the RA trained in facilitating focus group interviews will provide eligible participants with a study explanation and formal invitation to participate—informed, written consent will be obtained. Focus groups—6 to 8 participants per group—will occur over four to five sessions, and be 60 to 90 minutes in duration. The RA will lead groups

step by step through the SBIRT (version 1.0) by entering standardized data into the GUI and projecting the Web-based content onto a screen. Interviews will include open-ended questions to query (1) participants' overall impressions of the intervention, (2) factors related to participants' acceptability of, and satisfaction with, the intervention, and (3) theoretical underpinnings of the SBIRT. Probes will include prompts on SBIRT perceptions, preferences, and how to best incorporate the program into existing clinical processes—perceived strengths, limitations, and areas for improvement will also be explored. A closing discussion will query perceptions of the need for long-term support within and beyond primary care and how this support should be provided.

Focus group discussions will be transcribed in real time using a court reporter, which optimizes transcription accuracy and ensures confidentiality [44]. Data will be managed and analyzed using NVivo 10 (QSR, Melbourne, Australia). Qualitative data analysis is a cognitive process that includes comprehending, synthesizing, theorizing, and recontextualizing [45], and the method of qualitative description [46] will be used to develop a basic description of the data. Data will be analyzed in a line-by-line process. From the initial analysis, a coding scheme will be developed to identify all meaningful units and new themes will be added as necessary. Once each discussion is coded, themes will be grouped under general categories and a written description will be constructed to explain each category. To enhance methodological rigor, we will (1) triangulate participants' views by interviewing health care professionals, researchers, and parents, (2) employ concurrent data collection and analysis to inform amendments to the interview guide, and (3) implement a real-time member-checking protocol to ensure findings accurately reflect participants' personal perspectives—at the end of each group, the moderator will confirm and clarify discussed themes [39].

Phase III

Pilot-Testing

The objective of this phase is to pilot-test the refined SBIRT with parents (n≈30) to determine the feasibility of incorporating the intervention in primary care, including (1) accuracy of the randomization procedures, (2) ability to retain participants at follow-up, (3) practicality of clinician involvement, (4) suitability of the primary and secondary outcome measures, and (5) time to complete the intervention in the primary care waiting room. All of these elements are important to assess prior to determining the effectiveness of a newly developed intervention [25,47]. Upon recruitment and 1-month follow-up, the researchers will cease participant recruitment for a 2-week period to assess issues regarding feasibility—at this time, modifications may be made to study processes and procedures before initiating the pragmatic trial.

Pragmatic Trial

Trial Design

A parallel-group, double-blinded randomized controlled trial will be used to assess the effectiveness of the intervention. The trial has been registered publicly (ClinicalTrials.gov identification number: NCT02330588) [48] and adheres to

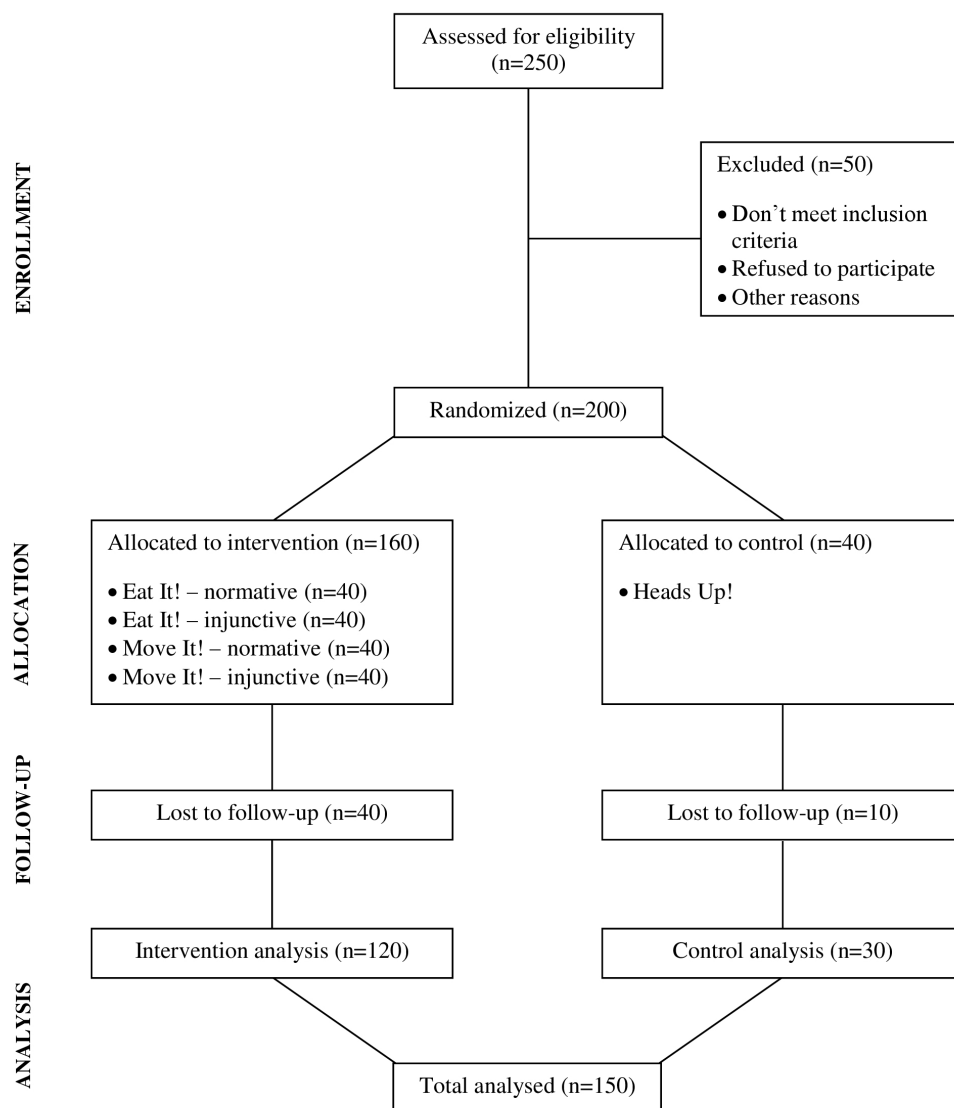
CONSORT guidelines [49]. Participants will be recruited and enrolled by an RA and RIPPLE will assign a unique, nonidentifying number to participants. The allocation sequence will be electronically generated within the GUI and to reduce the risk of selection bias, participants ($n=200$ parents) will be randomly assigned to one of five groups—*Eat It!* (normative), *Eat It!* (injunctive), *Move It!* (normative), *Move It!* (injunctive), or *Heads Up!* (control group). Group assignment will be done using blocked randomization—five arms, block size of five—to ensure equal group sizes— $n=40$ /arm, equal allocation ratio of 1:1—throughout the study. To reduce the risk of performance bias, the RCT will be double-blinded. Specifically, the study-designated RA (JLSA) will not be aware of participants' intervention assignment, unless participants request assistance with the program, thus potentially revealing their assignment. Research personnel will be blinded for the remainder of the research process, including outcome assessment, in order to minimize the risk of detection bias [50]. As well, study participants will not be aware of their assignment to the intervention or control groups. Prior to the intervention, participants will receive information that is sufficient to obtain informed consent, but inadequate so as to decipher between intervention groups. Although contamination is a possibility given the close proximity of participants, given that only one participant can be recruited at a time, enrollment and recruitment will be staggered and the opportunity for participants to discuss the intervention with each other is unlikely.

Sampling and Recruitment

Parents of children awaiting their pediatrician appointment will be recruited for the RCT. During this time, the RA will liaise with the intake nurse to identify families who are suitable for study participation. Families will be eligible for study inclusion if (1) children present with nonurgent medical issues, (2) children are 5 to 17 years of age, and (3) children attend their appointment with at least one parent. Parents (eg, mothers, fathers, legal guardians) will be eligible if they (1) self-identify as a child's primary caregiver, and (2) speak and read English. The nurse will also help to differentiate urgent (eg, febrile, acute asthma attack) and nonurgent (eg, medical checkup, asthma

follow-up) presentations, of which only the latter will be approached for recruitment. Families who are identified as eligible by the clinic nurse will be approached by the study RA in the waiting room of the primary care clinic. Average wait times in the Edmonton Oliver PCN are 15 to 30 minutes, so this time will be used to (1) recruit participants, (2) obtain informed, written consent (adult) and assent (child), (3) measure and input children's anthropometric data, and (4) deliver the brief, online intervention to parents on the study-designated tablet (iPad). If families present with more than one child and both are interested in participating, only the child with the next upcoming birthday will be enrolled—this will be done to ensure that each study participant represents an independent case. As a token of appreciation and to encourage parents to complete the 1-month follow-up measure, parents will be given a Can \$25 gift card to a local business (eg, grocery store).

Primary health care providers at this site have historically had around 2500 patient encounters per year [51], so our research staff will recruit families on approximately 2 days per week over several months to accumulate our study sample. Given the design of the SBIRT, parents will also need adequate time to complete everything at once (ie, saving and completing the intervention at a later date will not be possible within the SBIRT). With time constraints in mind, families will be approached to participate in the study if we—clinical/administrative staff, research team—believe parents will have sufficient time (ie, 15 to 20 minutes) to complete the intervention and research procedures while waiting for their scheduled clinical appointment. Although it is a potential barrier that some recruited parents may be unable to complete the program while they wait, previous studies have supported the feasibility of brief online interventions under similar conditions, for example, Freeborn et al [52]. Assuming 20 to 30% attrition at 1-month follow-up [53], complete data from approximately 150 parents is expected. Figure 1 represents a flow diagram of expected recruitment and retention. Based on primary care client demography, this sample size will allow us to enroll a diverse group of families that vary by age, ethnicity, family income, and weight status.

Figure 1. Flow diagram of predicted progress through RCT phases (enrollment, allocation, follow-up, and analysis).

Data Collection

Within the GUI, we will collect the following information (see Case Report Form in [Multimedia Appendix 1](#)): families' demographic information, children's weight status, resources and services chosen by parents, and parents' responses to both the intervention questions (unless allocated to the control group) and the theory-based questionnaire (see Phase I in Methods).

Data Management and Analysis

Security measures that adhere to provincial and federal privacy requirements will be integrated into the program. Access to the online SBIRT will be password protected, all data transactions between the Web and data services will be encrypted, and the server will be located behind a firewall to safeguard personal data.

Quantitative data analyses will be performed using SPSS version 22.0 (SPSS Inc, Chicago, IL, USA). Continuous variables will be described by univariate summaries, and frequency distributions will be determined for categorical variables. Box plots and histograms will display continuous variables, and bar

charts will display categorical variables. Recruitment rate and participant characteristics (eg, sex, weight status, demographics) will be calculated to assess enrolment tendencies and biases in subgroups. Retention rate, or the proportion of participants who remain in the study at 1-month follow-up, will be calculated to assess the likelihood of attrition within and between subgroups. A bivariate statistical model (eg, Wilcoxon rank-sum test) will be used to compare program completers versus noncompleters to assess attrition bias. Hierarchical linear modeling [54] will be used to assess intra- and interlevel individual differences and group changes in the predetermined outcomes. Specifically, the primary and secondary outcomes will be assessed at the individual level (ie, nested within each intervention group) and group level (ie, between each intervention group), both at baseline and at 1-month follow-up. This form of analysis is appropriate when observations are nested within groups and/or multiple time points. Statistical significance will be set at $P < .05$.

Results

This is a three-phase, multi-method study designed to build, refine, and complete testing of an online SBIRT to enhance parents' concern for, and motivation to, support children's

healthy lifestyle behaviors. Development of the project commenced in summer 2012, and the expected date of completion is fall 2016 (Table 1). The Health Research Ethics Board at the University of Alberta (Edmonton, AB) has approved this study.

Table 1. Timeline of study-related activities.

Study activities and substeps	Year and season ^a of study																	
	2012		2013			2014				2015				2016				
	S	F	W	Sp	S	F	W	Sp	S	F	W	Sp	S	F	W	Sp	S	F
Preparatory activities																		
Organization of the research team	✓																	
Ethics application		✓																
Develop the toolbox of resources		✓	✓															
Study activities																		
Phase I: Development			✓	✓	✓	✓	✓	✓	✓									
Phase II: Refinement										✓	✓							
Phase III: Testing												✓	✓	✓				
Knowledge translation																		
Formal meetings		✓		✓		✓		✓		✓		✓		✓		✓		
Research blog updates						✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Findings dissemination												✓					✓	✓

^aSummer (S), Fall (F), Winter (W), Spring (Sp).

Discussion

Distinctive Features

This paper highlights the study protocol for the development, refinement, and testing of a novel SBIRT designed to enhance parents' concern for, and motivation to, support children's healthy lifestyle behaviors, as well as link them with relevant resources and services to help prevent childhood obesity in primary care. Historically, SBIRTs have been developed and applied to facilitate positive changes related to addictive behaviors (eg, cannabis use, problem drinking). A recent review and meta-analysis of SBIRTs for screening of alcohol consumption in primary care found that the majority of participants across 22 trials demonstrated positive behavior change (ie, reduced consumption) at 12-month follow-up [23], a finding that suggests the positive effects of this brief approach may have the potential for longevity. Furthermore, in comparison to lengthier online interventions (ie, 60 minutes or longer), positive outcomes of brief interventions were not statistically different [23], highlighting that the dosage of exposure is not necessarily proportionate to the treatment effect, thus justifying the use of a time- and resource-limited approach. In addition to the potential for positive behavior change, specific program elements unique to SBIRTs (eg, automatic screening procedures, personalized feedback, menu of resources and services) are well-suited for primary care. Although this setting prioritizes frontline prevention of chronic diseases, primary care providers report a number of barriers and challenges to fulfilling this task [13,55]. Our intervention may address this deficit and

reduce the pressures and expectations faced by primary care health care providers who often lack confidence and skills in preventing childhood obesity [14]. Our SBIRT may also help families to overcome limited availability of health services for the secondary prevention of childhood obesity (eg, multidisciplinary weight management clinics, outpatient nutrition counseling). Lastly, our Web-based SBIRT for parents may enhance existing resources and health services for obesity prevention in children. For instance, the intervention may remove social barriers and provide anonymity for families that are reluctant to receive care and support in person.

Although the application of SBIRTs to the prevention of obesity in children remains untested, recent systematic reviews [11,15] have highlighted the advantages associated with online interventions (eg, family-based Internet programs, Internet counselling, Web-based interactive behavior programs) that are aligned with RIPPLE with respect to the aim of obesity prevention in children. For example, an online primary care-based program for preventing childhood obesity was well-received by clinicians and families, in which clinicians were more likely to speak with families about healthy weights, and parents intended to increase their children's vegetable and fruit intake, postintervention [26]. It is noteworthy, however, that the majority of such interventions have focused on time- and resource-intensive models, approaches that are often difficult to implement and sustain, particularly in primary care. Additionally, given that online approaches represent a relatively new niche of study, little is known regarding the impact of online interventions on weight-related health outcomes and

intentions to change lifestyle behaviors [56]. Taken together, there is a real need to develop and evaluate brief, Web-based interventions to help connect families with relevant resources and services that may *nudge* them towards healthy behavior changes in a setting where parents and children are already present and waiting.

Study Strengths

This project was developed in direct response to health systems gaps and priority areas in Canada. To date, the research team has received strong support from health care professionals and provincial health care organization decision makers, highlighting the support for, and relevance of, our research. Second, this research will directly inform how such a brief, parent-based approach to address childhood obesity can be incorporated into everyday clinical practice in primary care. Providing families with tailored feedback, practical resources, and information on local health services will help to overcome clinical barriers associated with the primary and secondary prevention of obesity in children. Lastly, findings from this developmental study will inform a future cluster clinical trial to test effectiveness of the intervention across multiple PCN clinics. Specifically, results from Phase III of this study will (1) help to estimate preliminary effect sizes of the SBIRT, informing a sample size calculation for a future cluster RCT, (2) confirm our ability to recruit and retain participants from primary care, and (3) determine appropriateness of primary and secondary outcomes, and follow-up time points.

Study Limitations

We acknowledge that our SBIRT is new and remains untested. Given this reality, there are a number of program components

(eg, theoretical underpinnings, duration of follow-up time period) that have been informed by related projects [57,58]. Because a number of research-related parameters remain unknown, our study design includes modifying the intervention (Phase II) prior to formal testing (Phase III), which will facilitate refinement of program structure, function, language, and aesthetics before initiating testing with parents in Phase III. We also appreciate that most SBIRTs have investigated participants' motivation to change their own individual behaviors, whereas our study assesses the motivation of parents to help change their children's behaviors, in other words, surrogate motivation. Given this degree of separation, parents' motivation may neither accurately reflect children's motivation to make lifestyle behavior changes, nor be sufficient to initiate behavior change. These are relevant issues that will be explored further in follow-up research that will build on this initial study.

Conclusions and Future Directions

Our applied health services research is timely and the objectives align with research priorities to prevent obesity in children. This protocol study encompasses the development, refinement, and testing of a parent-based, online SBIRT that will directly inform the feasibility of incorporating such an approach into everyday clinical practice. By providing families with tailored feedback and information on applicable resources and community services, our SBIRT will encourage family self-management of obesity-related behaviors in primary care. Findings from this project will confirm a number of feasibility-related parameters in the pilot study (eg, feasibility of incorporation into primary care, recruitment and retention rate, suitability of primary and secondary outcome measures) and preliminary effectiveness of the intervention, which will be tested in a future cluster RCT.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Case Report Form.

[PDF File (Adobe PDF File), 37KB - [resprot_v4i1e35_app1.pdf](#)]

Multimedia Appendix 2

CIHR Funding Reviews.

[PDF File (Adobe PDF File), 136KB - [resprot_v4i1e35_app2.pdf](#)]

Multimedia Appendix 3

CIHR Funding Information.

[[PDF File \(Adobe PDF File\), 5KB - resprot_v4i1e35_app3.pdf](#)]

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Abbreviations

AI-HS: Alberta Innovates – Health Solutions

CIHR: Canadian Institutes of Health Research

EH: Evolution Health

FRAMES: feedback, responsibility, advice, menu options, empathy, and self-efficacy

GUI: guided user interface

PCN: Primary Care Network

RA: research assistant

RCT: randomized controlled trial

RIPPLE: Resource Information Program for Parents on Lifestyle and Education

SBIRT: screening, brief intervention, and referral to treatment

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Original Paper

Bringing Feedback in From the Outback via a Generic and Preference-Sensitive Instrument for Course Quality Assessment

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Abstract

Background: Much effort and many resources have been put into developing ways of eliciting valid and informative student feedback on courses in medical, nursing, and other health professional schools. Whatever their motivation, items, and setting, the response rates have usually been disappointingly low, and there seems to be an acceptance that the results are potentially biased.

Objective: The objective of the study was to look at an innovative approach to course assessment by students in the health professions. This approach was designed to make it an integral part of their educational experience, rather than a marginal, terminal, and optional add-on as “feedback”. It becomes a weighted, but ungraded, part of the course assignment requirements.

Methods: A ten-item, two-part Internet instrument, MyCourseQuality (MCQ-10D), was developed following a purposive review of previous instruments. Shorthand labels for the criteria are: Content, Organization, Perspective, Presentations, Materials, Relevance, Workload, Support, Interactivity, and Assessment. The assessment is unique in being dually personalized. In part 1, at the beginning of the course, the student enters their importance weights for the ten criteria. In part 2, at its completion, they rate the course on the same criteria. Their ratings and weightings are combined in a simple expected-value calculation to produce their dually personalized and decomposable MCQ score. Satisfactory (technical) completion of both parts contributes 10% of the marks available in the course. Providers are required to make the relevant characteristics of the course fully transparent at enrollment, and the course is to be rated as offered. A separate item appended to the survey allows students to suggest changes to what is offered. Students also complete (anonymously) the standard feedback form in the setting concerned.

Results: Piloting in a medical school and health professional school will establish the organizational feasibility and acceptability of the approach (a version of which has been employed in one medical school previously), as well as its impact on provider behavior and intentions, and on student engagement and responsiveness. The priorities for future improvements in terms of the specified criteria are identified at both individual and group level. The group results from MCQ will be compared with those from the standard feedback questionnaire, which will also be completed anonymously by the same students (or some percentage of them).

Conclusions: We present a protocol for the piloting of a student-centered, dually personalized course quality instrument that forms part of the assignment requirements and is therefore an integral part of the course. If, and how, such an essentially formative Student-Reported Outcome or Experience Measure can be used summatively, at unit or program level, remains to be determined, and is not our concern here.

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KEYWORDS

medical education; nursing education; course assessment; course evaluation; student feedback; Internet; personalization

Introduction

Over several decades great efforts have been put into developing ways of eliciting valid and informative student feedback on courses they have taken in medical, nursing, and other health professional schools, and in continuing education and professional development. An important motivation has been “formative”, to help providers—teachers and related services—to improve what is offered. Their use in “summative” ways for administrative purposes, such as institutional promotion or staff evaluation, has increased greatly in recent years. However, whatever their motivation, items, and setting, the response rates have usually been low—only rarely above, or even approaching 50%—and potentially biased as a result. Many responses are produced cursorily, with little sense of engagement with a serious task. We see one of the main reasons for this as being its marginalized and optional status as “feedback” at the termination of the course, whether it is a day, or a year, long. Our goal is a new, generic, *course quality* assessment instrument and process, aimed at not only generating insights for the course provider into potential sources of improvement, but also, through the personalized and structured reflection it involves and encourages, enhancing the educational experience of the student. (In some countries and educational settings the term “evaluation” would be used instead of “assessment” in our context. We use the latter to embrace the former, for reasons that will become apparent.)

Why is a new instrument of this sort needed? A recent systematic review covers the vast literature on student evaluation and the instruments relating to it comprehensively and in depth [1]. While some of the numerous instruments are generic, applicable to all courses whatever the subject or focus, none produces a preference-sensitive index score, for example, an overall quantitative assessment that combines the individual student’s weightings for a set of quality criteria (dimensions) with their performance ratings for each of those criteria. Often course assessments are left as an unsynthesized profile of responses, but even where an index score is produced by some weighting procedure (including implicit equal weighting), the weights are not personalized. There is, therefore, a need for a generic and “dually personalized” measure of course quality, paralleling that in decision quality [2].

Beyond these two meta-criteria of genericness and preference-sensitivity, a third fundamental requirement is operational practicality. The instrument must be compatible with the time and other resources of students, on the one hand, and, if it were to be used summatively, capable of providing simple and actionable analyses by providers, on the other. But we see this practicality being established in the context of a substantially enhanced role for course assessment, which is now to be seen as a key source of the student’s benefit from the course. Without going so far as to suggest that, paraphrasing Socrates, “the unassessed course is not worth pursuing”, we believe that student assessment of the quality of the course they

are taking should be a formal part of it, not an optional, terminal add-on conceptualized merely as feedback. The idea is novel, but simply seeks to take advantage of, and gives direction to, the informal and unstructured judgements about, and reactions to, the course, that are occurring every moment the student is engaged with it.

Methods

Sources for the Course Assessment Instrument

A purposive survey of key references was sufficient to establish a comprehensive list of the attributes/criteria/dimensions that have been used in course assessment, evaluation, and feedback by students. Apart from the tabulation in Spooren [1], we consulted ten other sources: (1) Alderman et al [3], (2) Chalmers [4], (3) Coates [5], (4) Davies et al [6], (5) Fontaine et al [7], (6) Kember and Leung [8], (7) Marsh and Roche [9], (8) Ramsden [10], (9) Richardson [11], and (10) Palmer [12].

Since the instruments reported in these studies were the result of extensive research and validation, the task in constructing a new instrument was not to add to the resulting list of criteria, but to reduce it to ten, the absolute maximum practical for routine use, especially in relation to criterion weighting. Both sets of responses are elicited on a 0 to 10 scale. The ten criteria would need definitions that were meaningful, in the sense that a single value on a 0 to 10 ratio scale could be provided as a response at both the weighting and rating stages. For weighting responses 0, 5, and 10 are labelled as “of no importance”, “of moderate importance”, and “of extreme importance”, respectively, and those values are labelled as performing “extremely poorly”, “moderately well”, and “extremely well” for course rating. It is made explicit in the instructions (Figure 1 shows this, later) that the scales are to be interpreted as ratio ones, as is necessary for the expected value calculation that produces the MyCourseQuality-10 Dimensions (MCQ-10D) index score (eg, 8 is to be twice as important as 4 on the weighting scale). (Some of the 10 criteria necessarily embrace the subcriteria and subsubcriteria included in more complex assessment instruments, and in these cases, the respondent’s holistic high-level response will imply subweighting of these. For example, course materials may include different types of material, such as journal articles; videos; and applications for mobile devices.)

The final set of criteria for MCQ-10D was arrived at by considering the reported construct and content validity of the previous instruments, and maximizing comprehensiveness of coverage and conceptual independence within the constraint of 10 criteria. This necessarily involved making trade-offs based on value judgements, rather than purely statistical procedures.

The protocol for the piloting of the MCQ-10D enhanced course structure is organized using the Population, Intervention, Comparators, Outcomes framework [13].

Figure 1. Screenshot from video on hypothetical student completing MCQ-10D.

Assessment Part 1: Your Weightings for the Course Quality Criteria

1 Study the list of 10 attributes and become thoroughly familiar with their content.
 2 Identify the one that is **most important to you** (or one of those you would rank equally most important) and assign it a value on the scale where **10** means 'of extreme importance', **5** means 'of moderate importance' and **0** means 'of no importance'.
 3 Then identify the **least important to you** and assign it a value which reflects its relative importance compared with the most important. For example, if it is half as important as the most important, and you had give that 10, assign it 5.
 4 Then assign your importance values to the remaining 8 criteria, using the first two as benchmarks.

	0	1	2	3	4	5	6	7	8	9	10
CONTENT How important to you is it that the course delivers the specified content at the level prescribed?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
ORGANISATION How important to you is it that the course is well-organised and offers a clear structure and coherent progression?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
PERSPECTIVE How important to you is it that the course's perspective/theory is explicit, and, where appropriate, it offers alternative views?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
PRESENTATIONS How important to you is it that the presentations are relevantly informative, engaging, and stimulating?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
MATERIALS How important to you is it that the learning materials are relevantly informative, engaging, and stimulating?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
RELEVANCE How important to you is it that the course demonstrates its relevance to real world decision/policy making, practice or behaviour?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
WORKLOAD How important to you is it that the mandatory workload is in line with the credit award and is flexible in the manner specified?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
SUPPORT How important to you is it that the support and feedback from teaching and other staff (in line with that offered) is respectful and responsive?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
INTERACTION How important to you is it that the course provides and promotes the specified facilities for interaction with other students?	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
ASSESSMENT How important to you is it that the assignment requirements are clear and your assignments are graded fairly by them?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

Population

Students in health professional education courses, for example, medical schools, subject to approval by the relevant bodies. (There are two approved pilot sites that are left unnamed in this publication).

Intervention

Textbox 1 presents the full details of the MCQ-10D instrument. The Web-based survey in which it is embedded is live [14]. A video of a hypothetical student completing the survey is included as an appendix in this article (see [Multimedia Appendix 1](#)) (Figure 1) (Some of the questions supplementary to the instrument would be modified to suit the particular institution and course.).

MCQ-10D is completed in two stages, reflecting the aim to impact on the educational student experience from its beginning and throughout. Immediately prior to, or at the very start of the course, the student completes part 1, where they indicate the importance they personally assign to the 10 course quality criteria, on the 0 to 10 scale. (At both this point of time, and again in part 2 at the end of the course, they can indicate whether they had serious difficulty understanding any of the criteria and can leave comments on them.)

Students will be automatically reminded of the criteria at appropriate intervals (by email or announcements on their learning platform), for example, monthly, in courses lasting 8 weeks or more. In long courses, interim ratings may be appropriate, but these are not currently envisaged.

At the conclusion of the course, the student completes the lengthier part 2 of the assignment. In this, they provide their overall holistic assessments of course quality and satisfaction with it, followed by their ratings of the course on the MCQ-10D criteria, rephrased in the past tense.

Immediately after entering their ratings, students are presented with their MCQ-10D score in the Annalisa screen, which also displays the component ratings and weightings [15]. The score is the result of multiplying their ratings by their original weightings (normalized to add to 100%) and summing across all ten criteria. The student then has the opportunity to revise their weights, if they feel they are now different from the original ones they supplied (now visible to them), and thereby obtain a revised MCQ score. Next, they are able to see the partial contribution each criterion makes to the overall MCQ score, which will indicate to the providers the student's views as to the possible sources of improved course quality. Note that, for each individual student, these will reflect his or her personalized weightings, as well as ratings. Finally, students are asked to reflect on whether explicit attention to course quality criteria via MCQ-10D has had an effect on their experience of the course, and to respond to other questions of a comparative nature. These questions are not part of the instrument and will necessarily vary with the course and its institutional setting. Those included on the Internet version represent one possibility.

It should be stressed that MCQ-10D can be implemented in many software programs, including macro-enhanced spreadsheets (eg, Excel or open source equivalents). Annalisa is an implementation of Multi-Criteria Decision Analysis, or, as in this use, Multi-Attribute Value Theory, and is simply one piece of software that facilitates the dynamic, interactive reweighting we regard as a key feature of the instrument.

From the outset, students are aware that MCQ-10D is a part of the assignment work for the course, with 10% of the course marks awarded for completion of both parts, the second of which is completed after they are aware of the marks they have received for the other 90% of the assignment work. They can therefore predict their grade with certainty before completing, or not completing, part 2 of the MCQ-10D assignment.

Textbox 1. MCQ-10D, with Internet heading and popup text (line 1) and Weighting and Rating questions (lines 2 and 3) for each dimension.

CONTENT: scope of coverage and level of treatment
How important to you is it that the course delivers the specified content at the level prescribed?
To what extent do you think the course delivered the specified content at the level prescribed?
ORGANIZATION: clear structure and coherent progression
How important to you is it that the course is well organized and offers a clear structure and coherent progression?
To what extent did you find the course well organized and offered a clear structure and coherent progression?
PERSPECTIVE: explicit and offering alternative views where appropriate
How important to you is it that the course's perspective/theory is explicit, and, where appropriate, it offers alternative views?
To what extent did you find the course's perspective/theory was explicit, and, where appropriate, it offered alternative views?
PRESENTATIONS: relevantly informative, engaging, and stimulating
How important to you is it that the presentations are relevantly informative, engaging, and stimulating?
To what extent did you find the presentations relevantly informative, engaging, and stimulating?
MATERIALS: relevantly informative, engaging, and stimulating
How important to you is it that the learning materials are relevantly informative, engaging, and stimulating?
To what extent did you find the learning materials relevantly informative, engaging, and stimulating?
RELEVANCE: to real world decision/policy making, practice, or behavior
How important to you is it that the course demonstrates its relevance to real world decision/policy making, practice, or behavior?
To what extent did you find the course demonstrated its relevance to real world decision/policy making, practice, or behavior?
WORKLOAD: appropriate to credit level and flexible
How important to you is it that the mandatory workload is in line with the credit award and is flexible as specified?
To what extent do you think the mandatory workload was in line with the credit award and exhibited the specified flexibility?
SUPPORT: from teaching and other relevant staff
How important to you is it that the support and feedback from teaching and other staff (in line with that offered) is respectful and responsive?
To what extent did you find the support and feedback from teachers and other staff (in line with that specified) was respectful and responsive?
INTERACTION: with other students
How important to you is it that the course provides and promotes the specified facilities for interaction with other students?
To what extent did you find the course provided and promoted the possibilities for interaction with other students that were offered?
ASSESSMENT: assignment requirements clear and mine graded fairly
How important to you is it that the assignment requirements are clear and your assignments are graded fairly by them?
To what extent did you find the assignment requirements were clear and your assignments were graded fairly by them?

Comparators

Student reaction to the intervention will be gauged by responses to questions asking for their comparisons with the feedback system they conventionally experience. Also elicited will be their perceptions regarding the comparative effect of the intervention on their own educational experience, including the comparative quality and clarity of the opening course description.

No control group is envisaged, as it would be impractical, unethical, and possibly illegal. However, the group level results from MCQ-10D will be compared with the results from the standard feedback form that students are asked to complete anonymously in the institutions concerned.

Provider reactions to the intervention will be sought in a separate post course questionnaire, and interview/s which will involve requesting comparisons with their typical preparation of course descriptions, materials and presentations, their delivery of courses, and their perceptions of student performance and engagement.

Outcomes

Student reactions to the experience are as specified under the subsection Comparators, immediately above. The MCQ score could be interpreted as a Student-Reported Outcome Measure or Student-Reported Experience Measure, analogous to a Patient-Reported Outcome Measure or Patient-Reported Experience Measure [16,17].

Provider/faculty reactions to intervention are as specified under the subsection Comparators, immediately above.

Results

Initial piloting will occur in two courses during 2015, one in Australia and one in Denmark, with outcome results available by end of the year. However, other courses may be added on request.

Discussion

Student Course Assessment as Graded Assignment

In certification settings, such as medical schools, experience shows that a task will rarely be undertaken if it is optional and does not count substantively to the course award. In many cases, simple (weighted, but ungraded) task completion will be an appropriate and sufficient requirement, as it will be in the case of MCQ-10D. It will effectively be a mandatory part of the assigned work, given a small, but finite weight (10%) in the final grade. Its satisfactory completion, defined purely technically, will add 10% to the student's final mark. The actual course grade the student will receive is therefore predictable with certainty *before* the rating part of MCQ-10D is completed, or not.

If it is to be taken seriously, it is important that a course assessment instrument relates to the course as described in the rubric available to the student before enrollment (if it is an optional elective) or, at latest, at its commencement (if it is mandatory). The MCQ-10D instrument takes it for granted that the course has been designed to increase the person's degree of competency in relation to "knowing that", or "knowing why", or "knowing how", or some combination of these. The content in terms of facts, principles, ideas, concepts, theories and techniques to be covered, the levels and depths at which they are to be (or can be) studied, the broad ways they will be presented and can be engaged with, the type/s of individual support and group interaction on offer, and the way/s competency will be assessed for certification purposes, are all to be spelled out explicitly in the course description. Secondary outcomes of the intervention are likely to be an improved quality of course preparation and greater precision and clarity in relation to the course's aims and delivery methods, as well as wider potential benefits in curriculum development.

There is no provision *in the instrument* itself for the student to say they would have preferred the course to have been different from that offered. For example, to have some face-to-face sessions in a course clearly stated to be purely Internet, for basic material to be provided in what is clearly stated to be an advanced course, or for an "unflipped" course instead of the advertised "flipped" one. However, there is space in the survey, within which MCQ-10D is embedded, for this sort of comment, clearly differentiated and separated. We assume that alternative routes are available for forwarding such suggestions of changes to the course curriculum or rubric, some of which may involve increased resources being made available to the unit providers.

Students, like patients, are primarily persons, and should be treated as such. However, there is a central difference from medical or other health professional practice, in that the student is typically seeking certification from the provider for use in

subsequent career situations. They are, in fact, purchasing the service which leads to that qualification, be it on a single unit of study or continuing development, or a complete award such as a degree, as well as gaining wider and noninstrumental benefits. "Person-centeredness" remains a key principle, but is necessarily different in the certification situation from that in a pure learning situation, since the awarding body has a duty of care beyond the individual. The resulting power relationship needs to be acknowledged throughout education, and especially in the seeking of feedback. In our proposal, the sequence of events ensures that the content of the student's course assessment can have little influence on the grade awarded. Final submission of course ratings is essential to maximize marks, but can only occur after the student's grade is predictable with certainty, because they know their marks for all their graded assignments.

As with all other aspects of the course, the student is made aware of this assignment requirement and consents to it by enrolling.

MCQ is explicitly designed for formative use at the course level. Appropriately interpreted, it could serve as one component of a multi-criterial summative assessment for other purposes, but introducing a dually personalized measure of quality as an integral part of the course will pose major challenges for those who seek aggregated "feedback" at unit, program, or higher levels.

What Makes this Approach Different?

The key, almost paradigmatic, difference from previous instruments cited at the beginning of the paper is the use of the student's importance weightings for the criteria. A second key difference is that the criteria presented are limited to ten as a matter of practicality, because of the need to make, or confirm, the explicit trade-offs among the criteria necessary in order to arrive at an overall index, and, hence, opinion as to the overall student-assessed quality of this course.

The individual student receives an immediate and personalized response to their course assessment as soon as their ratings are entered. This makes it somewhat rare among feedback instruments, which in most cases provide only delayed and aggregated information, if any.

Ideally, the instrument will also be completed by the course provider/s in the spirit of self-reflection and professional development. This would provide the basis of exploring dyadic concordances and discordances in an open manner at both overall and criterion-specific levels, and, hence, in relation to both course processes and course outcomes. Ultimately, only transparent discourse, taking place on a sound empirical basis and in a way that reflects student and staff heterogeneity, has the potential to deliver—as well as document digitally—person-centered education. However difficult it may be to implement an approach such as that represented by MCQ-10D within current systems, regulations, and resources, it represents the target to be aimed at from a long term and longitudinal perspective.

We have developed an Internet generic and preference-sensitive instrument for assessing course quality from the student perspective. It is intended to be practically useful for all parties

who are willing to treat quality assessment as an integral part of a course, instead of as a marginal, terminal, and optional add-on as feedback, the focus of all previous instruments. Work is needed to test the instrument in a range of settings to establish its own quality and genericness, and how willing students and providers are to treat quality assessment as a process that both represents and creates educational added value.

This paper is a protocol to establish its feasibility and acceptability, and act as proof of method at the technical and organizational levels. It is to be piloted initially in courses in a medical faculty and a school for health professionals. We invite other health education providers to join in this piloting, using our software, and will be pleased to collaborate in proposals to translate the Internet instrument into other languages.

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Authors' Contributions

JD and MKK developed the concept of a dually personalized student-reported course quality assessment and produced the draft 10 item MCQ from a purposive survey of existing instruments for student feedback. JBN, JL, and GS commented on the instrument and proposed ways to implement it, drawing on the basis of their lengthy experience in developing, administering, and interpreting their institutions' conventional feedback systems. JD drafted the initial text, which was extensively revised in collaboration with MKK.

Conflicts of Interest

JD has a financial interest in the Annalisa software used in the current implementation of MCQ-10D on the University of Sydney server, but does not benefit from its use.

Multimedia Appendix 1

Video of hypothetical student completing MCQ-10D.

[[MP4 File \(MP4 Video\), 4MB - resprot_v4i1e15_app1.mp4](#)]

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Abbreviations

MCQ-10D: MyCourseQuality-10 Dimensions

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Proposal

"Test, Listen, Cure" (TLC) Hepatitis C Community Awareness Campaign

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Abstract

Background: Improved drugs have been approved for the treatment of hepatitis C virus (HCV), but many people are unaware of improved therapies that are now available to cure the illness in a high percentage of patients.

Objective: The objectives of the Test, Listen, Cure (TLC) Hepatitis C Community Awareness Campaign include the development and implementation of a health education and promotion campaign in Memphis, Tennessee, and surrounding areas of western Tennessee, eastern Arkansas, and northern Mississippi, to increase community awareness about HCV, and to provide up-to-date provider education on HCV screening and treatment. The health education and promotion campaign, which will be conducted in collaboration with area hospitals, clinics, and nonprofit organizations, will provide information about how HCV infection is transmitted, risk factors for the disease, the importance of screening and treatment, and the availability of improved treatment for the disease. A second objective will be to provide continuing professional education on HCV screening and treatment to a minimum of 200 area health care providers, including primary care and internal medicine physicians and residents, physician assistants, nurse practitioners, providers who care for homeless persons, and dialysis unit nurses.

Methods: Health education materials will be developed for this community awareness campaign that is culturally appropriate for African Americans and suitable for people with lower health literacy and educational attainment. Information will be compiled and disseminated about area providers who provide screening services and treatment for persons with HCV in order to facilitate linkages to care. Four focus groups of 8-10, African American adults aged 40-64, will be conducted to test the health education materials. The provider education on HCV will also address patient-physician communication and cultural competency. The National Medical Association regional chapters and expert physician consultants will provide assistance with delivering the education program.

Results: Results from this one year project will be available in early 2016.

Conclusions: Depending on the availability of funding and successful implementation of the project, the TLC campaign will be extended to similar cities in the United States.

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KEYWORDS

African Americans; continuing professional education; health promotion campaigns; hepatitis C

Introduction

Background

Hepatitis C, a leading cause of liver failure and liver cancer, is more common among at-risk populations including African Americans [1]. Many people who are infected with hepatitis C

virus (HCV) are unaware that they have the viral infection. Until this year, treatments for HCV were interferon-based and included the antiviral ribavirin, which have several unpleasant and potentially serious side effects including depression and anemia. Many patients were unable to tolerate these side effects and patient adherence was suboptimal. In addition, therapies such as interferon combined with ribavirin were not as effective

in achieving sustained remission in patients with genotype 1 HCV, which is more common among African Americans.

The Food and Drug Administration (FDA) recently approved new drugs for the treatment of HCV. These and other drugs are revolutionizing the treatment of this illness [2,3]. Interferon-free drug regimens for the treatment of HCV will likely become available for routine use by the end of 2014. However, many people are unaware of improved therapies that are now available to cure the illness in a high percentage of patients.

The overarching goal of the TLC Hepatitis C Community Awareness Campaign is to work with a community coalition of hospitals, clinics, and nonprofit organizations to raise awareness among adults and health care providers in Memphis, Tennessee, and similar cities in the United States, about the desirability of HCV screening and the availability of improved therapies for the disease. The materials developed for this community awareness health education and promotion campaign, which will be carefully evaluated, will be culturally appropriate for African Americans living in Memphis and similar localities in the United States. A further goal will be to provide up-to-date continuing professional education on HCV screening and treatment to area health care providers, including primary care and internal medicine physicians and residents, physician assistants, nurse practitioners, providers who care for homeless persons, and dialysis unit nurses. The provider education on HCV will also address patient-physician communication and cultural awareness.

Objectives

The objectives of this project include: (1) the development and implementation of a consumer health education and promotion campaign in Memphis, Tennessee to increase community awareness about HCV, (2) the provision of up-to-date provider education on HCV screening and treatment, and (3) the extension of the project to other cities in the United States that have sizeable African American populations. The consumer health education and promotion campaign will be conducted in collaboration with area hospitals, clinics, and nonprofit community-based organizations. It will provide information about how HCV infection is transmitted, risk factors for the disease, the importance of screening and treatment, and the availability of improved treatment for the disease. Consumer health education and promotion materials will be tailored for the community awareness campaign, which is culturally appropriate for African Americans and suitable for people with lower health literacy and educational attainment. Information will be compiled and disseminated about area providers who provide screening services and treatment for persons with HCV in order to facilitate linkages to care. Continuing professional education on HCV screening and treatment will be provided to area health care providers, including primary care and internal medicine physicians, physician assistants, nurse practitioners, providers who care for homeless persons, and dialysis unit nurses. Provider education on HCV also will address patient-physician communication and cultural competency.

Rationale for the Program

HCV is the most common chronic blood-borne pathogen in the United States [4]. Among noninstitutionalized people in the United States, the prevalence of HCV antibody is about 1.6%. There are an estimated 2.7 to 3.9 million individuals living with HCV in the United States [5]. HCV infection is about four times as common as HIV infection [6]. Persons born during 1945-1965 account for about 3/4 of all HCV infections in the United States. Many people who are infected with HCV (about 75%) are unaware that they have the viral infection [7]. Most patients do not experience any symptoms such as fatigue, fever, loss of appetite, nausea, vomiting, abdominal pain, joint pain, and jaundice [8]. Chronic HCV infection occurs in about 78% of infected patients [4]. About 7% to 24% of persons with chronic HCV infection develop cirrhosis after a period of 20 years [9]. The development of cirrhosis is hastened by increased alcohol consumption [7]. HCV-related end-stage liver disease is the most common indication for liver transplantation among adults in the United States [8]. The annual cost of untreated HCV in the United States has been estimated to be \$5.5 billion [10]. Risk factors for HCV infection include past or present injection drug use, sex with an injection drug user, blood transfusion before 1992, long-term hemodialysis, being born to an HCV-infected mother, incarceration, intranasal drug use, getting an unregulated tattoo, and other percutaneous exposures such as in health care workers [4]. In the presence of maternal HCV viremia, risk for maternal-to-child transmission is about 4% to 7%, and the risk for HCV transmission is even higher when the mother has both HCV and HIV infection [11]. Remote or long-term injection drug use is the most common risk factor for HCV infection.

The first-generation protease inhibitors approved by the Food and Drug Administration (FDA) for the treatment of genotype 1 HCV infection, telaprevir and boceprevir, led to a sustained virologic response in 68% to 75% of treatment-naïve patients [2,3]. In January of this year, the FDA approved two new drugs, daclatasvir and sofosbuvir, for the treatment of HCV. These and other drugs are revolutionizing the treatment of this illness. Interferon-free drug regimens for the treatment of HCV will likely become available for routine use later in 2014. However, even among those who have been tested and are aware of their HCV infection, many people are unaware that improved therapies are now available to cure the illness in a high percentage of patients. There is also a need to provide continuing professional education on HCV screening and treatment to primary care physicians and other health care providers, especially educational programs that also address patient-physician communication and cultural awareness. The successful treatment of HCV infection improves health-related quality of life and reduces mortality among patients with HCV [12]. Although the advent of highly effective therapies creates unprecedented opportunities to prevent HCV transmission and disease, there remains a pressing need to address racial disparities in screening and treatment for HCV.

The Institute of Medicine [13] recommended that action be taken to address this “underappreciated health concern for the nation.” In 2011, the US Department of Health and Human Services published a viral hepatitis action plan that highlighted

the need for community education, expanded access to HCV testing and treatment, and provider education [14]. The National Medical Association's Hepatitis C Task Force concluded that "there is an urgent need for an enhanced effort to increase awareness of hepatitis in general, and HCV in particular" [7]. The consensus panel (Task Force) recommended CDC pamphlets and other educational tools to educate the public about HCV "be tested to ensure concordance with African American culture, values, and attitudes" [7]. The consensus panel noted that about 14% of Americans and 24% of African Americans are functionally illiterate. The consensus panel also recommended that training on HCV be provided to current and future health care providers. Many physicians require education on the prevention and early detection of HCV, and on the new updated treatments [7]. The United States Preventive Services Task Force (USPSTF) recommends screening for HCV infection in persons at high risk for infection [15]. The USPSTF also recommends offering one-time screening for HCV infection to adults born between 1945 and 1965 [4]. Anti-HCV antibody enzyme-linked immunosorbent assay (ELISA) testing followed by confirmatory polymerase chain reaction testing has been found to accurately detect chronic HCV infection.

Liu et al [16] examined the proportion of current, unresolved HCV infections in the United States in a population aged > 40 years based upon HCV RNA positivity and HCV antibody test results. Of 13,909 participants examined, 304 were anti-HCV-positive. Of these, 238 or 75.3% had detectable viral RNA. The percentage of current, unresolved HCV infection was highest among nonHispanic blacks (91.1%).

As part of planning an education campaign to raise awareness about viral hepatitis in the United States, the Centers for Disease Control and Prevention conducted 16 focus groups involving a total of 119 adults aged 35 to 60 years in Boston, Chicago, and Houston [17]. Awareness and knowledge of viral hepatitis were low among all participants. Little was known about different types of hepatitis, risk factors, or how the viruses are transmitted. Many participants assumed that if they had viral hepatitis, they would have symptoms and knew they were infected [17]. The authors concluded that their findings indicate that significant and concerted educational efforts are needed to improve basic knowledge of viral hepatitis, and knowledge about transmission, risk factors, screening, and treatment. Lower educational attainment and lack of a primary care provider have been identified as barriers to HCV screening [18].

In the United States, those who have a low family income or were born between 1945 and 1964 have a disproportionate burden of HCV, along with Vietnam veterans and nonHispanic black males [19,20]. HCV infection is an important public health problem in many inner city neighborhoods where multiple health disparities are common, including coinfection of HCV and HIV [21,22]. Homeless adults have been identified as an at-risk population for HCV infection [6,23,24]. Strehlow et al [24] examined the prevalence, distribution, and risk factors for HCV infection among homeless adults using eight Health Care for the Homeless clinics, funded by the Bureau of Primary Health Care, United States Health Resources and Services Administration. Data were collected for 387 homeless participants through blood draws, chart reviews, and structured

interviews. The overall prevalence of HCV-antibody positivity was 31.0%. The majority (53.3%) of HCV-antibody positive, homeless participants were unaware of their status [24]. Gelberg et al [6] identified a community-based probability sample of 534 homeless adults from 41 shelters and meal programs in the skid row area of downtown Los Angeles, California. About 26.7% of the sample tested HCV-positive and 4.0% tested HIV-positive. In logistic regression analysis, independent predictors of HCV infection included older age, less education, prison history, and history of drug injection. Among HCV-infected adults, nearly half (46.1%) were unaware of their infection. Few had received any HCV-related treatment [6].

Black-White Disparities in HCV

African Americans had the highest mortality rates from HCV in the United States from 2004 to 2008, at 6.5 to 7.8 deaths per 100,000 persons and died from HCV 78.9% more often than whites [25]. This disparity in HCV mortality rates increased between 2008 to 2010 [7]. African Americans also are over-represented among newly reported cases of HCV [1,7]. National data on the prevalence of HCV among African Americans and other racial/ethnic groups are limited by the lack of inclusion of homeless populations and incarcerated persons. Incidence data based upon reported cases from the CDC Viral Hepatitis Surveillance System are limited by the failure to capture race/ethnicity for more than 50% of the cases [7]. Among US veterans who had Department of Veterans Affairs (VA) outpatient visits in 2011, 53.4% underwent HCV screening [26]. Among male veterans born from 1945 through 1965, the prevalence of HCV infection was 18.2%. The prevalence of HCV infection was highest among black veterans (12.3%). Tohme et al [27] examined the rates and determinants of HCV testing, infection, and linkage to care among US racial/ethnic minorities using data from the 2009-2010 Racial and Ethnic Approaches to Community Health Across the US Risk Factor Survey (n=53,896 minority adults). Overall, only 19% of respondents were tested for HCV, including about 60% of those reporting a risk factor. College-educated, nonHispanic blacks and Asians had lower odds of HCV infection than those who did not finish high school. Among those who were infected, 44.4% were currently being followed by a physician and 41.9% had taken HCV medications. The authors concluded that HCV testing and linkage to care among racial/ethnic minorities in the United States are suboptimal and that further HCV testing and prevention activities should be directed toward racial/ethnic minorities, especially those of low socioeconomic status [27]. Trooskin et al [28] studied 4407 charts from four primary care sites, two community clinics, and two academic, primary care practices in Philadelphia. They found that African Americans were less likely to be referred to a subspecialist for treatment when they tested positive for HCV infection [28]. The National Medical Association's Hepatitis C Task Force found that many of the risk factors associated with HCV prevalence and incidence are socially determined [7]. Black-white disparities in HCV treatment outcomes and progression to liver disease and/or primary hepatocellular carcinoma also have been reported [7]. African Americans are more likely to have advanced HCV-related tumor stage at diagnosis and less likely to receive

local or surgical therapy than whites, even with tumors that are localized to the liver.

Other studies have shown that effective patient-physician communication is related to improved adherence to medical regimens, better decision making, and increased satisfaction with the patient-physician relationship [29,30]. Cultural competency skills can assist patient-provider communication. Cultural competency influences how health messages are transmitted and perceived, how illness is defined, how symptoms are described, when and where care is obtained, and how treatment options are considered. Cultural competency includes the acquisition and integration of knowledge, with awareness, attitude, and skills about culture and cultural differences that enables health care professionals to provide optimal care to patients from different racial, ethnic, socioeconomic, and cultural backgrounds [31].

Patient health literacy is also important. Low health literacy has been associated with decreased use of preventive services such as screening tests, increased risk of having a chronic disease, increased use of emergency services, poorer treatment adherence, and poorer health outcomes [32]. The Institute of Medicine defines health literacy as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions” [33]. Disease prevention and treatment messages are often written at too high a reading level for individuals with marginal literacy skills.

Methods

The Campaign

To increase community awareness and encourage at-risk African American residents to be screened for HCV, a coordinated community-based health education and promotion campaign will be conducted in collaboration with the Shelby County Health Department, the Regional One Health, the University of Tennessee Medical Group, National Medical Association regional chapters, and local nonprofit organizations. The campaign will maximize media attention on HCV infection, screening, and treatment beginning in the second quarter of year one. Representatives will be invited from the local radio,

television, print and social media to participate and assist with the dissemination of information. The campaign will strive to ensure that all African American adults in Memphis, and other adults in the mid-south, are exposed to multiple messages about risk factors for HCV infection, HCV screening, and the availability of improved treatments for the disease. In addition to newspaper and OpEd articles and radio and television appearances and public service announcements, pamphlets and posters (small media) will be distributed at familiar community sites such as churches, markets, clinics, barbershops, hair salons, and laundromats. The identification of educational materials will be facilitated by resources distributed by the CDC Division of Viral Hepatitis website. Each material will be evaluated for readability and cultural sensitivity with the assistance of focus groups comprised of 8 to 12 African American men and women ages 40 to 70 years, recruited through collaborating hospitals and clinics. IRB approval will be obtained. Health literacy readability will be measured using the short form of the Test of Functional Health Literacy in Adults (S-TOFHLA) which takes 12 minutes to administer and consists of reading comprehension (2 passages) and numeracy (5 questions) sections. The Lipkus numeracy scale will be used to assess numeracy. The scale is comprised of general numeracy items and health specific numeracy items. Questions are scored as percent correct. The Cultural Sensitivity Assessment Tool will also be used in the focus groups to evaluate the cultural sensitivity of educational materials for African American adults. Scores range from 4 to 1 with scores < 50 indicating print materials are culturally insensitive. The theoretical theories or constructs will include the Health Belief Model, Social Ecological Theory, and social marketing techniques. Public service announcements and the importance of HCV screening and treatment will be disseminated through radio stations that target African American adults in Memphis and surrounding areas of the mid-south. The desirability of using black radio to disseminate health messages to the African American community and reduce health disparities has recently been highlighted [34]. Black radio has advantages over print media for circumventing low health literacy. There are several newspapers in Memphis and the mid-south region that belong to the National Newspaper Publishers Association, a black community newspaper organization, as shown in Table 1.

Table 1. Black community newspapers in the mid-south, United States.

Memphis Silver Star News	3019 Park Ave Memphis, Tennessee 38114 Phone: 901-452-8828 Email: silverstarnews@bellsouth.net
Nashville Pride	PRIDE Publishing Group 315 Deaderick Street, Suite 1575 Nashville, TN 37238 Phone: 615-292-9150
The Tennessee Tribune	1501 Jefferson St Nashville, TN 37208 Phone: 615-321-3268 Email: info@tntribune.com
Tri-State Defender	203 Beale Street, Suite 200 Memphis Tennessee 38103 Phone: 901-523-1818 Email: besmith@tri-statedefender.com

An innovative professional continuing education program will be developed and offered on three occasions to interested health care providers from Memphis and surrounding areas of the mid-south. Physicians and other providers will receive letters inviting them to participate with the assistance of CEOs, medical directors, and regional chapters of the National Medical Association. The curriculum for the educational program will be adapted from educational materials developed by the National Medical Association and other leading professional societies. The educational materials will be informed by the USPHS guidelines for screening for HCV. The learning objectives will be carefully specified. For example, at the end of the session, participants should be able to demonstrate usage of the U.S. Preventive Health Services Task Force (USPHSTF) guidelines, list methods of incorporating the PHS guidelines into their practices, and identify resources for educating their patients about HCV treatment options. Cultural competency and patient-provider communication training will be provided and the participating providers will be given opportunities to practice these skills in the context of providing HCV treatment. The duration of the continuing professional education will be limited to two, half-day, participatory sessions located at convenient community hospitals and clinics. The training program will be offered on three occasions with the assistance of National Medical Association regional chapters.

The participating health care providers will be asked to fill out self-administered questionnaires about their professional background and medical practice. Both pre- and post-educational intervention questionnaires will be administered so that their experience and confidence in providing HCV screening can be assessed, along with their knowledge and attitude about HCV treatment advances. Several questions will be included in the post-intervention questionnaire so as to allow the participating physicians to help evaluate the continuing education program and suggest future refinements.

Target Populations

The professional education program on HCV screening and treatment will target interested health care providers from Memphis and surrounding areas of the mid-south (primary care and internal medicine physicians and residents, physician assistants, nurse practitioners, providers who care for homeless persons, and dialysis unit nurses). These providers will be identified with the assistance of the University of Tennessee Medical Group, Methodist-Le Bonheur Healthcare, the Med Regional Medical Clinic, regional chapters of the National Medical Association, and other community and professional organizations.

The target population for the community awareness campaign consists of Memphis and surrounding areas of western Tennessee, eastern Arkansas, and northern Mississippi. Memphis has a population of 662,897 of which 419,614 (63.3%) are African Americans compared to 16.7% for the state. The poverty rate in Memphis is 27.2% and the overall poverty rate for the working poor is 49.3%. Of all households, 47.1% are headed by a single female. African Americans are less likely to graduate from high school and African American adults are less likely to have a college degree. Social determinants such as poverty, lower educational attainment, and unemployment are significant barriers and challenges to receipt of health care for many African Americans in Memphis and other US cities. In 2011, the rate of reported cases of acute HCV infection in Tennessee was 1.3 per 100,000 population, a rate second only to Oklahoma and Kentucky, although these data are limited by incomplete reporting in some states [7].

Plan for Evaluation

The implementation of the community awareness campaign will be monitored through process evaluation measures such as the number of pamphlets and brochures distributed at community sites, the number, date, and location of newspaper articles about HCV, and the number and date of radio public service announcements.

The health care providers who participate in the continuing professional education program will be asked to fill out self-administered questionnaires about their professional background and medical practice. Both pre- and post-educational intervention questionnaires will be administered so that their experience and confidence in providing HCV screening can be assessed, along with their knowledge and attitudes about HCV treatment advances.

Data Analysis Plan

Cross-tabulations of the data will be performed to analyze process evaluation data from the community awareness campaign and information collected as part of the continuing professional education program for health care providers.

Results

It is anticipated that results from this one year project will be available in early 2016.

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Conflicts of Interest

None declared.

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Discussion

Depending on the availability of funding and successful implementation of the project, the TLC campaign will be extended to similar cities in the United States. The advent of oral drug regimens for hepatitis C has increased the feasibility of increased population screening and successful treatment. Although the high cost of treatment has been an important barrier for many patients, the recent introduction of additional FDA-approved oral combination therapies has led to competition between manufacturers and some price concessions. There is a need for additional efforts to provide continuing professional education about these important developments and to increase community awareness about the availability of improved therapies for hepatitis C.

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Abbreviations

CDC: Centers for Disease Control and Prevention
FDA: Food and Drug Administration
ELISA: enzyme-linked immunosorbent assay
HCV: hepatitis C virus
RNA: ribonucleic acid
USPHSTF: United States Preventive Health Services Task Force
TOFHLA: test of functional health literacy in adults
VA: Veterans Affairs

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Protocol

The Telehealth Skills, Training, and Implementation Project: An Evaluation Protocol

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Abstract

Background: Telehealth appears to be an ideal mechanism for assisting rural patients and doctors and medical students/registrar in accessing specialist services. Telehealth is the use of enhanced broadband technology to provide telemedicine and education over distance. It provides accessible support to rural primary care providers and medical educators. A telehealth consultation is where a patient at a general practice, with the assistance of the general practitioner or practice nurse, undertakes a consultation by videoconference with a specialist located elsewhere. Multiple benefits of telehealth consulting have been reported, particularly those relevant to rural patients and health care providers. However there is a paucity of research on the benefits of telehealth to medical education and learning.

Objective: This protocol explains in depth the process that will be undertaken by a collaborative group of universities and training providers in this unique project.

Methods: Training sessions in telehealth consulting will be provided for participating practices and students. The trial will then use telehealth consulting as a real-patient learning experience for students, general practitioner trainees, general practitioner preceptors, and trainees.

Results: Results will be available when the trial has been completed in 2015.

Conclusions: The protocol has been written to reflect the overarching premise that, by building virtual communities of practice with users of telehealth in medical education, a more sustainable and rigorous model can be developed. The Telehealth Skills Training and Implementation Project will implement and evaluate a theoretically driven model of Internet-facilitated medical education for vertically integrated, community-based learning environments

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KEYWORDS

telehealth; medical education; enhanced broadband

Introduction

Background

Ensuring an appropriately trained and resourced medical workforce for regional, rural, and remote areas is critical to enhancing the welfare of rural Australians, as it is for the welfare of rural and remote communities globally [1]. Australian medical schools frequently arrange for some (or all) of their medical students to undertake part of their training away from major metropolitan areas with the aim of producing practitioners capable of, and motivated to, practice in regional, rural, and remote locations [2]. There is evidence that this approach results in sound educational outcomes [3,4]. In addition, this approach—together with targeted recruitment of graduates from rural areas—is highly important in creating a sustainable rural medical workforce [5].

Telehealth and Rural Medical Workforce Sustainability

Both a cause and effect of an inadequate rural medical workforce is lack of timely access to specialist advice for onsite rural health practitioners and patients [6,7]. One potential strategy for assisting rural patients and doctors who would benefit from specialist access is telehealth. Telehealth has been defined as the “use of telecommunication techniques for the purpose of providing telemedicine, medical education, and health education over a distance” [8]. For the purposes of providing support to rural primary care providers and patients, a telehealth consultation is where a patient at a general practice, with the assistance of the general practitioner (GP) or practice nurse, undertakes a consultation by videoconference with a specialist located elsewhere [9]. While telehealth consulting is reported to be underused in Australia [10], there is evidence that telehealth consulting can result in improved access to specialized health services for rural patients [11,12], upskill of rural GPs [13], improved rural workforce retention [13], significant health gains [12], and financial savings [12]. The recent Australian government-funded “Connecting Health Services with the Future” initiative was designed to address this issue by providing Medicare rebates and financial incentives for video consultations with specialists for patients outside of major metropolitan areas [9], supported by telehealth consulting standards set by the Royal Australian College of General Practitioners [14] and Australian College of Rural and Remote Medicine [15].

However, until recently, technical restrictions including requirements for necessary bespoke hardware, video cameras, and integrated services digital network (ISDN) connectivity [16] have limited most applications of telehealth in Australia,

limiting access and scalability [16]. For example, most professional quality video consulting applications, up until recently, have used fully featured Web-based medical video consulting software. These applications, including Skype, provide encryption for data transmission security and Medicare Australia standards level audit trails [17]. While there is evidence that exposure to telehealth consulting improves physician attitudes to its use [18], there are many reasons for the low rates of adoption, namely insufficient training as a barrier to the uptake and use of this technology [19]. Other barriers to adoption of telehealth have been identified including lack of adequate equipment, poor connectivity, lack of telehealth consulting skills, scheduling difficulties, inadequate reimbursement schemes, and patient reluctance [20–26]. Therefore, what is required is training for health professionals to optimize the video consultation care provided [27], supported networks of health professionals using the technology [27], stakeholder involvement in implementation, and well-developed business models.

Virtual Communities of Practice and Rural Medical Workforce Training

A further challenge to a sustainable rural workforce in Australia is securing sufficient clinical placement sites for the numbers of rural undergraduate, prevocational, and vocational trainees required by the health system [2]. A number of factors, including reduced hospital in-patient stay times, increased use of medical technology, expanding training numbers, and a recognition of the need for generalist medical exposure, have resulted in an increase in the demand for community clinical placements [28–30]. Of particular concern in Australia is the capacity of rural clinical schools to accommodate increased training numbers [2]. Thus, new paradigms of health care professional training are required as it is now not unusual for a general practice to host medical and nursing students, pre-vocational doctors in training, and vocational GP trainees.

To manage this number of learners without exhausting the clinician teachers (and while still providing quality medical care and educational training), innovative models of teaching are required. One such model is vertically integrated teaching where all levels of learner, from undergraduate to vocational, contribute to a learning environment [31]. One way of conceptualizing vertically integrated learning environments is as communities of practice (CoPs). CoPs can be defined as “groups of people who share a concern or a passion for something they do and learn how to do it better as they interact regularly” [32]. There is strong evidence from business literature that CoPs can be effective in workplace training with measureable improvements in outcomes [33]. Geographically dispersed learners may also

be connected by information technology tools to form virtual communities of practice (VCoPs) [34]. In medical education, VCoPs have been shown to be perceived by GP trainees to be useful in overcoming the isolation that can accompany training in rural areas [35].

The Role of Internet-Based Solutions for Rural Medical Workforce Challenges

Telehealth consulting has been reported to facilitate peer communication and reduce isolation for rural and remote doctors [11]. It has also been demonstrated that rurally relevant continuing medical education is effective in increasing practitioners' confidence to practice in a rural location, reducing isolation and increasing intention to continue to work in a rural area [36]. There is also evidence that VCoPs can be effective in fostering information sharing and reducing professional isolation in GP training [37]. With the above evidence in mind, the Telehealth Skills Training and Implementation Project (TSTIP), funded through the Australian government's Broadband Enabled Education, Skills and Services (BEES) program, aims to evaluate the introduction of two broadband Internet-based interventions in rural medical training. The first is the training of telehealth skills in medical schools coupled with the use of telehealth consulting as a teaching medium for undergraduate medical students. The second is the use of broadband-enabled "virtual clinics" to support high-quality medical education and promote vertically integrated teaching and VCoPs in rural general practice.

To guide the development of virtual communities of practice, with a view to improving knowledge sharing and overcoming medical professional isolation, the Health VCoP Framework has been developed [34]. This framework has been used in previous studies on GP training and covers the seven steps to be considered when implementing a VCoP. The steps include (1) organizing facilitation, both administrative and professional, (2) ensuring an ongoing champion and support from stakeholders, (3) establishing clear goals, (4) involving a "broad church" of users, (5) establishing a supportive environment, (6) measuring activity and progress against goals, and providing feedback to participants and opportunities for benchmarking, and (7) considering technical factors such as ease of use and access, synchronous and asynchronous interactions, and considering community factors such as providing high-quality content, building trust online, self-selection of membership, and encouragement of active and passive users.

The Health VCoP Framework will be used to help inform the project's activities and also provide a template for assessing the success (or otherwise) of the project in fostering CoPs and VCoPs among the project's participants. While creation of CoPs and VCoPs are aims of the project, there are other educational, technical, and administrative components of the trial that require evaluation. To aid conceptualization of the use of the Health VCoP framework for the project's implementation and evaluation, the project plan is discussed in entirety under the Health VCoP headings in the following sections, recognizing that several measures are not relevant to the framework.

Methods

Project Implementation

Health VCoP Step 1: Organize Facilitators and Moderators—Both Clinical and Administrative

Virtual Clinics

To support high-quality medical education and promote vertically integrated teaching in rural general practice, we will run a series of "virtual clinics". This will require both administrative and clinical facilitation. Clinicians associated with the University of Wollongong will provide clinical teaching, facilitating a virtual clinic that is transmitted to participating metropolitan, regional, rural and remote training sites, and to individual students and doctors who are involved in the program either through their connections with one of the universities involved or through one of the two GP training organizations involved.

The virtual clinic topics will be chosen with the aim of addressing problematic clinical issues for practice-based consulting in regional and rural areas. These sessions will be interactive with students, GP trainees, and GP preceptors in training sites being able to communicate, ask questions, discuss, and deliberate on clinical issues online in real-time. A key feature of the pedagogy of the virtual clinics will be a focus on teaching clinical reasoning in each case [38]. Pre-session reading and activities will be provided online before each session, and after session discussion will be available using interactive Web 2.0 technology. This provides an environment for creating a VCoP involving the students, GP trainees, GP preceptors, and tutors. Sessions will be recorded and made available to learners online after the live session.

A minimum of eight structured virtual clinics will be run during the trial, connected to participating GP practices, individuals, or educational facilities in rural and regional areas. Administrative facilitation will be undertaken by the TSTIP project team. Educational facilities suitable for involvement include the Shoalhaven campus of the University of Wollongong, the Southern Highlands facility of University of Wollongong School of Medicine, and the University of New England campus Armidale, New South Wales.

Telehealth Real-Patient Learning

Training sessions in telehealth consulting will be provided for participating practices and students. The trial will then use telehealth consulting as a real-patient learning experience for students, GP trainees, GP preceptors, and trainees. This educational model focuses on the student or GP trainee actively engaging in the patient's journey' [39] through the health system by being involved in the telehealth referral workup, consultation, debrief, and follow-up with consenting patients. It is also intended to provide experiential patient-based learning [40] of the utility of telehealth consulting for reducing professional isolation [11] in problematic clinical cases. It is planned that cases will then form the basis for in-practice teaching and also as subjects for the students' and GP trainees' reflective clinical logs. The students involved will be in the senior years of their

training (third and fourth year) and are already involved in “parallel consulting” where they see patients prior to (or with) the GP preceptor, take histories, perform physical examinations, formulate management plans with the GP, and assist the GP with procedures. Patient participants will supply consent for this participation in keeping with professional guidelines [14,41]. Student involvement in telehealth consults with consenting patients will be a natural extension of their roles within the GP training practices.

Health VCoP Step 2: Champion and Support

The TSTIP is a multicenter phased project. The development phase began on July 1, 2012. The implementation phase, the subject of this evaluation, began on August 1, 2013 and will be finalized by April 30, 2015.

The University of Wollongong General Practice Academic Unit (GPAU) dedicated TSTIP team will provide the project champion role, engaging and ensuring ongoing support from stakeholders partners including the project consortium, which consists of University of Wollongong,

University of New England, University of Newcastle, University of Notre Dame Australia (Sydney Campus), Deakin University, Coast City Country General Practice Training, and GP Synergy.

Health VCoP Step 3: Establish Clear Goals

The educational goals for the TSTIP are to use broadband Internet to facilitate (1) the acquisition of medical skills, knowledge, or attitudes that improve confidence to practice in less supported medical environments [36], and (2) the development of professional networks and communities of practice to reduce the sense of professional isolation in less supported medical environments [34,35].

Health VCoP Step 4: A Broad Church

The primary target audience for the trial is the cohort of medical students, post-graduate pre-vocational doctors in training, GP trainees, and GPs in the regional, rural, and remote catchments of the project consortium. Collaborators in the consortium include universities with medical students in rural placements and Regional Training Providers with GP trainees in approximately overlapping rural areas, predominately in New South Wales.

Health VCoP Step 5: Establishing a Supportive Environment

The activities of the trial are designed to foster supportive educational interactions. The strategies employed by the trial include ensuring encouraging and positive moderation of all sponsored educational sessions, moderation of online feedback during sessions, nesting learning where possible in the GP training practices where the students and registrars are placed, and engaging the local GP supervisors and regional academic leaders in the learning processes.

Health VCoP Step 6: Measuring Activity and Progress and Providing Feedback

Real-time feedback to participants regarding their responses to the clinical content of the virtual clinics is part of the interactive nature and an integral aspect of the learning environment. In

addition, the evaluation data from both virtual clinics and from telehealth consultations involving students and registrars that are collected as the project progresses will be used to continually review the project activities and adjust them appropriately. The evaluation approach, methodology, and metrics are discussed below.

Project Evaluation Approach

The experiential learning intrinsic to general practice-based clinical placements involves a mix of professional modeling and skills application, including the domains of clinical reasoning [38], evidence-based decision making, management processes, and professionalism [28,42]. The educational goals for the project's activities reflect these learning emphases. Complex attributes, such as professionalism, are not readily assessed in closed-response type evaluations [43,44]. Hence, the normal processes for evaluating the impact of educational activities (pre- and post-intervention testing) are not readily employed in this trial. Additionally, there are many facets of the trial, for example, its impact on practices, changes in practice systems, and procedures and scalability that require evaluation in addition to the educational outcomes. In order to undertake this complex and multifaceted evaluation, the authors have chosen to incorporate the principles of a Responsive Evaluation [45]. The approach broadens the evaluation to include a wide range of stakeholder issues. The goal of a responsive evaluation is “to enhance the understanding of a program from the...perspective of insiders” [46]. Thus, there is a need to identify all stakeholders and involve them in assisting to define the criteria for the evaluation. In this evaluation, this will include representatives of the funder through to practice staff and technical experts through to specialist consultants. Evaluation will commence at the inception of the project and will run in parallel with the trial activities. Participation in the evaluation is voluntary for the project participants.

A priori criteria, developed in conjunction with the funder during the project development phase include (1) the number of learners involved, (2) educational benefit of telehealth consulting and virtual clinics, (3) the development of professional learning networks (CoPs), (4) performance of information technology network components, (5) human-technology interactions, (6) cost implications, and (7) sustainability of telehealth real-patient learning and virtual clinics.

The results of the above assessments combined with focused interview data from all stakeholders will be used to evaluate whether telehealth (clinical and educational) is a sustainable teaching and learning activity for the participating institutional organizations and GP teaching practices.

Methodological Approach

Overview

The project evaluation seeks to understand the impact of technology-mediated educational interventions in the contexts of complex social and human systems. A multisite case study offers an appropriate methodology for this purpose with the ability to provide findings with high internal validity [47,48]. A multisite case study method permits the investigation of a contemporary phenomenon within its context, where boundaries

between context and phenomenon may be blurred and a variety of evidence sources are required [47,48]. This approach has the advantage of facilitating in-depth evaluation even when a limited sample size would not permit statistical generalizability of quantitative results [47]. The data to be collected from various facets of the trial in order to synthesize the case studies are discussed below.

Telehealth Skills Training

The telehealth consultation training sessions will be evaluated using surveys for students, GP preceptors, staff, and specialists administered at the end of the training program.

Activity Metrics

Data will be collected on an ongoing basis to track the learning activity for the trial. This includes numbers of participants in each component of the trial, the number of learning activities, and participant numbers. In addition, Internet usage data will be collected concerning the numbers and frequency of participants accessing and interacting with online learning activities.

Pre-Trial Participants' Views, Barriers, and Facilitators

Initially, semistructured interviews will be held with stakeholders (GP preceptors, GP trainees, students, specialists, patients, and staff) in order to assist the development of evaluation parameters. Semistructured, rather than structured interviews will be used to identify a range of views, experiences, barriers, and facilitators regarding telehealth-based medical education.

Telehealth Consultations

After selected telehealth consultations, the participants (GP preceptor, specialist, student, and patient) will be asked to undertake a structured survey that will seek their reflections on the individual session. To the extent possible, the surveys will be conducted straight after the consultation in order to minimize recall errors [49]. In addition to data on perceptions, performance, and satisfaction, students will also be asked to reflect on the learning experience provided through the consultation. During consultations, technical system data will be collected relating to the speed of the connection, quality of images, and network/hardware/software reliability.

Telehealth Virtual Clinics

Similarly, data from all virtual clinic sessions will be collected from the participants (GP trainee, GP preceptor, or student) who will be asked to undertake a structured survey that will seek their reflections on the individual session. Students will also be

asked to reflect on the learning experience provided through the virtual clinic session. Metrics concerning transmission speeds, numbers of users, interactions, and reliability of transmission will also be assessed. A mid-point analysis of collected data will be undertaken and adjustments to the trial introduced if required.

Post-Trial Participants' Views and Evaluations

At the end of the trial period, semistructured interviews will be conducted with the GP preceptors, trainees, specialists, students, practice staff, IT support, patients, and Graduate School of Medicine (GSM) staff to obtain their overall impressions of telehealth consulting, performance of the network components, and the effectiveness of the training program. The process of inter-institution collaboration will be explored through stakeholder interviews and review of artefacts such as meeting minutes and project documents.

Cost Implications

Data will be collected regarding cost implications for the GSM through financial record review. The process of the inter-institution collaboration will be explored through stakeholder interviews and review of artefacts such as project documents. Outcomes for patients (health and cost-related) and doctors/practices (professional and business) will be assessed using a variety of sources including interviews and practice (not patient) records. Informal data collection will be undertaken throughout the trial concerning participants' responses, concerns, successes, and challenges.

Case Study Recruitment and Data Collection

Table 1 outlines the proposed sites and estimated number of learners for the virtual clinic component of the case study. Table 2 outlines the proposed sites and estimated number of learners for the telehealth real-patient learning component of the trial. Table 3 summarizes the data to be collected and the analytical approach to the sets of data.

Descriptive analysis of quantitative data will be undertaken. Qualitative analyses will include content analysis and thematic analysis along established lines [50]. The Health VCoP Framework will be used as the theoretical framework for the qualitative analyses, as the development of communities of practice is a key hypothesized outcome of the trial [34]. All of the data sources will be synthesized and analyzed in a multicenter case study [47,48] to provide an in-depth evaluation of the trial, assess its sustainability, and guide future implementation.

Table 1. Proposed sites and learners for virtual clinic participation.

Site type	Locations	Number of practices/ sites	Number of learners (estimated)
GP practice	Armidale	3 practices	28
	Illawarra	8 practices	
	Shoalhaven	1 practice	
	Mudgee	1 practice	
	Grafton	1 practice	
	Southern Highlands	1 practice	
Education center	Shoalhaven; Southern Highlands University of Wollongong	2 sites	50
	Geelong (Deakin)	1 site	
	Sydney (University of Notre Dame Australia)	1 site	
	Armidale (University of New England)	1 site	

Table 2. Proposed number of sites and learners for the telehealth real patient learning participation in GP practice (these learners are also included in [Table 1](#) for virtual clinics).

Locations	Number of practices/ sites	Number of learners (estimated)
Armidale	3 practices	20
Illawarra	2 practices	
Shoalhaven	2 practices	
Mudgee	2 practices	
Grafton	1 practice	
Southern Highlands	1 practice	

Table 3. Data collection schedule and analyses.

Data collection time point	Activity	Data collected	Anticipated number of evaluation participants	Analysis method
Baseline, at start of active trial	Telehealth consulting training sessions for participating practices and students	Anonymous pre- and post-telehealth training session surveys for GP preceptors, practice staff, and students	GP preceptors n=8 Practice staff n=10 Specialists n=10	Descriptive analysis of quantitative data
	Baseline interviews	Coded, re-identifiable, audio-recorded, and transcribed semistructured interviews with GP preceptors, GP trainees, students, specialists, patients, and staff to identify a wide range of views, experiences, barriers, and facilitators regarding telehealth-based medical education	GP preceptors n=8 GP trainees n=6 Students n=20 Specialists n=8 Patients n=20 Practice staff n=10	Thematic analysis of interview transcripts
During trial	Telehealth consultations as a “real-patient” learning modality	Structured, site-coded, anonymous surveys after 24 telehealth consultations over the duration of the project seeking views of the participants (GP preceptor and/or GP trainee, specialist, student) concerning the individual sessions	GP preceptors n=10 GP trainees n=6 Students n=20 Specialists n=12	Descriptive analysis of quantitative data
	Telehealth consultations as a “real-patient” learning modality	During the evaluated 24 telehealth consultations aggregated, anonymous technical system data will be collected relating to the speed of the connection and network/hardware/software reliability	Technical data from 24 telehealth consultations	Descriptive analysis of quantitative data
	Virtual clinics as a learning modality	Structured, site-coded, anonymous surveys after all telehealth virtual clinic sessions over the duration of the project (12 in total) seeking views of the participants (GP preceptor and/or GP trainee, specialist, student) concerning the individual sessions	GP preceptors n=10 GP trainees n=6 Students n=70 Specialists n=4	Descriptive analysis of quantitative data
	Virtual clinics as learning modality	During the evaluated 12 telehealth virtual clinics, anonymous, aggregated technical system data will be collected relating to the speed of the connection, network/hardware/software reliability and participant interaction	Technical data from 12 telehealth virtual clinics	Descriptive analysis of quantitative data
	All activities	Data will be collected on an ongoing basis to track the learning activity for the trial. This includes numbers of participants in each component of the trial, the number of learning activities, and participant numbers	Coded, re-identifiable data from project records	Descriptive analysis of quantitative data
	Virtual clinic online interactive activities (post-session)	Aggregated, anonymous Internet usage data will be collected concerning the numbers and frequency of participants accessing and interacting with online learning activities relating to the project (pre- and post-virtual clinic online interaction)	Anonymous data from Internet Website usage statistics	Descriptive analysis of quantitative data
	All activities	Coded, re-identifiable informal data collection will be undertaken throughout the trial concerning participants’ responses, concerns, successes, and challenges	Coded, re-identifiable data from researcher field notes	Thematic analysis of written field notes

Data collection time point	Activity	Data collected	Anticipated number of evaluation participants	Analysis method
Follow-up post-trial	Post-trial interviews	Coded, re-identifiable, audio-recorded, and transcribed semistructured interviews with the GP preceptors, GP trainees, specialists, students, patients, practice staff, IT support, and university staff to obtain their overall impressions of the project including the performance of the project components, the effectiveness, and acceptability of the training program and cost implications	GP preceptors n=8 GP trainees n=6 Students n=20 Specialists n=8 Patients n=8 Practice staff n=10 IT support n=4 University staff n=6	Thematic analysis of interview transcripts
	Post-trial evaluation	The process of the inter-institution collaboration will also be explored through review of artefacts such as project documents	Coded, re-identifiable data from project records	Thematic analysis of project artefacts
	Post-trial evaluation	Data will be collected regarding cost implications for the GSM through financial record review. Outcomes for patients (health and cost-related) and doctors/practices (professional and business) will be assessed using a variety of sources including interview data, practice records, and Medicare data	Coded, re-identifiable data from interviews and project participants' records Universities n=5 Practices n=6 Patients n=8	Descriptive analysis of quantitative data Thematic analysis of interview transcripts and records
	Post-trial evaluation	All data sources will be synthesized and analyzed in a multicenter case study approach to provide an in-depth evaluation of the trial, assess its sustainability, and guide future implementation	All data sources	Mixed-methods multisite case study analysis

Health VCoP Step 7: Consideration of Technical Factors

The trial has focused resources on developing user-friendly, accessible technology with an in-depth technical needs assessment of participants prior to the trial, expert information technology membership in the project executive committee, a technical subcommittee dedicated to advising on technical matters, and constant user feedback concerning the usability of the technology through session evaluation reports. The technical aspects of the project will be adjusted and refined in response to feedback and the progress of the trial. High-quality content of educational sessions will be maintained by engaging content experts across the speciality fields addressed.

Ethical Considerations

Ethics approval for the project has been obtained through the University of Wollongong Human Research Ethics Committee (reference HE13/238).

Free and Informed Consent

The purpose of the evaluation will be explained to participants by researcher or project officer at each relevant data collection point, including the fact that all responses will be coded and de-identified and that participation is completely voluntary.

Confidentiality of Participants' Responses

Evaluation surveys will be anonymous. All interviews be transcribed, coded, and de-identified by a research assistant. Practice location data will not be reported, and comments reported in aggregate terms. For qualitative data, participants

will be assigned a code that will link their de-identified data to a confidential and secure master sheet that will contain participants' demographic details and location.

Ensuring Participants Can Withdraw From the Trial Without Detriment

All potential participants will be advised that their participation is voluntary and that they may refuse to participate or may withdraw from the study at any time without penalty.

Data Security

All information will be securely stored and accessible only by the project investigators.

Results

Results will be available when the trial has been completed in 2015.

Discussion

The TSTIP will implement and evaluate a theoretically driven model of Internet-facilitated medical education for vertically integrated, community-based learning environments. This is a pragmatic trial in working practices, with an evaluation method designed to capture the reality of outcomes, sustainability, and scalability of the project activities. Limitations of the project evaluation include a lack of data on formally assessable educational outcomes, an absence of controls, and a sample size inadequate for statistical generalizability of quantitative results.

However, the evaluation should provide detailed, highly internally valid data. The results will not only inform the project's expansion, but also be of value in informing similar initiatives elsewhere, with the goal of improving the sustainability of medical workforces and health care in rural and remote regions.

Conflicts of Interest

None declared.

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Abbreviations

CoP: communities of practice

GP: general practitioner

GSM: Graduate School of Medicine

TSTIP: Telehealth Skills Training and Implementation Project

VCoP: virtual communities of practice

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Protocol

A Participatory Approach to Designing and Enhancing Integrated Health Information Technology Systems for Veterans: Protocol

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Abstract

Background: The Department of Veterans Affairs (VA) has developed health information technologies (HIT) and resources to improve veteran access to health care programs and services, and to support a patient-centered approach to health care delivery. To improve VA HIT access and meaningful use by veterans, it is necessary to understand their preferences for interacting with various HIT resources to accomplish health management related tasks and to exchange information.

Objective: The objective of this paper was to describe a novel protocol for: (1) developing a HIT Digital Health Matrix Model; (2) conducting an Analytic Hierarchy Process called pairwise comparison to understand how and why veterans want to use electronic health resources to complete tasks related to health management; and (3) developing visual modeling simulations that depict veterans' preferences for using VA HIT to manage their health conditions and exchange health information.

Methods: The study uses participatory research methods to understand how veterans prefer to use VA HIT to accomplish health management tasks within a given context, and how they would like to interact with HIT interfaces (eg, look, feel, and function) in the future. This study includes two rounds of veteran focus groups with self-administered surveys and visual modeling simulation techniques. This study will also convene an expert panel to assist in the development of a VA HIT Digital Health Matrix Model, so that both expert panel members and veteran participants can complete an Analytic Hierarchy Process, pairwise comparisons to evaluate and rank the applicability of electronic health resources for a series of health management tasks.

Results: This protocol describes the iterative, participatory, and patient-centered process for: (1) developing a VA HIT Digital Health Matrix Model that outlines current VA patient-facing platforms available to veterans, describing their features and relevant contexts for use; and (2) developing visual model simulations based on direct veteran feedback that depict patient preferences for enhancing the synchronization, integration, and standardization of VA patient-facing platforms. Focus group topics include current uses, preferences, facilitators, and barriers to using electronic health resources; recommendations for synchronizing, integrating, and standardizing VA HIT; and preferences on data sharing and delegation within the VA system.

Conclusions: This work highlights the practical, technological, and personal factors that facilitate and inhibit use of current VA HIT, and informs an integrated system redesign. The Digital Health Matrix Model and visual modeling simulations use knowledge of veteran preferences and experiences to directly inform enhancements to VA HIT and provide a more holistic and integrated user experience. These efforts are designed to support the adoption and sustained use of VA HIT to support patient self-management and clinical care coordination in ways that are directly aligned with veteran preferences.

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KEYWORDS

veterans; patient-provider communication; Department of Veterans Affairs; mixed methods; patient-centered care

Introduction

Health Information Technology in the Veterans Health Administration

Historically, health information technology (HIT) applications and systems have been developed under the auspices of independent organizational program offices, and as a result, they may not optimally support or enable an integrated patient experience across technology platforms [1]. Monolithic systems that lack an integrated strategy can result in a fragmented user experience and lead to system and resource inefficiencies [2-4]. In contrast, the development and implementation of a comprehensive and integrated approach to HIT, based on patient preferences and goals in various contexts, can have meaningful effects on patient engagement, empowerment, quality of care, and health outcomes [5,6].

To enable a more patient-centered and integrated approach to HIT tools and services, the Department of Veterans Affairs (VA) chartered a Connected Health task force in 2012 to develop strategic recommendations that would enable a seamless, unified veteran experience across all VA sponsored patient-facing technologies (ie, any technologies that a patient uses directly). Task force recommendations included the development of a centralized governance structure that would integrate and standardize the development and deployment of VA digital health tools and services. The Office of Connected Health of the Veterans Health Administration (VHA) was established in 2013, and represents a centralized governance model for multiple VHA program offices responsible for patient-facing technology systems, including My HealtheVet, Web and Mobile Solutions, and the VHA Innovation Program [7]. The Office of Connected Health is part of the VA Central Office organizational structure and is responsible for aligning virtual care technologies.

As emphasized in the VA Strategic Plan [8], veterans need an integrated system of HIT resources and tools that are useful and easy to use, so they can take an active role in their health care management. Increasingly, these HIT tools must support virtual care, while also connecting with VA enterprise-wide clinical information systems,

The development and proliferation of virtual access to care supports an organizational approach that is personalized, proactive, and patient-driven...Advances in virtual care expand where health care services can be accessed, reduce the need for travel to medical facilities, and transform VA's delivery of health care and its effect on patients' health outcomes. (pg. 18). [8]

To date, the VA has invested in a multitude of electronic health resources, such as Telehealth, VetLink Kiosks, an electronic health record, a tethered patient portal known as My HealtheVet, and mobile-based applications to increase patient access, support self-management, enhance patient-provider communication,

and improve patient health outcomes. As noted by the task force, however, further integration and alignment of these HIT resources is needed to provide a consistent and optimal user experience (including common user interfaces and standardized information displays) that is based on veterans' needs and preferences.

Veterans Preferences for Health Information Technology Resources

To accomplish this effectively, it is crucial to understand the nuances of veteran preferences for using various types of HIT resources to accomplish common user tasks and to exchange information. Concurrently, a detailed assessment of current and future VA patient-facing technology platforms is needed in order to identify integrated approaches that will best support a more patient-centered experience. In alignment with the Office of Connected Health, this VA funded research is designed to: (1) conduct a comprehensive assessment of current and future patient-facing technology resources based on the input of an expert panel that includes organizational subject matter experts and key stakeholders; (2) learn which resources veterans prefer to use to accomplish their health related tasks within a given context; (3) identify veteran preferences for using VA resources to exchange information; and (4) explore how veterans want to interact with digital health resource interfaces (eg, look, feel, and function). The study aims are designed to support veterans' self-management and task accomplishment (eg, accessing lab test results, refilling a prescription, scheduling an appointment, communicating electronically, etc), and to improve continuity of care through the integrated use of the VA's electronic health resources. Specifically they are to: (1) explore the preferences of veterans with chronic comorbid conditions for using various VA electronic health resources, using participatory research methods (develop and refine visual modeling simulations of VA electronic resources based on direct veteran input); (2) develop a comprehensive Digital Health Matrix Model of current and future VA patient-facing electronic health resources and conduct an Analytical Hierarchy Process, a pairwise comparison process with expert panel members and veteran participants; and (3) collaborate with VHA Program Offices as operational partners to directly inform current and future patient-facing HIT redesign efforts.

In this paper, we describe our development processes and study protocol, which leverage stakeholder groups (subject matter experts, clinicians, and veterans) and a participatory research approach that purposively recruits participants as expert informants to express their preferred vision for the future of VA's system of electronic health resources. Products of this research will be used in tandem with VA operational efforts to increase the usability and usefulness of the VA's electronic health resources, and to support a more integrated and effective veteran experience in use of VA HIT electronic health resources.

Methods

Study Design Overview

This mixed-methods participatory descriptive study [9] collects data using both an expert panel (organizational subject matter experts, clinicians, and operational stakeholders) and a series of veteran focus groups. The expert panel constructs a Digital Health Matrix and subsequently analyzes it using a structured pairwise comparison process, based on Analytical Hierarchy Process techniques (see the Data Collection section) [10]. The purpose of the Digital Health Matrix Model will be two-fold, first, to create a novel comprehensive descriptive inventory of VA's electronic health resources, and second, to provide an informational tool which will enable expert panel members to complete pairwise comparisons of various electronic health resources.

To complete data collection, two rounds of veteran participant focus groups will be conducted, along with self-administered surveys to elicit veteran perspectives. Based on the first round of veteran focus groups, the research team will collaborate with members of the VHA Human Factors team to develop relevant process models, and then create a set of visual modeling simulations. A second round of focus groups with the same veterans from the first round will then be conducted to elicit feedback about the visual modeling simulations, and to complete pairwise comparisons adapted to the focus group format. These focus groups will contribute to a final set of visual modeling simulations and a refined Digital Health Matrix Model. This study is approved and regulated by the VA Central Institutional Review Board.

Sample and Sampling

In qualitative research, sample size relies on the quality and richness of information obtained [11,12]. Achieving conceptual saturation is the goal of qualitative research, and is not dependent on sample size, but on the ability of the data to support interpretations, for example theoretical saturation [11,12]. Furthermore, recruiting the right participants is critical to gaining the most valuable information to articulate an integrated vision for VA electronic health resources. We will conduct our research with two primary groups: (1) an expert panel; and (2) veterans. These sample groups are described in further detail in the following paragraphs.

Expert Panel

Organizational subject matter experts and key stakeholders will comprise the expert panel. This panel will include representation from all relevant VHA Program Offices and key clinical disciplines. The majority of these individuals are well known by the research team as key representatives for each of VA's electronic health resource platforms, clinicians, subject matter experts who work in this area of research, and Office of Connected Health representatives.

Snowball sampling will be used as needed to recruit members that represent all key stakeholders (eg, My HealthVet, Telehealth, Mobile Health, Vetlink Kiosks, phone/texting, clinicians, patient educators, etc). Potential expert panel members will be invited to participate via email. To ensure

robust input, expert panel members will also be invited to assess any gaps in representation, and nominate other experts or stakeholders to participate. This process will continue until all stakeholder groups are well represented. As indicated by VHA regulations, panel members are participating as employees during their regular work schedule, and thus will not receive compensation for their participation.

Veteran Sample

The research team is purposively recruiting up to N=48 veterans who have expressed interest in using HIT electronic resources as "expert informants" to inform the outcomes of this project. The sample will include English speaking veterans age 35 years and older, with at least two chronic comorbid conditions (eg, diabetes and high blood pressure), and who report using two or more VA electronic health resources or non-VA electronic resources more than once a month. Therefore, study exclusion criteria include veterans younger than 35 years of age with less than two comorbid conditions, who use fewer than two VA electronic health resources less than once a month. Because of the nature of this study, we exclude those who do not speak English; and/or who report a visual, hearing, or cognitive impairment. This part of the study is being conducted at two VA Medical Centers: (1) the James A Haley Veterans Hospital (Tampa, Florida); and (2) the VA New England Health Care System, (Bedford, Massachusetts).

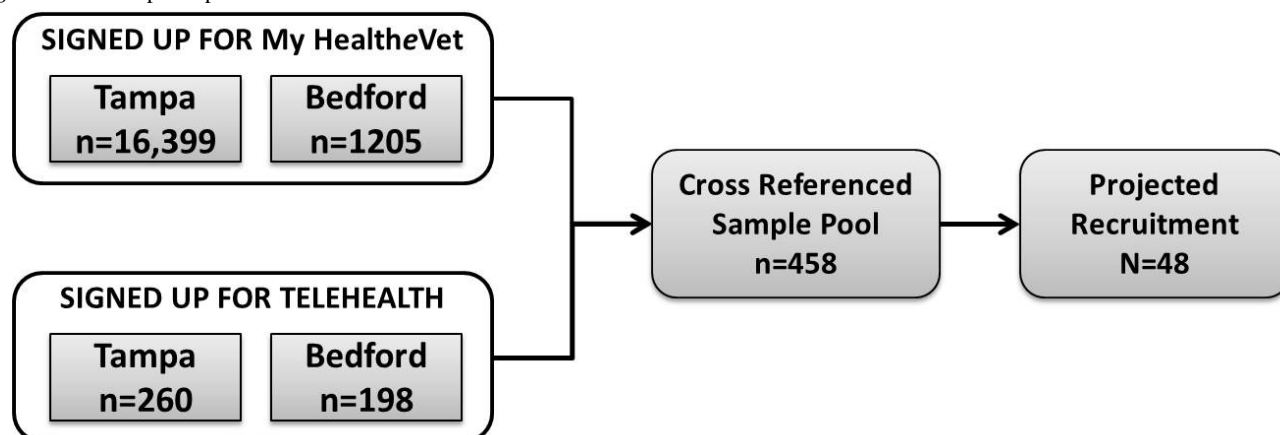
Purposive sampling will yield a sample pool for veteran recruitment efforts. We used administrative data to identify veterans registered for My HealthVet, who also completed the in-person process of authenticating their identity and opted in to use Secure Messaging. This approach identified 16,399 potential participants at Tampa; and 1205 potential participants at Bedford. Next we cross-analyzed the list of potential participants to identify veterans who have also used VA Telehealth services to ensure that study participants had access to use at least two forms of VA electronic health resources. In this process, we identified 260 potential participants in Tampa and 198 in Bedford. All 458 potential participants will be contacted and screened using a structured questionnaire to ensure information rich sources. We aim to recruit approximately 10% of the sample pool (48 participants), depending upon when theoretical saturation is reached. Figure 1 shows the recruitment process for veteran focus groups.

A structured screening interview tool was developed that includes items to address study age criteria and the occurrence of at least two chronic comorbid conditions (eg, diabetes, high blood pressure, COPD, etc). Based on Agency for Healthcare Research and Quality (AHRQ) recommendations, the screening interview tool also includes items to ensure veteran use of at least two VA electronic health resources (to make transactions; and access, store, manage, organize, and track information) [13]. This process of purposive sampling will ensure recruitment of individuals who already use available VA electronic health resources, and who may also utilize non-VA electronic resources. The screening interview tool also includes items to assess use of specific VA HIT resources, (including My HealthVet, Kiosks, mobile applications, Telehealth, etc), and to identify any visual, hearing, or cognitive impairment.

Study team members will contact potential study participants for recruitment via telephone utilizing the screening tool until domain and theme saturation is reached in data collection.

Veterans will receive up to US \$50 for their participation (US \$25 for participating in each round of focus groups).

Figure 1. Veteran participant recruitment flow chart.

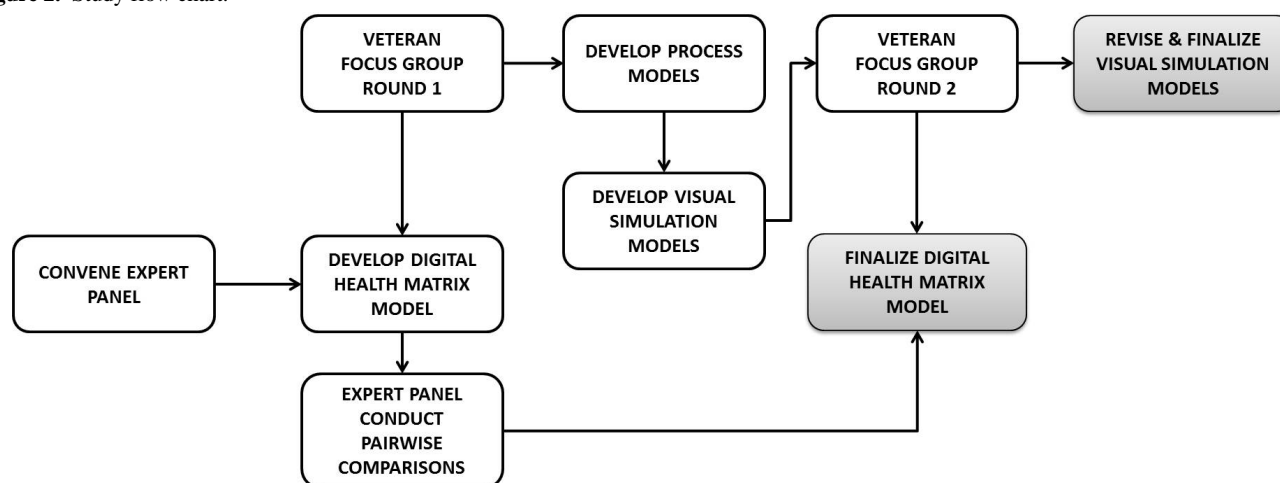


Data Collection

Data will be collected from expert panel members using a series of teleconference calls to inform the development of the Digital Health Matrix Model, and communication via email to request and obtain individual responses for a structured pairwise comparison activity that is based on Analytical Hierarchy

Process techniques. Expert panel members will also be invited to participate in an education session via teleconference that provides additional instructions on completing the requested pairwise comparisons. Data will be collected from veteran participants using a self-administered survey and focus group scripts. [Figure 2](#) shows the study data collection process.

Figure 2. Study flow chart.



Digital Health Matrix Model and Analytical Hierarchy Process Pairwise Comparisons

Pairwise comparison is an analytic hierarchy process (ie, method for understanding complex decision making) that directs participants to compare a series of items and decide which item is preferred. Participants then quantify their preferences using a numerical scale [10]. For the purpose of this study, veterans and expert panel members will use information provided by the Digital Health Matrix to compare and prioritize VA HIT and other VA and non-VA electronic resources. Pairwise comparisons will be conducted in four steps [10]. The first step is defining the problem, for example, what patient-facing electronic health resources are available to veterans, and what are the resource features and elements for prioritization. The research study team has identified relevant VA electronic health

resource platforms (eg, My HealtheVet, Mobile Health, VetLink Kiosks, Telehealth, etc), features (eg, Secure Messaging, Blue Button, Prescription Refill, etc), and elements for prioritization (eg, access/availability, specific resources, user groups, and context). This initial activity facilitates a focus on available electronic health resources, and their functions and features. This preliminary content will be revised throughout the process, particularly as data are collected from expert panel members and veterans in subsequent steps of the process.

The second step entails structuring the decision hierarchy and emphasizes expanding content developed in the first step through an information gathering process with subject matter experts, stakeholders, and veteran input. To complete this second step, we will develop a Digital Health Matrix Model that

represents a detailed inventory of available electronic resources, their features, characteristics, and contexts for use.

To develop the Digital Health Matrix Model, an expert panel will provide the appropriate clinical, administrative, and operational expertise and perspective. Expert panel stakeholder groups include clinicians (physicians, nurses, and patient educators) and representatives aligned with each of the VA electronic health resources (My My HealtheVet, Telehealth, Mobile Health, VetLink Kiosks, etc), veterans who participate in the focus groups will also provide additional input to inform the development and refinement of the matrix, especially during the first round of veteran focus groups.

The multi-axis Digital Health Matrix Model will include both currently available and future VA patient-facing platforms, their features, their availability, and conditions for appropriate use. Due to the complexity of VA electronic health resources and elements of interest, the Digital Health Matrix Model will be developed using an electronic Excel document with several sheets representing topics discussed during focus group interviews such as access, function, preferences, barriers to use, relevant user tasks, etc. Within each sheet, there will be a two-axis inventory of: (1) each electronic health resource (represented by row); and (2) domains (ie, broad categories describing related items) that emerge from focus group data and are relevant to the topic of each sheet. This matrix model will provide a descriptive blueprint for veteran decision making, and support the continued development of a more integrated system of VA patient-facing platforms and electronic health resources that meet the needs and preferences of veteran users. The organization of the matrix document will also allow content to be evaluated and prioritized based on the perceived usefulness of each electronic health resource within specific contexts. Due to the length and breadth of detail contained within the model,

we will develop search and categorization options to allow expert panel members to easily select and compare two (or more) resources while completing the pairwise comparison activity.

Both expert panel members and veterans will conduct a single activity that will complete the third and fourth steps of the process. There are two separate processes that will be used to complete these activities with the panel members and veterans. Using email, expert panel members will be provided a series of “worksheets” in a single document, with each worksheet representing a single health management task. Panel members will be asked to consider veterans preferences, cost, convenience, and workflow consequences, when completing the pairwise comparisons to determine which electronic health resources most effectively support health care management within the specific, predefined contexts. An adapted process will be completed by veterans during the second round of focus groups to ensure that their input is represented in the final model. Veterans will complete the pairwise comparisons and rank their preferences as a group to promote discussion.

In these final steps, electronic resources are compared (step 3) and ranked (step 4). Comparisons in step 3, allow the individual(s) to consider the value of using electronic health resources for a given health management task. In step 4, the selected electronic health resources are ranked to determine their level of priority over other options; numerical priorities are assigned on a scale of 1 to 3. This is done to calculate numeric weights for each alternative. The final scores provide a decision-making model that compares alternative electronic health resources for accomplishing specific tasks for managing a health condition. [Figure 3](#) shows an example of a pairwise comparison worksheet for a single task.

Figure 3. Pairwise comparison worksheet example.

Purpose of exercise: Determine which electronic resources most effectively support specific Veteran healthcare management tasks considering Veteran preferences, cost, convenience, and workflow.

Task: As a patient, I want to review my lab results.

Compare the two resources indicated in the box header. In white box, type the letter of the preferred resource. Rank the resource using the options in the pink box and type in small grey box at upper right. Score each resource by calculating the total ranking score.

Electronic Resource	Total Score at End of Comparison	A/B	A/C	A/D	A/E	A/F	A/G	A/H
A. Phone Call								
B. Text Message			B/C					
C. My HealtheVet - Blue Button				B/D				
D. Kiosk					C/D			
E. Mobile Device/Smart Phone App						C/E		
F. Telehealth/Device							C/F	
G. My HealtheVet - Secure Messaging								C/G
H. Insert Additional Option Here								

Rating Scale:
How much more to you prefer that resource?
1. Slightly better option
2. Moderately better option
3. Much better option

NOTES: Document your reasoning

Veteran Demographic Survey and Assessments

As previously noted, veteran participants will participate in two rounds of focus groups. At the first round of focus groups, veteran participants (up to N=48) will be consented and complete a baseline participant survey and assessment packet with a research team member in a private room. To collect demographic data, they will complete a 9-item demographic survey to ascertain age/date of birth, gender, race/ethnicity, education level, income level, marital status, and current medical conditions. There are thirty additional items that will be included to assess their electronic resource use (such as use of computer, Internet, smart phone, mobile technology, etc) and use of VA specific HIT resources such as My HealtheVet, Secure Messaging, etc. Health literacy will be assessed using two validated instruments: (1) the BRIEF health literacy screening, and (2) the Rapid Estimate of Adult Literacy in Medicine (REALM) survey. The BRIEF is a 4-item self-report screening tool to assess health literacy skills [14]. The REALM assesses health literacy by having respondents verbally articulate three columns of twenty-two health related terms [15]. Electronic health literacy will also be assessed using two instruments: (1) the eHealth Literacy Scale (eHEALS), and (2) the Computer-Email-Web (CEW) Fluency Scale. The eHEALS is a 10-item measure of eHealth literacy developed to measure consumers' knowledge, comfort, and perceived skills at finding, evaluating, and applying electronic health information to health problems [16]. The CEW Fluency Scale is a 21-item measure

of common computer skills [17]. Further details about the focus groups are described in the following sections.

Veteran Focus Groups

Veteran participants will be recruited as "expert informants". The first round will enable veterans to describe their preferences and needs when using HIT to manage their health and exchange information. Using data collected during this phase, the research team and VA Human Factors partners will create interactive visual modeling simulations of patient-facing electronic health resources. During the second round of focus groups, participants will review the visual modeling simulations and discuss how well they represent veteran preferences and needs. Veterans will have an opportunity to provide additional input and suggest specific revisions to ensure the visual modeling simulations effectively represent their needs and preferences. Participants will also complete an adapted version of the pairwise comparison process.

Veteran Focus Groups Round 1

Focus groups will last up to 2 hours and will be audio recorded. A moderator and facilitator will lead the focus groups, while VA operational partners and VA Human Factors representatives attend via teleconference technology. Participants will be introduced to the moderator, facilitator, and the teleconference attendees, and informed of their role and purpose for being present.

Participants will be asked questions about their preferences for using VA and non-VA electronic health resources, and specific reasons for use. Focus group questions will focus on, “The now”, resources they use (My HealthVet, VetLink Kiosks, mobile phone apps, Telehealth, eBenefits, etc), resources they prefer (both VA and non-VA), tasks they commonly do, barriers and facilitators for using the tools to complete these tasks, issues with resource availability, and tools that they may or may not use if they were available, and “The future”, what they want to

do, and how they want to do it. Participants will be asked to discuss: (1) their preferences for receiving information from VA and for providing information to VA to support their care; (2) their current use of electronic health resources, including which features they use, and their experiences using these resources to manage their health condition(s); and (3) their preferences for interacting with VA technology resources in the future. Sample script questions for the first round of focus groups are shown in [Textbox 1](#).

Textbox 1. Sample questions for first round of focus groups.

Preferences for exchanging information with VA:

Sharing information with your health care team is important, how would you like to be able to provide your health care team with information (for example, information that you keep track of at home)?

Use of electronic resources:

Please list all of the technology such as online resources, services, and tools (both VA and Non-VA) you currently use to manage your (condition).

Let's talk about the tasks you do to manage your (condition), using these technologies and applications.

Probes,

-How do you use (electronic resource) to manage (condition)?

-What is the primary reason you use (electronic resource)?

-Which features of (electronic resource) are most useful to you?

Interacting with VA technology in the future:

If you were going to design the way you interact with VA using technology to send and receive information, what would it look like? Let's draw what this system might look like together (use Post-it Pads and markers).

Can you give me an example of how VA electronic technologies could be used as an ideal system of VA electronic services that work together?

If you use the (electronic resource) to (task), would you expect the (electronic resource) to look exactly the same? If yes, how so?

Probes,

-How would you expect to see your information across tools (format)?

-How would you prefer labeling, colors, and backgrounds to be?

On smartphones and computers, there is a main page, or “dashboard” from which a user can navigate to all of their tools. How do you feel about having a dashboard of VA services and tools?

Developing Visual Model Simulations

During the focus group, participants will be provided with pens, pads, markers, and large pieces of paper to allow them to write down their thoughts and draw out imagery that represents their preferences and needs. They will also be invited to bring any mobile devices that they use, and to share their preferred electronic resources throughout the focus group discussion. The study moderator will also transcribe notes onto large sheets of paper displayed on the wall in order to allow participants to review and refer to notes and topics throughout the focus group discussion. This method will assist the study team in guiding the discussion.

After each focus group, all notes developed during the group discussion will be immediately transcribed, and all imagery drawn by participants during the session will be photographed and saved in an electronic format. All of these assets will be transferred to the assigned Human Factors team to inform the immediate development of visual modeling simulations based on all of the data provided by veterans in the first round of focus groups.

Developing Visual Model Simulations

Based on the data collected in round one of the focus groups, visual model simulations will be created by VA Human Factors experts using iRise version 8 (iRise, Enterprise Visualization Platform). Visual model simulations provide an effective method to rapidly create a graphic display of an electronic interface, but with limited functionality. This technique allows the user to see the graphic display (also known as wireframes), and experience it in its limited function. Focus group summaries and visual asset data (eg, drawings and sketches) gathered during the focus groups will be used to ensure that the participants' perspectives are represented in the simulations. The study team will use focus group data to develop detailed test case scenarios and process models that will be simulated to the specified look and feel using the iRise software by the VA Human Factors team. These simulated visual models will consist of mock application screens and Web pages for various resources of interest (ie, My HealthVet, Web, Mobile Health, Telehealth, and VetLink Kiosks). These models will allow veteran participants in the second round of veteran focus groups to provide feedback and make additional suggestions to further

refine the visual modeling simulations until they look and function as desired.

Veteran Focus Groups Round 2

The second round of veteran focus groups will be conducted with the same veteran participants from round one. In the second round of focus groups, participants will complete two activities: (1) provide feedback about the visual model simulations; and (2) conduct the pairwise comparison process group activity. We will provide exposure to the visual modeling simulations in group settings so that veteran focus group participants can react and provide specific feedback about these simulations and the degree to which they represent their needs and preferences. These interactive sessions will consist of a group setting, in which participants engage in a semiscripted simulation to review

each of the visual modeling simulations of patient-facing platforms. As recommended by Kushniruk [18,19], participants will participate in a “brainstorming” activity, where they will talk about their experience as they access and “use” the system features. This method allows interviewers to understand what considerations veterans experience with the simulated visual prototype interfaces. Participants will have the opportunity to review the visual modeling simulations, and will be asked to vocalize thoughts, feelings, and opinions while interacting with the interface. Participants will be asked to discuss: (1) their initial thoughts about the visual model simulations; (2) their perceptions about the format and layout of the visual model simulations; and (3) the usability and ease of use of the visual model simulations. Sample script questions for the second round of focus groups are shown in [Textbox 2](#).

Textbox 2. Sample questions for second round of focus groups.

Initial responses to visual model simulations:

What are your initial thoughts about the (electronic resource simulation).

Probe,

-What are 3 things you most like/dislike about the (electronic resource simulation)?

-Does this (electronic resource simulation) reflect the feedback you gave us when we met previously?

Feedback about format and layout:

What do you like/dislike about the (colors, size, layout)?

Probe,

-How would you change the (colors, size, layout) to make (electronic resource simulation) (more useful, easier to use)?

Usability and ease of use:

Describe a scenario in which you would use this (electronic resource simulation).

How would you (navigation/task) if you wanted to (health management task) for your (health condition)?

Usability Software to Facilitate Veteran Review of Simulations

Morae version 3.3 (Morae from TechSmith) usability software and audio recorders will be used to record and analyze revisions recommended by veteran focus group participants. This software has been utilized successfully in testing Web-based software [20,21], and allows for the live, remote observation of the users' experiences [22]. Morae will primarily be used to record data (respondents' reactions to the visual modeling simulations), and to then revise the simulations iteratively. Final visual model simulations will be disseminated to VA operational stakeholders to inform website redesign efforts which are currently underway.

The veteran focus group participants will also complete the pairwise comparison activity as a group to enable discussion about commonalities and differences in preferences. To accomplish this, adapted versions of the worksheets will be posted on large presentation style poster paper so that all participants can see the layout. A research team member will facilitate the pairwise comparison process with the group, allowing each participant an opportunity to select and rank electronic resources for a series of health condition management tasks. Pairwise comparisons completed by veterans will then be compared to those completed by expert panel members.

Data Analysis

Expert Panel and Veteran Analytical Hierarchy Process Pairwise Comparisons

Pairwise comparisons completed by participating expert panel members and veteran focus group participants will be reviewed by the study team and then collated to identify the preferred platform for each task and function based on expressed preferences, needs, benefits, and barriers. The collation process will allow all respondent's comparisons to be tallied to rank the usefulness of various electronic health resource platforms for completing distinct self-management and health care related tasks. The study team will also assess similarities and differences in the input provided by expert panel members versus veteran focus group participants.

Veteran Focus Groups

Descriptive analysis of survey and assessment data completed by veteran focus group participants will be conducted to identify sample characteristics. Qualitative data from the first round of veteran focus groups will be analyzed at two levels by three study team members. First, participant input captured on Post-it Notes will be transcribed to an electronic document. Study team members with qualitative research expertise will code the data from the Post-it Notes topographically into major domains and

subdomains in order to organize and summarize the data. Using this preliminary data analysis, the team will then use this input from veterans to expand the Digital Health Matrix Model in preparation for the pairwise comparisons. Analysis of this data will also inform the creation of the visual modeling simulations.

Due to the rapid iterative nature of this project, the second level of analysis will be completed when both rounds of veteran focus groups have been completed. The audio files will be transcribed and uploaded into the qualitative data analysis software program ATLAS.ti version 7.1 (ATLAS.ti Scientific Software Development GmbH) for comprehensive analysis. Additionally, Morae recordings will be reviewed to allow the team to document notes and relevant content in alignment with the audio recorded data. This data will be compared and compiled with qualitative transcripts to collate data assets.

Once all data are collated, content analysis will be completed in two primary steps, first, we will identify domains and taxonomic structures; and second, we will evaluate coding schemas for reliability and credibility. In the first step, we will identify codes, extract meaningful statements, and identify group domains and taxonomies. Participant comments will be organized to develop codes, and codes will be merged to develop categories. Categories will be grouped into a taxonomic structure that describes the dataset. Themes identified in the preliminary analysis will be compared to those identified in subsequent transcript analyses, and results will be integrated into a final taxonomic thematic structure [23]. To complete the second step of the analysis, data samples will be extracted and coded by at least two research team members and evaluated for interrater reliability and credibility.

Results

This paper describes a novel process and protocol for developing and implementing a mixed-methods participatory approach to evaluating and understanding veterans' preferences and vision for an integrated system of HIT electronic health resources to support health care and self-management. Leveraging expert panel stakeholders and subject matter experts, along with veteran patients as expert consultants, we describe a participatory approach that can be used in future research to dynamically evaluate user preferences for HIT systems and tools. This approach informs the development of a more integrated and connected system of electronic health resources that will support a more holistic patient experience across multiple platforms and tools, based on a patient-centered approach to virtual care. This study is finished with recruitment, is in final stages of data collection, and the preliminary stages of data analysis.

Discussion

Collaborative Approaches to Development

The optimal use of health information technology to improve health care delivery and help patients become active participants in their care and self-management is essential to address patients' ongoing health care needs [1]. HIT evaluation methods must be focused on the interactions and processes between patients, health care professionals, organizational structures,

and the technology itself, to design and implement electronic health resources in ways that optimally meet user needs [1-3]. There is a distinct value in developing collaborative approaches that convene a diverse set of stakeholders to methodically define a more integrated system of electronic health resources that is synchronized with patients' needs and preferences. A more holistic vision for "connected health" is crucial to improve resource efficiency, communication, cooperation, and collaboration across the organizational enterprise. From the end user perspective, an integrated system of electronic health resources that are standardized and synchronized will improve the end user experience, and ultimately the quality and efficiency of services provided [24]. As such, understanding the perspective of veterans, clinicians, VA operational stakeholders, and subject matter experts is vital to identifying an integrated system that can meet user needs in optimal ways [25,26].

Overall the goal of this study is to inform the VA's vision of an integrated system of HIT electronic health resources from the shared perspective of veterans, clinicians, subject matter experts, and other key stakeholders (eg, VA operational partners). This study illustrates an innovative approach to using participatory research methods with diverse stakeholders and technology resources to create a vision for an integrated user-friendly system of HIT patient-facing resources. To our knowledge, this is one of the few published protocols that inform the development of an integrated system of HIT resources within a large health care system that serves more than 2.5 million users (Veterans and Consumers Health Informatics Office, U.S. Department of Veterans Affairs, unpublished data 2014).

Study Limitations

Although this protocol is useful in developing valuable knowledge to inform system improvements, our study has limitations. First, although our sample size will be comparable to other qualitative mixed-methods studies [27], it is based on a small, yet representative purposively sampled group of participants and may not be generalizable to the general veteran patient population. Second, we are purposively recruiting veterans who are invested users of two or more platforms, as we feel they can provide salient in depth feedback. As such, we may miss valuable data that may represent noninvested users. Third, we are purposively including veterans with comorbid conditions because they are more likely to be consistently engaged in their health care to manage their conditions. As such, we may miss valuable data that may represent healthier participants. However, it should be noted that being in good health has been identified as a reason for not using available electronic resources [28]. Fourth, although this study includes multiple stakeholder groups, technological infrastructure capacity is not a primary focus, and thus may limit the VA's ability to fully integrate all of the suggestions made by the participating veterans and expert panelists. However, it should be noted that the technological capacity of the current infrastructure should not limit the vision for future electronic services. Future research should inform the continued development and refinement of the VA's vision for an integrated system of HIT resources, including both veteran patient user experiences and outcomes; and also clinical and organizational process considerations to ensure alignment with workflow

processes. Both are crucial to the success of the VA's Connected Health strategy.

Our use of mixed-methods to collect, analyze, and converge data from distinctly different sources supports the development of a product that is informed by users, clinicians, and operational Program Office representatives to identify an integrated set of electronic health resources that focus on usability and usefulness. These efforts are guided by best practices and will support a

user-based design to promote integration, synchronization, and standardization across an integrated system of patient-facing platforms and tools. In alignment with VA goals and the mission of VA's Office of Connected Health, these data will support the development and proliferation of user-friendly electronic resources that support virtual access to care that is personalized, proactive, and patient-driven to increase access, and transform the VA's delivery of health care [8].

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Conflicts of Interest

None declared.

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Abbreviations

AHRQ: Agency for Healthcare Research and Quality
CEW: Computer-Email-Web
eHEALS: eHealth Literacy Scale
HIT: health information technology
REALM: Rapid Estimate of Adult Literacy in Medicine
VA: Department of Veterans Affairs
VHA: Veterans Health Administration

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Original Paper

A Mobile Telehealth Intervention for Adults With Insulin-Requiring Diabetes: Early Results of a Mixed-Methods Randomized Controlled Trial

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Abstract

Background: The role of technology in health care delivery has grown rapidly in the last decade. The potential of mobile telehealth (MTH) to support patient self-management is a key area of research. Providing patients with technological tools that allow for the recording and transmission of health parameters to health care professionals (HCPs) may promote behavior changes that result in improved health outcomes. Although for some conditions the evidence of the effectiveness of MTH is clear, to date the findings on the effects of MTH on diabetes management remain inconsistent.

Objective: This study aims to evaluate an MTH intervention among insulin-requiring adults with diabetes to establish whether supplementing standard care with MTH results in improved health outcomes—glycated hemoglobin (HbA1c), blood pressure (BP), health-related quality of life (HRQoL), diabetes self-management behaviors, diabetes health care utilization, and diabetes self-efficacy and illness beliefs. An additional objective was to explore the acceptability of MTH and patients' perceptions of, and experience, using it.

Methods: A mixed-method design consisting of a 9-month, two-arm, parallel randomized controlled trial (RCT) was used in combination with exit qualitative interviews. Quantitative data was collected at baseline, 3 months, and 9 months. Additional intervention fidelity data, such as participants' MTH transmissions and contacts with the MTH nurse during the study, were also recorded.

Results: Data collection for both the quantitative and qualitative components of this study has ended and data analysis is ongoing. A total of 86 participants were enrolled into the study. Out of 86 participants, 45 (52%) were randomized to the intervention group and 36 (42%) to the control group. Preliminary data on MTH training sessions and MTH usage by intervention participants are presented in this paper. We expect to publish complete study results in 2015.

Conclusions: The range of data collected in this study will allow for a comprehensive evaluation of processes and outcomes. The early results presented suggest that MTH usage decreases over time and that MTH participants would benefit from attending more than one training session.

Trial Registration: ClinicalTrials.gov NCT00922376; <http://clinicaltrials.gov/ct2/show/NCT00922376> (Archived by WebCite at <http://www.webcitation.org/6Vu4nhLI6>).

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KEYWORDS

mobile telehealth; self-management; mixed-method design; diabetes; glycated hemoglobin (HbA1c); health-related quality of life; intervention fidelity; behavior change

Introduction

Overview

Diabetes currently affects approximately 366 million people and this number is expected to increase to 552 million by 2030 [1]. Diabetes care in England is estimated to take up between 5 and 10% of all National Health Service (NHS) expenditures [2]. The difficulties of living with diabetes, with its complex regimen and need for behavior change, is challenging, making good self-management difficult to achieve [3].

Telehealth (TH) offers patients the ability to record diabetes-related information electronically and transfer this to their health care professional (HCP), allowing them to be easily connected over time to HCPs. Using a mobile platform for TH, referred to as mobile telehealth (MTH), enables a transition from a health delivery model where monitoring is infrequent and discrete in clinics, to continuous and potentially noninvasive monitoring taking place across locations [4]. TH is believed to hold the potential to revolutionize care delivery processes by improving the efficiency and quality of the care [5], enhancing patient experience and health-related quality of life (HRQoL), increasing patient confidence in addressing their needs, and supporting self-management [6]. However, questions remain as to whether TH technologies will be acceptable and useful and lead to improved outcomes in all patients [7,8].

Several systematic reviews have examined the impact of TH in people with diabetes and yielded inconsistent or inconclusive findings [9-16]. Concerns about the quality of the studies in this area have been raised and the need for more robust methodologies emphasized [17-19]. To date, the focus has been on glycated hemoglobin (HbA1c) as a primary outcome and patient-reported outcomes have often not been examined [20]. There is also little research on the factors that influence patients' engagement with the technology, as well as on the process variables through which TH might impact health outcomes [21,22].

This study aimed to address some of these gaps in the literature. The evaluation in this study was informed by the recommendations made by the Medical Research Council (MRC) [23]. The MRC recommends that evaluations consist of several components, including a review of the literature, the use of theory to guide design and evaluation, and consideration for both outcomes and process variables. The importance of assessing intervention fidelity has also been underlined [24], as has the valuable contribution of qualitative methods to reach a better understanding of the factors that could help explain study findings [23].

Study Aims

The aim of this randomized controlled trial (RCT) is to evaluate the effectiveness of an MTH intervention on adults with insulin-requiring diabetes. The MTH intervention involved data transmission, feedback, and education. The intervention will be examined based on clinical outcomes—HbA1c and blood pressure (BP)—diabetes health care utilization, HRQoL, and self-management behaviors. Secondary aims are to assess the impact of MTH on process variables, including diabetes

self-efficacy and illness beliefs, and to test whether these mediate the potential effects of the intervention on the outcomes. Additional aims include the identification of predictors of MTH usage, the assessment of intervention fidelity, and the exploration of patients' experiences with, and perceptions of, the acceptability of MTH.

Theoretical Framework

The theoretical foundations guiding the concepts used in the study included Bandura's social cognitive theory [25], Leventhal's model of illness beliefs [26], and Davis's Technology Acceptance Model (TAM) [27]. These theories propose that self-efficacy and illness beliefs influence health behaviors, and that factors such as perceived usefulness and perceived ease of use determine technology usage. The key behavior change techniques involved in the MTH intervention—self-monitoring with feedback and education—have been related to changes in self-efficacy [28] and education has been linked to changes in beliefs [29].

Concepts from the TAM were selected to examine MTH usage as work using this model has shown that acceptability, which is determined by perceived usefulness and perceived ease of use, predicts usage behavior across a range of technologies. The information technology training provided, and the extent to which the technology is perceived to interfere in life, are two further factors shown to be related to technology usage [30,31], therefore, these factors are also included to address the question on predictors of MTH usage.

Methods

Ethical Approval and Registration

This study received full ethical approval from the Joint University College London/University College London Hospitals (UCL/UCLH) Committees on the Ethics of Human Research, Committee Alpha (09/H0715/69). The RCT has been registered with ClinicalTrials.gov (NCT00922376).

Hypotheses

The primary hypothesis is that standard care supplemented with MTH can achieve greater improvements in HbA1c and BP. Secondary hypotheses are that the intervention will result in greater improvements in self-management behaviors, HRQoL, and psychological well-being compared to standard care. In line with the theories, we further hypothesize that improvements in self-efficacy and illness beliefs will determine the change in health outcomes and that acceptability of MTH, self-efficacy to use MTH, and adequacy of MTH training will significantly predict telehealth usage.

Study Design

This study used a mixed-method design including a two-arm parallel RCT with repeated measurements—baseline, 3 months, and 9 months—and qualitative exit interviews with patients. A sequential design was used in that the RCT was conducted prior to the qualitative study. As such, the qualitative enquiry was embedded in the quantitative study and aimed to extend and help elucidate the quantitative findings.

Sample Size Calculation

A sample of 248 participants (124 participants per group) was required to detect significant group differences on the primary outcome, HbA1c, for a two-group and repeated measures design. These calculations were based on equal group sizes, an attrition rate of 30%, 80% power to detect differences at the $P=0.05$ significance level (two-sided), with correlations between measurements of .70, and an effect size of 0.21 standard deviation units.

Trial Population and Recruitment

Participants were recruited from a diabetes unit in a secondary care health center in a multi-ethnic East London borough of Newham. Eligible participants were insulin-requiring adults with a diagnosis of type 1 or type 2 diabetes whose most recent HbA1c was above 7.5%. Participants had to be sufficiently literate and fluent in English to complete the questionnaires and have telephone conversations with an HCP. Excluded from the study were people with prior experience using MTH, people who had not attended the clinic or had an HbA1c test done in the last 12 months, were pregnant, regularly travelled outside the UK for 3 weeks or more, required home visits by a district nurse for blood glucose (BG) monitoring and/or insulin administration, or had a diagnosis of kidney failure or sickle cell disease.

Consent

Participants with an appointment in the following 2 weeks were screened for eligibility and sent an information sheet, an invitation to take part, and an interest form. Participants who did not refuse the invitation were approached on the day of their appointment when the nature and implications of the research were explained. Potential participants were given time to consider participating in the study and those that were willing to take part were invited to sign a consent form for the RCT. Upon completion of the 9-month RCT, separate recruitment materials were sent to the intervention group participants to inform them about, invite them to, and obtain consent for, the qualitative interviews.

Baseline Assessment

Each participant was given the opportunity to complete the questionnaires with a researcher at the clinic or at home (with assistance, if required) using a prestamped envelope for return by postal mail.

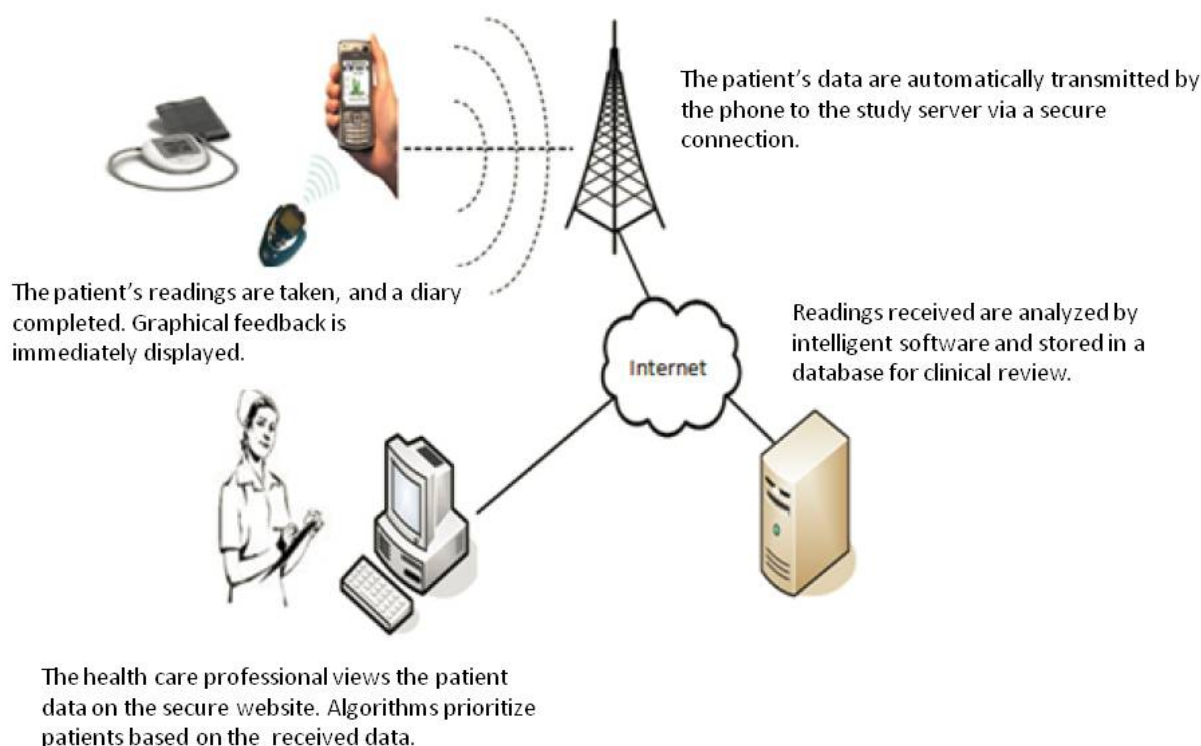
Randomization

Randomization occurred after the return of the baseline questionnaire. It was carried out in blocks of 20 participants using an online sequence generator. All participants were sent a letter informing them of the group they were allocated to, and intervention participants were telephoned to confirm the next steps. General practitioners were notified of their patients' involvement in the study and allocation group.

The Mobile Telehealth Intervention

Overview of the Mobile Telehealth Equipment and App

The MTH system assessed in this study was developed by a team of engineers in Oxford, England. Its design was based on earlier data transmission and diary apps, HCP advice, and user feedback, and designed according to criteria of ease of use, personalization, prompt feedback, integration to the user's lifestyle, and quality of care [32]. The MTH equipment consisted of a mobile phone (Sony Ericsson k810i) with MTH app software installed, charger, BG meter, BP monitoring device, and Bluetooth cradle. Figure 1 represents the architecture of the MTH system. The MTH app allows for the recording of several health parameters: BG and BP readings, time since last meal, level of physical activity performed so far that day, insulin dose, and weight. BG and BP were transmitted via Bluetooth and the remaining data were manually entered using the mobile phone keyboard. The MTH app could store up to 500 clinical readings, and both single and bulk data transfers from the mobile phone to the Web server were possible. Following data recording or transfer, immediate color-coded graphical feedback was displayed on the mobile phone screen. This included representations of (1) the last BG reading recorded in comparison to the average BG reading for the last month, (2) a histogram of the frequency of BG readings within different glycaemic ranges in the last month (see ranges for glycaemic states below), and (3) scatter plots of the BG and BP readings recorded in the last 5 days. More sophisticated graphical representations of the data transferred were available via a password-protected Web account interface. Color codes represented different glycemic states: blue for hypoglycemia (0-4 mmol/L), green for normoglycemia (4-10 mmol/L), amber for borderline hyperglycemia (10-12 mmol/L), and red for hyperglycemia (above 12 mmol/L).

Figure 1. Architecture of the MTH system evaluated.

Intervention Group Protocol

In addition to receiving standard care, intervention participants were provided with the MTH equipment and a BG strip prescription letter for the BG meter. Equipment was delivered to their home by an engineer who trained them to use it. Training sessions ended when a participant was able to collect, enter, and transfer data correctly alone. On this occasion, participants were encouraged to continue to self-monitor at the frequency recommended by their HCP, and to transfer all data at every self-monitoring occasion. Weekly BP self-monitoring was recommended for participants for whom BP monitoring had not been prescribed prior to the study. Participants in the habit of relying on their BG meter for a list of readings to show their HCP were asked to attend their routine clinical appointments with the MTH mobile phone. The mobile phone could display a list of date- and time-stamped clinical readings. Alternatively, HCPs at the clinic where recruitment took place had authorized access to participants' MTH data via a Web interface.

The intervention protocol included the MTH nurse completing the following actions:

1. Making *introductory phone calls* within 2 weeks of participants receiving MTH training to introduce herself, confirm contact details, and collect basic information on diabetes management.

2. Making *6 weekly educational calls* to deliver diabetes education. In the absence of patient-designated questions, the following topics could be covered: recognizing and managing hypoglycemia, aspects of lifestyle management in relation to alcohol, weight, smoking, food choices, physical activity, illness and diabetes, and insulin, as well as methods to optimize future diabetes routine appointments.

3. *Responding to participants' BG and BP readings.* BG readings varied according to participants' diagnoses (type 1 or 2) and medication (insulin and oral, or insulin only). Participants with one isolated hypoglycemic event were red-flagged for closer monitoring for 72 hours. The MTH nurse contacted participants with a borderline hyperglycemic reading and with recurring hyperglycemic and hypoglycemic events within 72 hours to assess the reasons for these low/high BG readings. Recurring hyperglycemia due to illness or medication changes was red-flagged for 24 hours for closer observation. Those with sufficient experience with insulin adjustments were encouraged to titrate their insulin dosage. Those who required a medication review were asked to schedule an appointment at the clinic. In more urgent situations (eg, possible ketoacidosis), the MTH nurse was required to advise the patient to visit an accident and emergency department. Education and reminders as to the importance of medication/lifestyle factors in the management of diabetes were to be provided as appropriate.

The MTH nurse was required to contact patients with four consecutive BP readings over 140/80 in a 14-day period to discuss medication and provide advice on lifestyle changes to improve BP. If a further four readings above 140/80 in a 14-day period occurred following a discussion with the participant on medication and lifestyle changes, the MTH nurse was required to refer the participant to a general practitioner.

The technical support team provided telephone support, organized a home visit where appropriate, and contacted participants who had not transmitted data for more than 7 days. A maximum of three successful telephone calls were made to encourage data transmission.

Control Group

Participants in this group received standard care that consisted of a 30-minute appointment with a diabetes specialist nurse every 3 to 4 months, and 1 annual or 2 semiannual appointments with a diabetes consultant. During working hours there was at least one diabetes specialist nurse available at the clinic to receive phone calls from diabetes patients.

Follow-Up Assessments

Participants were sent the 3- and 9-month follow-up questionnaires by postal mail with a prestamped envelope for return. Each participant was given the opportunity to complete their questionnaires with a researcher.

Health Care Professional and Engineer Training

All diabetes specialist nurses and consultants were provided opportunities to learn how to use the MTH equipment and access the MTH data via the Web interface. The MTH nurse received training to remotely access and navigate participants' electronic medical records. The engineer was taken through the steps to follow with participants and the content to cover in each MTH training session.

Evaluation Measures

Overview

As recommended in the MRC guidance for complex interventions [23], evaluation was designed to capture information on both processes and outcomes. The quantitative study data included clinical measures, self-reported questionnaires administered to participants, logs/electronic notes from the MTH app, and records kept by the technical support team, MTH nurse, and engineer of contact with participants. For self-reported data, standardized questionnaires with good psychometric properties were used wherever possible—see Table 1 for a summary of the data collected at the three time points. Less commonly used and self-developed questionnaires are described in greater detail below. Data from the qualitative component included transcripts from audiotaped, semistructured interviews conducted with intervention participants who agreed to take part in this part of the evaluation.

Demographics

Data on age, gender, education, ethnicity, country of birth, and whether English was spoken at home was collected.

Clinical Measures

Data on diabetes type, duration, medication, complications, daily insulin dose, number of daily insulin injections, and Body Mass Index (BMI) were taken from medical records. Comorbidities were collected using self-reporting by participants.

Familiarity With Mobile Phones

Familiarity with mobile phones was evaluated at the time of recruitment by asking all participants who enrolled in the study whether they owned a mobile phone (yes/no).

Primary Outcome Measure

The primary outcome measure, HbA1c, was collected from medical records.

Secondary Outcome Measures

BP readings were recorded from medical records. Diabetes self-management behaviors were measured using the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire [33], which focuses on dietary behaviors, exercise, foot care, BG testing, and cigarette smoking. An additional item asking participants to specify their weekly frequency of self-monitoring of BG levels was added to this assessment of behaviors. Generic HRQoL was assessed using the Short Form-12 (SF12v2) with a recall time of 4 weeks [34,35] and the Diabetes Health Profile (DHP-18) was used as a disease-specific measure of HRQoL [36]. Depression and anxiety were measured using the Center for Epidemiologic Studies Short Depression Scale (CESD-10) [37] and the State-Trait Anxiety Inventory (STAI-6) [38], respectively. Data on the number of appointments attended during the study at the diabetes clinic with diabetes specialist nurses and consultants were collected from medical records.

Process Variables

Self-efficacy for managing health was measured using the Health Education Impact Questionnaire (HeiQ, v3.0) [39], which is used to investigate the impact of health interventions on patient empowerment. It consists of eight subscales that can be applied independently, two of which were used in the current study. The *self-monitoring and insight* subscale assesses an individual's beliefs in his/her ability to monitor his/her health and the physical and/or emotional responses that lead to appropriate self-management. The *skills and technique acquisition* subscale captures the beliefs an individual has in his/her knowledge-based skills and techniques to self-manage his/her health.

Disease-specific self-efficacy was assessed using the Insulin Management Diabetes Self-Efficacy Scale (IMDSES) [40], which consists of five subscales on *general management*, *insulin management*, *dietary management*, *exercise management*, and *foot-care management*. In line with clinical practice at the diabetes unit where the study took place, references to urine testing were removed from the questionnaire (eg, the question "I cannot test my blood or urine when I am away from home" became "I cannot test my blood when I am away from home") and an item on *food exchange* (ie, "I can correctly exchange one food for another in the same food group") was removed, as this concept was not used in clinical practice or in diabetes

education classes. Diabetes-specific illness beliefs were measured using the Personal Models of Diabetes (PMD) scale [41] consisting of two subscales focusing on beliefs related to the seriousness of diabetes and treatment effectiveness.

Mobile Telehealth-Related Variables

Mobile Telehealth Self-Efficacy and Acceptability

In the absence of a currently available measure, a questionnaire was developed to capture individuals' beliefs about their ability to operate the MTH equipment. To facilitate item generation, a researcher used the MTH system for 1 week to identify the different steps and skills required to transmit data and review feedback. Ten items were generated in relation to data entry, data transfer, menu navigation, display of graphical feedback, and use of graphical feedback to identify BG patterns and make adjustments to self-management behaviors. Each item of the questionnaire begins with "I am confident that I am able to..." The same 5-point Likert scale of another diabetes self-efficacy measure [42] was used (1=No, definitely not, 2=Probably no, 3=Maybe yes, maybe no, 4=Yes, probably, 5=Yes, definitely). Principal component analysis revealed one factor—higher scores indicated greater self-efficacy to use the MTH equipment.

At the time of this study, there was no published and psychometrically valid questionnaire to measure acceptability of MTH, therefore, a questionnaire was developed to measure acceptability. Item generation was guided by previous empirical and theoretical work on user acceptance underlining the importance of perceived usefulness, perceived ease of use, and integration into life in determining acceptability and technology usage. A principal component analysis was performed to determine subscales, and three subscales—consisting of seven items, 13 items, and seven items, respectively—were identified. Participants were asked to rate their level of agreement with each item using a 4-point Likert scale (0=Strongly disagree, 1=Somewhat disagree, 2=Somewhat agree, 3=Strongly agree). In addition to this acceptability questionnaire, individual items were included in the intervention group's follow-up questionnaires to assess perceived adequacy (one item asking participants whether they would have liked more training) and quality of the MTH training (one item), quality of the technical support received over the phone (one item), frequency of usage

of the Web interface (one item), and perceived usefulness of the Web interface (one item).

Participants' Perceptions and Experiences of Use

Qualitative semistructured interviews were used to explore participants' perceptions of, and experiences using, MTH. An interview guide was developed based on previous research and areas of interest. It addressed several topics including initial thoughts and expectations about MTH, use of the technology, perceived impact on diabetes management, the relationship with the MTH nurse, technical problems, and suggestions for improvement. To limit the influence of social desirability on responses, the relationship between the research team, the MTH provider, and HCPs was clarified before the interview to underline the independent nature of the evaluation. Participants were also reminded that there were no correct answers to the questions asked and that both negative and positive feedback was valuable to help improve the MTH service. There are no hard and fast rules about sample sizes in qualitative enquiries—the required number of interviews remains a matter of judgment and experience in assessing the quality of the data collected against the purpose of the enquiry [43]. Recruiting MTH participants for interviews continued until data saturation occurred and no new themes emerged from the data on five successive interviews. Previous qualitative TH studies included fewer than 20 patient interviews [44,45], therefore, we expected to conduct between 10 and 25 interviews.

Usage and Intervention Delivery

Data transmitted by intervention participants were collected as they provide some indication of intervention receipt and adherence. Data on contacts made between the MTH nurse, technical support, the engineer, and intervention participants were also collected. This included the number of contacts, the medium used (ie, telephone, text message, in person), and topic(s) discussed. To assess whether the intervention was delivered as planned (ie, intervention fidelity), these data will be compared to the fixed components of the intervention protocol (ie, one training session for each intervention participant, one introductory MTH call, six weekly educational calls, and provision of technical support to solve technical problems).

Table 1. Assessment protocol and data collected at the three time points.

Assessments and measurement tools used (where applicable) ^a	Data collection time point		
	Baseline	3 months	9 months
Demographics	✓		
Clinical			
Type and duration of diabetes, complications, comorbidities, medication type	✓		
HbA1c	✓	✓	✓
BP, daily insulin dose	✓		✓
Psychological			
Self-efficacy (IMDSES, HeiQ)	✓	✓	✓
Illness beliefs (PMD)	✓	✓	✓
Health outcomes			
Self-management behaviors (SDSCA, weekly frequency blood testing)	✓	✓	✓
Quality of life (SF36, DHP-18)	✓	✓	✓
Psychological well-being (STAI-6, CESD-10)	✓	✓	✓
Number of appointments with diabetes nurses and consultants	Over 9 months		
MTH-related variables^a			
Acceptability of MTH (self-developed)		✓	✓
Self-efficacy to use MTH (self-developed)		✓	✓
Individual items on adequacy and quality of training, quality of technical support		✓	
Individual items on Web account usage and their perceived usefulness		✓	✓
MTH usage	Over 9 months		
Intervention fidelity^b	Over 9 months		
Patient perceptions			
Interview on MTH experience			✓

^aHbA1c: hemoglobin glycosylated; BP: blood pressure; IMDSES: Insulin Management Diabetes Self-Efficacy Scale; HeiQ: Health Education Impact Questionnaire; PMD: Personal Models of Diabetes; SDSCA: Summary of Diabetes Self-Care Activities; SF36: Short Form Health Survey; DHP-18: Diabetes Health Profile; STAI-6: State-Trait Anxiety Inventory-6; CESD-10: Center for Epidemiologic Studies Short Depression Scale-10; MTH: Mobile Telehealth.

^bAssessed in the intervention group only.

Data Analysis

The section below outlines the plans for data analysis which is currently ongoing.

Quantitative Data Analysis

Effects of the Mobile Telehealth Intervention

For the primary analyses on the effectiveness of the intervention on HbA1c, intention-to-treat analyses will be conducted using hierarchical linear models as they account for the correlations between repeated measurements. A significant *Group x Time* interaction will be interpreted as evidence for differential treatment effectiveness. Any demographic or clinical differences at baseline will be adjusted for. These primary analyses will be supplemented with secondary sensitivity analyses including only those participants who actively transmitted MTH data during the intervention period. Separate hierarchical linear models will be used to evaluate the effects of the intervention on secondary outcomes.

Mechanisms of Action of the Intervention

To evaluate whether diabetes self-efficacy and illness beliefs act as mediators of change in the outcomes, bootstrapping for mediation analyses using Preacher and Hayes macros [46] will be conducted using residualized change scores for relevant process and outcome variables.

Predictors of Usage

Hierarchical linear regressions will be conducted to examine the incremental contribution of baseline predictors and MTH-related variables in the prediction of MTH usage. Telehealth-related variables considered as potential predictors are based on the extended TAM model used in this study and include perceived usefulness, ease of use, integration into life, adequacy of training, and self-efficacy to use MTH.

Qualitative Data Analysis

A step-by-step guide for thematic analysis [47] will be followed to analyze the interview data. Transcripts will first be read

several times to become familiar with the data. Initial coding of the interviews will follow. The data will then be organized into themes and subthemes. The approach used will be inspired by the constant comparative method used in grounded theory and its combined elements of induction and deduction. This hybrid approach allows for themes identified in previous research to be considered during analysis, but also allows for unexpected findings to emerge from the transcripts. To improve the validity and reliability of the analysis, several researchers with previous experience in MTH and/or qualitative data will independently code some of the transcripts in order for themes to be compared and/or will participate in discussions on the extracted themes and supporting quotations.

Results

Overview

At this stage, data collection for both the quantitative and qualitative components of this study has ended and data analysis is ongoing. A total of 86 participants were enrolled into the study. Out of 86 participants, 45 (52%) were randomized to the intervention group and 36 (42%) to the control group. In this paper, the data presented on MTH training sessions are relative to the 44 intervention participants who received training. Data presented on other MTH-related variables including MTH usage, technical problems, and technical support experience are for the 40 intervention participants who completed the 9-month intervention.

Mobile Telehealth Training Sessions

Of the 45 participants allocated to the intervention group, 44 (98%) received training in the use of the MTH equipment (1 participant dropped out prior to finding out his allocation group). The majority of trained intervention participants (37/44, 84%) were able to transmit MTH data after the initial training session. A small group of those trained (7/44, 16%) required a second training session after experiencing ongoing difficulties in using the equipment correctly. Compared to the 37 intervention participants who only required one MTH training session—mean age 56.4 years (SD 13.9), 22% (8/37) with no formal education—these 7 participants were older and less educated—mean age 67.5 years (SD 8.6), 43% (3/7) with no formal education. These differences were not tested statistically given the small number of participants involved. At the 3-month follow-up, 17 (39%) of the 44 trained MTH participants reported they would have liked to receive more training. When asked at 3 months about the quality of the training provided, 29 (66%) of the 44 participants rated the quality of the training to be *good* or *very good*, 10 (23%) rated the quality as *adequate*, and 2 (5%) as *insufficient*.

Mobile Telehealth Usage

Table 2 describes the number of times participants transferred data during the trial, as well as the number of clinical readings

(ie, BG and BP readings) transmitted. The monthly number of data transfers ranged from 0 to 126 and the median number of transfers over 9 months was 63 (interquartile range [IQR] 242, mean 173.9, SD 232.8). Of the 40 participants, 10 (25%) of them were particularly active and transferred data between 202 and 778 times over 9 months. The monthly number of BG readings transmitted ranged between 0 and 186, and the median number of transfers over 9 months was 147 (IQR 337, mean 251.7, SD 278.0). In comparison to BG levels, BP was monitored less frequently. The monthly number of BP readings transmitted ranged between 0 and 66, and the median number of BP readings transmitted over 9 months was 19 (IQR 31, mean 33.6, SD 53.3).

Table 3 displays the timing at which BG readings were self-monitored.

Over the 9 months of the study, the median number of times physical activity and insulin dose data were transferred was 11.5 (IQR 60) and 15.0 (IQR 83), respectively. This corresponded to 40.8% (71/174) and 55.7% (97/174) of data transfer occasions for physical activity and for insulin dose, respectively. Weight information was rarely updated, with the average number of updates over 9 months being 4.08 (SD 9.47) times. A large proportion of participants (17/40, 43%) never updated their weight information.

Table 2 indicates that for all measures of MTH, usage decreased over time. The number of participants who did not transmit any data increased over the duration of the trial as seen in Figure 2. In the first month, all participants transmitted some MTH data. By month 9, there were 14 out of 40 (35%) intervention participants who did not transmit any MTH data.

Table 4 describes the different durations during which participants ceased to transfer MTH data. The majority of participants (22/40, 55%) transferred MTH data at least once every month. For the remaining participants, the number of months during which no data was transferred ranged from 1 to 8, with the majority of these participants transmitting data for at least 5 of the 9 months.

The Web interface was available to all participants, however only 5 (13%) and 6 (15%) of the 40 participants reported using the MTH Web interface at the 3- and 9-month follow-ups, respectively. The 5 participants that reported using the Web account at 3 months also reported using it at 9 months. Of the participants that used the Web interface at 3 months, 80% (4/5) reported weekly usage at this time point. Of the participants that used the Web interface at 9 months, 83% (5/6) reported monthly usage at this time point. All participants who used the Web account during the study reported that it was *quite a bit useful* or *very useful* for visualizing graphical feedback.

Table 2. Number of MTH data transfers and clinical readings transmitted during the 9-month study.

Month in trial	Number of data transfers, mean (SD)	Number of BG readings, mean (SD)	Number of BP readings, mean (SD)
Month 1	25.9 (34.2)	31.2 (37.5)	6.6 (10.5)
Month 2	23.4 (30.9)	31.4 (35.9)	5.1 (9.1)
Month 3	22.6 (31.5)	31.2 (37.0)	5.0 (9.6)
Month 4	20.8 (28.0)	27.9 (30.3)	3.3 (5.8)
Month 5	18.0 (20.5)	26.2 (27.6)	3.6 (6.0)
Month 6	16.3 (25.8)	26.7 (30.0)	3.4 (4.5)
Month 7	15.9 (26.0)	24.6 (31.9)	3.1 (5.7)
Month 8	16.1 (27.3)	28.6 (34.8)	2.2 (4.2)
Month 9	14.9 (25.2)	24.6 (33.3)	2.1 (3.9)
Over 9 months	173.9 (232.8)	251.7 (278.0)	33.6 (53.3)

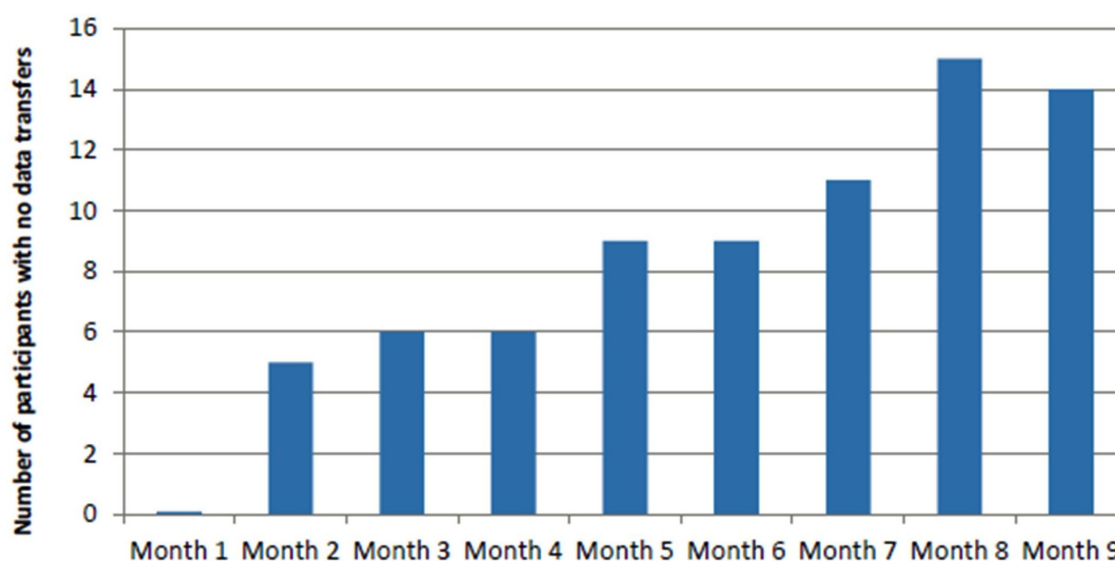
Table 3. Timing of self-monitoring of BG levels.

Timing in relation to meal	Number of BG readings (n=6959), n (%)
>8 hours after a meal ^a	1302 (18.71)
2-4 hours after a meal	1852 (26.61)
0-1 hour after a meal	1512 (21.73)
1-2 hours after a meal	969 (13.92)
4-8 hours after a meal	1324 (19.03)

^aBG readings taken >8 hours after a meal are likely to be fasting BGs.

Table 4. Length of time during which participants transferred no data during the study (n=40).

Number of months during which no data was transferred	Proportion of MTH participants, n (%)
0	22 (55)
1	2 (5)
2	2 (5)
3	6 (15)
4	1 (3)
5	2 (5)
6	1 (3)
7	1 (3)
8	3 (8)

Figure 2. Number of participants per month who did not transmit mobile telehealth data during the study.

Mobile Telehealth Technical Problems

In total, 26 of the 40 participants (65%) experienced technical problems during the study. The problems signaled were related to data transmission between devices not working properly (13 occurrences), faulty equipment or problems with equipment settings (10 occurrences), batteries on the mobile phone, BG meter, or Bluetooth cradle running out (12 occurrences), problems with the MTH app (3 occurrences), Web account log-in problems (2 occurrences), and step-by-step assistance to transmit MTH data required (8 occurrences). With the exception of complaints about the battery life in the mobile phones (3 occurrences), all technical problems were successfully resolved over the telephone or during a home visit scheduled within 1 week by the engineer on 6 occasions. Replacements for faulty equipment were sent through postal mail. The MTH Web server was down once during the study and repaired within 24 hours by the technical support team. The majority (19/22, 73%) of participants who reported having received technical support over the phone at 3 months indicated it was of *good* or *very good* quality.

Discussion

This study proposes a comprehensive assessment of an MTH intervention for people with insulin-requiring diabetes. The measurement of both clinical and patient-reported outcomes, the use of a qualitative enquiry alongside an RCT, and the focus on intervention delivery and usage still remain relatively uncommon in complex interventions [20,24,48] and are included in this study's design and scope.

The preliminary data presented in this paper shows that the initially targeted sample size of 248 was not reached. Several reasons may help explain the low participation rate experienced in this study, including poor attendance to clinic visits, changes to the clinic patient discharge policy, and recruitment to other

TH trials at the diabetes unit where our recruitment took place—the recruitment challenges experienced in this study will be discussed in another paper. Such recruitment difficulties are not uncommon in TH trials [49,50].

The early data presented on MTH usage in this paper clearly indicates a decrease in MTH usage over time. Gradual declines in usage have been observed in other TH studies [51-53]. A positive interpretation of these declines over time proposed by Larsen et al [52] is that participants may become less dependent on MTH because of perceived improvements in the management of their condition. Another possible explanation for the decrease in usage over time is that the novelty of the new technology wears off. Mobile phone network coverage is unlikely to have influenced MTH usage in this study as coverage is generally good in the UK and was not one of the problems the MTH participants reported experiencing. Other technical problems occurred, but our data showed they were dealt with successfully and promptly by the technical support team. Making sure that satisfactory technical support is provided in MTH studies is key as technical problems can result in increased dropouts and negative attitudes toward MTH [54].

The Web component of the MTH system remained unused by a large majority of the intervention participants (34/40, 85%) who completed this study. Participants were informed about the possibility of using the Web accounts at the beginning of the study. However, the MTH training sessions did not include instructions relating to the MTH Web accounts, therefore, this is likely to have contributed to their low use. Low Web account usage in this study may also have been related to the lack of Internet access in 63% of households in Newham [55], low perceived need of access or usefulness of this data, disinterest, or lack of awareness of the existence of a Web component.

Our study data showed that 39% (17/44) of MTH participants reported they would have liked to receive more training. Other studies have highlighted that some participants using TH may

require a period of adjustment and familiarization with technology, and that TH may be associated with technology-related anxiety [56,57]. Together with our findings, these studies suggest that some MTH users may benefit from attending more than one training session. Of the 44 MTH participants trained in our study, 7 (16%) were unable to use the MTH equipment correctly and required a second training session. Their characteristics suggested that factors such as age and educational attainment may be related to training requirements, however these relationships were not investigated statistically, given the small number of participants concerned. A small amount of research has examined factors related to TH usage compliance [51,58], but there has been little emphasis on

predictors of MTH training needs. Larger studies should aim to identify the individual characteristics associated with greater MTH training needs, which could further help improve the tailoring of MTH interventions.

This paper provides details of MTH usage data and other information collected in this study on the quality and adequacy of the MTH training sessions, and on the technical problems experienced by MTH participants. Few MTH studies provide sufficient information on technology usage, despite this being an important measure of participants' receipt and adherence to the intervention. The data presented in this paper are related to intervention fidelity and are, therefore, crucial in considering the internal validity of the study.

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Authors' Contributions

All authors were equally involved in the design of the study. JB was responsible for study implementation and data collection under the supervision of SN and SH. JB is the primary author of this paper, and revisions were made by SN and SH.

Conflicts of Interest

None declared.

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Abbreviations

BG: blood glucose

BMI: Body Mass Index
BP: blood pressure
CESD-10: Center for Epidemiologic Studies Short Depression Scale
DHP-18: Diabetes Health Profile
HbA1c: glycated hemoglobin
HCP: health care professional
HeiQ: Health Education Impact Questionnaire
HRQoL: health-related quality of life
IMDSES: Insulin Management Diabetes Self-Efficacy Scale
IQR: interquartile range
MRC: Medical Research Council
MTH: mobile telehealth
NHS: National Health Service
PMD: Personal Models of Diabetes
RCT: randomized controlled trial
SDSCA: Summary of Diabetes Self-Care Activities
SF12v2: Short Form-12
STAI-6: State-Trait Anxiety Inventory
TAM: Technology Acceptance Model
TH: telehealth

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Original Paper

Social Media in Adolescent Health Literacy Education: A Pilot Study

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Abstract

Background: While health literacy has gained notice on a global stage, the initial focus on seeking associations with medical conditions may have overlooked its impact across generations. Adolescent health literacy, specifically in dentistry, is an underexplored area despite the significance of this formative stage on an individual's approach to healthy lifestyles and behaviors.

Objective: The aim is to conduct a pilot study to evaluate the efficacy of three major social media outlets - Twitter, Facebook, and YouTube - in supporting adolescents' oral health literacy (OHL) education.

Methods: A random sample of 22 adolescents (aged 14-16 years) from an English-medium international school in Hong Kong provided informed consent. Sociodemographic information, including English language background, social media usage, and dental experience were collected via a questionnaire. A pre- and post-test of OHL (REALD-30) was administered by two trained, calibrated examiners. Following pre-test, participants were randomly assigned to one of three social media outlets: Twitter, Facebook, or YouTube. Participants received alerts posted daily for 5 consecutive days requiring online accessing of modified and original OHL education materials. One-way ANOVA (analysis of variance) was used to compare the mean difference between the pre- and the post-test results among the three social media.

Results: No associations were found between the social media allocated and participants' sociodemographics, including English language background, social media usage, and dental experience. Of the three social media, significant differences in literacy assessment scores were evident for participants who received oral health education messages via Facebook ($P=.02$) and YouTube ($P=.005$).

Conclusions: Based on the results of the pilot study, Facebook and YouTube may be more efficient media outlets for OHL promotion and education among adolescent school children when compared to Twitter. Further analyses with a larger study group is warranted.

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KEYWORDS

social media; health literacy; oral health literacy; dentistry; adolescents; oral health; health informatics

Introduction

Background

The notion of “health literacy” (HL) has established itself in the health care literature in the past 30 years [1] with increasing efforts made at adapting the concept to dental practice and oral health care research [2-10]. “Oral health literacy” (OHL) has, therefore, been defined as “the degree to which individuals have the capacity to obtain, process and understand basic oral and craniofacial health information and services needed to make appropriate health decisions” [11]. Various instruments have been developed to measure the oral health literacy levels of individuals [12] as related to specific conditions such as early childhood caries [13] and periodontal problems [14]. Little work, however, has been undertaken to explore associations between HL across generations, especially adolescent populations.

Adolescence and Health Literacy

While low health literacy is prevalent among all age groups, adolescents, to a more limited extent than adults [15], have been indicated as a group worthy of particular attention, with little research on this topic conducted, to date, in secondary school environments [16]. The motivation to address adolescent HL can be viewed in chronological terms given that adolescents are both current “dependent users” as well as the future “independent users” of the health care system [16]. As such, adolescence is a crucial period for adapting lifelong health behaviors and habits and may be a key juncture for HL interventions supporting informed, health-seeking lifestyles across adulthood. Existing studies have established that low adolescent literacy/health literacy is associated with risky behaviors including tobacco use and aggression [17], obesity [18], and lower levels of health-promoting behaviors [19]. As health systems increasingly rely on internet usage and, as adolescents are the early adaptors of new technologies, the suggestion that access to online health services, presents another medium to build health literacy [20] could be relevant to this specific group.

Social Networking Websites

The increasing dependence of patients on social media websites as a source of health care information indicates a need for future studies to assess their impact on health care utilization and outcomes [21]. Emerging social media websites play a vital role in online health searches [22]. Studies in the United States have revealed high usage of Web 2.0 social media sites such as Facebook, YouTube, Twitter, MySpace, and Second Life among Americans aged 18-30 years with two thirds of the population claiming to have visited these sites frequently [23,24]. Facebook has continued to expand its features to compete with instant sharing of videos, images and text updates. For example, during the 2008 US election, almost 8% of people polled under age 30 became an online Facebook “friend” of one of the presidential candidates [25].

With more than 100 million videos being viewed on YouTube everyday [26], researchers are recognizing that YouTube holds value for personal health decision-making [27]. Twitter is

another highly prominent and widely used medium with approximately 572,000 new accounts created in the month of March 2011 alone [28]. One recent study has used Twitter as a real-time avenue for monitoring public health, specifically for non-medical use of the psycho-stimulant drug, Adderall, among college students [29]. The effect of social media on oral health is under-researched, however, the available evidence demonstrates the importance of social media as a health education tool. Recent work has called for oral health care professionals to recognize the importance of social websites in shaping public opinion about their profession [30].

Adolescents and Media Literacy

Researchers have emphasized the need for empowerment education, particularly among children and adolescents [31-33], as an effective health education and prevention model for personal and social change [34-37]. Literature on media literacy and prevention has also demonstrated the importance of critical thinking skills for adolescents to make proper use of media and reduce health risk-taking [37-39]. Bergsma’s 2004 analysis of media literacy and the American Legacy Foundation’s Truth Campaign on tobacco misrepresentations indicated how younger generations “can be powerful advocates for social change through use of the media” [37]. In addition, she recommended that the primary focus of both media literacy and health promotion programs should be to identify the social concerns of youth in order to help them to channel their fresh perspective, unique energy and creativity toward accomplishing social change [37].

Life Course Analysis Theory for Social Determinants of Health

In addressing the need to examine health literacy and social media, this project has taken into account life course analysis theory into the social determinants of health. This approach focuses on individual levels and seeks to explore cognitive and affective processes determining behavior and lifestyle [38]. Research indicates that the stage of transition from primary to secondary school is a critical period in determining the health status of individuals and levels of health inequalities [39]. Life course analysis, therefore, places its focus on social context and the interaction between people and their environments in the passage through life [38]. Drawing on this theory, this study further explores the “importance of timing” and identifies “windows of opportunity” for adolescents [40] by conducting an oral health literacy intervention utilizing three major social media outlets, Facebook, Twitter and YouTube, with secondary school students. A core research question was, which social media platform has a greater impact on adolescents’ development of oral health literacy? Ultimately, the goal of this study is to produce greater understandings for health promotion providers on how to better utilize social media to disseminate health messages for the purposes of preventative and long-term benefits for adolescents and their future oral health.

Methods

Recruitment

This was a cross-sectional pilot study conducted on a random sample of 22 English-speaking adolescents (aged 14-16 years) recruited from grades 9 and 10 in an English-medium international school in Hong Kong. The parents were contacted through the school with an explanation of the objectives of the study and written informed consent was obtained. Participation was voluntary and no additional efforts were made to enroll the participants. Eligibility criteria included healthy, English-speaking participants who were 14-16 years old. Each social medium was randomly assigned to the study population in order to reduce the probability of bias. This study was approved by the Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (UW-12-385).

Materials

Two pre-trained examiners independently conducted the pre- and post-test oral health literacy assessments (REALD-30) and a good inter-examiner agreement was found with Kappa statistics [41]. As a validated word recognition instrument, REALD-30 was developed particularly for the oral health context [7]. It is interview-based, requiring participants to read aloud a list of 30 oral health-related words arranged in increasing order of difficulty (time is 2 minutes).

For the OHL education phase, participants received alerts posted daily for 5 consecutive days requiring online accessing of the modified and original OHL education materials which were reviewed by an expert panel. The online oral health education materials originated from multiple sources: public information provided by the Hong Kong Department of Health [42], educational websites, YouTube videos, and original materials developed and reviewed by an expert panel for this study. These were, therefore, seen as relevant to the target group. Any adaptations of existing online materials were based on the

modality of the target social networking medium (ie, text-only-Twitter, video-YouTube, and still images and text-Facebook). Each message posted on the particular social media outlet contained the same principal message.

Statistical Analysis

Data analyses were carried out using the Predictive Analytic Software (PASW) statistics version 18.0. The inter-examiner reliability was assessed with Kappa statistics. Descriptive statistics were produced to examine the profile of the study group followed by one-way Analysis of Variance (ANOVA), a statistical method used to test the differences between two or more means. Two sets of analyses were undertaken. First, significant differences of the mean between the three social media groups with respect to participants' sociodemographic characteristics were examined with Fischer's exact test. Second, the mean difference between the pre- and the post-tests of participants among the three social media groups were compared.

Results

User Statistics

Table 1 presents the sociodemographic profile of the study group. After random allocation, there was equal distribution of participants in both Grade 9 and 10 who received YouTube and Twitter, whereas 75% of Grade 9 students received Facebook. The average age of participants was approximately 14-15 years; the ratio of boys to girls was slightly higher in the YouTube group. More than 87.5% of the group's parents were employed with a monthly family income of over HKD 40,000. Of the participants, 60% were born in Hong Kong with predominantly 90% being of Chinese ethnicity. There was significant difference found with participants' birth country ($P=.02$). Participant's average years of speaking English were mixed but over 50% reported having spoken English for 5-10 years. Over 60% of the subjects reported regular past dental attendance.

Table 1. Sociodemographic profile of the study group (n=22).

		Twitter (n=6)		Facebook (n=8)		YouTube (n=8)		<i>P</i> value ^d
		n	Valid %	n	Valid %	n	Valid %	
Grade								
	Grade 9	4	66.7	6	75.0	4	50.0	0.66
	Grade 10	2	33.3	2	25.0	4	50.0	
Age								
	14 years old	3	50.0	6	75.0	4	50.0	0.83
	15 years old	2	33.3	2	25.0	3	37.5	
	16 years old	1	16.7	-	-	1	12.5	
Gender								
	Male	3	50.0	4	50.0	5	62.5	1.00
	Female	3	50.0	4	50.0	3	37.5	
Parent's employment								
	Unemployed	-	-	1	12.5	-	-	1.00
	Employed	6	100.0	7	87.5	8	100.0	
Country of Birth								
	China	3	50.0	-	-	-	-	0.02
	Hong Kong	3	50.0	7	87.5	7	87.5	
	Others	-	-	1	12.5	-	-	
Ethnicity^a								
	Chinese	1	100.0	7	87.5	1	100.0	1.00
	Others	-	-	1	12.5	-	-	
Years of speaking English								
	5-10 years	5	83.3	3	37.5	6	75.0	0.22
	11-16 years	1	16.7	5	62.5	2	25.0	
Parent's income^b								
	<30000HKD	-	-	-	-	-	-	1.00
	30000-40000HKD	-	-	1	14.3	-	-	
	>40000HKD	6	100.0	6	85.7	6	100.0	
Dental experience								
	Irregular	2	33.3	-	-	2	25.0	0.28
	Regular	4	66.7	8	100.0	6	75.0	
Social media experience								
	Seldom	-	-	1	12.5	1	12.5	0.32
	Sometimes	1	16.7	1	15.4	-	-	
	Often	1	16.7	5	62.5	4	50.0	
	Always	4	66.7	1	12.5	3	37.5	

^a12 participants did not complete this section^b3 participants did not complete this section^c1USD = 7.76HKD^d*P*-value of 2-sided Fisher's exact test (in 2 decimal places); Fisher's exact test was used to compare the proportions among the 3 different media groups.

Evaluation Outcomes

The self-reported social media experience was mixed between the three social media groups (Table 1). One-way ANOVA between the three groups revealed no significant associations between the social medium allocated and participants' sociodemographics, including English language background,

social media usage, and dental experience. The descriptive statistics of the pre- and post-test scores are shown in Table 2. Of the three social media, higher literacy scores were found in subjects who received oral health education messages via Facebook ($P=.02$) and YouTube ($P=.005$). There was high inter-examiner reliability with the kappa value as 0.81.

Table 2. REALD-30 scores pre- and post-test (score out of 30).

	Pre-Test				Post-Test				<i>P</i> value ^a
	Mean	SD	Min	Max	Mean	SD	Min	Max	
Twitter	16.17	1.83	14.00	19.00	18.00	3.90	15.00	25.00	.32
Facebook	14.50	5.40	7.00	22.00	17.38	4.62	13.00	24.00	.02
YouTube	14.50	5.42	7.00	21.00	18.63	3.42	14.00	24.00	.005

^aOne-way ANOVA

Discussion

Principal Results

The results of this pilot study indicate that the social media websites YouTube and Facebook may be more effective in increasing the levels of oral health literacy among adolescents when compared to a short, text message format such as Twitter. This may suggest that the additional audio-visual delivery of health education may improve (oral) health literacy levels more than a solely text-based medium. New Web 2.0 technologies have afforded multimodal literacies and ways to learn with multiliteracy research indicating that students engaged in learning that incorporates multimodal designs, on average, outperform students who learn using print-based, single modes only [43]. Our results support this work as those participants who received messages from Facebook and YouTube with visual plus text or audio-visual information scored significantly higher than text-based Twitter. Indeed, new instruments are embracing this need to assess multi-literacies within health literacy research [44]. However, due to the small number of participants in the pilot study, a larger sample size would make this implication more convincing.

Life-Course Analysis

In addition to highlighting the utility of social media for health literacy interventions and assessments, the results of this study support the life course analysis theory of the social determinants of health. Life course analysis is a sociological framework emphasizing that life decisions and behaviors are shaped by age, social structures, and historical change [45]. Facebook, as one of the most popular social networking sites is a new historical change in how we interact socially. Life course analysis also places focus on social context and the interaction between people and their environments in the passage through life [38]. The opportunity to increase engagement and interaction of digitally-connected adolescent learners through social media signals potential benefits for improving adolescent literacy [46].

Comparison With Prior Works

This is a pilot study to explore the effects of social media on the oral health literacy levels of adolescents. The literature indicates that social networks and participatory videos with

medical and dental content have started to gain influence in opinion formation by the members of the general public [40,47-51]. The importance of the wide availability and potential influence of YouTube videos regarding dentistry were emphasized in the study by Knosel et al which found that "education videos have a higher degree of usefulness and informational value for laypersons, dental students, and dental professionals than those found in the broader search category" [30]. A recent review has emphasized the importance of social media for disease surveillance concluding that "the growing evidence base regarding the utility of social media for disease surveillance will hopefully encourage academia, industry, the public service, and international organizations to consider social media in a serious light, particularly as a means of engagement rather than just disseminating information" [52].

Limitations

The study's results have to be considered in light of its limitations. First, this was a pilot study with a smaller sample size. The sociodemographic variations in the sample were not apparent. More work with larger sample sizes would support further exploration of the influence of sociodemographic variations and the effects of social networks on the oral health literacy levels of adolescents. Second, the participants were recruited from a high socioeconomic status group (monthly income \geq HKD 40,000). This could induce the probability of bias, if one is to infer increased access to technology and these social media because of financial status [53]. Third, this is cross-sectional study, and it would be difficult to establish causality if another time frame was chosen. Finally, the use of a simple word recognition instrument REALD-30 might also be a source of bias, because of its inability to measure the other dimensions (numeracy, reading comprehension, and conceptual knowledge) of oral health literacy [12,44]. However, the study has its own strengths both in terms of innovative material design and target population as well as its attention to the digital aspects of health literacy [53]. The result of future studies with larger sample sizes will also enable health care providers and educators to tailor simplified oral health education materials.

Conclusions

Based on the preliminary results of this pilot study, it has been possible to conclude that the audio-visual social media of

Facebook and YouTube may be more efficient for oral health promotion amongst a sample of adolescent school children when compared to a simple text-based medium such as Twitter.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Oral health educational materials.

[[PDF File \(Adobe PDF File\), 348KB - resprot_v4i1e18_app1.pdf](#)]

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Abbreviations

ANOVA: analysis of variance

HL: health literacy

OHL: oral health literacy

REALD-30: Rapid Estimate of Adult Literacy in Dentistry

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Original Paper

An Accumulated Activity Effective Index for Promoting Physical Activity: A Design and Development Study in a Mobile and Pervasive Health Context

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Abstract

Background: Increased physical activity has become a principal personal health goal worldwide because sufficient physical activity can reduce the risk of many adverse conditions. Motivating individuals to increase their levels of physical activity can increase life expectancy and contribute to a healthy life. Sharing and comparison of physical activity information by using the Internet, with fewer privacy concerns, might also help encourage people to promote and maintain sufficient physical activity. To promote and manage physical activity, an accumulated activity effective index (AAEI) is proposed in this paper.

Objective: The purpose of the AAEI design is to maintain and promote physical activity. The public can easily accept a clear indicator that reveals the current status of physical activity. The AAEI is not only an assessment and tracking tool for personal physical activity, but is also useful for goal setting and for sharing content with the Internet community.

Methods: The AAEI is derived from input in the form of accumulated physical activity, and evaluates the status of physical activities and days spent exercising. The term $AAEI(t_1, t_2)$ is an index of the accumulated physical activity in the time interval (t_1, t_2) , where the base unit of time is the day. The AAEI is determined according to accumulated physical activity and is adjusted using the previous status of physical activity. The previous status of physical activity is estimated according to the number of days spent exercising and the accumulated physical activity that has been performed. An analysis of the AAEI performance was conducted using a simulation model and a real-world trial with 2 participants.

Results: The AAEI increased as the physical activity and days spent exercising accumulated. Conversely, the AAEI decreased with lack of physical activity and increased resting days. In simulation, the shape of the AAEI line indicated different types of exercise. The moving average AAEI represented long-term exercise. In the real-world trial, the AAEI confirmed that the simulation results were comparable to actual conditions.

Conclusions: The AAEI proposed in this paper is a method that can be used to evaluate the status of a person's physical activity. The AAEI is a simple numeric indication that is estimated by analyzing accumulated physical activity and the average number of days spent exercising. The AAEI is suitable for tracking personal physical activity, reminding the user of achievement goals, and allows data sharing by using the Internet. The results have demonstrated that the AAEI is a useful tool for physical activity management.

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KEYWORDS

accumulated activity effective index (AAEI); physical activity; activity level

Introduction

Sufficient physical activity has substantial benefits for a healthy life. Regular and moderate intensity of physical activity, such as fast walking, running, and cycling, can reduce the risk of coronary heart disease, type 2 diabetes mellitus, and depression, as well as facilitate weight control [1-3]. Moreover, physical activity increases bodily health and improves cognitive functioning. It increases resistance to neurodegenerative diseases, dementia, and related cognitive impairments [4]. Unfortunately, 31.1% of adults worldwide are physically inactive. Physical inactivity increases with age and is more prevalent in high-income countries [1]. According to previous studies, physical inactivity is the fourth leading risk factor for mortality and noncommunicable diseases, and caused 5.3 million deaths worldwide in 2008 [5]. Physical inactivity increases the risk of many adverse health conditions and threatens global health. The elimination of physical inactivity can increase life expectancy and contribute to a healthy life.

Pervasive computing technologies are well suited for health care applications and have the potential to promote a healthy lifestyle. Several well-known studies have been proposed using pervasive computing technologies to assist individuals in achieving sufficient physical activity [3,6-9]. For example, the pedometer can become a human activity sensor used to monitor physical activity and promote health because walking is a health-boosting activity and a pedometer can help motivate and track progress. Although the accuracy of pedometers can be unreliable, they have been shown to motivate individuals toward a more active lifestyle [8-10]. The progress of measuring instruments has allowed multiple sensing modules to be built which can provide information such as blood pressure and heart rate. This information is critical in health care applications; however, the professional terms and complicated interface can confuse the public and can be a barrier to the popularization model for usage of such instruments; for the public, a simple indicator is easier to accept.

Motivating individuals to increase their levels of physical activity is a critical issue in health promotion. Numerous studies have focused on the social aspects revealing that the sharing and comparison of information regarding physical activity within the community can increase interest in, and enjoyment of, exercise and can motivate people to be more active [7,9,11]. The high penetration of Internet and community websites can enhance communication in groups and can be used as a medium to motivate physical activity. However, personal context information such as time, location, and heart rate when shared using the Internet can suffer personal privacy problems. Other studies suggest that goal setting can increase self-regulatory behaviors and improve physical activity [12]. An accumulated activity effective index (AAEI) is proposed in this paper for evaluating the status of physical activity and sharing related information with communities on the Internet. The AAEI is designed to provide a simple numeric indication of accumulated physical activity and days spent exercising, with fewer privacy concerns than personal context information. The AAEI is designed to increase awareness of physical activity by tracking physical activity, reminding the user of achievement goals, and

sharing this information with the Internet community. The AAEI is also suited for self-awareness in maintaining physical activity. The performance of the AAEI was illustrated using a simulation model and a short-term real-world trial using pervasive computing tools.

Methods

Accumulated Activity Effective Index

The AAEI was designed as a simple numeral indicator that directly reveals the physical activity status of the user by estimating both accumulated physical activity and days spent exercising. The design principles of the AAEI were (1) AAEI is a simple value to reveal physical activity; (2) AAEI corresponds to physical activity; (3) AAEI increases with more physical activity, is steady in fixed physical activity, and decreases with less physical activity; (4) AAEI corresponds to days spent exercising; (5) AAEI decreases with resting days; (6) AAEI decreases more with continued resting; (7) AAEI decreases less at rest if user has exercised before; and (8) AAEI is at or near zero if the user does not exercise in 7 days. The AAEI parameters and evaluating process (Equation 1) are described in Figure 1.

The term $AAEI(t_1, t_2)$ is an index of the accumulated physical activity in the time interval (t_1, t_2) , where the base unit of time is the day. The AAEI is greater than or equal to zero. The $AAEI(t_1, t_2)$ is calculated by tracking the sum of $AAEI(t_1, t_2-1)$ and the amount of physical activity in t_2 . The variable $MT(t_2)$ represents the amount of physical activity in t_2 , which is equal to the activity level multiplied by the exercise duration. The variable $E(t_2)$ is defined as the exercise expectation of physical activity in t_2 , which depends on the previous interval (t_1, t_2-1) status of physical activity include accumulated physical activity and days spent exercise. Parameter k is a constant value and is greater than zero to scale the AAEI. The design of k in a different constant or a variable can be a condition depending on $AAEI(t_1, t_2-1)$, $MT(t_2)$, or others. For example, k can increase with activity level, in which case participants exercise harder and can get a higher AAEI because AAEI increases more during vigorous activity. In another example, if k rises when $[MT(t_2)-E(t_2)] < 0$, the user needs to sustain physical activity to maintain AAEI.

The previous status of physical activity was defined as *exercise expectance*, which is greater than or equal to zero and was formulated using Equations 2 and 3 in Figure 1. The notion of exercise expectation, $E(t_2)$, was that if a participant had a high AAEI, a participant was expected to require more physical activity to increase the AAEI. Otherwise, AAEI would be stable or decrease. Another design objective for exercise expectation was to reveal days spent exercising. The more days a participant rested, the more the AAEI index decreased. The variable $A(t_1, t_2-1)$ is the basic value defined as $AAEI(t_1, t_2-1)/7$. The variable C is a constant greater than zero, which adjusts the decreasing percentage of resting. In the design principle, no decreasing is defined when there is no resting. In other words, if a participant exercises every day, the AAEI does not decrease.

Increasing constant C decreases the average AAEI, but does not increase the AAEI at the same amount of accumulated physical activity. Parameter α is a coefficient determined by previous accumulated physical activity. The variable W is a constant of attenuation that decreases the influence of previous physical activity. Thus, the greater the value of W , the more the previous accumulated physical activity and days spent exercising affect the exercise expectance. To achieve convergence, the absolute value of W should be less than 1 in Equation 3 in Figure 1. To receive the positive AAEI, the multiplication of k and C to the power of the summation of W to the power of $(i-1)$, where i goes from 1 to (t_2-t_1) should be less or equal to 7. In this study, for example, we set W at 0.5 causing the influence of previous

accumulated physical activity to decrease 50% after 1 day. The variable t indicates the day—zero for today, 1 for yesterday, and so forth. According to the aforementioned conditions, the range of α is between -2 and infinity, and the range of $E(t_2)$ is between $A(t_1, t_2-1) \times C^2$ and zero. The initial condition of the AAEI evaluation process to be set was $AAEI(t_1, t_2)=0$, $E(t_2)=0$, and α was null because there was no physical activity recorded before. The AAEI is useful for evaluation purposes from the first time a person performs physical activity. Because $A(t_1, t_2-i)$ is null the first time to estimate AAEI, parameter α is calculated the first time after physical activity is recorded. In our prototype experiment, the defined parameters $k=1$, $W=0.5$, and $C=2$ are used to examine the performance of the AAEI.

Figure 1. The accumulated activity effective index (AAEI) parameters and equations for the evaluating process (equation 1) and exercise expectance (equations 2 and 3).

Equations:

$$AAEI(t_1, t_2) = AAEI(t_1, t_2 - 1) + k \times [MT(t_2) - E(t_2)] \quad (1)$$

$$E(t_2) = A(t_1, t_2 - 1) \times C^{-\alpha} \quad (2)$$

$$\alpha = \sum_{i=1}^{t_2-t_1} \frac{MT(t_2-i) - A(t_1, t_2-i)}{A(t_1, t_2-i)} \times W^{(i-1)} \quad (3)$$

Parameters:

AAEI: $AAEI \geq 0$, an index	(t_1, t_2): time interval from t_1 to t_2 , unit: day
k: $k > 0$, a constant defined as 1	$MT(t_2)$: $MT(t_2) \geq 0$, activity level multiple duration in day t_2
$E(t_2)$: $E(t_2) \geq 0$, exercise expectation	$A(t_1, t_2 - 1)$: $AAEI(t_1, t_2 - 1)/7$
C: $C > 0$, a constant defined as 2	α: $-2 \leq \alpha < \infty$, a coefficient estimated by accumulated physical activity
i: i -th days before	W: $0 < W < 1$, a constant of attenuation defined as 0.5

Simulation Model

A simulation model was used to test the long-term performance of the AAEI. Based on the assumption adopted in previous analyses of human dynamics, human behavior comprises temporal statics, which are uniform and stationary. In other words, most human activities can be described using a Poisson process [13-14]. Based on these characteristics, the simulation model simulated participants partaking in exercise of various exercise durations, and the average activity level for each exercise had a Poisson distribution. The distribution of days of the week on which participants exercised was random. Different types of exercise habits were included to simulate the performance of the AAEI.

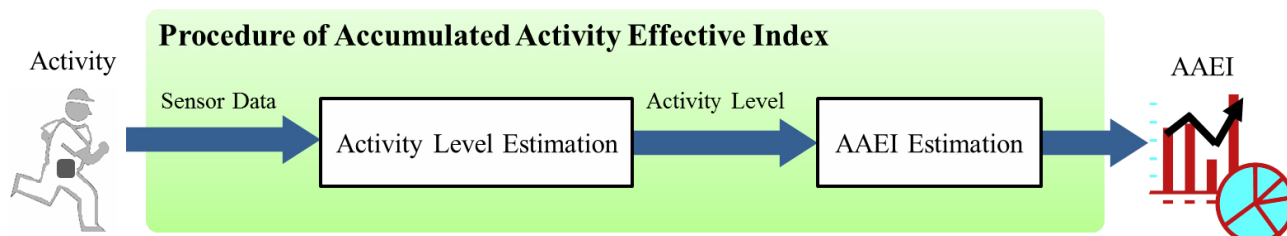
Real-World Trial

Two participants were recruited to test the AAEI performance in a real-world application. Before the AAEI evaluation, participants estimated their activity levels and exercise duration as inputs of physical activity evaluation process, as shown in Figure 2. Several methodologies were developed to estimate physical activity, such as calorimetry, double-labeled water, questionnaires, and wearable sensors. This study used a triaxial accelerometer (Opal, APDM Inc, Portland, OR, USA) to estimate activity levels because it is inexpensive, accurate, small, objective, sensitive, and suitable for the storing of personal records. Several studies have estimated activity levels by using accelerometers [15-17]. The activity level estimation methodology employed in this study was designed based on that of Liu et al [15]; the experimental results of this study showed high accuracy levels of approximately 80%. The

sampling rate of the triaxial accelerometer was 40 Hz. The sensor was worn on the right side of the front of the waist. To reduce any deviation in the estimation of activity level, the exercise tasks were limited to walking, fast walking, and

running, and were all performed using a running machine at various velocities. All participants were allowed to perform the tasks within their discretion during the 1-month trial period. The AAEI was estimated once per day.

Figure 2. The process in a real-world trial. The first stage was activity level estimation. The second stage was AAEI estimation. The sensor data translated to activity level in first stage and then converted to AAEI in second stage.



Results

General Results

The ideal amount and period of physical activity was used as input to illustrate the general performance of the AAEI. A total of 100 metabolic equivalent of task (MET)-minutes were evenly distributed over 1, 3, 5, and 7 day(s) in a week (Table 1) over a period of 4 weeks as shown in Figure 3. The AAEI increased when physical activity increased, did not increase when physical

activity was stable, decreased when physical activity decreased, and decreased further if continuous resting occurred. The weekly average of the AAEI over the 4 weeks is shown in Figure 3. The AAEI continued to increase in the first week, but became stable after the second week. The i -day (where $i=1, 3, 5, 7$) averages of the stable AAEI changed because of various resting days. The average percentage of the AAEI on different days of physical activity under stable conditions is presented in Figure 4.

Table 1. Input distribution of ideal and periodic physical activity in a week.

Exercise days per week	Input (MET-minutes)						
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1	0	0	0	0	0	0	100
3	0	33.3	0	33.3	0	0	33.3
5	0	20	20	0	20	20	20
7	14.3	14.3	14.3	14.3	14.3	14.3	14.3

Figure 3. (a) AAEI of ideal and periodic physical activity input and (b) week average of AAEI.

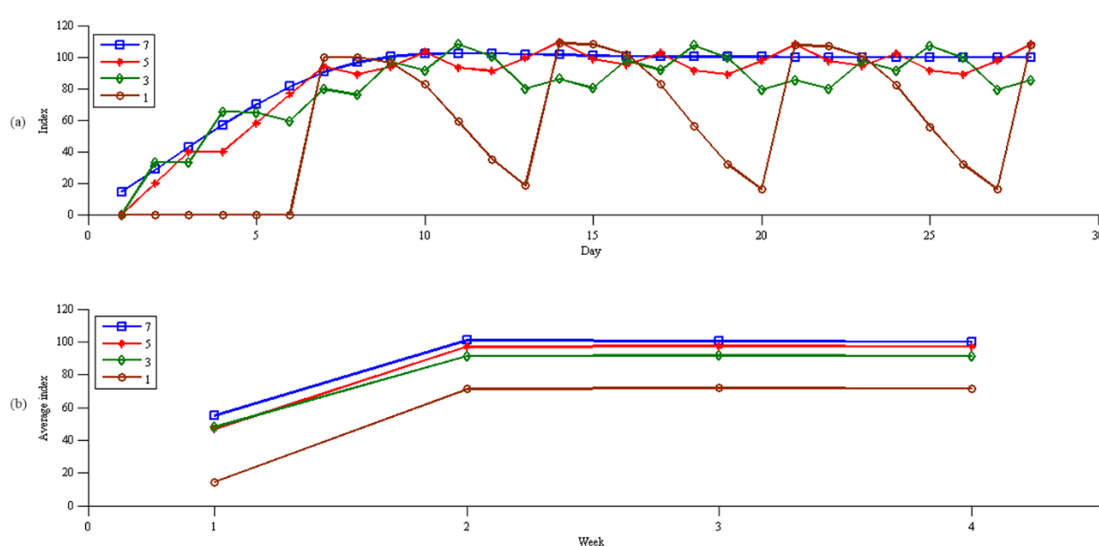
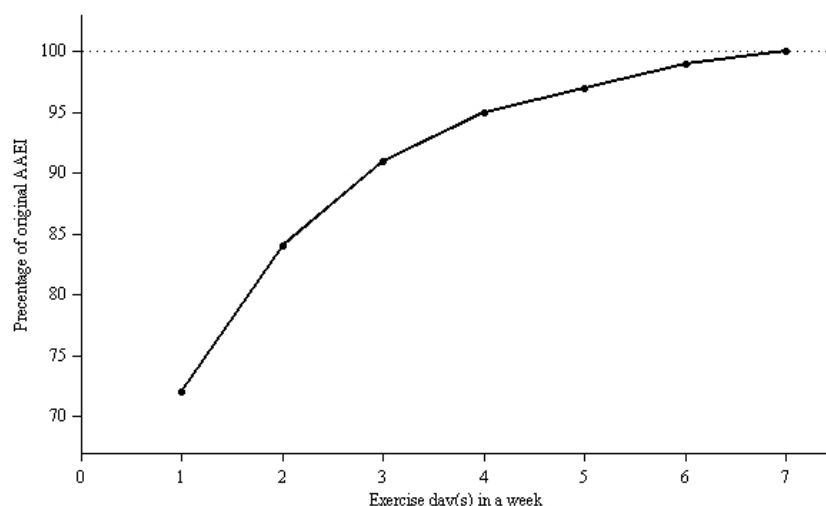


Figure 4. Average percentage of AAEI for different exercise days per week in an ideal situation.

Simulation Results

Three simulation results are presented to show the long-term performance of the AAEI. Each simulation result included different types of physical activity input to present different exercise conditions. Figure 5 shows the exercise protocol proposed by the World Health Organization (WHO), which recommends exercising 5 days per week, each exercise having a 30-minute duration and 5 MET on average. These recommendations were used as parameters and entered into the simulation model. The simulation model generated an average of 718 MET-minutes per week and 4.8 days spent exercising per week over a year. The average AAEI was 663 for 1 year. The ideal ratio of AAEI to physical activity (ideal AAEI/PA), as shown in Figure 4, was 0.97. The ratio of AAEI to physical activity (AAEI/PA) in the simulation was 0.92. The day line of the AAEI went up and down based on the average AAEI value. The longer-term moving averages showed smoother line changes than the average AAEI value.

Some people perform vigorous physical activity, but only for a short time interval. To simulate this condition, the simulation

model set 2 days of exercise per week, each with an average duration of 20 minutes, and an average activity level of 10 MET. The simulation model generated 313 MET-minutes per week and 1.6 days spent exercising per week, on average, over a year. The average AAEI was 254. The ideal AAEI/PA was 0.80 and the AAEI/PA was 0.81. Figure 6 shows the results of the simulation and the AAEI estimate. The day line of the AAEI formed a peak when physical activity was performed and formed a valley when there was a lack of physical activity.

To simulate physical inactivity, the simulation model was set at 2 days spent exercising per week, each with an average duration of 15 minutes and an average of 5 MET as parameters. The simulation model generated an average of 127 MET-minutes per week and 1.5 days spent exercising per week over a year. The average AAEI was 100. The ideal AAEI/PA was 0.78 and the AAEI/PA was 0.79. Figure 7 shows the simulated results; the day line of the AAEI formed a steep shape when continuous resting occurred and the AAEI line was often low and near the zero line.

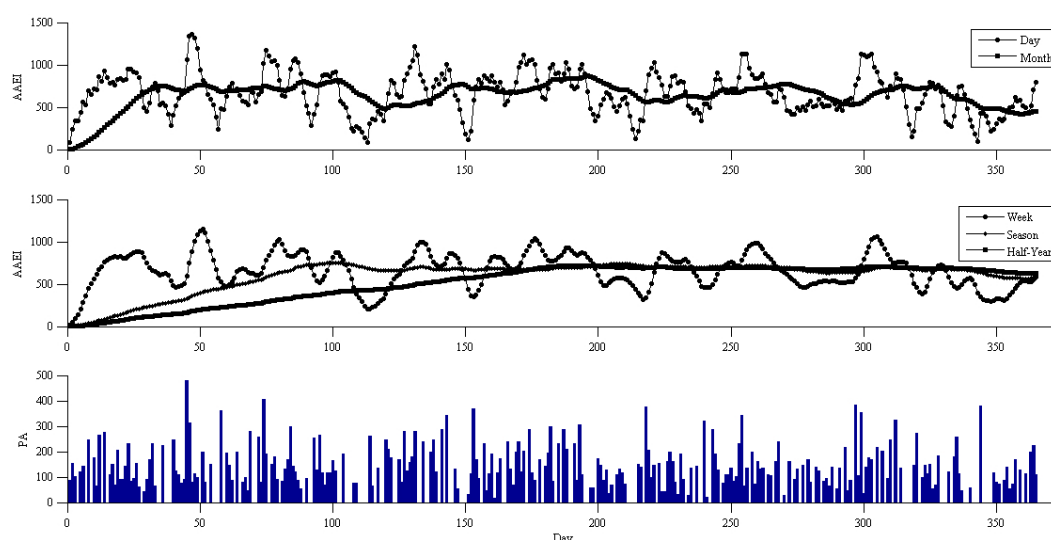
Figure 5. AAEI/PA simulation results with input of 5 days per week, duration of 30 minutes, and 5 MET.

Figure 6. AAEL/PA simulation results with input of 2 days per week, duration of 20 minutes, and 10 MET.

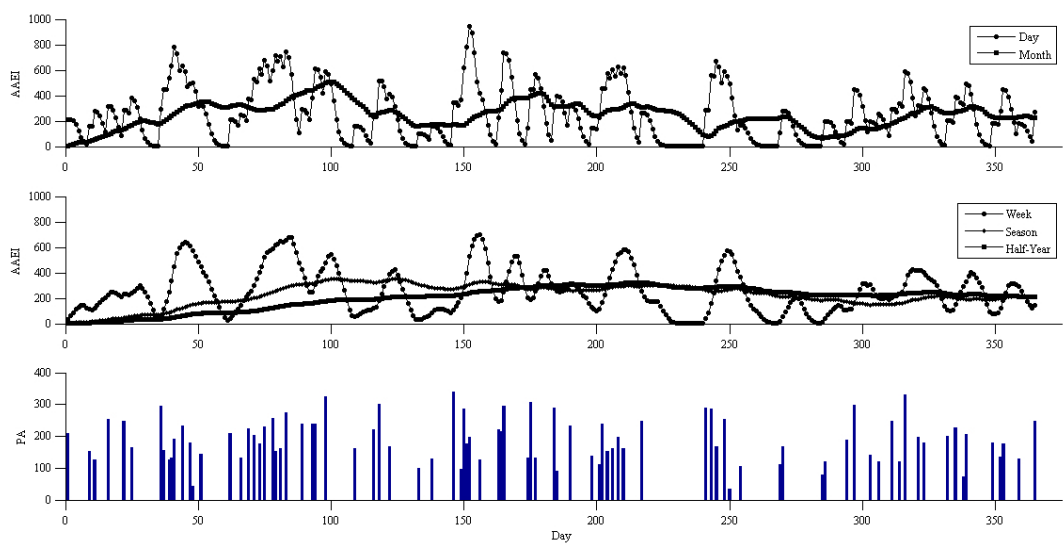
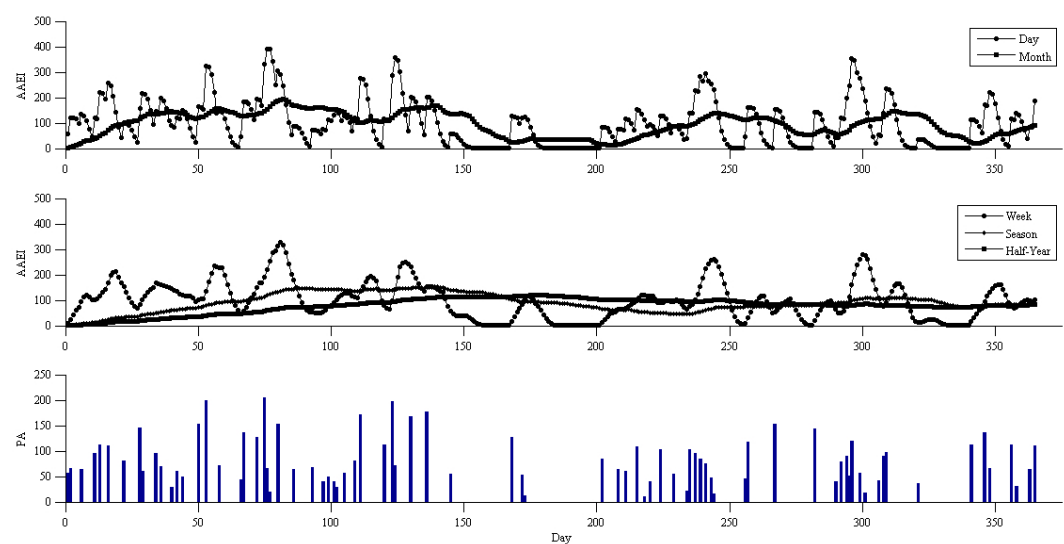


Figure 7. AAEL/PA simulation results with input of 2 days per week, duration of 15 minutes, and 5 MET.



Real-World Trial Results

A total of 2 participants were recruited to take part in the real-world trial test. The participants' characteristics are listed

in Table 2. The recorded physical activity was measured according to observation and activity diaries. Estimated values were measured according to an accelerometer. Table 3 lists the recorded and estimated total physical activity.

Table 2. Participant characteristics (N=2).

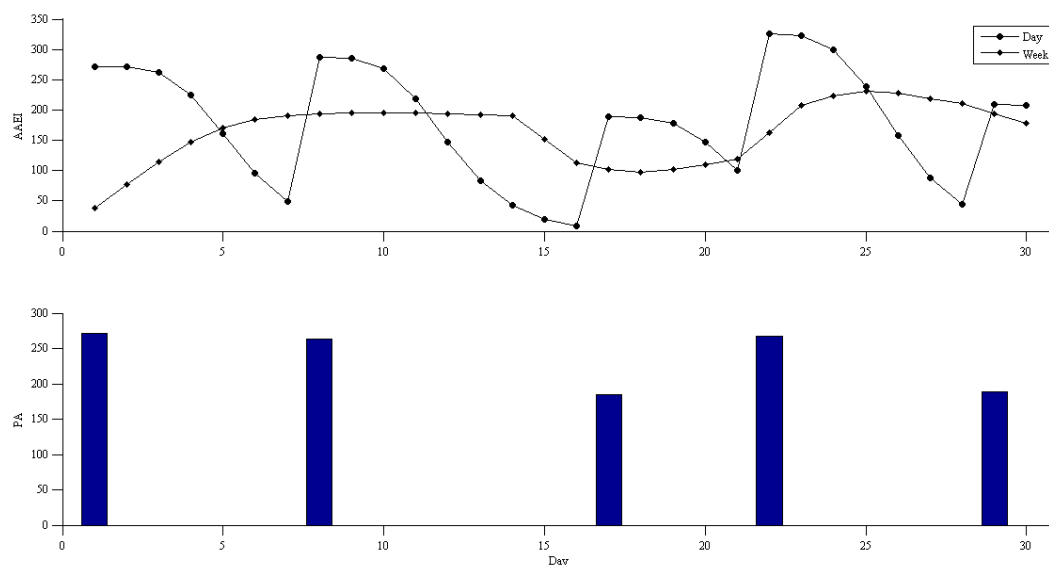
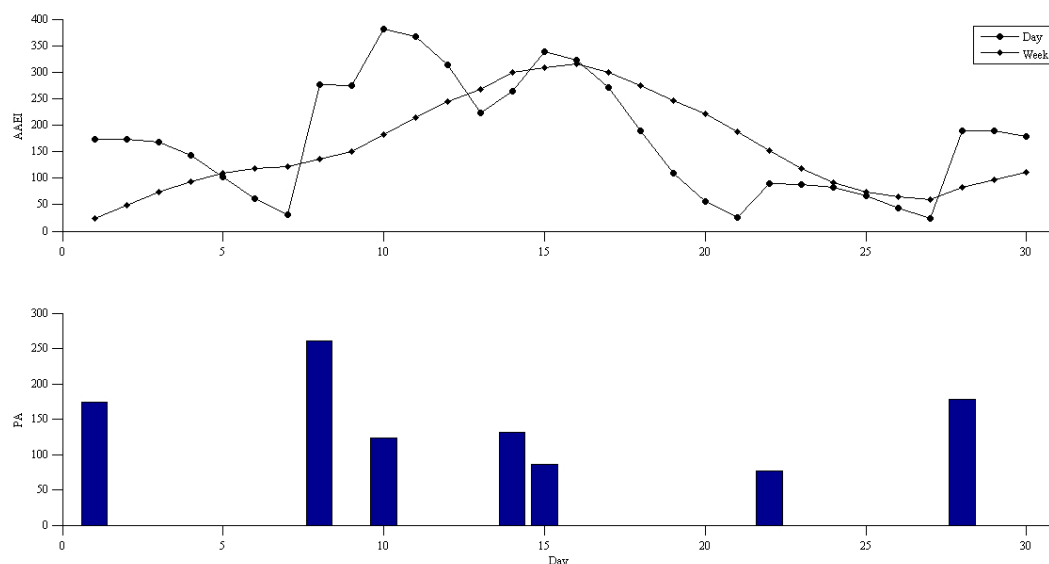
Variables	Participant 1	Participant 2
Gender	Male	Male
Age (years)	24	23
Body mass index	21.4	22.3
Medical status	Healthy	Healthy

Table 3. Result of total recorded physical activity and total estimated physical activity.

Participant	Total recorded value (MET-minutes)	Total estimated value (MET-minutes)	Ratio
Participant 1	1211	1178	0.973
Participant 2	945	1031	1.057

The average physical activity and days spent exercising shown in Figure 8 were 275 MET-minutes per week and 1.2 days per week, respectively. The average AAEI was 180, the ideal AAEI/PA ratio was 0.74, and the AAEI/PA was 0.65.

The average physical activity and days spent exercising shown in Figure 9 were 241 MET-minutes per week and 1.6 days per week, respectively. The average AAEI was 174, the ideal AAEI/PA ratio was 0.80, and the AAEI/PA was 0.72.

Figure 8. AAEI with physical activity (PA) of participant 1.**Figure 9.** AAEI with physical activity (PA) of participant 2.

Discussion

General Performance

The AAEI was determined using the accumulated physical activity and exercise expectance. In our study, the AAEI

increased when physical activity increased, did not increase when physical activity was stable, decreased when physical activity decreased, and decreased further if continuous resting occurred. The first week of ideal and periodic inputs increased because the AAEI accumulated from the first 7 days. After the

first week, the AAEI stabilized because of stationary input. Although the amount of physical activity in a week was the same, the AAEI altered on different days spent exercising. The more days participants exercised, the higher the AAEI was. The AAEI was directly proportional to the amount of physical activity accumulated in 7 days. The AAEI was primarily determined using the accumulated amount of physical activity and associated with the number of days spent exercising. The value of the AAEI was decided by accumulated physical activity more than days spent exercising. Exercise expectance, estimated using the previous physical activity status, accumulated physical activity, and number of days spent exercising, would revise the AAEI. Thus, the index usually decreased further when AAEI was high. We encouraged participants whose physical activity was low to be more active, and challenged those who performed large amounts of physical activity. A higher AAEI typically indicated more physical activity and days spent exercising; therefore, the decrease in percentage was more reasonable than fixed reducing. The constant C is used to revise the magnification of exercise expectance. A higher C value decreased the AAEI further in response to physical inactivity, but increased the AAEI little in higher physical activity situations. The setting value of the constant C can influence the average AAEI in general. Parameter k was defined as a fixed number in this study and, therefore, the AAEI directly revealed the status of physical activity. The parameter k was set to 1 because it can directly reveal the accumulated amount of physical activity. However, the setting value of k can differ depending on the status of physical activity in the Web-based application because of encouragement or challenge. The variable W is a constant of attenuation. We set W at 0.5 in this experiment causing the effect of the previous status to attenuate by 50% after each day.

Establishing a Simulation

The moving average AAEI across a range of durations revealed the varying physical activity statuses of the participants across different points in time. The long-term moving average AAEI varied slightly compared with the short-term moving average AAEI. When the short-term moving average AAEI line crossed the long-term line, it indicated that the physical activity of a participant was either higher or lower than before. We observed the index to ascertain whether the physical activity of the participant was increasing or decreasing. The simulation results reveal the phenomenon, but exhibited deviations in the amount by which physical activity decreased. Because the distribution of physical activity was not uniform in the simulation, the AAEI deviated from the estimate. The deviation of the AAEI was within 5% of the ideal situation. In the simulation model, in which the physical activity was the same as that recommended by the WHO, the achievement goal was an AAEI value of 600. If the participant reached the assigned index, he or she was likely to consider that sufficient physical activity had been performed. The other 2 simulation results exhibited insufficient physical activity in various exercise habits. The shape of the AAEI line demonstrates the different habits of the participants. A high and sharp peak of the AAEI line on the graph reveals that the participant partook in vigorous physical activity, but only over a short period. A flat and low shape of the AAEI line

indicates the participant was physically inactive. The AAEI value in these 2 cases did not exceed 600; therefore, their physical activity was insufficient. An arc-shaped AAEI line with low, oscillating amplitude located at a high index (greater than 600) indicates that the participant partook in sufficient and regular physical activity. The AAEI can be used as an analysis tool for improving physical activity.

Real-World Trial

The recorded physical activity was measured through observation as well as through analysis of activity diaries, and it generally agreed with the estimated value. Although the level of accuracy of the estimated value seems considerably high, the deviation was slightly compensated by overestimating and underestimating, but it still made it possible to evaluate the AAEI in a real-world application. Both participants were physically inactive in 1 month. Generally, the results of the AAEI demonstrated the physical activity status. The AAEI increased with increased physical activity and decreased with decreased physical activity. The AAEI decreased gradually, rather than suddenly. However, the deviation of decrease was much higher than in the simulation results, possibly because of nonuniform distribution in the short-term experiment. The AAEI did not immediately provide feedback to the participants and only showed the feasibility of real-world implementation of the AAEI. Based on previous studies [7,9,11], sharing and comparison can motivate people to be more active by increasing their interest in and enjoyment of physical activity. Goal-setting theory is based on the concept that people occasionally require a clearly defined goal to motivate them to achieve. The AAEI is not only an assessment and tracking tool for personal physical activity, but also a goal-setting and achievement-sharing tool in social contexts.

Implementation of the Accumulated Activity Effective Index

Measurement of the level of activity and the energy cost was a fundamental task before the AAEI estimates were made. Therefore, the characteristics of the measurement of activity levels were crucial to the AAEI estimates because measurement of activity level can directly reveal participants' physical activity. If the level of activity can be measured accurately, it can be useful in calculating the AAEI. One can apply preferred activity-monitoring devices and the proposed AAEI to measure physical activity for individual well-being management. Furthermore, the proposed AAEI is also useful for goal setting and for sharing content with the Internet community under the same criterion.

Conclusions

The AAEI is proposed in this paper as a means of evaluating the status of physical activity. It can track personal physical activity, remind the user of his or her achievement goals, and share this information by using the Internet. The AAEI is a simple numeric indication that is estimated by accounting for accumulated physical activity and the average number of days spent exercising. The AAEI records the accumulated physical activity that has been performed in a week and reveals any differences in exercise habits. The moving average presents a

long-term value that can be used for assessment purposes. The AAEI fulfills the requirement of prompting physical activity.

Based on social aspect theory, the AAEI is a useful tool that can be employed to promote physical activity.

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Conflicts of Interest

None declared.

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Abbreviations

AAEI: accumulated activity effective index
MET: metabolic equivalent of task
PA: physical activity
WHO: World Health Organization

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Original Paper

Development and Evaluation of an Educational E-Tool to Help Patients With Non-Hodgkin's Lymphoma Manage Their Personal Care Pathway

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Abstract

Background: An overload of health-related information is available for patients on numerous websites, guidelines, and information leaflets. However, the increasing need for personalized health-related information is currently unmet.

Objective: This study evaluates an educational e-tool for patients with non-Hodgkin's lymphoma (NHL) designed to meet patient needs with respect to personalized and complete health-related information provision. The e-tool aims to help NHL patients manage and understand their personal care pathway, by providing them with insight into their own care pathway, the possibility to keep a diary, and structured health-related information.

Methods: Together with a multidisciplinary NHL expert panel, we developed an e-tool consisting of two sections: (1) a personal section for patients' own care pathway and their experiences, and (2) an informative section including information on NHL. We developed an ideal NHL care pathway based on the available (inter)national guidelines. The ideal care pathway, including date of first consultation, diagnosis, and therapy start, was used to set up the personal care pathway. The informative section was developed in collaboration with the patient association, Hematon. Regarding participants, 14 patients and 6 laymen were asked to evaluate the e-tool. The 24-item questionnaire used discussed issues concerning layout (6 questions), user convenience (3 questions), menu clarity (3 questions), information clarity (5 questions), and general impression (7 questions). In addition, the panel members were asked to give their feedback by email.

Results: A comprehensive overview of diagnostics, treatments, and aftercare can be established by patients completing the questions from the personal section. The informative section consisted of NHL information regarding NHL in general, diagnostics, therapy, aftercare, and waiting times. Regarding participants, 6 patients and 6 laymen completed the questionnaire. Overall, the feedback was positive, with at least 75% satisfaction on each feedback item. Important strengths mentioned were the use of a low health-literacy level, the opportunity to document the personal care pathway and experiences, and the clear overview of the information provided. The added value of the e-tool in general was pointed out as very useful for preparing the consultation with one's doctor and for providing all information on one website, including the opportunity for a personalized care pathway and

diary. The majority of the revisions concerned wording and clarity. In addition, more explicit information on immunotherapy, experimental therapy, and psychosocial support was added.

Conclusions: We have developed a personal care management e-tool for NHL patients. This tool contains a unique way to help patients manage their personal care pathway and give them insight into their NHL by providing health-related information and a personal diary. This evaluation showed that our e-tool meets patients' needs concerning personalized health-related information, which might serve as a good example for other oncologic diseases. Future research should focus on the possible impact of the e-tool on doctor-patient communication during consultations.

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KEYWORDS

eHealth; personalized care; non-Hodgkin's lymphoma; patient education; care pathway; consumer health information; empowerment; personal care management

Introduction

Overview

In the current digital era, patients are overloaded with health-related information. Many patient associations, health care institutes, hospitals, scientific societies, and guideline working groups provide their own information through websites and flyers. Unfortunately, the increasing call for personalized health-related information is still unmet [1-3]. On the one hand, this information need includes tools that provide support during interaction with caregivers, such as question sheets, decision aids, and option grids [4-6]. These tools aim at providing information about available (treatment) options and possible risks to make a well-informed decision. Decision aids, for example, are shown to be effective with regard to improvement of patients' involvement and health-related knowledge [7].

On the other hand, patients ask for more insight into their personal care pathway, including diagnostics, therapy, and aftercare [8], which makes it easier to act as managers of their own care. This also points to personalized care, which can be defined as the delivery of care that is tailored to an individual patient. Important elements are (1) the delivery of care that is responsive to individual preferences, needs, values, and possibilities, and (2) as much as possible, patients' engagement in their own care and health. The latter point needs a well-informed patient, who has insight into his personal care pathway. In the literature, roadmaps or care pathways concerning patient care are mostly directed to professionals [9,10]. However, making these available for patients could help them in their personal care management.

In addition, reliable health-related information is particularly important for patients, where the Internet is an information source of growing importance. A national survey in the United States showed that 59% of adults searched online for health-related information in 2012 [11]. In European countries, over 80% of adults used the Internet as the main source for health-related information in 2011 and 2012 [12,13]. Several quality criteria have been developed worldwide to monitor the quality of easily accessible health-related information on the Internet [14]. The best-known quality criteria are found in the Health On the Net Code of Conduct (HONcode) for websites [15]. Previous research showed that it remains difficult to accurately monitor all information posted on the Internet, for

example, online information concerning cancer and other disease-related topics is still of poor quality [16-21].

For non-Hodgkin's lymphoma (NHL), a heterogeneous group of over 40 types of malignant lymphomas, an abundance of health-related information is available online. Previous research showed that patients diagnosed with NHL would like to have access to more complete and personalized information on diagnostics, therapy, and aftercare [2]. In response to this, we developed a unique e-tool for NHL patients. This study is, to our knowledge, the first description on the development and evaluation of a personalized care pathway for NHL patients that is also linked to the available health-related information concerning NHL.

Aim and Objectives

This paper describes the development and evaluation of a unique, educational e-tool for NHL patients, aiming to help patients manage and understand their personal NHL care pathway. This is done by providing insight into their personal care pathway based on the data patients enter and by providing essential information about NHL care. Additionally, patients are given the possibility to register personal experiences in their care pathway, as they would in a diary. We hypothesize that having access to all the information available in the e-tool, patients will have a better understanding of their disease and will be able to act as managers of their own care pathways during interaction with their caregivers.

Methods

Setting

The e-tool described in this paper was developed in the context of the PEARL study (improvement of patients' hospital care for non-Hodgkin's lymphoma), aimed at improving hospital care for patients diagnosed with NHL [22]. In a previous study, insight into current NHL care was acquired by measuring quality indicators at the patient level [23]. Together with the barriers and facilitators found, as perceived by patients and physicians [2], a tailored improvement strategy was developed. Next to several physician-directed tools, an e-tool for patients was included in the improvement strategy. This paper describes the development and evaluation of an e-tool for NHL patients.

E-Tool Development

Overview

We started with the development of a mock-up storyboard, and with the help of a system developer this was converted into a distinctive e-tool for NHL patients, tailored to address the patients' barriers found in previous research [2]. The barriers included lack of insight into the patients' personal care pathway, and lack of written information about diagnostics and therapy. This is why the e-tool developed consists of two sections: (1) a personal section for patients' own NHL care pathway (roadmap) and their experiences with NHL care, and (2) an informative section including information on NHL. The complete e-tool aims to help patients manage the care they receive during their NHL care trajectory. The webmaster of the Dutch Lymphoma Patient Association (Hematon, known as LVN before 2014) and an expert panel, including a hematologist, radiologist, pathologist, radiation oncologist, epidemiologist, and a senior researcher, were closely involved in the e-tool development. Quality criteria from the HONcode were taken into account during the development process.

Personal Section of the E-Tool

In this section, users were able to document dates and experiences of first consultation, diagnostics, and therapy. The aim was to provide insight into the patients' personal care pathway. We developed a general (ideal) NHL care pathway based on the national guidelines and recommendations available in the Netherlands. These included, among others, the Dutch NHL guidelines, recommendations of the Cooperative Trial Group for Hematology Oncology (HOVON) and the Dutch Society of Hematology (NVvH), general recommendations for acceptable waiting times, and an NHL guideline based on patients' perspectives of Hematon. Internationally available guidelines were consulted when applicable. The ideal care pathway, including date of first consultation, date of diagnosis, and start date of therapy, was used to set up the format for the personal care pathway (roadmap).

Informative Section of the E-Tool

Users had access to reliable information on NHL and NHL care through this section of the e-tool. The aim was to cluster all reliable, online available information and make it understandable for all users. Too much or confusing information and a high health-literacy level were avoided as much as possible. The Dutch NHL guidelines, NVvH, HOVON, the Dutch Cancer Society (KWF), and several NHL-related websites (eg, Radiotherapie Nederland, Chemo and nu, Hematon, and Hematologie Groningen) were used as sources of NHL information for the content. These sources are frequently recommended and used by professionals, so the content can be considered as authorized by them. We cooperated with the webmaster of Hematon to make sure that the information included was complete and accurate. The format of the e-tool was based on the NHL care pathway as described in the guidelines and on user experiences with other websites.

E-Tool Evaluation

After evaluation of the concept of the text by the expert panel, an external hematologist, and the webmaster of Hematon, an

assessment was set up to evaluate both sections of our e-tool concerning applicability. We recruited NHL patients via Hematon and a university hospital in the Netherlands. Patients were eligible when they had, or have had, a non-Hodgkin's lymphoma, were over 18 years old, and had access to the Internet. Family and friends of 3 members of the project team were asked to participate as laymen. The e-tool was evaluated by patients and laymen using a 24-item questionnaire—19 yes/no questions, including space for reasoning, and 5 open-ended questions, including improvement suggestions. The questionnaire included questions on layout (6 questions), user convenience (3 questions), menu clarity (3 questions), information clarity (5 questions), and general impression (7 questions), for example, strengths and missing information. This method allowed us to obtain as much information as possible to improve our e-tool. The expert panel was invited by email to give general feedback on the e-tool.

Results

E-Tool Development

Overview

We developed an e-tool, consisting of two sections—a personal section and an informative section. The content of the sections will be described below, followed by the results of the evaluation of the e-tool applicability. The e-tool is available in Dutch [24] for participants of the PEARL study and will become publicly available in 2015. The e-tool started with a general introduction, which described the aim of the e-tool and gave a short overview of the personal and informative sections of the e-tool. Both sections were formatted in chronological order (diagnostics, therapy, aftercare), which is in line with the NHL care pathway as described in the guidelines and seen in clinical practice. Additionally, background information was available concerning the PEARL study, participating hospitals, and contact information.

Personal Section of the E-Tool

This section consisted of questions concerning a patient's personal NHL care pathway, which allowed patients to develop a unique overview of all diagnostics, treatments, and aftercare/follow-up that they have had. Questions were divided into four items:

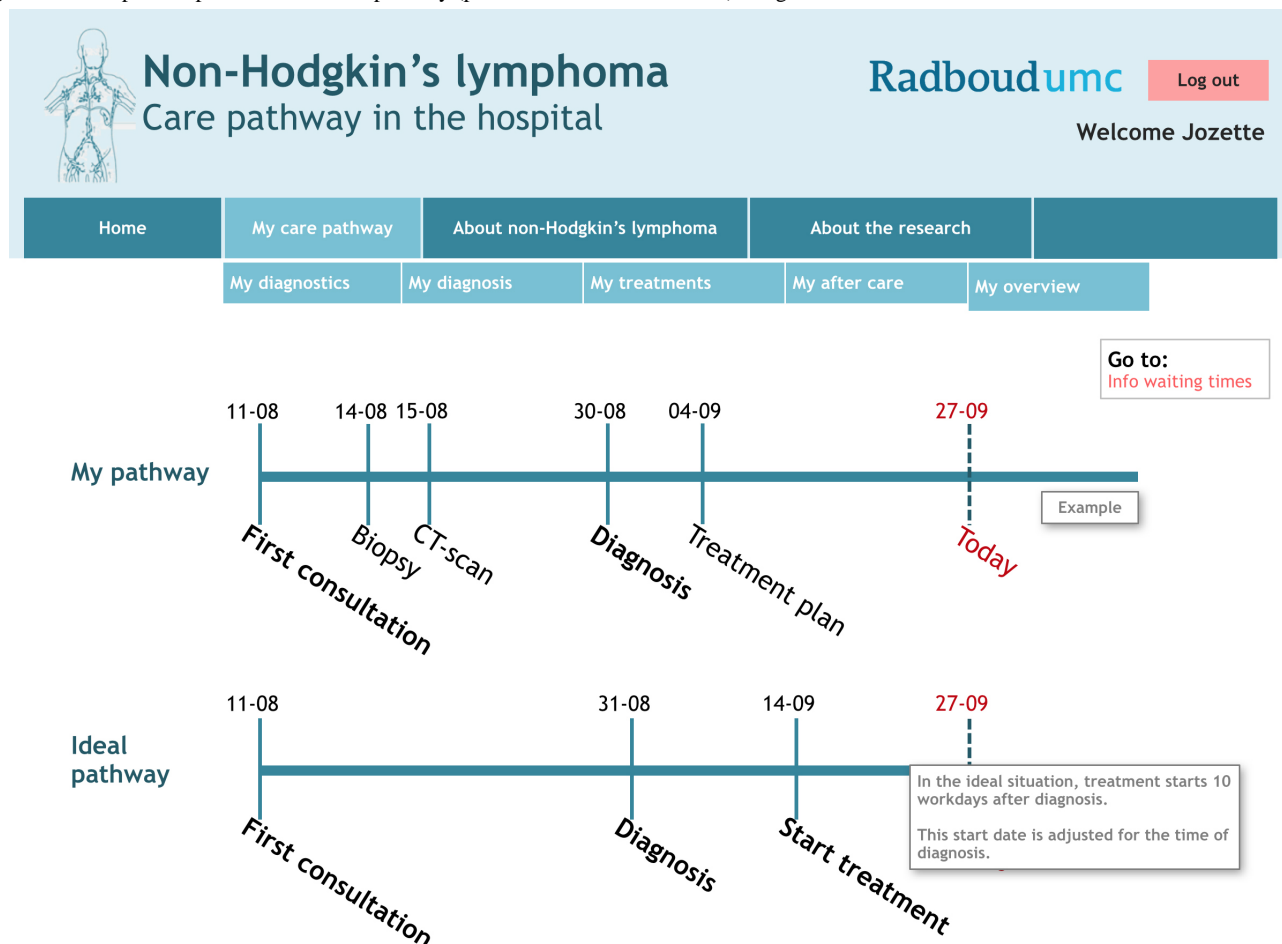
1. Diagnostic examinations, including items such as type and date of the examination, executed by whom, and in which hospital.
2. Diagnosis, including date of first consultation, date of diagnosis, type of NHL, stage of the disease, risk profile, date of treatment plan, hospital name, and physician name.
3. Therapy, including type and date of therapy, executed by whom, and in which hospital.
4. Aftercare, including items such as type and date of aftercare, executed by whom, and contact information.

An easy link from the personal section to the informative section was provided next to each item. In this way, patients could look up the underlying information belonging to the different items.

Additionally, it was possible to create a diary, to document their own experiences with the different diagnostic examinations or treatments. Information filled out in this diary was only visible to the patients themselves. Finally, an overview of the personal NHL care pathway was obtained using the answers to the

questions. The personal diary—chronologically visualized experiences with NHL care—was provided when applicable. An example of the personal NHL care pathway (roadmap) is shown in Figure 1.

Figure 1. Example of a personal NHL care pathway (personal section of the e-tool). Original is in Dutch.



Informative Section of the E-Tool

This section consisted of NHL information from reliable online sources, divided into six information items:

1. NHL in general, including a description of what NHL is, symptoms, and most occurring NHLs.
2. Diagnostic examinations, including items such as blood sample, tissue biopsy, bone marrow biopsy/aspirate, PET/CT-scan, and additional examinations.

3. Diagnosis, including stage, international prognostic index (IPI) score, treatment plan, and additional support.

4. Therapy, including wait-and-see, radiotherapy, chemotherapy, immune therapy, stem cell transplantation, and clinical trials.

5. Aftercare, including response evaluation and monitoring.

6. Waiting times.

External links for more extensive information were added as much as possible, together with short educational movies created by KWF or Hematon. An example of the informative section is shown in Figure 2.

Figure 2. Example of informative section of the e-tool. Original is in Dutch.

Non-Hodgkin's lymphoma
Care pathway in the hospital

Radboudumc Log out
Welcome Jozette

Home My care pathway About non-Hodgkin's lymphoma About the research

General Diagnostics Diagnosis Treatments After care Waiting times

Treatments
On this page, you can find more information about different types of treatment

Go to:
My treatments

► Wait-and-see

▼ Radiation therapy

Radiation therapy is a treatment where radiation is projected at the tumor location. This will damage the cells at this specific location. Not only cancer cells, but also healthy cells will be impaired. The impairment will slow down cancer cell growth or even stop it completely. Healthy cells have a mayor advantage: they are better able to recover from this damage than cancer cells.

Common side-effects of radiation therapy are:

- Fatigue
- Skin problems (e.g. red skin)
- In case of radiation of the neck: dry mouth, decreased taste and smell ability
- In case of radiation of the abdomen: nausea, diarrhea
- In case of radiation around the sexual organs: decreased fertility
- In case of radiation of the hair/scalp: hair loss

How radiation therapy exactly works is shown in the short movie below (source: www.kwfkankerbestrijding.nl)

E-Tool Evaluation

We asked 20 people to participate in our test, including 14 NHL patients and 6 laymen. In total, 13 people logged in and 12 returned the questionnaire, which resulted in a 60% (12/20) response rate. Little feedback was given by 1 participant by email and he did not return the questionnaire. The mean age of the 12 participants (patients and laymen) that completed the questionnaire was 56 years (SD 11), with a range of 30-70 years. Of the participants, 42% (5/12) were female and 67% (8/12) had a high education level (college or university). Additionally, all 6 panel members and the external hematologist provided general feedback by email.

Table 1 includes the results of our e-tool evaluation (applicability) using closed questions among NHL patients and laymen. Overall, the evaluation of the e-tool was highly positive. Table 1 shows at least 75% (9/12) satisfaction on each section. Concerning layout, all responders were satisfied with the clarity of the text, writing style, and clarity of the illustrations and short videos. When looking at the user convenience, 11 out of 12 participants (92%) were satisfied with the format and speed of the e-tool. In relation to menu clarity, all participants found the menu format intuitive and the information needed was easy to find. Information clarity, including understandability of the text, was evaluated positively as well. Only 2 out of 12 participants (17%) thought too much medical terminology was included.

Table 1. Results of the e-tool evaluation among NHL patients and laymen (closed questions).

Question	Positive response, n (%)	
	Patients (n=6)	Laymen (n=6)
Layout		
Is the text clear?	6 (100)	6 (100)
Are you satisfied with letter type and size?	3 (50)	6 (100)
Are you satisfied with the writing style?	6 (100)	6 (100)
Is the use of colors attractive to you?	4 (67)	5 (83)
Are there enough illustrations and short videos to support the text?	5 (83)	5 (83)
Are the illustrations and short videos clear?	6 (100)	6 (100)
User convenience		
Is the e-tool easy to use?	4 (67)	5 (83)
Is the format of the e-tool easy to understand?	5 (83)	6 (100)
Are you satisfied with the speed of the e-tool?	6 (100)	6 (100)
Menu clarity		
Does the composition of the menu seem natural?	6 (100)	6 (100)
Are you satisfied with the navigation through the e-tool?	5 (83)	5 (83)
Is it easy to find the information you are looking for?	6 (100)	6 (100)
Information clarity		
Is the information provided on the e-tool understandable?	6 (100)	6 (100)
Does the e-tool make use of too much medical terminology? ^a	4 (67)	6 (100)
Do you understand what NHL is, after reading the information provided on the e-tool?	6 (100)	6 (100)
Do you understand what treatment options are available, after reading the e-tool?	6 (100)	6 (100)
General impression		
Are there any flaws/errors in this e-tool? ^a	5 (83)	5 (83)
Would you use this e-tool if made available to you?	5 (83)	6 (100)
Are there any redundant items in this e-tool? ^a	6 (100)	6 (100)

^aPercentage of negative responses presented, caused by negative questioning.

Table 2 includes the results of our e-tool evaluation using open-ended questions, and shows mainly positive remarks about the e-tool and some improvement points, according to NHL patients and laymen. Valuable strengths mentioned by the participants included the use of a low health-literacy level, the opportunity to document their personal care pathways and experiences (diary), and the clear and helpful overview of the information provided. The added value of the e-tool in general was pointed out as very useful for preparing for their consultations with their doctors and for providing all information in one website, including the opportunity for a personalized care pathway and diary.

In general, the e-tool is considered to be a good initiative to help patients manage their NHL care. For example, one participant wrote, "I think this tool is excellent and that it will be helpful in dealing with the fact that you are diagnosed with NHL. The tool can contribute to an optimal doctor-patient contact." There were no distinct differences in feedback between

patients and laymen, except that patients provided more comments concerning missing items and general remarks.

Improvement points proposed by the expert panel included addition of a search function and contact button, adding items to the personal care pathway section, suggestions for links to general cancer websites, and some wording issues (data not shown).

During the review of the e-tool, all feedback was taken into account. The majority of the revisions concerned wording and clarity. With respect to layout, the font size regarding explanatory text was enlarged and the color of the submenu was made less bright. Regarding user convenience and menu clarity, the navigation at the bottom of each page was made clearer. No revisions were made concerning information clarity. In addition, more explicit information was included about immune therapy, experimental therapy, and psychosocial support. As well, items for the patients' risk profiles and stages of disease were added to the personal section.

Table 2. Results of the e-tool evaluation among NHL patients and laymen (open-ended questions).

Question	Response
Information clarity	
What does this e-tool add to the information provided by your doctor?	<p>Makes everything much clearer and understandable.</p> <p>Makes it possible to read everything at a quiet moment.</p> <p>Provides good preparation for consultation with your doctor.</p> <p>Provides a great overview of all necessary information.</p> <p>Provides a good overview of your own care pathway.</p> <p>The e-tool is very useful for the patients' relatives.</p> <p>Makes it possible to compare with the ideal pathway.</p>
General impression	
What are improvement points for this e-tool?	<p>More expressive color use.</p> <p>For patients that forget updating their care pathway, are there alerts?</p> <p>Better navigation through the care pathway.</p> <p>Clearer definition of first consult.</p>
What are the strengths of this e-tool?	<p>Opportunity to document your personal care pathway.</p> <p>Opportunity to document your experiences in a diary.</p> <p>Possible to compare with quality criteria (ideal pathway).</p> <p>Low health-literacy level.</p> <p>Clear and calm colors.</p> <p>Clear overview of medical information and terminology.</p> <p>Clear layout and navigation.</p> <p>External links to additional information about NHL.</p> <p>Overview of information gives the opportunity to translate this to yourself.</p>
What did you miss on this e-tool?	<p>Overview of lymph vessels.</p> <p>Information about immune therapy and clinical trials.</p> <p>Information about psychosocial support.</p> <p>Information about second opinion.</p>
General remarks?	<p>Great overview of available NHL information.</p> <p>Other websites are fine, but this e-tool provides more specific information.</p> <p>I already have my own diary, which I will use in the future.</p> <p>The tool gives the opportunity to create your own care pathway and diary—this has a positive influence on dealing with the fact that you are diagnosed with NHL.</p> <p>This e-tool can contribute to an optimal doctor-patient contact during consultations.</p>

Discussion

Principal Results

In this study, we showed the development and evaluation of a unique e-tool for, and by, patients with non-Hodgkin's lymphoma. Based on the evaluation, the e-tool is a feasible tool that gives patients insight into their personal care pathway and informs them about NHL. The overall positive feedback implies the e-tool's added value of providing personalized health information, which is often an unmet need for patients. Taken as a whole, this is the first e-tool in the field of oncology that aims at helping patients in their personal care management and provides an additional overview of information about NHL.

Comparison With Prior Work

Involving patients in the development of health care improvement tools has been an upcoming phenomenon in the past several years. Nowadays, the patient's voice is incorporated

more often in clinical guidelines, quality indicators, and shared decision-making instruments [8,25,26]. It is important to support patients involved in developing health care improvement tools. For example, a wiki has been established for, and tested by, patients involved in the development of a guideline on infertility [27]. The shared decision-making instruments themselves also have a supporting role, as they try to help patients in making informed decisions [6,28-30]. However, not all decision aids are directed to patients [31,32] and they usually do not provide insight into the complete personal care pathway.

Studies focusing on personalized care pathways and assistance with patients' personal care management are sparsely described in the literature. Most studies concerning the development of patient care pathways or roadmaps concentrate on the education of physicians [33,34] or other health care professionals [10]. Ryhänen et al [35] and Dykes et al [36] developed tools to educate patients about their care pathway. Dykes et al aimed at providing education about the anticipated length of stay and

treatment plan after acute myocardial infarction. Development and evaluation of a breast cancer pathway, an Internet-based patient education program, was described by Ryhänen et al. In line with our e-tool, these studies focused on patient education concerning the patient care pathway. However, these studies did not include information tailored to the individual patient, such as a chronological overview of the personal care pathway or a diary. Attack et al [37] developed an online patient education system including health-related information tailored to the individual patient. Physicians were able to “prescribe” information that met the patient’s need. However, this system was not focused on the total care pathway and was only pilot-tested in 8 patients. Our e-tool is the first that combines the unmet needs of patients, including personalized information about the patients’ care pathways and the possibility to create a diary, together with an overview of all necessary NHL information.

Limitations

Four limitations were identified with respect to this e-tool. First, this e-tool has been developed for NHL patients, a patient category with a more advanced age—incidence of NHL increases with age—that might not be active on the Internet. However, the mean age of NHL patients included in this study was 61 years (SD 7), and a previous study on possible barriers in NHL care also showed inclusion of patients of all ages [2]. Furthermore, health-related Internet use seems to increase over time in Europe among people of all ages [38]. Second, the questionnaire used to evaluate the e-tool was not validated, but based on evaluation factors derived from the human, organization, and technology-fit (HOT-fit) framework [39]. We believe that the questionnaire developed included all necessary items to extensively evaluate the e-tool.

Third, the evaluation study only assessed feasibility of the e-tool on a small scale. Unfortunately, no information was available about the 7 nonresponders, and a relatively high percentage of the responders were highly educated, which could have introduced some bias. A next step in the implementation is to test the e-tool in daily NHL care and evaluate user experiences on a larger scale. This might give insight into the possibilities for making the e-tool appropriate on an international level and it might serve as a good example for other oncologic diseases.

Finally, the e-tool is not yet certified by the HONcode. However, all eight items of the code of conduct for medical and health websites as described by HON were taken into account during the development of the e-tool [40]. After testing the e-tool at a larger scale we intend to apply for certification.

Conclusions

We have developed a personalized approach using an e-tool for NHL patients. This tool contains a unique way to help patients with their care management—it provides insight into the personal care pathway and offers general information about NHL. In this evaluation study, we report high satisfaction rates and some improvement points for future use. We expect that the e-tool will have a positive impact on both patient empowerment and doctor-patient communication, since patients are more informed in lay language about NHL and their personal care pathway. It is suggested that better-informed patients are able to ask more specific questions, which makes it possible to improve the management of their personal care. Finally, this e-tool may play an important role in dealing with NHL, particularly the personal diary option, which has the potential to provide psychosocial support for personal experiences in NHL care. The usage and effects of the e-tool should be tested and evaluated in future research, which is included as one of the purposes of the PEARL study [22].

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Authors' Contributions

RH, PO, and LW had the basic idea for this e-tool study. RH, PO, and JS were responsible for the research question of the study. NB and JvK commented on the design of the study, and all authors commented on the design of the e-tool. JS wrote the first draft of this manuscript and was responsible for the revisions. All authors critically reviewed the drafts and approved the final manuscript before submission.

Conflicts of Interest

None declared.

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Abbreviations

HONcode: Health On the Net Code of Conduct
HOT-fit: human, organization, and technology-fit
HOVON: Cooperative Trial Group for Hematology Oncology
IPI: international prognostic index
KWF: Dutch Cancer Society
NHL: non-Hodgkin's lymphoma
NVvH: Dutch Society of Hematology
NWO: Dutch Organization for Scientific Research

PEARL: improvement of patients' hospital care for non-Hodgkin's lymphoma

ZonMW: Netherlands Organization for Health Research and Development

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Original Paper

Development of a Web-Based and Mobile App to Support Physical Activity in Individuals With Rheumatoid Arthritis: Results From the Second Step of a Co-Design Process

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Abstract

Background: Long-term adherence to physical activity recommendations remains challenging for most individuals with rheumatoid arthritis (RA) despite evidence for its health benefits.

Objective: The aim of this study was to provide basic data on system requirement specifications for a Web-based and mobile app to self-manage physical activity. More specifically, we explored the target user group, features of the future app, and correlations between the system requirements and the established behavior change techniques (BCTs).

Methods: We used a participatory action research design. Qualitative data were collected using multiple methods in four workshops. Participants were 5 individuals with RA, a clinical physiotherapist, an officer from the Swedish Rheumatism Association, a Web designer, and 2 physiotherapy researchers. A taxonomy was used to determine the degree of correlation between the system requirements and established BCTs.

Results: Participants agreed that the future Web-based and mobile app should be based on two major components important for maintaining physical activity: (1) a calendar feature for goal setting, planning, and recording of physical activity performance and progress, and (2) a small community feature for positive feedback and support from peers. All system requirements correlated with established BCTs, which were coded as 24 different BCTs.

Conclusions: To our knowledge, this study is the first to involve individuals with RA as co-designers, in collaboration with clinicians, researchers, and Web designers, to produce basic data to generate system requirement specifications for an eHealth service. The system requirements correlated to the BCTs, making specifications of content and future evaluation of effectiveness possible.

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KEYWORDS

eHealth; Internet intervention; physical activity; rheumatoid arthritis; behavior change techniques; participatory design

Introduction

There is solid evidence of the benefits of physical activity (PA) in individuals with rheumatoid arthritis (RA), for example, improved functional capacity and decreased risk of cardiovascular disease [1-3]. Despite these apparent benefits, only 11% of individuals with RA report pursuing healthy PA regimens based on recommendations [4]. Integration of PA into everyday life remains a challenge, even with the development of interventions targeting the specific needs of this population [2,3,5-8]. Consequently, new strategies are required to achieve long-term adherence to PA recommendations.

The challenges are partly due to PA being a complex behavior determined by a number of bio-psychosocial factors [9-11]. Social cognitive theory (SCT) [12] has helped identify factors important for health behavior change in chronic conditions, such as the importance of self-regulation skills to facilitate PA in individuals with RA [13]. This theory has also been recommended to inform self-management interventions in arthritis to increase its effects [14].

Another mechanism of increasing the impact and scope of PA interventions is using the Internet. The Internet has the potential to reach large populations [15,16] and is convenient and readily accessible [17]. To the best of our knowledge, only one previous study has evaluated the effects of an Internet-supported PA intervention for individuals with RA [7]. However, the results showed that only minor integration of PA into participants' everyday life was achieved [18]. In addition, this intervention did not explicitly incorporate behavior change techniques (BCTs) to self-manage PA [7].

A BCT is defined as the active component (eg, goal-setting, self-monitoring) of a behavioral intervention that alters or redirects the target behavior [19]. Self-monitoring with at least one additional BCT has been reported to increase the efficacy of PA interventions [20]. The use of a BCT taxonomy in the development of a PA intervention may improve reports on the content of the intervention, help identify effective intervention components, and facilitate comparison of results between studies.

A new strategy used to develop interventions is participatory design [21]. This method has frequently been applied to the organizational development and design of health information systems [22,23]. Participatory design allows users to be actively involved as co-designers [21,24]. More recently, participatory design has been used to design Internet-based health care services for multiple purposes and target groups [25-28]. We have not been able to identify any previous study involving individuals with RA in the development of an Internet service to support the self-management of PA.

In this project, we co-design a Web-based and mobile app for the self-management of physical activity in patients with rheumatoid arthritis. During the first step of the co-design process, focus-group participants diagnosed with RA presented ideas on core features that would be important to consider when developing the app. These features included content,

customizable options, the user interface, and access and implementation [29].

This report presents results from the second step of the co-design process. The overall aim was to provide basic data on system requirement specifications for a Web-based and mobile app for PA self-management in individuals with RA. Specific objectives included exploring the characteristics of the future target-user group, the features of the future app, and the correlation between established BCTs and system requirements, that is, what the app should provide, arrange, or do.

Methods

Design

To involve the participants as co-designers, we applied a participatory action research design [30]. Data were collected during and in between four workshops in February and March 2013 at Uppsala University, Sweden. We used multiple methods for data collection and analysis to capture dimensions of participants' proposals, preferences, and agreements. This study was approved by the regional ethical review board in Stockholm (D.nr. 2010/1101-31/5).

Selection of Participants

A sensibly sized co-design group (N=10) was formed to capture different perspectives. We included 5 adults diagnosed with RA, a clinical physiotherapist, an officer from the Swedish Rheumatism Association (SRA), a Web designer, and 2 physiotherapy researchers (ID, CO) with knowledge of the theory of health behavior change and evidence-based knowledge on PA in RA. The inclusion criteria were individuals with adequate communication skills in Swedish who had access to the Internet and were comfortable using it. In addition, we wanted the participants with RA to reflect the diversity of the population of RA regarding age, gender, years with diagnosed RA, and PA habits.

To ensure the participants had the required knowledge, all participants were identified through our research and clinical network. The first author (ÅR) contacted them by email, and those who provided preliminary consent received verbal information about the study. Written information and a questionnaire on background characteristics, expertise, PA behavior, and Internet habits were then disseminated. Participants provided their final consent for participation by attending the first workshop. Tables 1 and 2 present the participants' characteristics, expertise, and experiences.

In addition to the participants, 4 researchers were present during the workshops. Of these researchers, one acted as a video camera operator (CM, with experience in qualitative, video-based research and group interaction), one had overall responsibility for alignment of the process (PÅ, with expertise in behavioral medicine), and 2 of them acted as non-participatory observers (CK, with expertise in health informatics; ÅR, with expertise in musculoskeletal disorders). A moderator (with expertise in the design of Web-based and mobile apps and experience of group moderation) facilitated the entire process during and between the workshops.

Table 1. Demographics of participants (N=10).

Participants	Age, year	Gender	Children <18 years	Living with other adults	Years since RA diagnosis	Other chronic disease	Education & work experience
1. RA	73	Male	No	Yes	>10	No	High school
2. RA	69	Female	No	Yes	>10	No	University, PA/Exercise, Health care, Research, Exercise group leader
3. RA	69	Female	No	No	>10	No	University <3 years
4. RA	43	Female	Yes	Yes	>10	Yes	University <3 years
5. RA	34	Female	Yes	Yes	5-10	No	University, Health care, Research
6. Clinical PT ^a	49	Female	Yes	Yes	No	No	University, PA/Exercises, Health promotion, Health care, Research, Exercise group leader
7. SRA ^b	46	Male	No	No	No	Yes	University, Product development, Management
8. Web designer	57	Male	No	Yes	No	No	University <3 years, PA/Exercise, Computer programming, Product development, Management, Health promotion
9. Researcher	59	Female	No	Yes	>10	Yes	University, PA/Exercise, Health care, Research, Management
10. Researcher	53	Female	No	Yes	No	No	University, PA/Exercise, Health care, Research, Management, Exercise group leader, Health promotion

^aPhysiotherapist^bSwedish Rheumatism Association

Table 2. Computer, mobile phone, and PA experiences of participants (N=10).

Participants	Internet use	Uses/have tried PA apps	Own a mobile phone	Meet PA recommendations aerobic exercise 30 min \geq 5 days/week ^a	Meet PA recommendations strength training \geq 2 days/week ^a
RA	Several times/day	No	No	Precontemplation phase	Maintenance phase
RA	Several times/day	No	Yes	Maintenance phase	Maintenance phase
RA	Several times/day	No	No	Used to	Precontemplation phase
RA	Several times/day	No	Yes	Maintenance phase	Maintenance phase
RA	Several times/day	Yes	Yes	Action phase	Preparation phase
Clinical PT ^b	Once/ week	No	No	Maintenance phase	Used to
SRA ^c	Several times/day	Yes	Yes	Preparation phase	Preparation phase
Web designer	Several times/day	Yes	Yes	Maintenance phase	Maintenance phase
Researcher	Several times/day	Yes	Yes	Action phase	Contemplation phase
Researcher	Several times/day	No	Yes	Maintenance phase	Preparation phase

^aPhysical activity habits were assessed with the question “Do you follow the recommendations for health enhancing physical activity, as described above?”, with the possible answers “maintenance phase” (has followed the recommendations for at least 6 months), “action phase” (has followed the recommendations less than 6 months), “preparation phase” (plan to follow the recommendations within 1 month), “contemplation phase” (plan to followed the recommendations within 6 months), “precontemplation phase” (do not plan to followed the recommendations within 6 months), used to (used to be physically active but have been less physically active the previous months).

^bPhysiotherapist

^cSwedish Rheumatism Association

The Workshops

The four workshops occurred at intervals of 1-4 weeks. They took place in university lecture rooms with interactive boards (SMART boards). The first workshop began by presenting the aim, overall content, procedure of the workshops, and the participants' different roles and expertise during the workshops. Discussion started with the results from the first step of the co-design process, that is, core features of the future app based on the outcomes of the previous focus-group interviews [29]. Three authors (ÅR, CM, and PÅ), the Web designer, and the moderator planned each workshop iteratively such that each

workshop was built on the results and experiences from the preceding workshop.

Table 3 presents an overview of the major content of and participants at each workshop. Even though the participants had ensured they could be present at all four workshops, some of the participants had to cancel due to unplanned life events such as sickness.

A pilot workshop was held prior to the start of the study, with the aim of testing data collection procedures, for example, technical solutions for the video recordings, the interactive board, and the feasibility of the observation protocols.

Table 3. Overview of the four workshops with a description of major content and attending participants.

Workshop	Major content
Workshop 1: Brainstorming (P ^a =1,2,5,6,7,8,9,10)	Introduction Warm-up session Brainstorming on needs and proposed features
Workshop 2: Brainstorming and narrowing (P=1,2,3,4,5,6,7,8,9,10)	Warm-up session Transforming the participants needs to proposed feature Creation of the first preliminary framework of the app Focus group interviews ^b
Workshop 3: Specification of features on the app (P=1,2,3,4,6,7,8,9)	Presentation of available PA apps Presentation of the first preliminary framework presented as a mobile phone app Creation of the second preliminary framework of the app
Workshop 4: Specification of features on the app (P=1,2,3,5,6,7,8,9)	Presentation of the second preliminary framework presented as a mobile phone app Continuous specification of features Focus group interview ^b

^aThe participants attending the workshop.

^bFocus group interviews were performed to explore the participants' experiences and perceptions of co-design. These data will be analyzed and presented elsewhere.

Data Collection

Data were collected during the workshops using (1) an online notice board (Trello), (2) interactive boards, (3) Post-it notes grouped on plastic sheets, (4) video recordings, and (5) observation protocols. Postings on the online notice board were also collected between the workshops. The interactive boards and Post-it notes grouped on plastic sheets were used to produce preliminary frameworks, that is, outlines of the arrangement of contents and functionalities for the future app, which provided "visual guides" on how the workshop participants' proposed features could be arranged on a future Web-based and mobile app.

In addition, focus-group interviews were performed immediately after the second and fourth workshops to explore the participants' experiences and perceptions of being involved in the co-design. These data will be analyzed and presented elsewhere.

Data Management and Analysis

Between each workshop, the first author (ÅR) mapped out and outlined the video recordings and compiled the observation protocols from the 2 non-participatory observers. Additionally, the preliminary frameworks produced on the interactive board and the plastic sheets were programmed by the moderator as mobile phone apps to be presented at the following workshop.

After the final workshop, 3 authors (ÅR, PÅ, and ID) analyzed the data by triangulating the different data-collection methods. The main analysis was based on the postings on the online notice board and the preliminary frameworks (Table 4). These data were clarified and validated by use of the data from the observation protocols, the video recordings, the Post-it notes on outcome measures, and the programmed mobile phone apps (Table 5).

Table 4. Overview of the data collection for main analysis.

Data	Postings on the online notice board	First preliminary framework produced on the interactive board	Second preliminary framework produced on a plastic sheet with grouped Post-it notes
Characteristics of the target user group	X		
Features	X	X	X

Table 5. Overview of the data collection for clarification and validation.

Data	Observation protocols compiled from 2 non-participatory ob-servers	Video recordings	Post-it notes grouped on plastic sheets on PA performance and health outcome measures	Preliminary frameworks pro-grammed as a mobile phone app
Characteristics of the tar-get user group	X	X		
Features	X	X	X	X

Data on the characteristics of the target-user group, that is, the users of the future app, were retrieved from a list compiled on the online notice board (ÅR). These data were clarified and validated by examining sequences on the video recordings where the issue was discussed. The observation protocols helped to identify these sequences.

The features and system requirements were analyzed by one author (ÅR). Data on features were retrieved from the online notice board and the first and second preliminary frameworks. First, the data from the online notice board were condensed and grouped into clusters reflecting similar core meanings. The clusters were then reformulated to system requirements, that is, what the app should provide, arrange, or do. Each system requirement was then correlated with features in the first and second preliminary frameworks. In the latter workshops, participants agreed to combine these two preliminary frameworks, which resulted in the first version of the app. Again, the process was validated and complemented with additional data from selected video sequences identified in the observation protocols.

Next, the system requirements were coded based on established BCTs using a taxonomy [19]. The taxonomy consists of 93 BCTs clustered into 16 hierarchical groups (1-16); techniques with similar active components are grouped together. Each technique was given a code (eg, 1.1, 1.2, 2.3) and labeled,

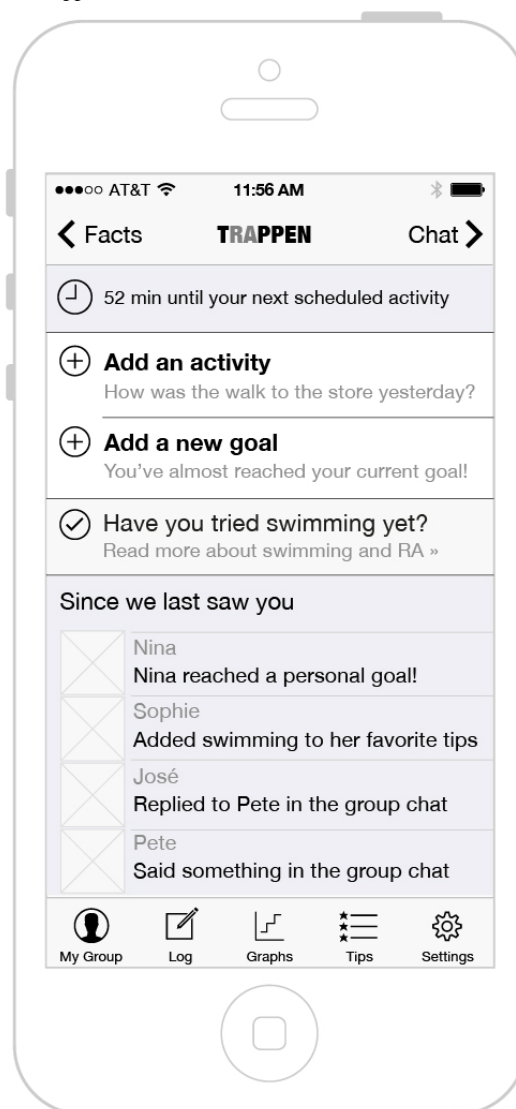
defined, and exemplified. The first author (ÅR) coded the system requirements. The fourth author (ID) reviewed the coding, and disparities were discussed. Following the third iterative cycle of reviewing and discussing the coding, the 2 authors (ÅR and ID) agreed upon the coding. The last author (PÅ) was then introduced to the analysis, resulting in one further revision of the coding, the clustering of features, the wording of the system requirements and their correlation with features on the app.

Results

The App

Participants agreed that the app should be based on two preliminary frameworks: (1) “My self-monitoring”: a calendar feature for planning, setting goals, and recording PAs and progress, and (2) “My peer group”: a small community feature for positive feedback and support from peers. The app should support the maintenance of PA and was proposed as being a lifelong companion that should encourage PA during good and bad disease periods. As one of the participants expressed, “I want to be able to use the app even during periods when I do my exercises and feel healthy”. The proposed name of the app was “tRAppen,” which correspond to “stairs” in English and derives from terms related to PA, RA, and app in Swedish.

An illustration of the welcome screen of the Web-based and mobile app on a mobile phone is provided in Figure 1.

Figure 1. Illustration of the welcome screen of the app.

Characteristics of the Target User Group

The users of the future app should be adults with RA, and the interface should be conducive to use by younger and older individuals. Users should have some experience with exercise and should be interested and prepared to self-manage PA with respect to individual goals and activity levels. They should also be experienced Internet users.

Features and System Requirements

Participants' proposals on what the app should provide, arrange, or do were compiled into clusters and reformulated as system requirements.

Table 6 presents the system requirements and the possible correlating features on the app. The presentation follows a thematic structure including system requirements and features associated with the following: (1) Recording (what data to record on the app, eg, goal setting, planning, and performance), (2) Visualization (what data to obtain from the app, eg, feedback

on personal and peers' performances and health status), (3) System Alerts (how to receive reminders or rewards from the app), (4) Social Interaction (how to provide and receive encouragement and support from individuals with RA), and (5) Facts and Information (text and links about PA in RA).

Correlation Between System Requirements and Behavior Change Techniques

All system requirements correlated to a BCT consistent with Michie's taxonomy [19] (Table 7). The coding resulted in 24 BCTs related to goals and planning (5 codes), feedback and monitoring (4 codes), social support (3 codes), shaping knowledge (1 code), natural consequences (2 codes), comparison of behavior (2 codes), associations (1 code), comparison of outcome (1 code), rewards and threats (3 codes), identity (1 code), and scheduled consequences (1 code).

An overview of the clustered features, system requirements, BCTs, and associated features in the future Web-based and mobile app is provided in Multimedia Appendix 1.

Table 6. Presentation of the system requirements and features on the app structured according to theme.

System requirements ^a	Features
1. Recording: goal setting, planning, and self-monitoring of PA performance and health status	
Provide information and instructions to enable the users to set SMART (specific, measurable, accepted, realistic, time limited) goals	Features to support SMART goal setting including a calendar for PA planning
Provide the user with the possibility to record PAs performed	A calendar feature for recording of PAs performed
Provide the users with instructions on how to perform RA specific tests and to record the outcomes	A feature to support the performance and recording of RA specific physical tests and self-rate health tests
Easy access for continuously review and modify set goals	A feature available on the welcome screen, to enter the goal setting screen, to review set goal
Easy access and recording of PAs performed, rewards, and self-tests	A feature available on the welcome screen, to enter the registration screen, to record the PA performed
Provide information and instructions on individual rewards	Features to support identification and registration of individual rewards
2. Visualization: feedback on personal and peers' performances and health status	
Provide the users with feedback on PAs performed and on health outcome	Features to provide visualized feedback on PAs performed in relation to physical fitness and health, displayed as diagrams or bars
Provide the users with feedback and prompts, on PAs performed and on health outcome	A status indicator showing 'my health and/or PA' status, eg, as traffic lights or percent
Arrange for the users to share PA performance and health status	A feature to show peer group members, name, pictures/avatars, and health status/PA goal achievement
Visualization of planned PA	A feature to visualize the next planned PA on the welcome screen
3. System alerts: receive reminders or rewards/punishments from app	
Enable the system to react to individuals not following the action plan by sending reminders to facilitate adherence to the plan	Features for the system to send reminders as text messages and emails in accordance with individual action plan
Enable the system to give individual rewards	Features for system rewards, eg, medallions, stars
Arrange for the system to send "punishment" if planned PA is not performed	Features for system "punishments", eg, send an angry face
4. Social interaction: give and receive encouragements and support from individuals with RA	
Enable peers to communicate with each other to help solve problematic situations, to comment on PAs performed/not performed, give specific exercise instructions, and to share own experiences of PA	A chat feature
Enable a supportive climate for peers to: ask for and give advice on physical activity, and receive and give emotional support	Comment areas
Provide peers with devices to send encouragements	A feature for the possibility to send encouragements/likes
5. Facts and information: texts and links on up-to-date information about PA in RA	
Devices to facilitate short tips on good PAs in everyday life	A feature available on the welcome screen to present short tips on good exercises in everyday life
Provide the users with information about positive health consequences of PA and information to reduce fear of movement	A feature to present up-to-date information on PA and access to links related to PA in RA, eg, the SRA ^b
Provide the users with films and instructions on different PAs	A library with short films on PA on different levels
Provide information about who will supply the app, the intention, and objectives	A section with this information

^aWhat the app should provide for, arrange for, or do.^bSwedish Rheumatism Association.

Table 7. The system requirements with corresponding BCTs included in the app, presented according to the hierarchically groups described in the taxonomy.

System requirements ^a	Behavior change techniques
Goals and planning	
Provide information and instructions to enable the users to SMART (specific, measurable, accepted, realistic, time limited) goal setting	Goal setting behavior—Code 1.1: Set or agree on a goal in terms of the behavior to be achieved Action planning—Code 1.4: Prompt detailed planning of performance of the behavior
Peers being able to communicate with each other to help solve problem-atic situations	Problem solving—Code 1.2: Analyze, or prompt the person to analyze, factors influencing the behavior
Easy access for continuously review and modify set goals	Review behavior goal—Code 1.5: Review behavior goal jointly with the person and consider modifying goals
Enable the system to react to individuals not following the action plan	Discrepancy between current behavior and goal—Code 1.6: Draw attention to discrepancy between a person's current behavior and previously set outcome or behavioral goals or action plans
Feedback and monitoring	
Provide the users with feedback on PA performed	Feedback on behavior—Code 2.2: Monitor and provide informative or evaluative feedback on performance of the behavior
Provide the user with the possibility to record physical activities performed	Self-monitoring of behavior—Code 2.3: Establish a method for the person to monitor and record their behavior
Provide the users with instructions to enable the users to perform RA-specific tests and to record their performances	Self-monitoring of outcome—Code 2.4: Establish a method for the person to monitor and record the outcome of their behavior
Easy access and recording of PAs performed, rewards and self-rate health tests	Self-monitoring of behavior (2.3); Self-monitoring of outcome (2.4)
Provide the users with feedback on health outcome	Feedback on outcome of behavior—Code 2.7: Monitor and provide feedback on the outcome of performance of the behavior
Social support	
Facilitate for peers to comment on PAs performed/not performed	Social support (unspecified)—Code 3.1: Advise on, arrange, or provide social support or non-contingent praise or reward
Enable a supportive climate for peers to ask for and give advice on PA	Social support (practical)—Code 3.2: Advise on, arrange, or provide practical help
Enable a supportive climate for peers to receive and give emotional support	Social support (emotional)—Code 3.3 Advise on, arrange, or provide emotional social support
Shaping knowledge	
Peers being able to give specific descriptions on how to perform exercises	Instructions on how to perform a behavior—Code 4.1: Advise or agree on how to perform the behavior (includes skills training)
Devices to facilitate the provision of short tips on good exercises in everyday life	Instructions on how to perform a behavior (4.1); Also coded as Prompts/cues (7.1)
Natural consequences	
Provide the users with information about positive health consequences of PA	Information about health consequences—Code 5.1: Provide information about health consequences of performing the behavior
Provide information to reduce fear of movement	Information about emotional consequences—Code 5.6: Provide information about emotional consequences of performing the behavior
Comparison of behavior	
Provide the users with films and instructions on different PAs	Demonstration of the behavior—Code 6.1: Provide an observable sample of the performance of the behavior, for the person to aspire to or imitate
Arrange for the users to share PA performance and health status	Social comparison—Code 6.2: Draw attention to others' performances to allow comparison with own performance.
Associations	

System requirements ^a	Behavior change techniques
Provide the users with prompts to stimulate PA	Prompts/cues—Code 7.1: Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behavior
Visualization of planned PA	
Enable the system to send reminders to facilitate adherence to the action plan	
Devices to facilitate the provision of short tips on good exercises in everyday life	Prompts/cues (7.1); Also coded as Instructions on how to perform a behavior (4.1)
Comparison of outcome	
Provide information about who will supply the app, the intention, and objectives	Credible source—Code 9.1: Present verbal or visual communication from a credible source
Rewards and threats	
Provide information and instructions on individual rewards	Material incentive—Code 10.1: Inform that valued objects will be delivered if effort/progress in performing the behavior
Provide peers with devices to send encouragements	Social reward—Code 10.4: Arrange verbal or non-verbal reward if there has been effort and/or progress in performing the behavior
Enable the system to give individual rewards	Non-specific incentive—Code 10.6: Inform that a reward will be delivered if and only if there has been effort and/or progress in performing the behavior
Identity	
Enable peers to share own experiences of PA	Identification of self as a role model—Code 13.1: Inform that one's own behavior may be an example to others
Scheduled consequences	
Arrange for the system to send “punishment” if planned PA is not performed	Punishment—Code 14.2: Arrange for aversive consequence

^aWhat the app should provide for, arrange for, or do.

Discussion

Principal Findings

The co-design participants agreed that features enabling self-monitoring and peer support were important to self-manage and maintain physically active lifestyles in individuals with RA and that such features should be included in the future Web-based and mobile app.

The app should provide information and instructions to enable SMART (specific, measurable, accepted, realistic, time limited) goal setting, activity planning and recording of PA performance and progress. The participants suggested that these requirements be integrated into a calendar feature. Recent research has identified a calendar feature as the most useful tool in increasing PA in the general adult population [31]. Furthermore, self-monitoring of PA and goal setting is known to improve the efficacy of PA self-management interventions [20,32].

The app should also provide visual feedback on PA performance and health outcomes. It was suggested that these features be displayed in diagrams or as health status indicators. Feedback on PA performance is associated with increased effects of interventions [20], which is consistent with health behavior change theories describing feedback important for motivating, reinforcing, and guiding individuals [17]. The feedback may take a variety of forms, for example, verbal print communication or telephone counseling. Our participants requested visualized feedback. However, the difficulty of designing diagrams to

encourage PA was highlighted. Research is limited in this area; however, how feedback is provided visually has previously been demonstrated to be important [33].

Participants also agreed that peer support was important in maintaining a physically active lifestyle. It was suggested that the future app should include small communities of peers consisting of 10 individuals with RA, who would be expected to provide advice, encouragement, and help in providing solutions to problematic situations. The majority of self-management programs for individuals with arthritis include online or face-to-face support from health care providers [14]. However, the Arthritis Self-Management Program [34,35] is based on small communities of patients moderated by a trained peer. The program has been demonstrated to have a positive impact on disease symptoms, general health, and health care consumption. We hypothesize that the knowledge and expertise of peers with RA is one effective strategy for facilitating the maintenance of PA. However, future studies are required to test this hypothesis.

Peer support was one of several features that were perceived as unique and of significant importance for supporting the maintenance of PA in individuals with RA. The importance of easily modifying established goals based on variations in the disease course was also emphasized by the participants as a specific requirement for the population of RA. This was perceived to be crucial to encourage and self-manage PA during arthritis episodes. Our participants also wanted to monitor and follow up on health status. To support this desire, written and

visual instructions on how to perform PA and health tests specific to RA were suggested to be included in the app.

Programs supporting different health behaviors are growing in number. Health care-delivered Internet programs/interventions targeting PA behavior have been reported effective in adult populations as well as in populations with different diseases and disabilities [15,32,36]. Similar to these interventions, the future app will include peer support, self-monitoring (eg, goal setting), and feedback. In addition, there is a growing number of commercial mobile apps available targeting PA. However, a recent review concluded that there is still a lack of mobile apps that incorporate theories on behavior change [37]. Most PA apps include predesigned exercise plans, exercise instructions and registrations, and lack the inclusion of social interaction and personal goal setting [37]. The future Web-based and mobile app will differ from existing mobile apps by inclusion of features deliberately derived from theories on behavior change. It will also be adapted to the specific needs of the population of RA.

The importance of social support and self-monitoring when self-managing PA is described in learning and behavior change theories [12,17,38]. Self-monitoring is a method used to self-regulate a behavior. Self-regulation skills, defined as an individual's ability to endure short-term negative outcomes to achieve a long-term goal [38], are described in SCT [12]. The participants in our study emphasized the importance of features supporting self-regulation, such as setting and reviewing goals, planning and recording PA performance and receiving feedback. Social interaction is also described in SCT as being important for self-management. Social interaction may be part of self-regulation when peers who encourage behavioral control are accessible [17,38]. Social interaction also provides observational learning or peer modeling, another main construct in SCT [38]. Features to show the peer-group members' PA and general health status and chats or comment areas for users to share experiences may be examples of the aforementioned SCT construct.

Limitations

This study has some limitations. Although the participants diagnosed with RA ($n=5$) varied with respect to age, gender, years living with the disease, and PA habits, the small number reduced the variations in proposals and preferences. The limited number of participants was due to the requirement of creating a convenient work group ($N=10$). The creation of two separate work groups was also considered; however, it was not possible due to economic and time limits. However, the results from the first step of the co-design process [29] were the starting point for the workshops; thus, they may have added to variations in proposals considered in this study. Nevertheless, this study may lack a description of features essential for the target users of the future app. In summary, the generalizability of the results from this study to the target user group of the future app remains unknown. In the next step of the development process, it is therefore important to test the first versions of the Web-based and mobile app in iterative cycles with representatives from the target-user group.

Another limitation is associated with the participants' experiences of mobile apps to support their PA. Only 40% of the participants with RA reported having tried similar apps, which may have hampered discussions on features of our future app. However, to facilitate the discussions during the workshops, the features were discussed as "I want to be able to...". These proposals were then translated into possible features on a computer or mobile phone by the moderator or the other participants.

Strengths

One strength of this study is the use of a BCT taxonomy to describe the intervention. Our results show that the system requirements were possible to associate with theoretically derived BCTs using the taxonomy established by Michie et al [19]. Previous studies reporting on the use of BCT taxonomy have used it to describe and compare intervention features [39-41]. We experienced a few obstacles when using the taxonomy. The features had to be clearly described to fit to a single corresponding BCT. The video recordings enabled us to obtain that additional data. There is also an interpretation component to be aware of when using the taxonomy. To improve the credibility of the coding in this study, 3 researchers were involved in the coding, which enabled discussion of disparities and how to interpret the definitions in the taxonomy. Coding the system requirements based on the taxonomy provided an additional description of the features. A future challenge for the development of mobile apps aimed for behavior change is the question of how to combine the inclusion of several BCTs that seem to be preferable to enable behavior change, and a user-friendly and simple application. Hence, in the future, we need to identify how many and which BCTs to include in our future app.

Another strength is the use of co-design, that is, active involvement of users throughout the development process. Involvement of users in development of health services has been described as significant for the viability, usability, and effectiveness of services [21,42]. We propose that this method of co-designing decreases the interpretation of the users' requirements and preferences due to the ability to discuss the uncertain matters during the production of the requirement specification. However, this method is also time consuming and challenging with regard to, for example, the importance of merging the different perspectives and the difficulty involved in managing the professional role. The opportunities and challenges of co-design as performed in this study will be further explored and reported elsewhere.

Conclusions

This study provides basic data on a requirement specification of an eHealth service to support the maintenance of physical activity adapted to the specific needs of individuals with rheumatoid arthritis. The participants agreed on the importance of including features for self-monitoring and peer support in maintaining a physically active lifestyle. The results are consistent with learning and behavior change theories, which describe physical activity as a complex behavior determined by personal, behavioral, and environmental factors. The system requirements correlated with BCTs, which may improve the

possibility of replicating and evaluating the future Web-based and mobile app and, furthermore, enables the identification of how many and which BCTs to include, thereby advancing our knowledge of health behavior change.

The use of co-design in this study is based on our assumption that people living with a chronic disease, such as RA, have

experiences and knowledge that can improve health care services. There may also be an intrinsic value for people with RA knowing that the app was developed by peers. By involving the users in the requirement specification, we hope to be able to further refine the features according to the users' needs. In the next step of development, the first version of the app will be produced and tested by new users.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Overview of the clustered features, system requirements, BCTs, and associated features on the app, thematically grouped based on associations with Recording, Visualization, System Alerts, Social Interaction, and Facts and Information.

[[PDF File \(Adobe PDF File\), 62KB - resprot_v4i1e22_app1.pdf](#)]

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Abbreviations

BCT: behavior change technique
PA: physical activity
RA: rheumatoid arthritis
SCT: social cognitive theory
SRA: Swedish rheumatism association

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Original Paper

Development of MijnAVL, an Interactive Portal to Empower Breast and Lung Cancer Survivors: An Iterative, Multi-Stakeholder Approach

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Abstract

Background: MijnAVL (MyAVL) is an interactive portal being developed to empower cancer survivors. Literature review and focus groups yielded the selection of features such as access to the electronic medical record (EMR), patient reported outcomes (PROs) and related feedback, and a physical activity support program.

Objective: Our aim was to present a final design of MijnAVL based on (1) health professionals' evaluation of proposed features, (2) cancer survivors' evaluation of a first draft, and (3) cancer survivors' evaluation of a functional online prototype.

Methods: Professionals from various disciplines gave input to the content of and procedures related to MijnAVL. Subsequently, 16 cancer survivors participated in an interview to evaluate content and graphic design of a first draft (shown with screenshots). Finally, 7 survivors participated in a usability test with a fully functional prototype. They performed predefined tasks (eg, logging in, finding a test result, completing a questionnaire) while thinking aloud. Descriptive statistics and simple content analysis were used to analyze the data of both the interviews and the usability tests.

Results: Professionals supported access to the EMR (eg, histology reports, lab results, and their letters to general practitioners). They also informed the development of PROs and the physical activity support program. Based on the first draft, survivors selected the preferred graphic design, approved the features and provided suggestions for the content (eg, explanation of medical jargon, more concise texts, notification by emails). Usability tests revealed that it was relatively easy to navigate the website and use the different features. Recommendations included, among others, a frequently asked questions section and the use of hyperlinks between different parts of the website.

Conclusions: The development of MijnAVL, an interactive portal to empower breast and lung cancer survivors, was performed iteratively and involved multiple groups of end-users. This approach resulted in a usable and understandable final version. Its effectiveness should be determined in further research.

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KEYWORDS

cancer survivors; interactive portal; development; usability testing; empowerment

Introduction

Background

People diagnosed with cancer or who have been successfully treated for cancer (cancer survivors) often experience a range of physical (eg, fatigue, pain) and psychosocial (eg, distress, disruption of work and social relationships) health problems as a result of their disease and its treatment [1]. The majority of cancer survivors want to know as much as possible about their diagnosis, treatment, side effects, and health promotion [2,3]. Also, although we know that physical activity can have positive effects on both the physical and psychosocial well-being of cancer survivors [4,5], many survivors do not meet physical activity norms [6,7]. To cope with the cancer-related problems, fulfil information needs, and promote physical activity, efforts are required to enhance patients' knowledge, skills, and motivation to positively influence their health, often referred to as patient empowerment [8].

In the Netherlands, 94% of the population has daily access to the Internet. Among the elderly, this varies from 20% (age 75 and older) to 55% (age 65-75), and it is expected that these figures will continue to increase [9]. Apart from information, online interventions can be provided via the Internet, and these eHealth initiatives are likely to increase patient empowerment [10]. To empower breast and lung cancer survivors of the Antoni van Leeuwenhoek hospital, part of the Netherlands Cancer Institute (a comprehensive cancer center in Amsterdam), we are developing "MijnAVL" (MyAVL), a personal, interactive portal. In developing the portal, we have initially focused on the population of breast and lung cancer survivors because of their distinct disease characteristics, impairments, rehabilitation needs and options, and the relatively high incidence of these tumors [11]. The focus on breast and lung cancer relates primarily to the specific content of the portal, but not to its design features or overall functionality. We expect that the design and functionality of the portal will be applicable to a wide range of cancer survivors.

Features of MijnAVL

The features of MijnAVL are primarily based on a literature review of Web-based interventions for patient empowerment and physical activity in various chronic diseases. We identified features of interactive portals that are likely to be relevant for cancer survivors, including education, self-monitoring, feedback (tailored information), self-management, personal exercise program, and communication with professionals and/or fellow patients [12]. Subsequent focus groups revealed that health professionals were most interested in portal features that would provide them with relevant information about the health status of their patients, while cancer survivors preferred the features that could fulfil their information needs. These preferences led to the following set of requirements for MijnAVL: (1) patient education: relevant information about diagnostic tests, treatments, and rehabilitation opportunities, (2) an overview of past and future appointments, (3) access to the electronic medical record (EMR): reports of diagnostic tests and lab tests, letters to general practitioners, etc, (4) patient-reported outcomes (PROs) and related feedback for patients: symptom and

health-related quality of life outcomes including a summary of scores, accompanied by relevant information on the different outcomes (eg, background information and tips for fatigue), and (5) a physical activity support program: tailored physical activity advice based on a set of questionnaires.

Survivors can access MijnAVL by providing their DigiD username and password accompanied by a code that is sent to their mobile phone. DigiD is a safe authentication method related to one's social security number, that is used primarily (but not exclusively) by various governmental services.

The objective of the current study was to describe the development of MijnAVL by "translating" the proposed set of requirements into final content and design based on (1) health professionals' evaluation of content, (2) cancer survivors' evaluation of a first draft of screenshots (interviews), and (3) cancer survivors' evaluation of a functional prototype through usability tests.

Methods

Overview

MijnAVL was developed using a stepwise approach involving both health professionals and cancer survivors from our institute, as this increases the likelihood of the portal being accepted and actually used in daily practice [13,14]. The Institutional Review Board exempted this study from formal review, and all cancer survivors provided written informed consent.

Health Professionals' Evaluation of Content

We obtained health professionals' feedback during various sessions in which the proposed portal features were presented in PowerPoint. With regard to access to the EMR, we organized group sessions for breast and lung cancer separately, and in both sessions approximately 10 professionals participated (medical oncologists, surgeons, radiotherapists, nurse practitioners). We discussed which parts of the EMR should be accessible and under what conditions. After we had constructed a first draft of MijnAVL, these professionals participated again in a group session. Seven professionals joined a group session to discuss when PROs should be completed and what type of feedback should be provided to both health professionals and survivors. In addition, we had individual interviews with a medical oncologist, 2 surgeons, a nurse practitioner, and a social worker about the feedback that could be provided based on PRO scores. The advice to be given in the physical activity support program was written and discussed in collaboration with 5 physical therapists and a rehabilitation physician.

Cancer Survivors' Evaluation of a First Draft (Semistructured Interviews)

Cancer survivors were eligible when they were adult, under curative treatment or within 3 years of treatment completion, had a basic fluency in Dutch, and had at least minimal experience with computers and Internet. We organized semistructured interviews until saturation of qualitative data occurred (ie, no new information came up) [15]. Ten breast and 6 lung cancer survivors with a mean age of 61.4 (SD 9.8, range 45-77) years participated; 75% of participants were female. The

majority of the survivors were highly educated, and 14 individuals had been using the Internet daily for more than 2 years.

Participants completed a questionnaire on sociodemographics and verbally consented to audiotaping of the session. Subsequently, the researcher (WK or WG) presented screenshots with two types of graphic design and examples of the intended content of MijnAVL. In a semistructured interview, we focused on portal design and content, especially regarding access to the EMR, PROs, and the physical activity support program. Participants also reported what they considered to be the most positive and negative aspects of the portal and suggestions for possible improvements.

The interviews were analyzed by a simple content analysis [16] of the notes taken by the researcher and, if notes were not sufficient, listening back to the audiotapes. The data were structured according to each feature of MijnAVL or the category graphic design. The results from these semistructured interviews were used to develop a functional prototype of the portal. Before conducting the usability tests, the technical functioning of MijnAVL was rigorously tested in numerous iterations by the research team.

Cancer Survivors' Evaluation of a Functional Online Prototype (Usability Tests)

Eligibility criteria and recruitment procedures were identical to those of the semistructured interviews. We organized individual sessions in a lab setting until saturation occurred [15]. Five female breast cancer and 2 male lung cancer survivors, with a mean age of 50.6 (SD 5.7, range 44-61) years, participated in a usability test. They all had been using the Internet for more than 2 years, and about half had graduated from college or university.

First, participants completed a questionnaire on sociodemographics and agreed to audiotaping of the session. Then they performed various tasks, including logging on to the portal, completing a questionnaire digitally, checking future appointments, and finding the results of a lab test. During task performance, they were encouraged to think aloud, which provided insight into how they were performing these tasks [17]. After completion of the tasks, the researcher asked about the positive and negative aspects of the portal. Finally, participants completed a questionnaire on their expectations regarding the portal, based on the Unified Theory of Acceptance and Use of Technology (UTAUT) [18], and on anticipated effects on patient empowerment, based on the Patient Activation Measure [19]. Data analysis was similar to that of the interviews, except for adding usability as a category to organize the data. Results were used to produce the final design of MijnAVL.

Results

Health Professionals' Evaluation of Content

Access to the Electronic Medical Record

The majority of health professionals supported patients' access to the reports of lab tests, histological examinations, and letters from the hospital to general practitioners. However, they

expected that this information would evoke anxiety and many questions. Therefore, professionals involved in lung cancer care especially had reservations about showing radiology reports, specifically due to ambiguous test results and the generally poor prognosis of lung cancer survivors. They indicated several conditions for providing test results: development of an accompanying medical dictionary, introductory texts for each report, and a delay of 2 weeks before sharing the test results online (to ensure that test results are personally discussed with patients first).

Patient Reported Outcomes and Related Feedback

Health professionals recognized the potential benefits of PROs (being aware of a patients' symptoms and quality of life), but they also expected an increased workload due to having to discuss these various issues with their patients in more detail than might typically be the case. Patients should preferably complete PROs at diagnosis, after completion of treatment, and at each follow-up visit. Health professionals preferred having PRO data summarized graphically, with clear indication of problem areas (especially worsening of symptoms), the clinical significance of scores, and suggestions for referral. They were reluctant about automated advice to patients about different symptoms because they believed that the etiology of many symptoms is too complex to allow for standardized advice. It was therefore decided to provide patients with an overview of the PRO results, supplemented by more general information and advice related to each domain of the questionnaire. For example, if survivors reported clinically relevant levels of fatigue, they would be directed to information on cancer-related fatigue. Professionals from all relevant disciplines assisted in drafting this type of information.

Physical Activity Support Program

Because the support to be offered in the program is relatively non-specific (ie, it is aimed at increasing general levels of physical activity), we opted for a stand-alone, computerized system (providing advice based on a questionnaire). It was decided to cover the following factors in the physical activity questionnaire: "stage of change", nutritional status, possible contraindications for physical activity, treatment phase (during or after treatment), tumor type (breast or lung cancer), whether the patient is participating in a supervised exercise program, and if yes, whether additional information on physical activity is desired. Two well-known theoretical models were used to generate the physical activity advice: Social Cognitive Theory [20] and Theory of Planned Behavior [21]. All information and advice was written in a collaboration between the researchers, the physical therapists, and the patient education service of the hospital.

Cancer Survivors' Evaluation of a First Draft (Semistructured Interviews)

Overview

In general, participants were positive about MijnAVL and the majority of them were familiar with the DigiD authentication method to log in. Major positive aspects of MijnAVL were involvement in the health care process and the accessibility of

information (transparency), whereas negative aspects were too lengthy texts and use of medical jargon.

Access to the Electronic Medical Record

Access to the EMR was appreciated, but concerns were raised about being able to understand the information provided and the potential worry or upset that could result. These concerns appeared to be justified, as most patients understood less than half of the information provided in the radiology and pathology reports. However, this improved when they were provided with a dictionary of terms. Results of clinical lab tests were easier to understand because reference values were already provided in the tables. Some participants wanted to receive additional contextual information, for example, which specific blood test values indicate that one is able to receive a new cycle of chemotherapy or how blood markers are related to lifestyle factors (such as cholesterol levels). Access to the letters to the general practitioner were considered as a good summary by some, and one participant wanted to be provided with the treatment plan and results from multidisciplinary meetings.

Patient Reported Outcomes and Related Feedback

Participants wished to receive a notification (eg, text message, email, or a notification on the homepage of MijnAVL) when they needed to complete a questionnaire. Most participants were able to understand graphical summaries of the PROs, and there was no clear preference for line charts versus bar charts. The

majority wanted to see changes over time, both positive and negative.

Physical Activity Support Program

Many of the participants (11/16) expected that this would increase awareness of the importance of being physically active during and directly after treatment. Five were already quite physically active and would not need such a program. Participants expected to receive information on which activities are allowed (or discouraged) during treatment, and more personal information on rehabilitation and reimbursement of rehabilitation programs. The examples of this type of information and advice were judged to be interesting, understandable, reliable, of appropriate length, and quite motivating. An example of a graph presenting the amount of physical activity undertaken (based on self-report) during the past week was relatively easily understood.

Graphic Design

The preferred homepage contained large buttons with icons that indicated the features of MijnAVL; this was perceived as highly accessible. The favored content page was divided into several blocks of main text with the possibility to click for more information. Participants liked that the information was illustrated by visual images. Recommendations and resulting changes in portal design and content are shown in [Table 1](#).

Table 1. Recommendations and changes in portal design and content based on semistructured interviews with cancer survivors (N=16).

Recommendation	Adjustment(s)
Graphic design	
The term “physical activity advice” is not very appealing.	Physical activity advice was changed to “keep fit”.
The overall look of MijnAVL is somewhat boring.	A photo was added to the background to improve the overall visual attractiveness.
The large red text box indicating patient number, name, and date of birth should be displayed on the homepage only.	The text box was deleted from all pages except for the homepage. Instead, identical information was displayed on top of the menu on the left.
Provide the specific location in the hospital in the overview of appointments.	None (technically not possible).
Content: Access to the EMR	
Provide detailed information about the different elements of the blood (What does that abbreviation mean? What is the function of this element?).	A link to the website of the Dutch Society of Clinical Chemistry and Laboratory Medicine (NVKC), containing this information, was included.
The information from the EMR should be provided in a way that a layman can understand.	A medical dictionary was created.
Content: PROs and related feedback	
It is necessary to receive a notification when you have to fill out a questionnaire.	An email will be sent when a new questionnaire needs to be filled out.
Content: Physical activity support program	
The explanatory text accompanying the graph with physical activity information is too complicated.	It is technically not (yet) possible to include graphs, so the information is provided in a table. The explanatory text was adjusted and simplified accordingly.

Cancer Survivors' Evaluation of a Functional Online Prototype (Usability Tests)

Overview

More than half of participants (5/7) mentioned the overview of appointments to be the most positive aspect of MijnAVL, followed by access to the EMR, the reliability of the information, and the fact that all information is gathered at a single location. Less positive aspects included concerns about possible computer hacking and the comprehensibility of information from the medical record. MijnAVL was rated as 7.9 on a 10-point scale (10=excellent). Suggestions for additional features included an option to ask questions online (e-consult) and a frequently asked questions section (with both portal-related and cancer-related issues).

Access to the Electronic Medical Record

Participants highly appreciated the accessibility of information from the EMR, especially the possibility of reading over information. The standard dictionary with medical terms on MijnAVL was helpful but did not contain all words that participants were looking for. The clinical lab results were relatively easy to understand, although deviating values should be highlighted.

Patient Reported Outcomes and Related Feedback

Participants were content with the possibility of completing PROs online instead of in the hospital. There were some complaints about response options, and 3 participants thought that the questionnaire was too long. However, as we are using validated questionnaires, these factors could not be changed. All were able to interpret their scores per domain as shown in the tables and valued the availability of information and advice on many aspects of quality of life.

Physical Activity Support Program

Five participants thought that they would benefit from the tailored advice of the program; the remaining two indicated that they were already intrinsically motivated to be physically active. One explicitly mentioned that it is good to incorporate a specific

goal such as the Dutch Norm of Physical Activity. Some questions of the questionnaire related to the program were hard to answer, for example, on the amount of physical activity in the past week (recall problems). The table showing the amount of high and moderate intensive exercise was clear to everyone.

Graphic Design

Participants were satisfied with the clear, simple, and accessible layout. Letter type and font size were good, and the menu bar on the top of the page was perceived as convenient. It was recommended to place the most important information at the top of each page and keep the information as concise as possible. Many participants noted that they were inclined to skip the introductory texts and first look for the "real" information (eg, a table with their personal quality of life scores).

Usability

All participants managed to log in to the website, although one experienced problems due to the browser used. They were able to navigate through MijnAVL with little or no help and typically used the menu bar on top of the page to go to other features of MijnAVL. The menu on the left was used to navigate within a single feature. Participants made several navigation errors. One tried to find the results from a mammogram by clicking on the appointment during which the mammogram was taken, while this information could be found in the EMR. Three experienced difficulties with finding the quality of life questionnaire to be filled out, as well as with finding the additional information on quality of life domains. Most of them first visited the "Keep fit" page to find the physical activity questionnaire, as they associated this with physical activity. However, this one could actually be found under the button "questionnaires". The final task, logging out from MijnAVL, was not a problem. An overview of recommendations and adjustments based on the functional prototype are shown in [Table 2](#).

Expectations

[Table 3](#) shows the results of the questionnaire on expectations of MijnAVL and expected effects on patient empowerment.

Table 2. Recommendations and adjustments based on usability tests (N=7).

Recommendation	Adjustment(s)
Graphic design	
The button to log in should be placed on top of the login page.	The button to log in was moved to the top of the login page, followed by instructions on what to do when you forgot your password or need to request a DigiD account.
Introductory and/or explanatory information should be provided in a pop-up.	None (technically not possible yet).
Content: Access to the EMR	
The denomination “medical imaging” is not clear and should be changed to “radiology”.	This term was not changed, as “medical imaging” also contains the results of nuclear medicine.
The meaning of the letters L (low) and H (high) accompanying clinical lab results should be elucidated.	The introductory text was extended with a sentence explaining the meaning of L and H.
It would be convenient if you could search in the medical dictionary.	Planned for a next phase (technically not possible yet).
The menu on the left should contain only the test results that you have actually received.	Planned for a next phase (technically not possible yet).
Content: PROs and related feedback	
You have to scroll a lot when filling out the questionnaires.	None (technically not possible).
The educational materials should be placed in alphabetic order.	Planned for a next phase (technically not possible yet).
Content: Physical activity support program	
A hyperlink to the physical activity questionnaire is required on the “Keep fit” page when physical activity support has not yet been provided.	This hyperlink was added.
User performance	
More direct hyperlinks between the different features would be helpful.	These hyperlinks were added where possible.
A section with frequently asked questions would be helpful.	A list with frequently asked questions related to login procedures and who to approach in case of questions was added.
Informational movies would make MijnAVL more attractive.	Planned for a next phase (due to time restrictions).

Table 3. Expectations based on UTAUT and expected effects on patient empowerment (N=7).

	Negative ^b , n	Neutral ^b , n	Positive ^b , n
Statements based on UTAUT^a			
Using MijnAVL will contribute positively to my feelings of control with regard to my health status	1	1	5
MijnAVL will be easy to use	0	0	7
People who are important to me would think that I should use MijnAVL	3	4	0
I have the knowledge and resources to use MijnAVL	0	0	7
I will be able to use MijnAVL	0	0	7
I feel positive about MijnAVL	0	0	7
Using MijnAVL will evoke emotional feelings	2	1	4
I intend to use MijnAVL	0	1	6
Statements related to patient empowerment^a : “By using MijnAVL...”			
...my knowledge about my disease, treatment, and effects will increase	0	3	4
...I can take an active role in my own health care	1	4	2
...I am confident I can help to prevent or reduce problems associated with my health	2	3	2
...I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself	4	0	3
...I am confident that I can tell a doctor concerns I have even when he or she does not ask	1	2	4
...I will be motivated to maintain lifestyle changes	1	6	0

^aAll statements were rated on a 5-point scale ranging from 1 (completely disagree) to 5 (completely agree).

^bNegative=score 1 + 2; Neutral=score 3; Positive=score 4 + 5.

Discussion

Principal Findings

In this paper, we have described the development of the final design of MijnAVL, an interactive portal to empower cancer survivors. Health professionals provided feedback on the proposed content of and conditions required for MijnAVL, and contributed to the development of information and advice. Cancer survivors participated in interviews to evaluate a first draft of screenshots and performed usability tests with a functional prototype. Their suggestions concerning graphic design, content, and usability were taken into account as much as possible in generating the current version of MijnAVL, within the limits imposed by technology and time (see [Figures 1-3](#) and [Multimedia Appendix 1](#)).

In general, both health professionals and cancer survivors were positive about the development of MijnAVL. Cancer survivors appreciated the features that provided them with relevant information and especially the overview of appointments and access to their EMR. However, it is known that patients, in general, do not fully understand their medical records [22]. This could explain why they indicated that a dictionary or some other type of aid was needed to understand all the information in the EMR. Other studies have also shown that an explanation of medical jargon, abbreviations and acronyms, and additional information on tests and results [23] or an online dictionary [24] are useful and necessary tools. Although the participants in this study have provided a suggestion in this regard (eg, that it should be possible to search in the dictionary), further research is

needed to determine the specific content and optimal format of these tools.

Related to this, health professionals expected that patients' access to the EMR would lead to an increased workload, because patients would find it difficult to understand the medical information and it could evoke anxiety and many questions. Indeed, based on a usability test, study participants expected that using MijnAVL would evoke emotional feelings. However, these expectations may not be justified, as several studies have shown that giving cancer patients access to their EMR does not increase anxiety levels [25,26]. Furthermore, Rodriguez et al [27] have shown that, according to 75% of the physicians and nurses participating in their study, workload did not increase after the implementation of patients' access to laboratory results. The fear of an increased workload also applied to the introduction of PROs, due to the expected time needed to prepare consultations and discuss results. However, previous trials have shown that the use of PROs does not increase the duration of consultations [28,29].

Survivors' feedback regarding PROs and the physical activity support program was more diverse. While the majority saw value in these features of the portal, some did not. It is important that participants not only value the usability of MijnAVL, but that they are also aware of its aim (increasing patient empowerment). In this study, survivors anticipated that using MijnAVL would only moderately improve empowerment ([Table 3](#)). It may have been difficult for them to judge the actual value of MijnAVL and its interactive features based on a usability test only. An alternative explanation could be that the features

need further adjustment and fine-tuning to enhance their effectiveness.

Our results indicated that professionals were primarily interested in PRO scores indicating a worsening of symptoms, whereas survivors preferred to see both worsened and improved scores. This could be due to their different perspectives: professionals need to help the patient to reduce symptom burden, while survivors apparently want to monitor changes in their symptom

experience and functional health, both positive and negative. When feeding back the results of PROs to health professionals and survivors, it is important to take into account their unique preferences. What also needs to be fine-tuned, is the way that information is provided. For example, survivors suggested that educational materials should be placed in alphabetic order, which is not yet possible due to technical restrictions. However, we acknowledge the importance of providing information in the most convenient manner.

Figure 1. MijnAVL: Homepage.

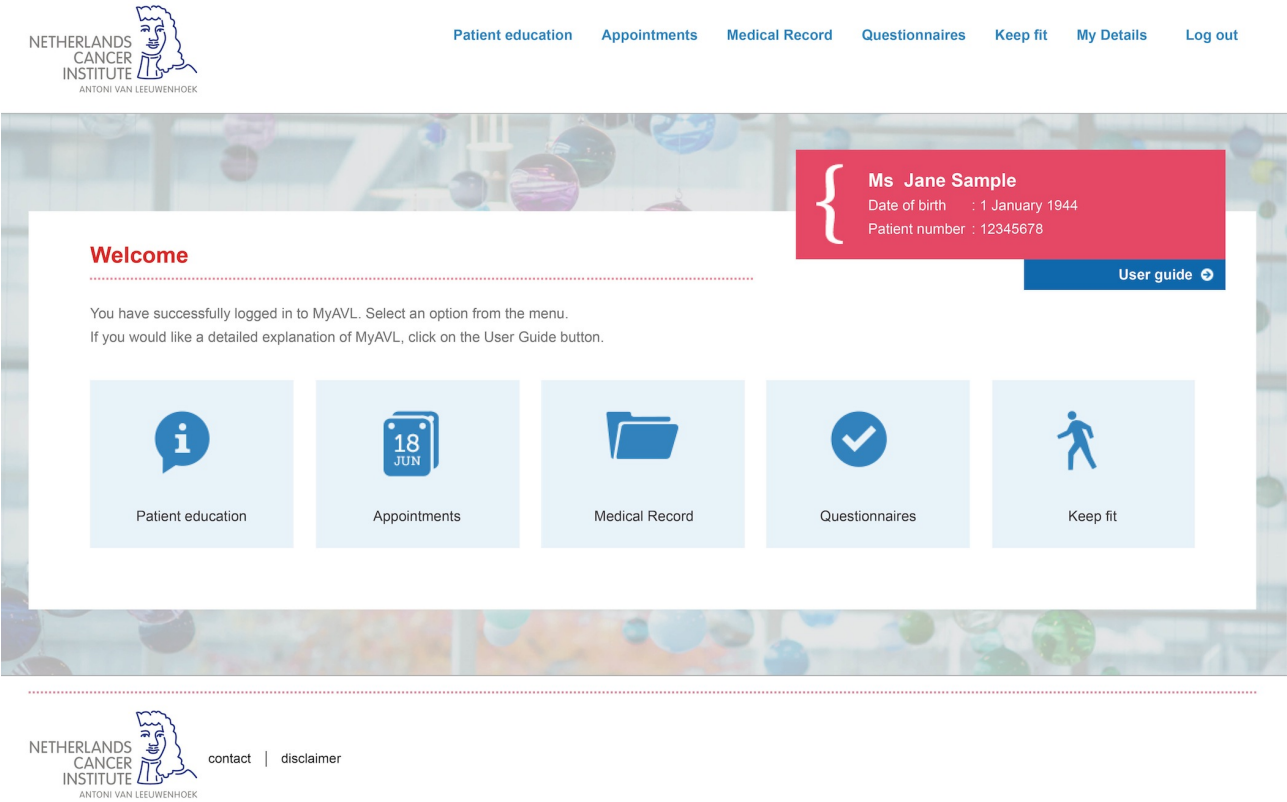
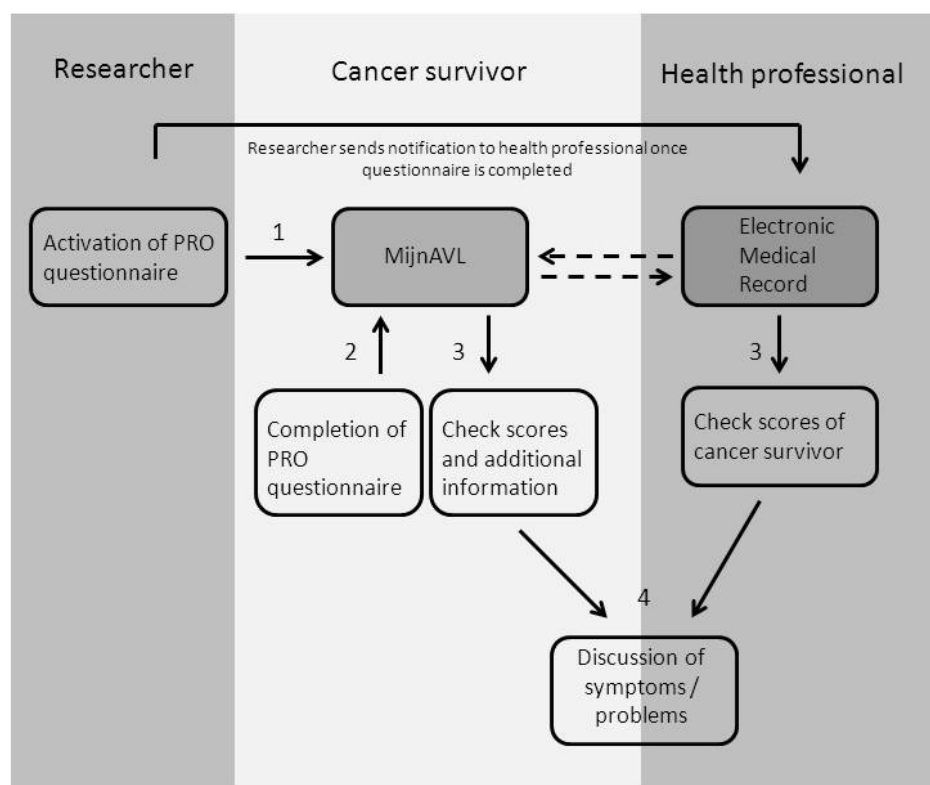
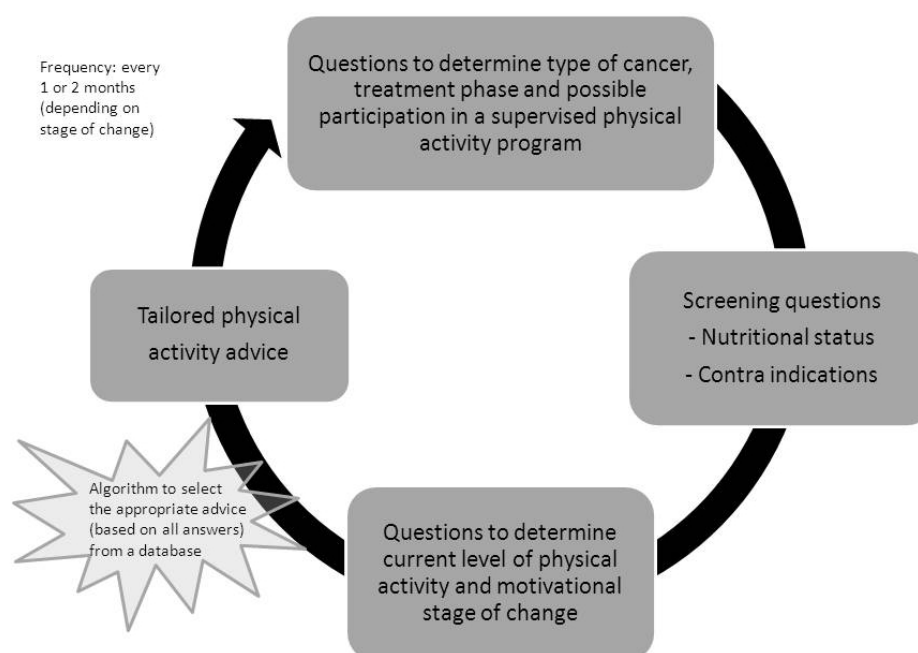


Figure 2. Interactive feature of MijnAVL: PROs.**Figure 3.** Interactive feature of MijnAVL: physical activity support program.

Limitations

Several possible limitations of this study need to be considered. First, the number of participants in this study was relatively small (16 and 7 participants in the interviews and usability tests, respectively). However, it is known that serious problems are most likely to be discovered with the first participants, and the last sessions did not reveal any new issues (saturation), so we

assume that these numbers were sufficient [30]. Second, participants were probably more likely to be interested in and able to use MijnAVL than those who declined (response bias). Indeed, important reasons for non-participation were not having a computer and disinterest, suggesting that our sample may well be representative of the target population of computer literate patients who have interest in such a system. It is a challenge to motivate and enable the non-participants to use MijnAVL in

order to benefit from its features. Finally, this was a single center study conducted in a specialized cancer center. The results may not be entirely applicable to other settings, in which the treatment of cancer is just one of many different disciplines.

Strengths

An evident strength was that we used a multi-stakeholder approach in which all relevant end-users were involved. Both health professionals and cancer survivors provided feedback during the developmental process of MijnAVL, ensuring that the portal fits their needs as much as possible. Second, the development of MijnAVL included multiple iterations, with the results of the previous iteration being incorporated in the next prototype. We were able to detect possible problems regarding content and design at an early stage and to adjust MijnAVL accordingly, resulting in a user-friendly portal.

Although similar initiatives have been undertaken successfully in other chronic disease areas such as diabetes, congestive heart failure and chronic obstructive pulmonary disease [12,31,32], the use of information technology to enhance patient empowerment is relatively new in the field of oncology. The features of MijnAVL reflect different trends that are currently seen in oncology, such as electronic symptom monitoring (eg,

[33,34]), hospital-based systems to provide patient education, and to a lesser extent, access to medical record information. MijnAVL incorporates these various features, targeting different aspects of cancer survivorship simultaneously. We anticipate that the portal will enhance empowerment by increasing survivors' knowledge and understanding of their disease and its treatment, by providing personally relevant information, by allowing them to self-monitor their symptoms and functional health, and by providing tools for becoming more physically active. We are currently conducting a pilot study to evaluate the effects of MijnAVL on empowerment and satisfaction.

Conclusions

In this paper, we have described an iterative approach, involving all relevant stakeholders and end-users, to develop MijnAVL. Content and usability were improved based on the feedback of participants, which has resulted in a user-friendly portal with the potential to empower cancer survivors. Ongoing and future research is needed to evaluate the efficacy of MijnAVL in daily clinical practice in terms of meeting the information needs of cancer survivors and health professionals, in enhancing patient empowerment, and ultimately in contributing to the quality of life of cancer survivors.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Screenshots of MijnAVL.

[[PDF File \(Adobe PDF File\)](#), 1MB - [resprot_v4i1e14_app1.pdf](#)]

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Abbreviations

EMR: electronic medical record

PROs: patient-reported outcomes

UTAUT: Unified Theory of Acceptance and Use of Technology

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Original Paper

Engaging Community Stakeholders to Evaluate the Design, Usability, and Acceptability of a Chronic Obstructive Pulmonary Disease Social Media Resource Center

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Abstract

Background: Patients with chronic obstructive pulmonary disease (COPD) often report inadequate access to comprehensive patient education resources.

Objective: The purpose of this study was to incorporate community-engagement principles within a mixed-method research design to evaluate the usability and acceptability of a self-tailored social media resource center for medically underserved patients with COPD.

Methods: A multiphase sequential design (qual → QUANT → quant + QUAL) was incorporated into the current study, whereby a small-scale qualitative (qual) study informed the design of a social media website prototype that was tested with patients during a computer-based usability study (QUANT). To identify usability violations and determine whether or not patients found the website prototype acceptable for use, each patient was asked to complete an 18-item website usability and acceptability questionnaire, as well as a retrospective, in-depth, semistructured interview (quant + QUAL).

Results: The majority of medically underserved patients with COPD (n=8, mean 56 years, SD 7) found the social media website prototype to be easy to navigate and relevant to their self-management information needs. Mean responses on the 18-item website usability and acceptability questionnaire were very high on a scale of 1 (strongly disagree) to 5 (strongly agree) (mean 4.72, SD 0.33). However, the majority of patients identified several usability violations related to the prototype's information design, interactive capabilities, and navigational structure. Specifically, 6 out of 8 (75%) patients struggled to create a log-in account to access the prototype, and 7 out of 8 patients (88%) experienced difficulty posting and replying to comments on an interactive discussion forum.

Conclusions: Patient perceptions of most social media website prototype features (eg, clickable picture-based screenshots of videos, comment tools) were largely positive. Mixed-method stakeholder feedback was used to make design recommendations, categorize usability violations, and prioritize potential solutions for improving the usability of a social media resource center for COPD patient education.

KEYWORDS

COPD; health communication; social media; patient education

Introduction

Approximately 12.7 million adults have chronic obstructive pulmonary disease (COPD) [1] and experience complications, such as breathing exacerbations that require frequent hospitalization [2]. Patients with COPD generally receive little information on the social and behavioral dimensions of living with breathing problems, such as techniques to improve self-management, self-efficacy, and self-regulation of dyspnea (ie, shortness of breath) [3,4]. Moreover, few patients with COPD are ever referred to pulmonary rehabilitation, primarily because most programs operate in outpatient hospital settings [5,6]. Pulmonary rehabilitation helps provide patient education on rehabilitative skills such as pursed-lipped and diaphragmatic breathing, stress management, and customized exercise [7,8]. With limited instruction and skill-building resources available to patients, a majority of patients living with COPD are unable to modify their lifestyles, which ultimately increases their risk of hospitalization [9]. Research suggests the most significant improvements in reducing health care utilization due to COPD complications have been achieved from educational interventions designed to meet the dynamic self-management learning needs of patients [3,10-12].

Educational programs in COPD management interventions frequently include smoking cessation, medication use, exercise, breathing strategies, exacerbation prevention, and stress management [13]. Patient education can help individuals living with COPD to achieve fundamental objectives such as increased knowledge and self-efficacy, which are both associated with exacerbation-related health care utilization [10,14,15]. While patient education is fundamental to improving outcomes in COPD, older patients often experience impairments to memory and abstract reasoning which causes low health literacy [16,17], limited compliance with complex self-management guidelines [18], and increased dependence on the health care system [19,20]. Low health literacy also often goes unrecognized by health care providers [11,18].

Over the past decade, the Internet has become a common place where patients with chronic disease can access health information, improve health literacy, and interact socially with peers regarding common health conditions [21-24]. Patients with COPD have participated in online self-management programs that have shown moderate levels of usability and effectiveness [25,26]. However, one previous usability study of an eHealth behavior change intervention in COPD asked participants to read lengthy tailored messages in fixed educational modules, which was ultimately determined to be too much health information for most patients to process [26]. Patients with chronic disease generally report difficulty accessing comprehensible disease-related content on the Internet, which has led to slow adoption of consumer health care technologies for chronic disease self-management [27-29]. In particular, elderly and minority patients commonly experience

difficulty using two-way health communication technologies (Web 2.0) [24,30], which often results in greater attrition and nonuse of online, chronic disease self-management interventions [31,32]. Therefore, the design of easy-to-use, interactive websites for patients living with chronic disease is becoming increasingly important as the shift towards patient empowerment and self-control of health outcomes continues to become more and more pervasive throughout the health care system [33,34].

Information and communication technologies, such as social media, have the potential to expand the reach of strategic health communication interventions that promote disease prevention and life-saving health protective behaviors. Social media is a “tool or platform that derives its content and principal value from user engagement and permits those users to interact with content as part of a larger movement in communications organized under Web 2.0” [35]. Specifically, social media is well suited for providing patients with motivational messages and key behavioral change resources that prompt and facilitate good health [34]. Creating easy-to-use social media resources that enable two-way health communication among patients with chronic disease(s) and their informal caregivers (eg, friends, family members) may help to extend the efficacy of traditional patient education on self-management [32,36].

Older adults with chronic disease often possess low eHealth literacy, or a low ability to seek, find, understand, and appraise online health information and apply knowledge gained to addressing or solving a health problem [37]. For these reasons, it is important to explore the use of empowering, low-tech self-management tools that can be effectively controlled by the user. To prevent user dissatisfaction and abandonment of technology, consumer health informatics tools should be designed to allow even the novice user to interact with, and manipulate, the interface to accomplish personal task objectives with few errors [38]. Self-tailored, chronic disease self-management programs structure interactive, self-directed learning experiences that cover topics such as stress management, personal fitness/exercise regimens, and preparing healthy meals. The concept of self-tailoring patient education is based on self-efficacy theory [39]. This theory proposes that sociocognitive support resources are best suited to help groups and individuals pursue mastery experiences that build self-confidence for initiating, performing, and maintaining time-bound behavioral action plans that are both beneficial and achievable [40]. Vicarious learning opportunities facilitated through interactive health communication technology represents a practical approach to using Web 2.0 for self-management that can augment patient-provider communication and motivate health behavior change. A systematic review of Web 2.0 chronic disease self-management interventions revealed that these types of programs may reduce health distress and activity limitation, improve health status, and foster more active patient engagement [32].

To date, no usability studies have evaluated patient use of popular social media to access and engage in online COPD patient education on respiratory therapy and self-management support. Usability testing is a fundamental step in patient-centered technology design that uses a systematic process to evaluate end users' goals such as efficiency, avoiding errors, satisfaction, and learnability [33]. Usability studies enable researchers to discover strengths and weaknesses in prototype technologies by exploring end users' experiences using new technologies in controlled computer laboratory settings [41]. In contrast, community-engaged research (CEnR) methods take place outside of controlled laboratory settings. These methods are designed to foster collaborations with, and among groups of, people affiliated by geographic location, special interest, or similar situations with the goal of addressing issues that affect the health and well-being of the group [42]. Engaging the community of interest during the development and testing of consumer health technologies is critical to ensuring that potential users feel a part of the development process and find the product to be applicable and practical for use [42]. Therefore, the purpose of this study was to use community-engaged research principles within a mixed-method research design to evaluate a self-tailored, social media website prototype for medically underserved patients with COPD.

To maximize benefits for medically underserved patients, our focus was on stimulating users without overburdening them with lengthy text, excess content, and potentially disorienting technical features (eg, pop-ups). Clickable screen captures of 167 discrete respiratory therapy and COPD patient education video segments were uploaded into a structured social media platform. Formative testing and validation of this video content is reported elsewhere [36,43,44]. Literacy-sensitive comment boxes were attached to each video with built-in breaks for visual clarity. A heuristic evaluation of the preliminary technical architecture version of the social media website prototype was conducted by a small panel of external health care communication experts [38]. Results from this evaluation helped to identify usability violations in the initial website prototype design prior to undertaking the current study. This involved conducting a community-engaged usability and acceptability evaluation with medically underserved patients with COPD.

Methods

Procedure

Overview

An adapted version of the Website Development Model for the Healthcare Consumer (WDMHC) [45] was used to evaluate the user-centered social media website prototype built according to user characteristics (eg, age, gender, education, race/ethnicity, health status, eHealth literacy) and information goals supported through appropriate technical functions. Specifically, three phases of the WDMHC that were used were (1) evaluation of technological design and features using interviews with potential users and experts, (2) computer-based usability testing using think-aloud methodology, and (3) one-on-one retrospective interviews with patients using validated interview rubrics and questionnaires.

The Priority-Sequence Model [46] was used to assist in the priority and sequence decision making for the usability research design. A multiphase sequential design (qual → QUANT → quant + QUAL) [47] was incorporated into the current study, whereby a small-scale qualitative (qual) study informed the design of a social media website prototype that was evaluated during a primary computer-based usability study (QUANT). Results from the computer-based usability study were explored via validated questionnaires (quant) and retrospective, in-depth, semistructured interviews (QUAL), where patients were given the opportunity to discuss usability strengths and weaknesses present within the social media website prototype following their computer-based sessions. Moreover, what was learned during the sequential phases of developmental research helped the research team to identify high-priority technical and formatting modifications for the COPD social media resource center. The study protocol was approved by the University of Florida's Institutional Review Board (IRB)-01, within its medical center.

Phase I: Evaluation of Design and Features of Social Media Website Prototype (qual)

Sample

In this study, "community" was operationally defined as stakeholders affected by, or involved with, the treatment of COPD. Community stakeholders included patients with COPD, informal caregivers (eg, friends, family members) of those with COPD, clinicians who treat patients with COPD, researchers who study COPD, community health agencies that advocate on behalf of patients with COPD, and any other individuals or organizations involved with providing health services to patients with COPD. Therefore, 5 medically underserved patients with COPD and 5 health care communication experts, who possessed experience working with patients living with COPD, were interviewed to gather information on desirable features of a mock-up for a COPD patient education social media website. Patient interviewees were recruited by research navigators affiliated with a CEnR program at a large research-intensive university in the southeastern United States. This particular CEnR program has a mission to eliminate research disparities based on access, race, and age, by fostering communication and reciprocal trust between traditionally underrepresented communities and academic researchers. The health care communication experts interviewed in this study included an internationally renowned patient education researcher, an experienced health communication researcher with experience designing Web-based applications for underserved populations, an applied physiologist with clinical experience directing hospital-based pulmonary rehabilitation programs, an expert on using exercise therapy in older adult populations, and a medical doctor with specialty in pulmonary medicine.

Procedures

All patient and expert interviewees were sent a brief description of the site's intended purpose via email, and were asked to review a mock user interface of the social media website prototype (Figure 1).

The preliminary social media website prototype design was conceived to follow specific user-centered design principles appropriate for older adults [48]. The website membership model accommodated all authenticated users with a single sign-on process using unique log-in credentials (ie, usernames and passwords). All text files, documents, and images were integrated into the prototype and converted using Adobe Dreamweaver, a Web-development application, and uploaded using HTML files as mock-up screens. To maximize the appeal of the social media website prototype among potentially nontech-savvy patients with COPD, we used concrete and realistic visuals with clear captions. We also adopted several design recommendations suggested by Choi and Bakken [33], who developed a Web-based educational portal for parents with children in neonatal intensive care units. These adopted

recommendations included (1) using an ordered format for topics, (2) listing categories clearly, (3) keeping pages short and concise, (4) using large buttons adequately spaced apart, and (5) maintaining design simplicity in drop-down menus and window placement. The simple design and shallow Web architecture of the social media website prototype benefitted from a contrasting color scheme, consistent sans serif fonts, minimal amount of written text, and one-touch point-and-click access to most site applications. All website functions and navigation tools were outlined using purposeful graphical representations and information displays that complied with our content strategy and visual design standards for medical information sites on the Internet [48-50]. Results from the patient and expert interviews helped the researchers create a functional social media website prototype.

Figure 1. Original mock-up of the online COPD patient education social media website.



Phase II: Computer-Based Usability Testing With Patients (QUANT)

Sample

Typically, 5 to 12 individuals representing the intended user audience are involved in think-aloud testing [49,51]. In this study, a convenience sample of 8 English-speaking adults with COPD was referred into the study by study navigators at the university's CEnR program. Individuals were eligible to participate if they met the following inclusion criteria: (1)

registered in the CEnR program, (2) willing and able to travel to the community health center, (3) 40 years of age or older at the time of enrollment, (4) able to speak and read the English language, and (5) possessed at least some experience using the Internet over the previous 3 months. Participants were excluded from participating if they (1) had a history of major cognitive impairments or comorbid psychiatric illnesses which could adversely impact their ability to understand and use a website, and/or (2) were interviewed during Phase I of the study. All potential participants were made aware that they would receive

a US \$40 gasoline/supermarket gift card upon completing the session.

Think-Aloud Protocol

The think-aloud usability method [51] measures performance on typical tasks for which a particular end-user technology is designed. It primarily consists of two stages: (1) eliciting and recording end users' cognitive thoughts while they attempt to navigate and complete tasks using the technology, and (2) measuring and analyzing the recorded thoughts and interactions of end users using the technology by following a standard protocol [52]. The goal of the computer-based think-aloud testing was to provide an in-depth understanding of each patient's experience of the following: (1) navigating the social media website prototype, (2) finding and commenting on posted videos, and (3) using interactive comment boxes with threaded discussion forums. These sessions took place at the university's community health center in a controlled computer laboratory, where all participants used the same laptop computer. Sessions lasted approximately one hour. The protocol was pilot-tested with one COPD patient who was not involved with participating in the actual usability testing.

Prior to beginning each usability session, one member of the research team provided each patient with a brief explanation of

the research study, including information on human subject protections, audio/video recording, anonymity, and confidentiality of the data to be collected. It was emphasized to each patient that the study was not designed to evaluate the user's ability to use the website, but rather it was a test of whether the website worked as intended (ie, test of the website, not the user). Following informed consent, the moderator, who was not involved in the development of the social media website prototype, provided brief instructions to each patient regarding how to use the laptop keyboard and external mouse. Following this brief training, patients were instructed to familiarize themselves with the social media website prototype layout and develop a unique log-in (username and password). Each registered patient was then asked to complete a representative sample of nine social media tasks (Table 1). To account for variability in user search preferences and operational skills [53,54], the think-aloud protocol included both directed (ie, asking for specific information) and semidirected (ie, open ended to allow for multiple solutions) social media tasks. For example, patients were asked to search for particular video titles and screenshots (directed), and they were also asked to express themselves in simulated social interactions online by posting and replying to sample comments using comment boxes and a threaded discussion forum (semidirected).

Table 1. Nine think-aloud usability social media task directives.

Task number	Task identifier	Task request
1	Create account	First, please create a log-in that will allow you to sign in to the website. Since you don't already have an account, you will have to create one. Please complete <i>only</i> the fields that have an asterisk, and then click the sign-up button at the bottom of the page to create your account.
2	Review video labels	Next, please review the video category labels on the left-hand side of the computer screen in blue. Are there any category titles that you do not understand?
3	Rate video labels	Now, of these categories you just reviewed, please indicate which look interesting to you.
4	Locate video	Please find the <i>Deep Breathing</i> video under the blue <i>Stress Management</i> category label. Then click on the picture of the video and click the play button to view the video.
5	Post comment on video	Now that you have watched the <i>Deep Breathing</i> video, please post a one-sentence comment underneath the video indicating whether you found it informative.
6	Post/respond to discussion board	Next, please find the blue <i>Talk to Other People with COPD</i> category label at the bottom of the page, and post a one-sentence comment on one of the topics that are listed. Make the post about anything you feel like sharing. That's the <i>Talk to Other People with COPD</i> category that we are asking you to locate.
7	Locate and play a recommended video	Now, click on one of the videos that are <i>Recommended for You</i> , and play the video. Please stop the video after 10 seconds.
8	Explore website ^a	Imagine you have just found this website online at your home or at the library. For the next 5 minutes or so, please explore the website however you would like. Feel free to talk about what you find, and tell us whether the health information you find is useful to you. This time is yours, so please use the website however you would like, and remember to tell us about your experience as often as you would like.
9	Sign out of website	For your final task, please sign out of the website.

^aThe think-aloud moderator was instructed to limit further exploration of additional website prototype functions after 5 minutes had elapsed. However, participation was not halted if participants were in the middle of watching a patient education video or actively contributing to a discussion thread. Participants who chose to stop exploring the website prototype before 5 minutes had elapsed were given the freedom to do so.

The moderator used modified usability methods [55] to motivate participants to talk out loud as they executed each task on a laptop computer. This modified methodology enabled the researchers to gain a better understanding of the cognitive processes that patients used to search for, and judge, the videos and functions of the social media website prototype. If the

patient requested assistance during one of the tasks, the moderator instructed him/her to think about, and talk out loud about, alternative strategies. Mistakes were not addressed by the moderator, but were noted by two members of the research team who were taking field notes. If a patient requested assistance while thinking aloud, the moderator would ask

participants to (1) make an attempt to repeat the task again, and (2) think again about what they were being asked to do. Assistance was provided if patients (1) chose not to explore an unfamiliar function independently (eg, posting comments to an online discussion board), (2) “froze” in front of the screen, or (3) verbalized that they were about to give up on the task [56]. If giving up was not explicitly verbalized, but the patient’s demeanor indicated confusion or frustration, then the moderator asked whether or not additional help was needed to continue. If the patient responded affirmatively with a verbal “yes” or a nod of the head, then assistance was provided.

Two methods were used to determine the reliability of the computer-based think-aloud usability test results: (1) member checking by the moderator and (2) cross-validation of paper-and-pencil field notes of participants’ experiences and comments documented by two members of the research team. Two researchers independently reviewed all transcripts and questionnaire data to control for systematic and response bias.

Phase III: Retrospective One-on-One Interviews (quant + QUAL)

Immediately following completion of the computer-based, think-aloud usability sessions, one member of the research team administered a series of structured usability and acceptability questionnaires with questions on demographics and use of electronic devices and the Internet to access health information. These structured surveys were followed by one-on-one, semistructured interviews where patients were asked to discuss their satisfaction with all website prototype features, including whether or not they found the social media features to be functional.

Measures

Phase I: Evaluation of Design and Features of Social Media Website Prototype (qual)

Following each interviewee’s review of the mock-up, one member of the research team scheduled a telephone interview to ask five general semistructured questions regarding the design of a multimedia COPD patient education website (see [Multimedia Appendix 1](#)). Up to five tailored probing questions were also developed to request further clarification on responses pertaining to each interviewee’s area of expertise. Interviewees were also asked to discuss what types of interactive communication technologies would be appropriate for disseminating respiratory therapy education to medically underserved patients with COPD. All telephone interviews were audiotaped and responses were transcribed and reviewed.

Phase II: Computer-Based Think-Aloud Usability Session (QUANT)

While patients completed nine social media tasks using the social media website prototype, several measures were recorded, including task completion (*independent*, *with prompts* when intervention by the moderator was needed, or *incomplete*), task performance (*good*, *reasonable*, or *poor*), amount of time spent completing each task (both for independent completers and completers requiring moderator prompts), and the number of participant requests for assistance per task. Task performance

was rated as *good* when operational skills were judged as adequate by two members of the research team, *reasonable* if the task was completed but not rated as *good* by both researchers, and *poor* if patients exhibited any difficulty when attempting the task. The following scale was used to evaluate level of agreement between researcher ratings of task completion, performance, and number of requests for assistance per task: 0 (*no agreement*), 1 (*a little agreement*), 2 (*much agreement*), and 3 (*total agreement*). Cross-validation of coder ratings across each category yielded intercoder agreement ranging between 2 and 3 (mean 2.8, SD 0.3). Differences in the distribution of codes were discussed by the two researchers during analysis until consensus was reached. In cases where consensus could not be agreed upon, a third researcher was consulted to reach a conclusion on all outcomes of interest.

Phase III: One-on-One Retrospective Usability Interviews (quant + QUAL)

Following each computer-based think-aloud usability session, patients were asked to complete a validated 18-item usability and acceptability questionnaire [57] to evaluate ease of use, usefulness, and satisfaction with the website prototype. Statements were evaluated on a 5-point Likert scale ranging from 1 (*strongly disagree*) to 5 (*strongly agree*). Data collected in this study using the 18-item questionnaire showed evidence of good internal consistency (Cronbach alpha=.89). Participants were also asked to answer demographic items on gender, age, education, self-reported COPD severity (*mild*, *moderate*, *severe*, *very severe*), experience using the Internet for health information, and eHealth literacy. The item eHealth literacy was measured using the eHealth literacy scale (eHEALS), a self-report instrument where participants are asked to rate eight statements related to comfort and skill finding, evaluating, and applying health information from the Internet on a 5-point Likert scale ranging from 1 (*strongly disagree*) to 5 (*strongly agree*) [58]. Data collected in this study using the eHEALS showed evidence of good internal consistency (Cronbach alpha=.83). Patients were also asked why other patients with COPD may or may not choose to use a fully functional, online version of the social media website prototype. [Multimedia Appendix 2](#) lists the 10 open-ended questions—with associated probes—that participants were asked to consider.

Data Analysis

Phase I: Evaluation of Design and Features of Social Media Website Prototype (qual)

Qualitative data from interviews with health care communication experts and patients with COPD were analyzed using ATLAS.ti version 7 qualitative analysis software. Thematic analysis [59] was used to identify overarching themes. One member of the research team transcribed the data and assigned brief verbal descriptions (ie, codes) to small chunks of data. Codes were altered and modified during the analysis based on the full picture of the data as ideas developed. On the basis of these emergent codes, themes from these interviews were identified to generate overall recommendations for the social media website prototype design.

Phase II: Computer-Based Usability Testing With Patients (QUANT)

The computer-based think-aloud usability sessions (eg, mouse movements, text inputs, navigation, verbalizations, video output, and cursor movement) were recorded using Camtasia Relay [60]. The level of assistance, performance, total amount of time to complete each task, and number of patient requests for help were entered into an SPSS version 21.0 database for analysis. Frequency and descriptive statistics were computed for all quantitative variables.

Phase III: One-on-One Retrospective Usability Interviews (quant + QUAL)

Patients' sociodemographics, health characteristics, health-related Internet use, eHealth literacy, and scores on the 18-item website usability and acceptability questionnaire were entered into an SPSS version 21.0 database for analysis. Frequency and descriptive statistics were computed for all quantitative variables. A one-sample *t* test was conducted on usability and acceptability scores to evaluate whether the mean was significantly different from the midpoint (ie, 3 or *moderately agree*) of the 5-point response scale.

ATLAS.ti version 7 qualitative analysis software was used to code, label, and analyze all qualitative data collected from

patients during the one-on-one retrospective interviews. Deductive constant comparison analysis [61] was used to identify chunks of data (ie, related portions of the transcripts) and group them into meaningful parts that were fit into codes established top-down according to four human-computer interaction categories from the literature [21,48,62]: (1) interaction and navigation (ie, the way users work with the site), (2) information architecture (ie, organization of links and hierarchy of content categories), (3) presentation design (ie, graphical interface and all visual elements of the page), and (4) information design (ie, preparation of communication products to achieve specified performance objectives). For example, the *interaction and navigation* category was subdivided into categories such as *user input*, *search options*, *loading speed*, *ability to click through buttons and icons*, and *help options*. Table 2 lists subcategories used to derive codes for each human-computer interaction category. When chunks of qualitative data did not fit codes within each of the four human-computer interaction categories, inductive codes were constructed and similar chunks were assigned to emergent themes. To calculate the frequency of themes identified during these interviews, a classical content analysis procedure [63] was used to count the number of times codes were applied to data.

Table 2. Subcategories referenced to derive top-down codes applied to qualitative transcripts.

Heuristic category	Subcategories applied to transcripts
Interaction and navigation	Consistency of features Able to click through buttons and icons Easy to scroll Visual and textual feedback based on user input Search options Loading speed Help options
Information architecture	Video placement and labeling Organization of topics and labeling Page design to facilitate task completion and intuitive access to content Dividing and classifying content into categories (ie, related topics grouped together) Descriptive labels with keywords that are easy to understand
Presentation design	Visual elements: form, content, arrangement, light (or contrast), and color Type size and legibility (font size, type of font, etc), layout, and visual searching Easy to read Text and background contrast Adequate white space Appropriateness of images Availability of external links
Information design	Ease of locating information Comprehensiveness Accurate, reliable, and credible health information Relevance of health information Empowering Willingness to return to the site General appreciation for the site Recommend the site to others in the future

Results

Phase I: Evaluation of Design and Features of Social Media Website Prototype

Patient Feedback

Patient interviewees indicated that they were pleased with the design of the preliminary website prototype (Figure 1), noting that use of a single website for health information on COPD would be both valuable and convenient to use. Furthermore, they appreciated the idea of being able to access an online clearinghouse of videos organized using clear links and picture-based screenshots. They also appreciated being able to communicate with other patients like them. To eliminate potential for confusion, patients also discussed the importance of using terminology that could be clearly understood by patients. One interviewee noted the need for videos that explained how COPD might feel on a day-to-day basis (eg, when to expect breathlessness, how to avoid stress, how to clean inhaler). Rigorous evaluation of the website before, during, and after development was also noted as important by the patient interviewees. For example, the URL planned for the website was originally “patientflix.com”, yet 4 of the 5 patient panelists suggested changing to domain name to include “COPD” within the URL to enable patients to locate the site using terms such as “COPD” on search engines like Google.

Expert Feedback

The use of structured social networking among patients was something viewed as valuable among the expert interviewees. One expert with experience working in pulmonary rehabilitation noted, “The more you can have information come from other patients, the better...they can get a lot out of talking to other patients.” Another medical doctor with expertise in pulmonary medicine supported the design of an on-demand, evidence-based video-sharing website to empower patients to answer personal disease-related questions. Of the expert interviewees, 3 with

expertise in health communication research methods suggested keeping the scope of an online program small and simple to allow formative user feedback to drive further development of the site. These experts also suggested tracking engagement metrics to determine which patient education videos were most popular among users. Formative testing of the website with patients was viewed as important prior to releasing it online in order to determine how patients might want to access, use, and navigate the site to obtain and share health information.

Phase II: Computer-Based Think-Aloud Usability Session

Patients' Demographic Information

There were 8 patients with moderate (4/8, 50%) to severe (3/8, 38%) COPD who participated in the computer-based usability and acceptability testing. The patient group was made up of 5 (63%) males and 3 (38%) females. Patients ranged in age from 47 to 66 years old (median 54.5 years, interquartile range [IQR] 41.5–67.5 years), with both Caucasians (5/8, 63%) and African Americans (3/8, 38%) participating in the study. Patients reported living with several comorbidities, such as high blood pressure (6/8, 75%) and arthritis/joint problems (6/8, 75%). Most were either never married (3/8, 38%) or divorced/separated (3/8, 38%), and all patients reported completing high school (5/8, 63%) or possessing between 1 and 3 years of college-level education (3/8, 38%).

Computer-Based Think-Aloud Usability Session

Overview

The total length of time of the computer-based usability sessions ranged from 30 minutes, 24 seconds to 49 minutes, 26 seconds (median 36 minutes, 47 seconds), and the total completion rate of all 9 social media tasks attempted by the 8 participants was 93% (67/72)—58% independently (41/72) and 37% with moderator prompts (26/72). Table 3 describes completion times, performance, and time needed to complete each task during the think-aloud sessions.

Table 3. Completion, performance, time needed, and number of requests for assistance during each social media task among think-aloud participants (n=8).

Completion characteristic	Social media tasks								
	Task 1: Create account	Task 2: Review video labels	Task 3: Rate video labels	Task 4: Locate video	Task 5: Post comment to discussion board	Task 6: Post/respond to discussion board	Task 7: Locate and play recommended video	Task 8: Explore website	Task 9: Sign out of website
Level of assistance, n (%)									
Independent	3 (38)	8 (100)	8 (100)	4 (50)	4 (50)	1 (13)	4 (50)	5 (63)	4 (50)
Moderator prompt assistance	5 (63)	0 (0)	0 (0)	3 (38)	4 (50)	5 (63)	3 (38)	3 (38)	3 (38)
Incomplete	0 (0)	0 (0)	0 (0)	1 (13)	0 (0)	2 (25)	1 (13)	0 (0)	1 (13)
Performance, n (%)									
Good	3 (38)	8 (100)	8 (100)	2 (25)	3 (38)	1 (13)	4 (50)	5 (63)	4 (50)
Reasonable	3 (38)	0 (0)	0 (0)	5 (63)	5 (63)	2 (25)	3 (38)	2 (25)	3 (38)
Poor	2 (25)	0 (0)	0 (0)	1 (13)	0 (0)	5 (63)	1 (13)	1 (13)	1 (13)
Time for independent completion, minutes:seconds									
Median	2:16	0:21	0:28	0:14	0:28	1:03	0:27	4:22	0:22
Minimum	0:46	0:08	0:15	0:09	0:54	1:03	0:22	3:03	0:05
Maximum	3:53	0:52	1:19	0:37	1:22	1:03	0:35	7:23	0:40
Time for completion with prompts, minutes:seconds									
Median	3:49	N/A ^a	N/A ^a	0:40	0:50	2:40	0:50	5:14	0:23
Minimum	3:00	N/A ^a	N/A ^a	0:37	0:25	0:59	0:21	4:58	0:09
Maximum	5:58	N/A ^a	N/A ^a	1:20	1:16	3:22	1:30	5:19	0:29
Requests for assistance made by participants, n	27	1	0	9	7	24	6	8	7

^aNot applicable due to successful task completion by participants without prompts from the moderator.

Task 1: Create Account

Overall, patients struggled when attempting to create a personal log-in on the social media website prototype. Patients requested assistance from the moderator 27 times during the computer-based testing sessions. Only 3 of the 8 participants (38%) were able to complete this task independently. Creating the log-in also took longer than the majority of the other tasks, especially among participants who completed the task after being prompted to do so by the moderator (median 3 minutes, 49 seconds).

Tasks 2 and 3: Review and Rate Video Labels

All participants (8/8, 100%) were able to independently locate, read, understand, and comment on the importance of each patient education category label organized on the structured social media platform. Only 1 request for assistance was made during Task 2, and 0 requests for assistance were made during Task 3. Participants found the *Physical Activity*, *Infection Control*, *Medication Management*, and *Lifestyle* category labels to be among the most interesting.

Tasks 4 and 5: Locate and Post a Comment on Video

The majority of patients performed at least reasonably well when locating the *Deep Breathing* video within the blue *Stress Management* category tab (Task 4) and posting a sentence comment about whether or not it was informative (Task 5).

Task 6: Post and Respond to Discussion Board

Although the majority of patients were able to locate videos and post comments on them, they struggled to use a separate online discussion board embedded within the social media website prototype. Of the 8 participants, 5 (63%) performed poorly on this task, requesting additional prompts to access and add content to the discussion board threads. Of the 8 participants, 2 (25%) were unable to contribute to the discussion board at all, even after prompts from the moderator. Overall, participants requested assistance 24 times when attempting to complete this task.

Task 7: Locate and Play a Recommended Video

Half of the participants (4/8, 50%) independently located videos marked as *Recommended*. The other half of participants exhibited some difficulty deciphering which videos were marked as *Recommended* for them on the user interface. Overall, patients

requested assistance during this task a total of 6 times, with half (4/8, 50%) of the patients recording a performance of *good*.

Task 8: Explore Website

Of the 8 participants, 5 (63%) spent between 3 minutes, 3 seconds and 7 minutes, 23 seconds (median 4 minutes, 22 seconds) exploring the social media website prototype independently. Participants receiving prompts from the moderator while exploring the website prototype spent more time using prototype functions (median 5 minutes, 14 seconds) when compared to participants who browsed the website prototype independently (median 4 minutes, 22 seconds). However, the variation in exploration time was less among participants who received moderator prompts (median range 4 minutes, 58 seconds to 5 minutes, 19 seconds).

Task 9: Sign Out of the Website

Participants exhibited difficulty determining how to sign out of the social media website prototype—only half (4/8, 50%) of the participants were able to sign out on their own.

Phase III: One-on-One Retrospective Usability Interviews (quant + QUAL)

Patient Use of Internet for Health Information (quant)

Table 4 describes patients' self-reported use of the Internet and social media/networking for health information. Patients reported accessing the Internet using different devices such as desktop computers (4/8, 50%), laptop computers (2/8, 25%), mobile phones (3/8, 38%), and other mobile devices such as iPads or tablets (2/8, 25%). Less than half (3/8, 38%) of the study participants reported using popular social media websites such as Facebook and Twitter for health information, and no participants reported belonging to online support groups or making entries into online health diaries/blogs.

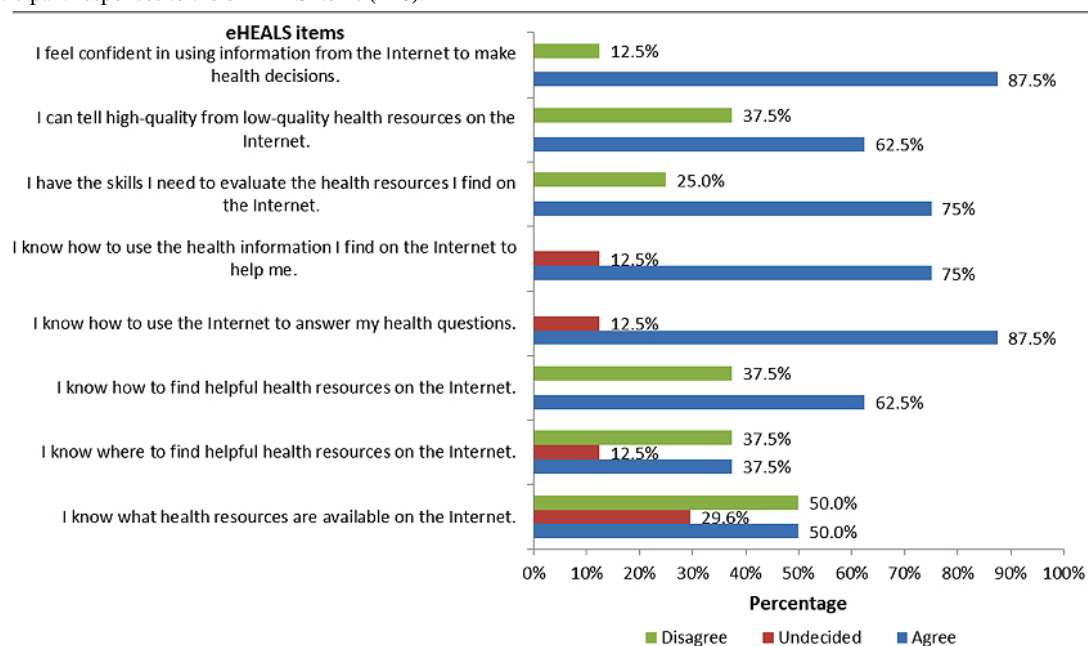
Table 4. Self-reported Internet use for health information among think-aloud participants (n=8).

Method used to access health information	n (%)
Electronic device(s) used to access Internet ^a	
Desktop computer	4 (50)
Laptop computer	2 (25)
Mobile phone	3 (38)
Mobile handheld device	2 (25)
Use of social media/networking for health information	
Facebook, Twitter, LinkedIn	3 (38)
Online support group	0 (0)
Online diary or blog	0 (0)

^aParticipants could self-report using more than one device to access the Internet for health information.

Figure 2 illustrates the response frequencies of each eHEALS item. Responses were grouped into the following categories: *agree* (ie, *strongly agree* and *agree* responses), *undecided*, or *disagree* (ie, *strongly disagree* and *disagree* responses). The two statements with the highest level of agreement were, "I feel confident in using information from the Internet to make health

decisions" (7/8, 88%) and "I know how to use the Internet to answer my health questions" (7/8, 88%). Statements with the greatest level of disagreement were related to knowledge of health resources that are available on the Internet (4/8, 50) and where to find helpful resources on the Internet (3/8, 38%).

Figure 2. Participant responses to the eHEALS items (n=8).

Website Acceptability and Usability (quant)

As shown in Table 5, responses from the 18-item website usability and acceptability questionnaire ranged from 4 to 5 (mean 4.72, SD 0.33) on the 5-point Likert scale. The mean

score on the questionnaire was significantly higher than the midpoint (3, *moderately agree*) of the rating scale (95% CI 4.48-4.96, $t_7=14.71$, $P<.001$). Results from this survey indicated that participants were very satisfied with the purpose, layout, and functionality of the social media website prototype.

Table 5. Scores on the 18-item website acceptability and usability questionnaire among think-aloud participants (n=8).

Acceptability and usability item	Mean (SD) ^a
The website was easy to use.	4.88 (0.35)
I would recommend this website to others.	4.75 (0.71)
The information on this website was easy for me to understand.	4.75 (0.71)
The website made me think about something new.	4.13 (0.99)
The website was attractive.	4.25 (0.89)
The website was interesting.	4.75 (0.46)
I could tell the program was designed for patients with COPD like me.	5.00 (0.00)
I enjoyed using the website.	4.88 (0.35)
The website was useful.	4.75 (0.46)
The website could help me improve my COPD self-management skills.	4.50 (0.76)
The website was easy to navigate.	4.50 (0.76)
The graphics on the website went along with the information and videos that were presented.	4.75 (0.46)
I liked the colors used on the website.	4.75 (0.71)
I liked the font that was used on the website.	4.88 (0.35)
I liked the way the website was organized.	4.63 (0.52)
I liked the way the website screen layout looked.	4.75 (0.46)
I thought the information presented on the website was relevant to me.	5.00 (0.00)
I would use the website the next time I am looking for COPD self-management information.	5.00 (0.00)

^aScale responses ranged from 1 (*strongly disagree*) to 5 (*strongly agree*).

Usability Strengths (QUAL)

Overview

Most patients (6/8, 75%) noted that using most of the social media functions on the website prototype was easier than expected. One patient stated the following:

I was actually impressed, because I was a little nervous (at first). When I first got in front of the computer, I was like “Oh God”, but the way it (the website prototype) was set up, it wasn’t scary. If I can do this, a lot of other people can [Patient 1, male, 53 years]

Several patients described the clickable tabs as “empowering” by enabling them to self-select videos and materials applicable to their own disease-related concerns. One patient noted the following:

See, I don’t smoke so that isn’t a big interest to me (cursor pointing to smoking cessation), but for other people it could be. [Patient 8, female, 55 years]

Another patient commented the following:

See like now, with the list about what else I can do, I can experiment with that. You know what I’m saying. And it will educate me more than I have going on now. [Patient 7, male, 49 years]

Reaction to Role Model Actors

Of the 8 participants, 3 (38%) responded positively to the clickable video boxes containing screenshots of age-appropriate, diverse role model actors. One participant commented on benefitting from the following:

...what they are showing you about what you want to do and then they (video narrator) would explain it with the vocal part too. [Patient 4, male, 64 years]

Another participant commented the following:

Plus, they are showing real-life people doing what they are supposed to be doing. People can read stuff, but when they actually see a video—this is how you use this medicine, use as the doctor says, or use as directed, you got a video showing how to (actually)

use it properly...you’ll get the maximum effects.
[Patient 3, male, 54 years]

Likelihood to Visit Website

All participants (8/8, 100%) strongly agreed that they would use the website the next time they were in need of information on COPD, especially if they were at home. One participant noted the possibility of visiting the site using a mobile device (eg, mobile phone, tablet computer), stating the following:

If I was at work and having problems, I would go through it. I would use it at home, because if you have an iPad, you can pull it up. You know your phone, because you never know if you are going to be out somewhere and have problems, you can go, “Oh, let me look over here.” [Patient 8, female, 55 years].

Usability Violations (QUAL)

Overview

While very positive feedback was obtained during the follow-up retrospective usability interviews, there were also several usability violations that were identified. Below is a synthesis of perceived usability violations discussed according to two heuristic categories assessing human-computer interaction—*information design* and *interaction and navigation*.

Information Design

The majority of participants reported difficulty locating links to sign in and log out of the website prototype. Participants described difficulty signing in and out of the website prototype 19 times—it was the social media website prototype’s most severe usability violation in this human-computer interaction category (Table 6). Several participants expected a sign-out or log-out button to be positioned at the bottom right-hand corner of the page, yet, in the website prototype that was evaluated by patients, the log-out link was placed in the upper right-hand corner, causing participants to experience some confusion. Half of the participants (4/8, 50%) also reported some difficulty locating patient education videos under different self-management categories. Comments related to this violation were coded 9 times, with participants noting that some video heading labels were vague and needed more clarification (Table 6).

Table 6. Two main heuristic categories with usability violations.

Heuristic category	Usability violation theme	Frequency of codes ^a , n
Information design	Difficulty locating sign-in and log-out links on user interface.	19
	Confusion locating videos in certain self-management categories.	9
Interaction and navigation	Frustration with using discussion forum applications.	46
	Difficulty filling in fields and submitting user information using the log-in interface.	19
	Confusion navigating to self-management category tabs that contained sought-after videos.	9

^aIdentified within themes during constant comparison analysis.

Interaction and Navigation

Of the 8 participants, 7 (88%) discussed having difficulties using the group discussion forum. Comments related to this difficulty appeared 46 times in the transcript (Table 6). Of the 8 participants, 5 (63%) participants specifically commented that the topic-delimited threaded discussion board was disorienting and confusing. Participants described feeling reliant on the moderator to “tell them what to click on” in order to enter and reply to comments. In addition, 4 of the 8 participants (50%) discussed frustration when entering information into fields for creating a unique user account. Several participants also noted that they were reluctant to seek out videos when additional scrolling was needed to navigate to video category labels. Of the 8 participants, 2 (25%) attributed their difficulty with navigation to visual problems experienced when looking at the laptop screen. One participant noted the following:

I just got to keep the screen close to me for my vision. These glasses are going out. My sight changes with my diabetes. [Patient 5, male, 66 years]

Discussion

Principal Findings

Usability evaluation is a useful and cost-efficient way to formatively test patient education websites [5,33,64]. In this study, a multidisciplinary group of health care communication experts and COPD patients collaborated to develop and evaluate a low-computer-literate social media resource center focused on COPD patient education. Patients in this study reported higher than anticipated education levels (ie, all had graduated from high school) and also self-reported the use of a variety of electronic devices to access the Internet for health information. Overall, patients in this study reported feeling confident using information from the Internet to make health decisions and answer health-related questions, yet fewer were confident in their ability to locate health information on the Internet. A little less than half of the participants reported current use of social media to find and share health information.

Usability Strengths Present in Social Media Website Prototype

Overall, the majority of the violations identified during a heuristic evaluation of the website prototype [36], conducted prior to patient-based usability testing, were not discovered in the computer-based think-aloud testing reported here. This was not unexpected, because most usability problems identified via heuristic evaluation are minor, very specific, and cause little trouble for the system's users [65]. All participants in the usability study strongly agreed that the website prototype was easy to navigate and designed for patients like them. While questions remain regarding the effects of educational components in COPD self-management interventions and respiratory therapy programs [66], evidence suggests that effective communication between patients with COPD and their

providers is associated with better quality of care and confidence in dealing with breathing problems [67]. There is a need for further exploration into innovative methods for using social media to support more effective patient-provider communication. Use of social media and mobile devices such as mobile phones and tablet computers may improve accessibility to COPD patient education. This would fill a key gap inhibiting effective patient-provider communication related to the prevention and management of breathing exacerbations.

Almost 60% of adults in the United States and 61% of people worldwide own a mobile phone, while over 40% of Americans and 17% of individuals globally own a tablet computer [68,69,70]. Patient use of mobile devices increases the potential to disseminate patient education to individuals who demonstrate at least moderate levels of eHealth literacy, and have the means to purchase and benefit from mobile devices connected to the Internet. However, as mobile medical apps continue to show much promise for delivering a range of patient interventions, including patient education, it will become important to monitor and manage the quality and safety of using mobile devices for delivering health information to patients [71]. Moreover, it is suggested that comprehensive usability testing be conducted on chronic disease self-management prototypes that are designed for use on mobile platforms.

Usability Weaknesses Present in Social Media Website Prototype

Similar to other usability research evaluating health-related websites [33], users had difficulty signing in and logging out of their user accounts on the website prototype. Despite this difficulty, most participants discussed how having a personal log-in account on the social media site would help them feel as if they officially belonged to a patient community. Also, participants were very dissatisfied with the interactive threaded discussion board. They disliked having to locate a self-management discussion topic link from among 10 possible options, demonstrating difficulty determining which links needed to be clicked to post an original comment and/or reply to comments made by others. Most participants remarked that submitting a post to comment boxes placed underneath discrete videos represented a far less cumbersome task.

Social Media Website Prototype Redesign and Modification

Mixed-methods data from the computer-based think-aloud session and retrospective one-on-one interviews informed the development of a system redesign plan that focused on making improvements related to two primary usability heuristics—*information design* and *interaction and navigation*. In total, 13 changes were identified and proposed for the social media website prototype categorized into the information design (n=7) and interaction and navigation (n=6) heuristic categories (Table 7). Modifications took approximately 4 months to complete.

Table 7. Website prototype design resolutions made following usability testing with participants.

Heuristic category	Specific examples of design resolutions
Information design	<p>Increased visibility of the sign-in link by embedding it into the <i>Welcome</i> tab in large, bold sans serif font.</p> <p>Modified screenshots of videos that were not reflective of video content.</p> <p>Split up 15-minute video on <i>Diet and Nutrition</i> into 11 shorter video segments.</p> <p>Added a video dictionary of COPD terms (A-Z) for users to reference when encountering unfamiliar terms.</p> <p>Edited user comment tool to make it less disorienting when uploading and responding to comments.</p> <p>Complete redesign of discussion board.</p> <p>Removal of asp.net MVC Open forum discussion platform to be replaced with more user-friendly interactive forum technology.</p>
Interaction and navigation	<p>Increased font size requirements for username label, written comments, and reply links within discussion forum.</p> <p>Incorporated Google Analytics into back end of the website prototype to track number of activated sessions, average session duration, bounce rate, number of page views per session, percentage of returning and new visitors to the site, time spent on the site, etc.</p> <p>Decreased number of required fields to become a registered user on the site.</p> <p>Made clear headings with arrows on page to direct users to click on recommended videos.</p> <p>Made all video labels describing content clickable (originally only the screenshot was clickable).</p> <p>Improved site architecture to limit the need for scrolling to locate online videos and resources.</p>

General examples of technical improvements included reprogramming some video content, modifying and sharpening the design of the user interface, and improving the interactive functions to make them more intuitive. Other more specific examples included (1) improving the scroll-bar function to limit the need for scrolling to find videos and post/reply to user comments, (2) modifying the log-in tool to reduce the number of required fields by half, and (3) changing the location of the sign-in link on the home page by placing it in a more prominent location on the *Welcome* tab. The computer software used to design the discussion forum was also supplanted with a more user-friendly interactive technology to make the discussion board easier to use (with fewer customization options). We expect these changes will facilitate more meaningful use among patients and informal caregivers, with fewer possibilities for

errors when posting and replying to comments from fellow users.

In addition, several visual presentation elements were refined to create a more ergonomically functional design. For example, the tab containing videos recommended for specific users (ie, *Videos Recommended for You*) was modified to make the tab heading and video labels more distinguishable by increasing the font size, putting “YOU” in all capital letters, and using dark blue text (instead of orange text) to provide a better contrast with the light blue background. The research team also completed a thorough review of all hyperlink labels and changed 18 category label headings to make terms more understandable and action oriented (ie, beginning with verbs). Brief two-to-three-sentence written descriptions of each video were also placed underneath each video screen to clearly explain the content covered in each video (Figure 3).

Figure 3. Screenshots of beta version of COPDFlix social media resource center, modified following usability evaluation.



Study Limitations

Although usability evaluation examines the relationship between users, technological tools, and associated tasks in a specific working environment, user performance and acceptance in a controlled setting does not always convey the entire picture regarding usability. Even though describing system features, functions, and interfaces from the user perspective is essential to ensure the design of usable systems, perspectives from a limited sample of potential users may not be generalizable to larger patient populations [72,73]. Small-scale usability testing is also not sufficient for generating metrics that can be analyzed through common statistical tests [74]. It is important to note, however, that a small sample of approximately 8 subjects is the minimum recommended sample size for determining satisfaction and usability in formative testing of computer-based systems [52,75,76]. In addition, participants in this small sample included representation from females (3/8, 38%) and African Americans (3/8, 38%), two subpopulations often underrepresented in studies of individuals with COPD.

In the current study, the modified think-aloud protocol provided the moderator with the flexibility to intervene during the computer-based usability sessions to encourage participants to continue on with tasks, which may be considered a source of error leading to distorted self-reports [55]. The modified think-aloud technique can redirect participants' attention to a self-evaluation of task accomplishment, which could change

their thought processes. However, in this study of medically underserved patients with COPD, participants seemed to value additional prompts from the moderator to help point them in the right direction. To decrease the potential for experimenter bias, the moderator was instructed to minimize intervention during the verbalization process by only reminding each subject to "keep talking" if and when subjects stopped talking in front of the computer. This subtle intervention generally does not disturb and/or bias ongoing cognitive processes among users [55]. However, there were times during the think-aloud protocol when participants stopped thinking out loud when they were concentrating on a given task, and instead started talking about their personal health issues, especially when they saw topics on the social media website prototype that coincided with their personal health issues. Retrospective questionnaires and interviews administered following the computer-based think-aloud protocol likely minimized the effects of any cognitive or task flow interruptions experienced by patients [21,52].

Patients in this usability study self-reported higher than expected education levels and moderate eHealth literacy, which limits the applicability of results to older patients with COPD who may possess lower education levels and minimal experience using the Internet. In this study, we were unable to evaluate environmental factors (eg, Internet access points, connection speeds) that may influence use of a social media resource center among diverse patient populations. Patients were also only

exposed to the social media website prototype at one point in time, limiting our ability to examine any longitudinal effects of visiting various sections of the site at variable doses over time. Evaluating new technology with iterative rounds of testing is a key principle of prototyping, so the lack of a second round of computer-based usability testing precluded the collection of additional feedback regarding the revised social media website prototype. Future pragmatic clinical trials should attempt to further evaluate the usability, acceptability, exposure, and engagement with the subsequent Web-release version of the prototype among larger cohorts of patients with COPD.

Conclusions

Human-computer interaction researchers in health care have acknowledged the need for a comprehensive, integrated model for human-computer interaction with health care technologies [21,77]. In this study, mixed-methods stakeholder feedback was used to make design recommendations, categorize usability violations, and prioritize potential solutions for improving the usability of a social media resource center for COPD patient

education. Combining conventional methods of computer laboratory testing with low-cost qualitative methodologies enabled our multidisciplinary research team to use qualitative and quantitative data to make targeted modifications to a COPD social media resource center website prototype, later named "COPDFlix" prior to Web release. The website prototype possessed moderate error rates, and was generally well-received and perceived to be learnable among a community-based group of medically underserved older adults with COPD. While we were unable to address every usability problem identified during testing, we were able to prioritize the most important problems in need of modification. Future studies should explore pedagogical methods for teaching patients how to use social media to locate and evaluate evidence-based health information on preventing and managing behavioral risk factors associated with chronic diseases like COPD. Integrating use of a social media resource center within comprehensive COPD patient education programs may help to improve patient outcomes, such as health-related quality of life, exacerbation frequency, and cost of care.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Key informant interview rubric.

[PDF File (Adobe PDF File), 42KB - [resprot_v4ile17_app1.pdf](#)]

Multimedia Appendix 2

Retrospective one-on-one interview questions on experience using the prototype (with probes).

[PDF File (Adobe PDF File), 42KB - [resprot_v4ile17_app2.pdf](#)]

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Abbreviations

CEnR: community-engaged research

COPD: chronic obstructive pulmonary disease

eHEALS: eHealth literacy scale

IQR: interquartile range

IRB: Institutional Review Board

WDMHC: Website Development Model for the Healthcare Consumer

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Original Paper

The Effect of Online Chronic Disease Personas on Activation: Within-Subjects and Between-Groups Analyses

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Abstract

Background: Although self-management of chronic disease is important, engaging patients and increasing activation for self-care using online tools has proven difficult. Designing more tailored interventions through the application of condition-specific personas may be a way to increase engagement and patient activation. Personas are developed from extensive interviews with patients about their shared values and assumptions about their health. The resulting personas tailor the knowledge and skills necessary for self-care and guide selection of the self-management tools for a particular audience.

Objective: Pre-post changes in self-reported levels of activation for self-management were analyzed for 11 chronic health personas developed for 4 prevalent chronic diseases.

Methods: Personas were created from 20 to 25 hour-long nondirected interviews with consumers with a common, chronic disease (eg, diabetes). The interviews were transcribed and coded for behaviors, feelings, and beliefs using the principles of grounded theory. A second group of 398 adults with self-reported chronic disease were recruited for online testing of the personas and their impact on activation. The activation variables, based on an integrated theory of health behavior, were knowledge of a given health issue, perceived self-management skills, confidence in improving health, and intention to take action in managing health. Pre-post changes in activation were analyzed with a mixed design with 1 within-subjects factor (pre-post) and 1 between-group factor (persona) using a general linear model with repeated measures.

Results: Sixteen pre-post changes for 4 measures of activation were analyzed. All but 2 of the within-subjects effects were statistically significant and all changes were in the direction of increased activation scores at posttest. Five significant differences between personas were observed, showing which personas performed better. Of low activation participants, 50% or more shifted to high activation across the 4 measures with minimal changes ($\leq 5\%$) in the reverse direction.

Conclusions: The majority of participants using a persona-tailored learning path reported high levels of satisfaction with their online user experience and increased levels of activation about their own health. In the body of work on patient activation, the current study adds to understanding of both short-term impact and the content of a brief, online intervention for engagement of specific groups in self-management.

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KEYWORDS

chronic disease; self-management; Internet; patient-centered care

Introduction

Management of a chronic disease requires knowledge about that disease, skills for handling problems related to the disease, confidence in being able to execute those necessary skills, and intention to do so [1]. Without this requisite self-care, a patient's condition often deteriorates, sometimes irreversibly [2]. Despite many efforts to ameliorate these conditions through enhanced patient self-management, the prevalence rates for diseases such as diabetes [3] and asthma [4] continue to increase while the rates for other diseases such as heart disease [5] and depression [6] have not declined as hoped. The overall profile of health points to the necessity of increasing patient activation with self-care as a first step in successful disease management.

The construct of activation is receiving more attention as a predictor of patient behavior. Recent cross-sectional surveys have found a range of measures of activation predictive of information seeking [7], health status [8-12], satisfaction with care and provider interaction [13,14], and self-management [11,15]. However, comparatively little work has been done on ways to increase activation, and all interventions have been some type of in-person instruction and/or coaching [15,16].

Personas generated from the Mental Models paradigm offer a form of tailored messaging which may boost activation. In this approach, personas are created through nondirected interviews with consumers to determine the user experience, common values, and assumptions about a given product [17]. In the domain of health and disease management, personas are a tool for understanding what a person who has identified with a given persona would do with their self-care, their expectations about the outcomes of treatment, and what additional information might be useful to them in making their decision to take action [18,19].

Personas may be particularly effective online in addressing different patient perspectives about self-management of chronic diseases [20,21]. Online material is readily accessible for many people, can be presented in a range of visual forms, and allows for iterative exploration at the convenience and interest of the user. Personas may add to the versatility and usefulness of online health education materials since they are tailored for specific audiences. Patients' selection and reaction to personas may be of use to clinicians seeking to understand the perspectives and preferences of their patients.

This paper summarizes user feedback on 11 online personas developed for 4 prevalent chronic diseases with the aim of increasing activation. The effectiveness of the self-selected personas was assessed first with averaged pre-post changes on the 4 elements of activation. Effectiveness was also analyzed with a tally of the percentage of people with a low level of activation who moved toward a higher state and vice versa. In addition, aspects of user experience with their selected persona are also summarized. The following research questions were asked:

1. Are there changes in self-reported activation level when a consumer selects a health persona and receives persona-specific self-management information and tools?

2. Are there differences between persona groups in self-reported activation metrics of knowledge, skills, confidence, and intent to act?
3. Is there a shift in activation level from the lowest levels of activation at pretest to higher activation at posttest across the personas?

This paper provides the first empirical evidence of how use of a chosen persona affects level of activation in consumers with 1 of 4 chronic diseases. Thus, the results summarized here provide direction as to how a particular methodology might be used to engage and activate individuals with a chronic disease.

Methods

Overview

The description of the methods is divided into 2 main sections. The first section provides an overview of the process used to develop the chronic disease personas. This includes a summary of the recruitment process, interviews, coding of the interview content, and construction of the entire persona.

The second section presents details on the recruitment of the online users for evaluating the impact of the personas on personal activation for chronic disease self-care, a description of the user experience, a description of the scales used pre- and postreview of the personas, and the data analysis plan.

Persona Development

Theory

The Mental Model methodology was used to construct a total of 11 personas related to the 4 courses on chronic disease. This method was developed by Indi Young, cofounder of the design agency Adaptive Path. The methodological approach creates the mental models of audiences by aggregating affinity themes of behaviors, beliefs, and feelings expressed by members of the target audience during nondirected interviews [17]. Applying a mental model to a program gives developers greater insight into the moods and motivations of their audience.

Patient Interviews

Creation of each persona began with completion of 20 to 25 nondirected interviews with consumers recruited from telephone-based recruitment services using a national database and publically published residential information. Interviewees consisted of geographically distributed American adults between the ages of 25 and 65 years with type 2 diabetes mellitus, depression, coronary artery disease (CAD), or asthma reported as their main chronic disease.

The interviews lasted on average 60 minutes per person and were conducted by 1 of 4 interviewers recently trained in the Mental Model methodology [11]. Interviewers avoided influencing the words used by interviewees by asking very open-ended questions such as "What is it like, day to day, to have asthma?" or "Walk me through a day of your life as you deal with asthma." Interviewees were asked to elaborate on issues they brought up, especially regarding behaviors or tasks they said they did.

The interviews were transcribed and subsequently coded for behaviors, feelings, and beliefs using the principles of grounded theory [22]. Interview data were organized into patterns based on the conceptual similarity of the data, also known as affinity themes. Two coders independently reviewed each transcript and then met with at least 1 other more experienced coder to mediate any disagreements and facilitate reliable, consistent coding. Exemplars of statements expressing behaviors, feelings, and beliefs for a given chronic disease were discussed until consensus was achieved.

Persona Construction

An interdisciplinary team of physicians, a clinical psychologist, experts in user experience, and experts in health content

Table 1. Elements of all chronic disease personas.

Persona characteristic	Description
Emotional hook	The fundamental emotion through which this persona can be connected with
In short	A succinct summary of the main thrust of this persona
Actual quote	A representative quote meant to portray something this persona might say
How I feel / perception of depression / openness to treatment	These represent the different variables that together establish the nature of this persona
Description	A short narrative describing this persona
Unique tasks	The affinity themes from the mental modeling process that map to this persona
Learning objectives	The instructional goals and clinical objectives for this persona
Content needs	The content required to address the learning objectives of the specific persona
Global content needs	The content required to address common learning objectives that span all personas for a given condition

For each persona, 4 to 5 information modules drawn from the Healthwise knowledgebase, patient instructions, and care support pages were matched to the chronic disease and validated by medical content specialists and a medical writer (eg, the “Getting Heart Smart” modules included “Will I Be Okay?,” “What Happened?,” “What Can I Do?,” “Why Medicines Work,” and “Who Can Help?”). Although a standard set of core modules served as the starting point for each persona, these modules were then condensed or enhanced to fit the unique content and tone needs of each persona. The final module concluded with 1 scenario-based question asking the participant to practice applying the concepts they learned up to that point. A summary tab kept a running tally of the modules completed

reviewed all the information from primary and secondary sources to outline the characteristics of the personas. Primary source data were the transcribed interviews previously mentioned; secondary sources per persona included 10 to 20 qualitative studies that included actual patient quotes published in English-based, medically reviewed journals within the last 10 years. Based on the main objective of the persona, the team labeled the individual represented. For example, CAD personas were labeled “Getting Heart Smart,” “Staying Heart Healthy,” and “Putting Your Heart First.” Table 1 lists the elements common to all personas constructed for the study.

and in progress, with the participant’s response to the question signifying completion of that module.

The key distinguishing factors upon which the modules were tailored included behavioral variables such as locus of control, perception of risk, presence of symptoms, perception of condition, openness to treatment, confidence, and acceptance of diagnosis. The number of modules available to a persona differed depending on the respective learning objectives and the persona’s information density tolerance. In contrast to the practice of profile creation, the tailoring of these personas hinged primarily on behavioral variables instead of demographic characteristics. Table 2 provides a listing of the 11 personas with key elements for each.

Table 2. Chronic disease personas with descriptions of key elements.

Condition persona name	Emotional hook	Summary	Representative quote	Tasks
Asthma				
Tune in to You: Minimizing Maria	I'm managing	Not that big of a problem	"Well it doesn't bother me every day...It's not chronic or anything like that."	Feel so accustomed to living with asthma; it doesn't bother me every day
Take Control: Steady Eddy	I'm okay	It's a problem but it's reasonably controlled	"I had cats but I ended up finding a home for them because the allergies and asthma were pretty bad."	Keep the dust down; rather not rely on my inhaler
Be Your Best: Severe Shauna	I'm struggling	It's a problem and I'm worried	"My only hope is just that I can get it better somehow."	Feel I have to be really careful; go in if it's really bad
Coronary artery disease				
Getting Heart Smart: Anxious Andy	I'm scared	Scared and open	"I never thought of death as I do now. That's disturbing to me. It crops up once in a while."	Fear having another heart attack; I have to change in order to live
Putting your Heart First: Complacent Casey	I'm fine	All quiet on the healthfront	"...considering it has been what 7 years ago now that I had open heart surgery...I think I am doing fine when it comes to my heart disease."	Not top of mind when no longer experiencing symptoms; doubt meds
Staying Heart Healthy: Backburner Bobby	I'm spent	Not now, I've got soooo much to deal with	"Heart disease doesn't play a part in my life [right now] because I have bigger problems."	Care for myself inconsistently; avoid thinking about CAD
Depression				
Finding Your Way: Lost Linda	I'm lost	Tell me I can feel better	"I miss my old self."	Feel I am failing; I was not able to see I was depressed; feel it's a result of physical pain
Breaking the Cycle: Not Again Nate	I'm worried	Not again	"I need help before my next depression episode. It hits harder every time."	Fear the next episode; keep busy to distract myself; feel unnerved friends don't understand
Climbing Out: Stuck Stella	I'm stuck	This must be as good as it gets	"I've been this way for a very, very long time."	Feel I have tried it all; get totally fed up; believe I will always be this way
Type 2 diabetes				
Keeping it Simple: No Med Ned	I'm determined	Highly motivated to avoid meds and reverse the diagnosis	"I can overcome this on my own. I'm going to do everything I can to avoid medications."	Control blood sugar through lifestyle changes; avoid meds
Making a Change: Open Oscar	I'm willing	Living with but doesn't prioritize or understand condition	"Whatever you say doc."	Be compliant with the doctor's plan; please the doctor

Online Persona Testing

Sample

An open Internet-based survey was used to test the impact of the personas on activation for chronic disease self-care. Contact with potential survey participants was initiated by the Sample

Network, an online marketing research company specializing in online sampling and recruitment. The announcement given subsequently was used to initially identify participants. Demographic characteristics were collected by the sample provider and were used to ensure a representative sampling. The announcement was:

The purpose of this study is to obtain consumer feedback on information on chronic diseases produced by a not-for-profit health education company.

No personal information will be collected.

Participation is voluntary. If you choose to participate please complete both the pre and post questionnaires as well as at least 1 lesson from the health course. You will receive an incentive for participation per your terms of participation in Sample Network.

The Web-based questionnaires and the health course lesson will take an average of 15 minutes to complete.

Membership in the Sample Network's panels is incentive-based. Various methods are used to vet panel participants and ensure quality responses (eg, the frequency with which participants are allowed to respond to surveys is regulated to weed out professional survey takers). Data were collected April 20-26, 2012. Sample Network provided the necessary URL to their panel members. Sample Network prevents duplicate entries from the same IP address.

Anonymous survey responses were collected on the Healthwise survey platform and subsequently analyzed.

The average recruitment rate for the final convenience sample across the 4 chronic diseases was 13.99% (398/2843) as calculated by the number of people expressing interest in participation versus the number found to be eligible according to their self-report of a chronic disease and a targeted persona path (asthma: 15.1%, 98/651 potential respondents; CAD: 26.2%, 98/364 potential respondents; diabetes: 19.0%, 101/531 potential respondents; depression: 9.96%, 103/1034 potential respondents). Differences in recruitment rates across the chronic conditions were due to challenges in matching respondents with certain personas and ensuring an even distribution of respondents across personas. There was a completion rate of 100% for those respondents included in the final sample. Complete surveys were analyzed with no adjustments to the initial responses.

User Experience

Participants self-selected into a persona by choosing a path based on a path title, an image, and a path quote. [Multimedia Appendix 1](#) provides an illustration of what participants with depression were presented with to make their choice of persona.

To ensure balanced feedback across all the learning paths within a course, an equal number of participants were recruited for each path. Approximately equal subgroup sample sizes were achieved by screening at the first stage of recruitment. Once a learning path was full, individuals who voted for that path and who would have qualified for that path based on their presurvey response were not allowed to be part of the sample. An average of 100 users were tested for each chronic disease course. There was no difference in completion rates across the 11 personas.

Respondents were required to spend at least 4 minutes completing a lesson before they were allowed to proceed to the postquestionnaire. Average time spent in the lesson was 13 minutes. Timeframe for elimination of too-brief responses was based on usability testing with prior users. Only 1 response to

each question was allowed, and respondents could review their answers and make changes using the "back" button.

Construction of software allowed for switching personas within a given course. There were 44 of 398 (11.1% of total sample) who chose a different learning path or persona from the one they voted for at the time of recruitment into the survey. The "Keeping it Simple" persona for the type 2 diabetes course accounted for 25% of those who switched. Switching from the initially selected learning path occurred for 1 to 5 people across the other personas. For purposes of this analysis, all people responding to the activation measures were grouped into their final persona regardless of initially selected persona. [Multimedia Appendix 2](#) provides a complete description of the 3 depression personas.

Scales

Activation is conceptualized here within the framework of an integrated theory of health behavior which brings together theories of self-efficacy, stages of change, health beliefs, and intention to change [23,24]. The integrated theory incorporates elements of decision making predictive of a wide range of behaviors. The accepted measures are knowledge of a given health issue, perceived skills in making personal health better, confidence in being able to make personal health better, and intention to undertake changes in behavior for improvement of personal health (for purposes of this study, intention to act was focused on the week directly after participation in the study).

Participants were asked to assess their standing on the 4 elements of activation (knowledge, skill, confidence, and intention) on a 5-point Likert scale (1=strongly disagree to 5=strongly agree) at the beginning and end of the online course. These scales were taken from a previous study conducted with decision aids [25]. Participants were also asked to rate the course on a 6-point Likert scale according to the following descriptors: clear, helpful, trustworthy, taught something, built confidence, motivated to act, and worth sharing with others. Last, participants were asked at the conclusion of the course, using a 5-point Likert scale, to assess the degree to which they learned some new information that will be useful in their day-to-day life, whether the course gave them a new idea about something to try, and whether they were confident they could use something they learned from their course.

Following the example of Heller et al's analysis of patient activation [13], low-activated respondents were classified as giving a response of 1, 2, or 3 to each of the 4 measures of activation. Scores of 4 and 5 designated activated patients. Surveys with complete responses were analyzed with no adjustments for the responses.

Data Analysis

Data were analyzed with a mixed design with 1 within-subjects factor (pre-post) and 1 between-group factor (persona). The general linear model with repeated measures in SPSS version 21 (IBM Corp, Armonk, NY, USA) was used for the analysis [26]. Since the pre-post dependent measures were significantly correlated with each other ($P=.05$), the multivariate results for Pillai's trace (V) and related statistics are reported [27]. The assumption of equality of covariance matrices of the dependent

measures was tested with Box's test of equality of covariance matrices. In no instance was a significant difference ($P < .001$) for these observed covariance matrices found, thus meeting a key assumption of homogeneity of variance-covariance matrices [28]. Post hoc comparisons for significant between-subjects main effects were analyzed with the Bonferroni test [29]. Pearson's chi-square test of association was used to analyze relationships between pre and post measures of activation and aspects of user experience.

Participants

All participants agreed to a standard statement about personal privacy and use of their responses for research purposes. Consent was obtained a second time with users responding to the question, "Do you agree to the use of your survey responses as noted above?"

Results

A total of 398 participants were recruited (249 women and 149 men). In all, 86.7% (345/398) of the participants were white/non-Hispanic; 7.0% (28/398) of the sample was African-American, and the rest were Native American, Asian, or multiracial (25/398). Of the sample, 89.9% (358/398) had completed at least some college coursework. Overall, participants tended to be middle-age and older with 5.0% (20/398) in the 18 to 24 age range, 15.1% (60/398) in the 25 to 34 age range, 39.9% (159/398) in the 35 to 54 age range, and 39.9% (159/398) in the 55-years-and-older category.

Potential associations between the sociodemographic variables and course selected were of interest for understanding the user experience. There was a significant association between age

and course used ($\chi^2_{15}=72.5$, $P < .001$), with CAD and diabetes course participants being older (51.5%, 52/101 and 64.2%, 61/95 were 55 years or older, respectively) as compared to participants in the other courses.

There was also a significant association between gender and course used ($\chi^2_6=47.8$, $P < .001$). Women were more likely to participate in the asthma course (female: 79.6%, 82/103; male: 19.4%, 20/103), and the depression course (female: 76%, 75/99; male: 24%, 24/99). Men were more likely to participate in the CAD course (female: 38%, 36/95; male: 61%, 58/95). Participation in the diabetes course was approximately equal (female: 54.5%, 56/101; male: 43.6%, 44/101).

For the final rating, 80% (318/398) of respondents rated their course positively (strongly agree and agree) in terms of clarity, helpfulness, trustworthiness, teaching something new, worth sharing, and increased confidence. Participants in the depression course were less likely to feel the course had taught them something ($\chi^2_{12}=22.3$, $P=.03$) or that they were confident they could use something they had learned ($\chi^2_{15}=24.4$, $P=.05$).

Tables 3-6 present the pre-post activation scores by tailored learning path personas for each of the 4 chronic disease courses. Each activation measure was identified as a repeated pre-post dependent variable and the personas were identified as the between-subject factor. Significant within-subject multivariate results for Pillai's trace are reported along with the associated F statistic and degrees of freedom. Values for partial eta squared are presented as a measure of effect size; in this case, the proportion of variance explained that is not explained by other variables.

Table 3. Results of general linear model with repeated measures analyses of chronic health disease personas: asthma.

Activation metrics	Personas, mean (SD)						V	F (df)	P	η^2_{partial}
	Be Your Best (Severe Shauna)		Take Control (Steady Eddy)		Tune in to You (Minimizing Maria)					
	n=32		n=32		n=32					
	Pre	Post	Pre	Post	Pre	Post				
Knowledge										
Within	3.88 (1.19)	4.41 (0.56)	3.84 (1.11)	4.16 (0.95)	4.28 (0.68)	4.44 (0.56)		11.14 (1,93)	.001	0.11
Between							0.11	1.96 (1,3)	.15	
Skills										
Within	3.75 (1.24)	4.41 (0.67)	3.75 (1.08)	4.06 (0.91)	4.00 (1.05)	4.38 (0.71)		16.05 (1,93)	<.001	0.15
Between							0.15	0.770 (1,3)	.51	
Confidence										
Within	3.88 (1.29)	4.41 (0.67)	3.64 (1.14)	4.03 (1.05)	3.94 (1.08)	4.28 (0.73)		17.16 (1,94)	.01	0.15
Between							0.15	1.43 (1,3)	.24	
Action										
Within	3.68 (1.42)	4.19 (0.98)	4.23 (0.71)	4.17 (1.02)	3.19 (1.14)	3.61 (1.17)		17.16 (1,94)	.001	0.15
Between							0.15	2.24 (1,3)		

Table 4. Results of general linear model with repeated measures analyses of chronic health disease personas: coronary artery disease.

Activation metrics	Personas, mean (SD)						V	F (df)	P	η^2_{partial}
	Getting Heart Smart (Anxious Andy) n=33		Putting Your Heart First (Complacent Casey) n=26		Staying Heart Healthy (Backburner Bobby) n=32					
	Pre	Post	Pre	Post	Pre	Post				
Knowledge										
Within	4.24 (1.12)	4.48 (0.62)	4.08 (0.80)	4.27 (0.67)	4.38 (0.75)	4.50 (0.62)		3.29 (1,89)	.07	
Between							0.04	1.37 (1,3)	.26	
Skills										
Within	4.00 (1.10)	4.52 (0.57)	3.73 (1.00)	4.04 (0.60)	4.39 (0.90)	4.42 (0.61)		7.90 (1,89)	.006	0.08
Between							0.08	4.67 (1,3)	.01	0.09
Confidence										
Within	4.03 (0.95)	4.42 (0.80)	3.42 (0.90)	3.92 (0.94)	4.23 (0.99)	4.42 (0.72)		9.68 (1,89)	.002	0.10
Between							0.10	7.09 (1,3)	.003	0.14
Action										
Within	3.68 (1.42)	4.19 (0.98)	4.26 (0.71)	4.17 (1.02)	3.19 (1.14)	3.61 (1.17)		13.43 (1,89)	<.001	0.14
Between							0.15	1.93 (1,3)	.15	

Table 5. Results of general linear model with repeated measures analyses of chronic health disease personas: depression.

Activation metrics	Personas, mean (SD)						V	F (df)	P	η^2_{partial}
	Breaking the Cycle (Not Again Nate)		Climbing Out (Stuck Stella)		Finding Your Way (Lost Linda)					
	n=33		n=32		n=32					
	Pre	Post	Pre	Post	Pre	Post				
Knowledge										
Within	3.88 (0.96)	4.15 (0.67)	3.94 (0.80)	4.13 (0.83)	4.13 (1.01)	4.16 (0.68)		3.12 (1,93)	.08	
Between							0.03	0.308 (1,3)	.74	
Skills										
Within	3.70 (0.92)	4.00 (0.79)	3.45 (1.03)	3.77 (1.23)	4.09 (0.96)	4.09 (0.69)		4.53 (1,93)	.04	0.05
Between							0.05	2.72 (1,3)	.07	
Confidence										
Within	3.73 (1.01)	3.97 (0.77)	3.30 (1.21)	3.48 (1.35)	4.13 (0.83)	4.25 (0.67)		4.69 (1,95)	.03	0.05
Between							0.05	6.17 (1,3)	.003	0.12
Action										
Within	3.79 (0.86)	4.15 (0.71)	3.33 (1.19)	3.67 (1.24)	4.09 (0.78)	4.19 (0.69)		11.61 (1,95)	.001	0.11
Between							0.11	4.87 (1,3)	.01	0.09

Table 6. Results of general linear model with repeated measures analyses of chronic health disease personas: type 2 diabetes.

Activation Metrics	Personas, mean (SD)				V	F (df)	P	η^2_{partial}
	Keeping it Simple (No Med Ned)		Making a Change (Open Oscar)					
	n=48		n=49					
	Pre	Post	Pre	Post				
Knowledge								
Within	3.90 (1.10)	4.17 (0.72)	4.27 (0.88)	4.47 (0.58)		5.44 (1,95)	.05	0.05
Between					0.05	3.96 (1,2)	.22	
Skills								
Within	3.66 (1.17)	4.20 (0.76)	4.18 (0.88)	4.43 (0.61)		13.76 (1,97)	<.001	0.12
Between					0.12	7.02 (1,2)	.07	0.07
Confidence								
Within	3.59 (1.19)	4.04 (0.96)	4.14 (0.88)	4.44 (0.68)		14.23 (1,97)	<.001	0.13
Between					0.14	8.63 (1,27)	.004	0.08
Action								
Within	3.49 (1.16)	4.08 (0.91)	3.98 (0.86)	4.24 (0.82)		23.35 (1,93)	<.001	0.20
Between					0.20	3.46 (1,2)	.07	

All but 2 of the within-subjects effects were significant at the .04 level or less on all pre-post activation measures. No pre-post differences in knowledge were observed for the depression course or the CAD course. Across personas within the 4 courses on the 4 pre-post activation measures, all change was in the direction of increased scores at posttest. Five between-subjects

effects were significant at the .01 level or less. No statistically significant interactions were observed between the within-subject factor and the personas as a between-subject factor.

Five post hoc contrasts were observed to be significant at the .01 level or less for the 5 between-subjects effects for which these contrasts could be calculated. (Diabetes had only 2 learning paths and, therefore, contrasts could not be calculated.) Within CAD, “Putting Your Heart First” was the least positively assessed tailored content learning path and “Staying Heart Healthy” was the most positively assessed for confidence (mean difference=0.55, $P=.009$) and skills (mean difference=0.52, $P=.01$). “Putting Your Heart First” was also least positively assessed for confidence as compared to “Getting Heart Smart” (mean difference=0.65, $P=.002$). The tailored content learning paths for the depression course were mixed, with “Climbing Out” more negatively assessed for confidence (mean difference=0.79, $P=.002$) and “Breaking the Cycle” more negatively assessed for action as compared to “Finding Your Way” (mean difference=0.64, $P=.01$).

The same mixed within-subjects and between-subjects design was used to analyze pre-post differences in knowledge, skills, confidence, and intention with course status (completed or in progress) as a 2-level between-subjects factor. All within-subjects effects were found to be significant at the $P=.001$ level or less (pre-post knowledge: $V=0.04$, $F_{1,396}=24.76$, $P=.001$, $\eta^2_{\text{partial}}=0.04$; pre-post skills: $V=0.06$, $F_{1,396}=40.34$, $P=.001$, $\eta^2_{\text{partial}}=0.06$; pre-post confidence: $V=0.07$, $F_{1,396}=43.05$, $P=.001$, $\eta^2_{\text{partial}}=0.07$; pre-post intentions: $V=0.07$, $F_{1,396}=43.60$, $P=.001$, $\eta^2_{\text{partial}}=0.07$). There were no significant between-subjects effects.

Overall changes in pre-post levels of activation were first examined for shifts in the lowest levels of activation (1, 2, and 3) at pretest to high activation at posttest (4 or 5). Across the 4 courses at pretest, a total 84 of 398 respondents (21.1%) were classified as being low activation on knowledge, 110 (27.6%) were classified as being low activation on skills, 123 (30.9%) were classified as being low activation on confidence, and 137 (34.4%) were classified as being low activation on intention to act. All chi-square associations between pre and post measures of activation were significant at $P<.001$.

Tallying the number of participants shifting from the lowest levels of activation to the highest levels at posttest across the 4 chronic conditions, 76% (66/87) of low activation for knowledge changed to high activation, 64.2% (70/109) of low activation for skills changed to high activation, 56.1% (69/123) of low activation for confidence changed to high activation, and 51.4% (71/138) of low intention to act changed to high activation. Conversely, the percentage of respondents with the highest level of activation (5) decreased to the lowest levels (1, 2, 3) at posttest by 5% for knowledge, 3% for skills, 5% for confidence, and 8% for intention to act.

In total, 45.9% (183/398) of the total sample provided written, free-field details on what they planned to change short-term regarding their health. Exercise was the most frequently mentioned change (67.1%, 267/398 of write-in responses), followed by changes in diet toward healthier eating (41.9%, 167/398 of write-in responses). Additionally, individuals with asthma stated they would pay more attention to triggers and medicines (19%, 18/96 of all asthmatics) and 26% (25/97) of

those with depression wrote in that they would try and relax more, be less stressed, and/or be more positive.

Discussion

Principal Findings

The results of this study document a generally positive reaction to online chronic disease personas constructed from feedback from individuals with 1 of 4 chronic diseases who had selected a persona with whom they felt affinity. The majority of participants using a chosen learning path reported high levels of satisfaction with their user experience and increased levels of activation with regards to their own health. The participants who selected personas within the depression course reported the smallest changes in activation overall. Within a chronic disease, “Putting Your Heart First” was related to lower activation levels at posttest as compared with the other 2 CAD-tailored content personas. The calculated effect sizes ranged from 0.05 to 0.15, bracketing the overall similar small effect size of 0.074 reported by Noar et al [30] for tailored print messages and the posttest effect of 0.14 reported for Web-delivered behavior change interventions [31]. The implications of the participants’ experiences are considered after acknowledgment of key methodological limitations.

In the body of work on activation, this study adds to understanding of both short-term impact and the content of a brief, online intervention. Descriptions of the actual elements of interventions for increasing activation are sparse [15,32]. Therefore, a contribution of this study is more details on the structure and content of the personas used to address a person’s level of activation. A second contribution arises from use of the Internet to deliver the activation materials to individuals with a chronic disease. Other efforts at activation have relied on various forms of in-person, one-on-one health coaching, telephone contacts, and/or information campaigns [16,33]. The Internet offers another portal convenient for many to use and flexible in delivery [34].

Limitations

A major limitation is reliance on self-reports of both health status and intention to change their interactions with their physician about management of the participant’s chronic condition. Additional research is required to determine if individual behavior actually does change and, if so, which specific behaviors were altered and for how long. This would be especially important given that the sample recruited through the online survey service for this study was skewed toward a higher-educated, primarily white/non-Hispanic group.

Understanding of the impact of the personas would be further enhanced with inclusion of a comparison group formed through random assignment. A comparison group was not included here because of limitations of resources. Inclusion of a comparison group would allow for more direct testing of the content of the persona on patient activation against standard patient educational material. This, in turn, would provide a gauge of the advantages gained through a persona and the tailored material contained therein.

Additionally, the sample sizes within a given tailored content learning path were relatively small. However, Pillai's trace is considered the most reliable of the multivariate measures and offers the greatest protection against type I errors with small sample sizes. [27] The Bonferroni method controls the overall type I error and is the method commonly used for all pairwise comparisons tests. MANOVA is robust to violations of multivariate normality and to violations of homogeneity of variance-covariance matrices if groups are of nearly equal size (n of the largest group is no more than 1.5 times the n of the smallest group).

In terms of completeness of theory, this study assessed 4 of the 8 variables deemed important for behavioral change from 1 integrated theoretical paradigm [24,35]. Further research would be needed to determine the contribution of the environment, pros and cons, social norms, and consistency with self-image. Also, a potential limitation is use of single items for determination of knowledge, confidence, skills, and intention. However, other studies of the role of activation in self-care have relied on fewer and less theoretically based measures [7,13].

Clinical Implications

Health systems and individual clinicians are in the midst of a tsunami of change given the transition to Accountable Care Organizations and other forces within the health care system [36,37]. Additionally, health systems are transitioning to population-based care and aiming to reach increasing number of patients in more automated ways. We believe in order to engage populations of patients in their own self-management, automated interventions must be designed from the patient perspective. Personas founded on the user's emotions, thoughts, and actions put the patient at the center of the experience and create resonance and engagement. Once patients are engaged, use of automated self-management programs puts the best behavior change science right in the palm (ie, cell phone) of the patient's hands. These interventions may act as clinician extenders with the behaviorally designed self-management tools helping the patient know how to achieve the recommended goals in their day-to-day life.

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Conflicts of Interest

Catherine Serio, PhD: Dr Serio is the Senior Director, Health Behavior Change, for Healthwise. Healthwise is a not-for-profit company whose mission is to help people make better health decisions. She was the lead behavioral scientist for the design and development of the persona-based behavior change intervention. She is not compensated for the sale of Healthwise products.

Jason Hessing, MSED: Jason Hessing is the Lead Interaction Designer, User Experience for Healthwise. Healthwise is a not-for-profit company whose mission is to help people make better health decisions. Hessing served as both the lead designer and user experience researcher for the design and development of the persona-based behavior change intervention. He contributed to the survey instrument design for this research and facilitated the collection of participant data. He is not compensated for the sale of Healthwise products.

Becky Reed, MSEP: Becky Reed is the Senior Director, User Experience, for Healthwise. Healthwise is a not-for-profit company whose mission is to help people make better health decisions. Reed was a contributing User Experience designer for the development of the persona-based behavior change intervention. She is not compensated for the sale of Healthwise products.

Christopher Hess: Christopher Hess is employed as a Medical Writer/Editor and Content Strategist at Healthwise. Healthwise is a not-for-profit company whose mission is to help people make better health decisions. Hess was the content lead for the design and development of the persona-based behavior change intervention. He is not compensated for the sale of Healthwise products.

Janet Reis, PhD: Dr Reis provided analytic support to Healthwise as a consultant from Boise State University. This support includes completion of the analyses included in the manuscript submitted to the *Journal of Medical Internet Research*. The data files were provided for independent analysis and verified against a preliminary, internal analysis done within Healthwise. The analyses reported in the manuscript were completed on the Boise State University campus. Dr Reis has had no role at any time in the development or sales of any Healthwise products.

Multimedia Appendix 1

Introduction to depression personas.

[PDF File (Adobe PDF File), 82KB - [resprot_v4ile20_app1.pdf](#)]

Multimedia Appendix 2

Overview of depression personas.

[PDF File (Adobe PDF File), 301KB - [resprot_v4i1e20_app2.pdf](#)]

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Abbreviations

CAD: coronary artery disease

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Original Paper

Competency-Based Assessment for Clinical Supervisors: Design-Based Research on a Web-Delivered Program

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Abstract

Background: Clinicians need to be supported by universities to use credible and defensible assessment practices during student placements. Web-based delivery of clinical education in student assessment offers professional development regardless of the geographical location of placement sites.

Objective: This paper explores the potential for a video-based constructivist Web-based program to support site supervisors in their assessments of student dietitians during clinical placements.

Methods: This project was undertaken as design-based research in two stages. Stage 1 describes the research consultation, development of the prototype, and formative feedback. In Stage 2, the program was pilot-tested and evaluated by a purposeful sample of nine clinical supervisors. Data generated as a result of user participation during the pilot test is reported. Users' experiences with the program were also explored via interviews (six in a focus group and three individually). The interviews were transcribed verbatim and thematic analysis conducted from a pedagogical perspective using van Manen's highlighting approach.

Results: This research succeeded in developing a Web-based program, "Feed our Future", that increased supervisors' confidence with their competency-based assessments of students on clinical placements. Three pedagogical themes emerged: constructivist design supports transformative Web-based learning; videos make abstract concepts tangible; and accessibility, usability, and pedagogy are interdependent.

Conclusions: Web-based programs, such as Feed our Future, offer a viable means for universities to support clinical supervisors in their assessment practices during clinical placements. A design-based research approach offers a practical process for such Web-based tool development, highlighting pedagogical barriers for planning purposes.

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KEYWORDS

competency-based education; preceptorship; e-learning; pedagogy; constructivist; dietitian

Introduction

Support for Supervisors to Assess Clinical Competence

Within the dietetics profession, students are required to complete 20 weeks of placement, with half of that time spent in developing and demonstrating competence in individual case management [1]. The assessment of the clinical competence of student dietitians is a shared responsibility between the university and the health sector [1], with the assessments made by site supervisors during clinical placements providing a key source of evidence of student competence [2]. The difficulties faced by site supervisors in assessing student performances during clinical placements are clearly reported in the literature [3,4]. Clinicians therefore need to be supported by universities to use credible and defensible assessment practices [5]; however, the geographical distribution of placement sites prohibits face-to-face education of all supervisors.

Web-Based Delivery

Web-based delivery of education to support clinical supervisors has been successfully used by the professions of medicine, nursing, and physiotherapy [6-9]. The Web-based mode transcends geographical and time constraints [10] and may be more accessible to clinicians, particularly those in rural or community-based settings who may be sole practitioners within a multidisciplinary team [11]. Web-based delivery provides an efficient means to share resources and avoid duplication [12]. Professional development delivered via the Web has been shown to achieve equivalent outcomes (satisfaction, knowledge retention, and change in practice) when compared to face-to-face delivery [13,14].

Pedagogy

When developing a Web-based learning program, both the discipline-specific content and the learning process need to be considered. Constructivist pedagogy, in which learners construct their own meaning by forming connections through collaboration and reflection between their prior knowledge and new experiences (authentic real-world problems), has been recommended for Web-based delivery [15,16]. Collaboration can be supported within a virtual community using a central online discussion forum [17]. This learner-centered approach to Web-based education allows participants to be independent self-paced learners and to select learning content in a way that meets their learning style [16,17]. Rowe and Rafferty [18] have demonstrated improved user engagement with Web-based learning by self-regulated learning strategies such as activation of prior knowledge, self-monitoring, and reflections. There is evidence to suggest video-based learning material may improve learner engagement [9,19-21]. Effective Web-based delivery must also consider the usability and accessibility of the program [22,23].

Objective

Programs to educate supervisors in the use of more credible and defensible assessment practices are currently non-existent. This paper explores the potential for a Web- and video-based constructivist tool to support clinical supervisors to use credible and defensible assessment practices during clinical placements.

The program aims to use authentic video-based learning material and metacognitive activities such as self-monitoring and reflection to support clinical supervisors to transform their assessment practices. The study also considers the interdependence between pedagogy, usability, and accessibility.

Methods

Design-Based Research

The Web-based program “Feed our Future” was developed using a design-based research approach adapted from Wang and Hannifin [24]. This approach has been used in the design of technology-enhanced learning environments for the way in which it advances design, research, and practice concurrently [25]. Design-based research addresses a practical problem in context, is informed by theory, and is refined through an iterative process of formative feedback and reflection in consultation with participants [25]. In the final stage of product development in design-based research, the intervention is pilot-tested and evaluated. This stage is then used to inform final revisions of the program [24].

Stage 1: Program Development

In October 2012, research consultation and initial development of the program commenced concurrently.

Research Consultation

Research presented in the publication, “Credible and defensible assessment of entry-level clinical competence: Insights from a modified Delphi study” [26], informed the development of the professional content of the program. This research was conducted with a panel of experienced clinical supervisors (potential end-users) and explored the issues of judgment and subjectivity in the assessment of health professional competence. The paper includes a focused literature review on credible and defensible competency-based assessment practices including the need for a shared definition of competence [27], clearly defined standards [28], a global approach to assessment [29], consideration of the learning context [30,31], multiple sources of evidence [32], and the need for an interpretive community of assessors [33].

Development of the Prototype

An interview with Professor Sue Ash, a member of the original taskforce that developed the dietetic competency standards in 1994 [34], and participated in their reviews [35,36], was recorded as expert opinion. This recording was incorporated into the program to provide clarity on the definition and application of the competency standards within the dietetics profession.

Evidence suggests that resources to support assessments such as visual representation of entry-level performance may increase the consistency of supervisor assessments [37]. As an outcome from the research consultation, 11 video recordings of authentic dietetic student-client consultations were produced for the program (mean duration 60 minutes; residential aged care and outpatient settings), with corresponding assessments of each student's performance made by the panel of experienced clinical supervisors [26].

Information technology (IT) expertise from an academic was sought to select an appropriate delivery platform. Consideration was given to budget and timeline, security, usability, incorporation of different file types, with particular considerations of video recordings, and capacity to provide feedback to participants on their learning.

The first prototype of Feed our Future was completed within 8 months using the website builder WIX as the delivery platform. The planned learning outcomes for the program were for supervisors (1) to feel more confident in their approach to assessment, and (2) to use credible and defensible competency-based assessment practices. The program comprised four learning modules, each including questions to consider, problem-based learning and self-monitoring activities, key concepts, and suggested readings. A pre-program quiz, a post-program quiz, a discussion forum, and a practice capstone module were included.

Formative Feedback

Feedback obtained during the Feed our Future program development included several sources. An advisory group comprised of industry, academic, student, consumer, and regulatory representation provided direction on the research and the development of the Web-based program. Potential end users trialed the prototype and provided feedback via a market stall/booth established at the Annual National Conference of the Dietitians Association of Australia (DAA) in May 2013. The DAA's Board of Directors also reviewed the program.

Stage 2: Pilot Test and Evaluation

Participants

A purposeful sample of nine dietitians located in a variety of health care sites and involved in the University of Canberra's clinical placement program was invited, via email, to participate in this study. These potential end-users were provided with access to the password-protected website and asked to pilot-test the program over a 4-week period. The Human Research Ethics Committee (HREC) of the University of Canberra approved the study protocol (12-209) that conformed to the provisions of the Declaration of Helsinki.

Data Generated From Feed Our Future

Data generated as a result of user participation during the pilot test including participation rates and outcomes from the pre-test, discussion forum, multiple choice quiz, and the post-test, were reviewed. In the pre-test and post-test, participants were asked to (1) rate their level of confidence with assessing a student's competence during his/her clinical placement using a 10-point scale (1=not at all confident; 10=extremely confident), (2) rate a student's performance as observed from a video recording (the method of assessment is described elsewhere [26]), and (3)

provide a qualitative description of how they would ensure their assessment of a student's competence during his/her clinical placement was credible and defensible. Content analysis was used to analyze the qualitative responses from the discussion forum, informed by the focused literature on credible and defensible assessment practices described in the research consultation section [26].

Qualitative Evaluation

User experiences during the pilot test were explored using an interpretivist qualitative approach. During the pilot test, users were invited to reflect on a series of questions to be discussed at a later interview. Interviews were held in a focus group for those who could attend (n=6) and in the format of individual interviews, via telephone, for the remainder (n=3). Focus groups were chosen to make use of group dynamics to stimulate discussion in a secure environment [38]. The focus group and individual interviews were facilitated by the primary researcher and began with a scripted introduction outlining the research and ethical considerations. Users provided informed signed written consent that included permission for their interview to be audio-recorded. In the focus group session, a research assistant was employed as a scribe.

The interview questions were developed by the first author in consultation with LW and MJ and covered (1) the overall experience of using the Feed Our Future program, (2) what they learned, (3) whether and in what way their thinking had been challenged, (4) whether it had prompted them to change the way they assessed students on their clinical placement, and (5) suggestions to improve the program. Users were also asked to describe their workplace and experience with supervising and assessing students up to the time of viewing the program.

Recordings were audiotaped, transcribed verbatim by two researchers, and crosschecked for accuracy to maintain the integrity of user responses. Transcripts were analyzed independently by the primary researcher and one research assistant with themes highlighted using van Manen's highlighting approach to thematic analysis [39]. Pedagogical themes arising from the focus group and individual interviews were compared and found to be similar enough to pool. Exemplar quotations illustrating each theme were identified.

Results

Stage 1: Program Development

Formative Feedback

Table 1 presents the formative feedback that was generated from the advisory committee, dietitians at the Dietitians Association of Australia's (DAA) National Conference, and from the DAA Board of Directors.

Table 1. Formative feedback and subsequent refinement to the program.

Source	Feedback	Refinement
Advisory Committee		
	Learner-centered approach	No change recommended
	Professional content	Emphasized that competence cannot be assessed from a single performance.
	Use of authentic videos	Keep videos footage in context
	An interpretative community of assessors	Include a feedback session with insights from students ^a
End users at DAA conference stall		
	Need for aesthetic improvements ^a	Reduced the amount of text per page Removed images that did not add meaning Increase consistency across modules Added audio file introduction Provided a program overview
	Further supports required to improve navigation ^a	Included direction arrows on each page Added a file path to each page Made all modules accessible from the homepage
	Ongoing IT issues with playing videos ^a	YouTube videos also made accessible through Dropbox as .mp4 file type Added contact details for IT support on homepage
	Discussion forum not accessible on WIX ^a	External discussion forum added
Dietitians Association of Australia (DAA) Board		
	Program endorsement under consideration	Review by the Australian Dietetics Council pending ^a
	Approved for dissemination through the Dietetics Information and Nutrition Education Resource Database (DINER) accessible to all DAA members	
	Agreed to promote program through professional online newsletter to DAA members	

^aThese items need addressing; all other items were supported/addressed.

Stage 2: Pilot Test and Evaluation

Participants

Of the nine users that pilot-tested Feed our Future, two were from rural and seven from urban locations, four worked in hospitals and five in community settings, five were experienced supervisors, two reported some experience, and two had little or no experience with supervising students.

Data Generated From Feed Our Future

Data generated by participants after pilot-testing the program Feed our Future are presented in [Tables 2-4](#). In the pre-test, the mean confidence level for users with their assessment approach (using a 10-point scale: 1=not at all confident; 10=extremely

confident) was 5.75 (range 2-9). In the pre-test, only five out of eight users rated the student performance, as observed from the video recording, in a similar way to the panel of experienced supervisors (see [Table 3](#)). In their qualitative responses, only some concepts supporting credible and defensible competency-based assessment practices were identified by the users (see [Table 4](#)).

Although technical issues prevented some users from participating, the discussion forum was used for introductions and to share learning and reflections. The average score achieved from the multiple choice quiz by users was 86%. Technical issues delayed participants' completion of the program and hence no results are available from the post-test.

Table 2. Data generated from Feed our Future: participation.

Program feature	Number of users (n=9) n (%)
Pre-test	8 (89%)
Forum	4 (44%)
Multiple choice quiz	7 (78%)
Post-test	0 (0%)

Table 3. Data generated from Feed our Future: pre-test results Question 2: assessment rating of student's performance by users.

Rating scale used to assess student's performance	Number of users who rated the performance at each stage (n=8) n (%)
Novice	1 (13%)
Intermediate/beginner ^a	5 (63%)
Entry-level competent	2 (25%)

^aConsistent with the panel rating.

Table 4. Data generated from Feed our Future: pre-test results Question 3: content analysis from qualitative responses informed by focus literature review [26].

Competency-based assessment practice considered by users	Number of users (n=8) n (%)
Defined standards	7 (88%)
Global approach	2 (25%)
Supervisor collaboration	3 (37%)
Evidence-based	6 (75%)

Qualitative Evaluation

The analysis of interview transcripts revealed three pedagogical themes: (1) constructivist design supports transformative online learning, (2) videos make abstract concepts tangible, and (3) accessibility, usability, and pedagogy are interdependent.

Theme 1: Constructivist Design Supports Transformative Online Learning

Although the post-test was not completed by users due to technical issues, qualitative feedback from the focus group and personal interviews showed an increase in user confidence as demonstrated by this exemplar quote:

From doing this, I now feel like I would be able to confidently have a final clinical placement student.
[Focus Group User # 3]

The constructivist design assisted users to apply their learning as demonstrated by the exemplar quotes in Table 5. The program enabled users to compare their assessments of an individual student performance with those made by a panel of experienced supervisors. As one user commented:

We can use this process for moderation, if we have a number of different supervisors that watch a particular video, we could use it to make sure that our assessments are similar... [Personal Interview User #9]

Through participation in the program, users achieved consensus in their understanding of entry-level performance.

Table 5. Constructivist design supports transformative online learning.

Pedagogical feature	Exemplar quote
Learner-centered approach	I found the program very accessible, I found it well structured, I found it sort of oriented towards self-learning, and that you could complete it in different parts. (Focus Group User #5)
Authentic problem-based learning activities	I sort of never really thought about how to apply the competencies, and the types of patients, the different wards that we have in the hospitals... doing that activity where it had each of the competencies broken down and how you'd apply them ...I was like, 'oh' I can totally figure out how to do it...(Focus Group User #2)
Metacognitive activities	I suppose it just made me sort of reflect on my transition from being you know a student to a new grad and it made a bit more sense, being able to apply it [the competency standards] in different situations...(Focus Group User #3).

Theme 2: Videos Make Abstract Concepts Tangible

Users supported the use of video-based learning material:

you can read about it, but actually seeing the videos of an assessment, and knowing where they sit on the scale [from novice to expert]...you know we always want to see stuff in action. [Focus Group User #3]

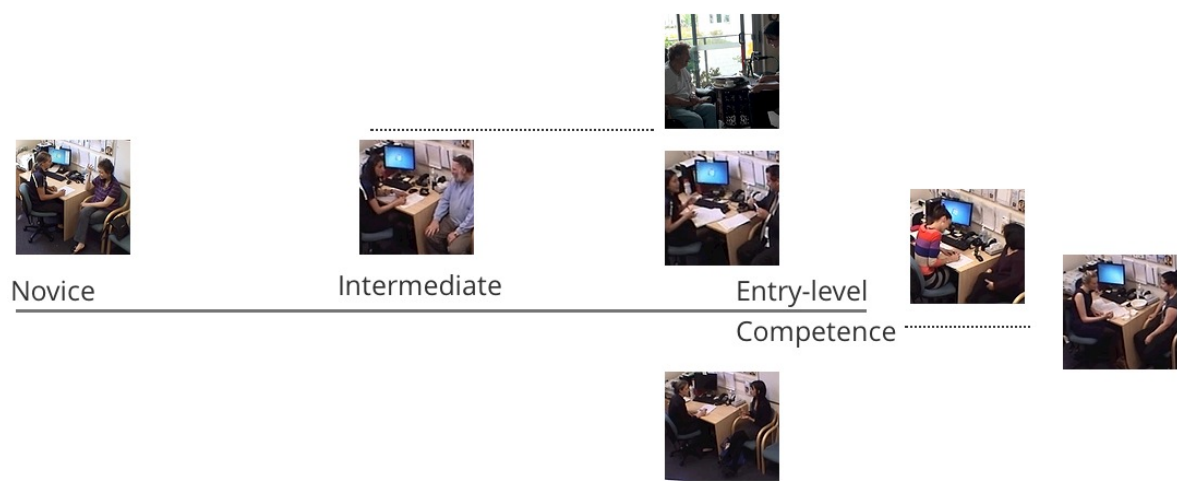
They commented that prior to completing the program they had found the learning content “difficult to apply” and “frustrating at times”. The users found that the video representations of the

authentic student-patient consultations allowed their understanding of “entry-level” competence to become more tangible.

I really liked the videos that when, at the end of them would show the scale of where the students were, like from the beginning to the end. [Focus Group Participant #2]

As demonstrated by Figure 1, organizing the videos on a scale helped the supervisors to distinguish between a novice, intermediate, and entry-level student performances.

Figure 1. Visual representation of competency development using videos.



Theme 3: Accessibility, Usability, and Pedagogy Are Interdependent

IT access and capacity at some worksites limited engagement with the program:

I’m computer literate but not really up-to-speed with some technological advances I suppose. I was a bit frustrated with some of those things...I suppose once

I get annoyed with something I’m not inclined to go back. [Personal Interview User #7]

Table 6 summarizes accessibility and usability barriers experienced by users and presents revisions made to improve the program.

Product Release and Dissemination

Table 7 presents the final learning content for Feed our Future. Figures 2-4 present screenshots of the final interface.

Table 6. Program features: barriers and solutions.

Program feature	Barriers	Solutions
Usability	Shared computer workstations	Changed to university-hosted delivery platform that supported individual log-ins and was compatible with Internet Explorer.
	Internet browsers available at some worksites not compatible with delivery platform	
	Clearer expectations required for learning modules including time commitments	An introductory video and program outline (including endorsement, program description, learning outcomes, learning content, background, acknowledgements, evaluation processes, and certificate of completion) were added to the program.
Authentic video-based learning material		
	Security restrictions for YouTube videos	Change to university-hosted delivery platform with embedded videos. Alternative access made available through Dropbox. Videos saved in generic .mov version.
	Length of patient /student encounters reduced engagement	Videos edited and shortened; average 8.5 min. (range 0.58-18.17)
	Network capacity issues	
Virtual online community		
	Security restrictions prevented participation at some sites	Changed to university-hosted delivery platform with embedded discussion forum

Table 7. Learning content included in Feed our Future.

Time (minutes)	Learning objective	Learning experiences	Self-monitoring
15	Before you begin	About this program Engage your prior knowledge / Pre-test evaluation Introducing the learning modules	
30	To understand how the competency standards are defined, developed, and used by the dietetics profession	Reading: Competency-based assessment Video: Development of competency standards with Sue Ash	Multiple choice quiz
30	To explain the relationship between context and competence	Reading: Competence and context Video: A case example of a non-traditional setting Video: Challenges of the future workforce with Sue Ash	Reflection
60	To apply unit 4 of the competency standards (DAA, 2009) in your clinical setting	Reading: Applying the competency standards-1 Problem-based learning activity: Entry-level competence in your clinical setting Reading: Applying the competency standards-2	Reflection
90	To evaluate student performances from authentic student-client consultations using a credible and defensible approach to competency-based assessment	Reading: Applying the competency standards-3 Scaffolded case study: Assess a video of an authentic client consultation	Compare with assessments by experienced supervisors
60-180	To consolidate credible and defensible competency-based practices using authentic student-client consultations	Case studies: Assess videos of authentic client consultations	Compared with assessments by experienced supervisors
15	What you have learned	Post-test evaluation Certificate of completion References	

Figure 2. Final interface home page.

Feed Our Future

e-Learning for Clinical Dietitians

Please click the arrow below to listen to the introduction



Announcements



An Interpretive Community

Please use this forum to discuss your learning, assessments and comments about the program. Through collaboration we can justify our thinking, learn from the ideas of others and re-assess our judgements.

All journal articles included in the Suggested Readings can be accessed [here](#).



e-reserve

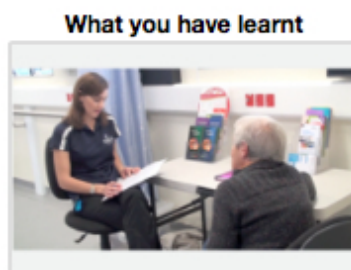
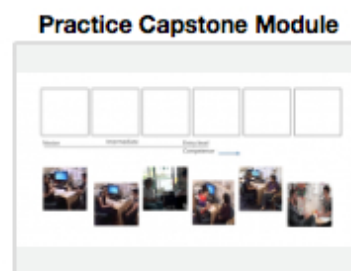
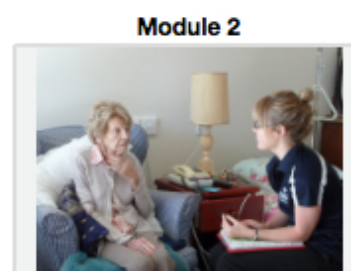
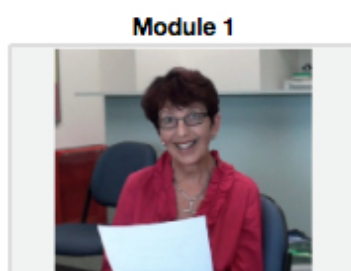
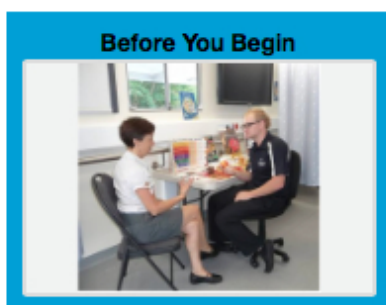


Figure 3. Final interface learning modules.

[◀ BEFORE YOU BEGIN](#)[MODULE 2 ▶](#)


MODULE 1

You should allow 30 minutes to complete this module.


Learning Objective:
To describe how the competency standards are defined, developed and used by the dietetics profession.

Questions to Consider:
(1) How would you describe competence?
(2) How are the competency standards used in the dietetics profession?
(3) Why is the approach used to develop the competency standards relevant when considering the assessment of student competence during Individual Case Management (ICM) clinical placements?

Learning Activities:
Step 1 - Read the on-line book below about the definition, development and use of [competency-based assessment](#) in the dietetics profession.


 [Competency-Based Assessment](#)

Step 2 - Watch this video. It is the first of a series of interviews with Professor Sue Ash who was a member of the task force that developed the Dietitians Association of Australia (DAA) National Competency Standards and who was involved in their later reviews in 1988 and 2008.



[Click for iPad / iPhone](#)

Assess Your Understanding:
Complete this three question multiple choice quiz to check your understanding of the key concepts included in this module.

 [Feedback Quiz](#)

KEY Concepts:

- Competence is required to function successfully in the workplace.
- Competence is part of a continuum of life-long learning from novice to expert.
- The competency standards (DAA, 2009) provide the criteria to assess if a student is ready to enter the profession.
- The competency standards (DAA, 2009) describe the job roles of dietitians in Australia.
- The competence standards (DAA, 2009) are intended to be used together as an integrated whole.

Suggested Reading:
Ash S, Phillips S. What is dietetic competence? Competency standards, competence and competency explained. *Australian Journal of Nutrition and Dietetics*. 2000; 57: 147-51.
Ash S, Dowling K, Phillips S. Mixed methods research approach to the development and review of competency standards for dietitians. *Nutrition & Dietetics*. 2011; 68 (4) : 305-315.

Figure 4. Final interface practice modules.

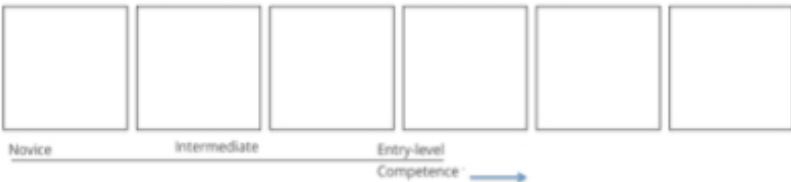
◀ MODULE 4
WHAT YOU HAVE LEARNT ▶

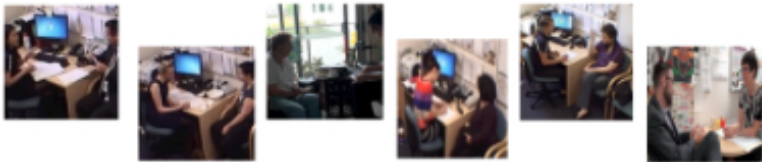
PRACTICE CAPSTONE MODULE

You should allow 1 - 3 hours for this module.

Please note: The students/dietitians included in the following case studies have generously allowed their learning to be transparent. In practice these students would have been active participants in their assessments. All of these students/dietitians are now qualified dietitians.

These case studies are provided to give you a chance to consolidate your practice. Select as many as you feel is necessary.






Step 1 - Click on the Case Study Folder.


Step 2 - Open the attached worksheet (word document).


Step 3 - Watch each video and record any behavioural cues in the worksheet.


Step 4 - Write your global qualitative description of the students' performance. Consider all the units of competency (DAA, 2009) together as an integrated whole. Ask yourself, "How well is the student able to 'Pull it all together?'" Use the [Behavioural Descriptors](#) to consider the learning context.


Step 5 - Look at the feedback below each case study to compare your assessment to the consensus judgement made by the panel of experienced supervisors.

 [Behavioural Descriptors](#)

 [Case Study 1](#)



 [Feedback from the panel of experienced supervisors.](#)



Discussion

Principal Results

This paper describes the development of the first research- and Web-based learning program to support clinical supervisors in their assessments of student dietitian competence during clinical placements. This case example demonstrates the value of a design-based research and consultative approach to developing a program. The use of a Web-based mode has the potential to disseminate expertise and research findings nationally, overcoming geographical and time boundaries, in the provision

of continuing professional development to health practitioners who assess student performance.

Comparisons With Prior Work

The results of the pilot test supported the pedagogical design of Feed our Future. The program encouraged independent self-paced learning and catered to different learning styles as recommended by Ng'ambi and Lombe [16]. Participants demonstrated new understandings that aligned with the programs' learning objectives of the program through the use of authentic student-client consultations, problem-based learning activities, and reflections. Kyeong-Ju Seo and Engelhard [9]

achieved similar results with their constructivist Web-based continuing education program for physiotherapy supervisors with their participants perceiving improvements in the quality of their clinical education skills and practices. The approach used in this study highlights the interdependence of pedagogical, usability, and accessibility considerations [22] with the iterative process and the end-user involvement facilitating the identification of barriers to effective educational outcomes.

Participants in the pilot test found the video recordings of student-client consultations to be helpful in learning about competency-assessment practices. Clinical vignettes in traditional face-to-face learning programs have been used to assist supervisors to gain a shared understanding of entry-level competence in physiotherapy [37]. When used in Web-based delivery, videos have been shown to help engage students and improve learning outcomes [20,21,40]. Maloney and colleagues [19] found learners preferred videos in comparison to other learning materials made available through a Web-based resource repository. Developing a Web-based program with a large number of videos (n=20) in Feed our Future was technically challenging. The decision to edit and divide the videos was driven by network capacity limitations, but Guo's research [41] suggests that short (6-9 minute) videos also have pedagogical advantages.

Consistent with the findings of Cook and Steinert [14], users appreciated material that was relevant, well-organized, and had clear expectations including time commitments. The participation rates for the discussion forum in this study were low despite the fact that other studies have identified conversational discussion and social bonding as key factors for successful Web-based education [14]. This feature is also key to constructivist pedagogy [16] and aligns with the notion of an interpretive community of assessors [33]. Possible solutions to address the lack of engagement with discussions may include more active moderation on the forum, blended Web-based learning with face-to-face contact, a social media approach that conforms to workplace security restrictions, or more assistance with technical problems [14].

Technical barriers experienced in the pilot-testing of Feed our Future such as IT incompatibilities between organizations'

infrastructure, software and Internet browsers, security restrictions, and bandwidth limitations are not unique [42]. Universities have very few security restrictions and are able to use programs such as YouTube to achieve positive learning outcomes [43]. Awareness that this freedom may not be available in some health settings is required if effective Web-based programs are to be available for use by clinical supervisors working in these settings.

Feed our Future, like many programs [44,45], was developed on a limited budget. Lack of IT expertise, infrastructure, and associated software, were limitations to the development of this program. Two years was required to complete the design-based research approach. Despite the advantages, the development requirements for Web-based programs are more labor intensive than face-to-face delivery [44,45].

Limitations

The research-based design and national consultation used for the development of this program was robust. The sample size and the qualitative design of the pilot test and evaluation, although consistent with similar studies [46,47], does not support generalization of the results. Rather, these findings have been used to inform and improve the innovative product. Due to the lack of comparison with other modes of delivery, conclusions cannot be drawn as to whether Web-based delivery was the preferred option by clinical supervisors. The design-based research approach, however, offers supporting evidence for Web-based pedagogical approaches [25]. Further research is required to measure whether the learning of participants translated into actual changes in their competency-based assessment practices, and to determine the uptake of the program nationally.

Conclusion

Web-based programs, such as Feed our Future, offer a viable solution for universities to provide professional development to geographically dispersed clinical supervisors in preparation for their students' clinical placements. A design-based research approach offers a practical process for Web-based tool development.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

DAA: Dietitians Association of Australia
IT: information technology

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Original Paper

Developing a Healthy Web-Based Cookbook for Pediatric Cancer Patients and Survivors: Rationale and Methods

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Abstract

Background: Obesity has been a growing problem among children and adolescents in the United States for a number of decades. Childhood cancer survivors (CCS) are more susceptible to the downstream health consequences of obesity such as cardiovascular disease, endocrine issues, and risk of cancer recurrence due to late effects of treatment and suboptimal dietary and physical activity habits.

Objective: The objective of this study was to document the development of a Web-based cookbook of healthy recipes and nutrition resources to help enable pediatric cancer patients and survivors to lead healthier lifestyles.

Methods: The Web-based cookbook, named “@TheTable”, was created by a committee of researchers, a registered dietitian, patients and family members, a hospital chef, and community advisors and donors. Recipes were collected from several sources including recipe contests and social media. We incorporated advice from current patients, parents, and CCS.

Results: Over 400 recipes, searchable by several categories and with accompanying nutritional information, are currently available on the website. In addition to healthy recipes, social media functionality and cooking videos are integrated into the website. The website also features nutrition information resources including nutrition and cooking tip sheets available on several subjects.

Conclusions: The “@TheTable” website is a unique resource for promoting healthy lifestyles spanning pediatric oncology prevention, treatment, and survivorship. Through evaluations of the website's current and future use, as well as incorporation into interventions designed to promote energy balance, we will continue to adapt and build this unique resource to serve cancer patients, survivors, and the general public.

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KEYWORDS

obesity; pediatric cancer; survivorship; nutrition; cooking

Introduction

Childhood Cancer Survivors and Obesity

Obesity has been a growing problem among children and adolescents in the United States for a number of decades. According to the Centers for Disease Control and Prevention, in 2012, nearly 20% of children ages 6-11 were obese, compared

to only 7% in 1980; among adolescents (ages 12-19), 21% were obese, compared to 5% in 1980 [1]. This alarming trend is mirrored in survivors of childhood cancers, which is a population that has benefited from improved treatments, leading to a cure rate of 83% [2]. However, childhood cancer survivors (CCS) are more susceptible to the downstream health consequences of obesity such as cardiovascular disease, endocrine issues, and risk of cancer recurrence due to treatment

received [3-5]. Therefore, obesity prevention in this population requires specific action.

Unhealthy eating habits developed during treatment routinely persist into survivorship. For example, chemotherapy often changes the taste and smell of foods, decreases appetite, increases satiety, and causes nausea and vomiting [6,7]. Frequently, parents and providers are permissive of allowing patients to succumb to poor food choices to accommodate these issues. As a result, strategies to promote healthy diets in CCS must include the continuum of cancer care, beginning with treatment. A cross-sectional survey conducted to determine CCS quality of life found that most survivors did not meet recommended dietary and physical activity guidelines [8]. CCS also reported an interest in computer-based healthy lifestyle interventions [8]. Another survey found that most parents and CCS desired to live a healthier lifestyle, but their behavior fell short [9]. CCS may also adopt sedentary behaviors and poor eating habits, which contribute to chronic health issues [5,10].

“@TheTable”

In an effort to build resources that enable pediatric cancer patients and survivors to lead healthier lifestyles, we developed a Web-based cookbook called “@TheTable”. Freely available, this website provides unique features that address healthy eating during treatment and throughout survivorship. The website is mobile phone, with Internet access capability, and tablet compatible and recipes are searchable by many criteria including symptoms. Also, individual recipe ingredients can be added and subtracted in real time, with caloric information adjusting immediately. Here, we describe the development process, novel aspects, and current and future applications for the cookbook website.

Methods

Creating the Website

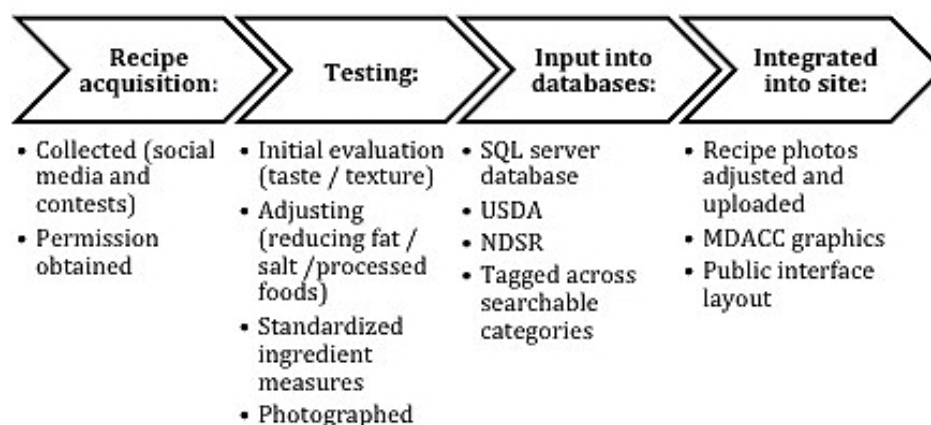
The “@TheTable” website was created by a committee of individuals associated with the University of Texas MD

Anderson (MDACC) including a registered dietitian, patients and family members, a hospital chef, and community advisors and donors. Research staff organized the sourcing and testing of recipes and managed the entry of recipes and caloric information into Web-based databases. An in-house core facility at MDACC, called e-Health Technology, was commissioned to build the website with the information provided by research staff.

Collecting the Recipes

Figure 1 shows the process of adding recipes to the cookbook. Recipes were collected from MDACC patients, employees, local restaurants, chefs, the Houston Culinary Guild, and through contests on social media, including the University of Texas MD Anderson Children’s Cancer Hospital’s (MDA-CCH) Facebook and Twitter pages. The committee set guidelines to ensure recipes were simple and nutritious including a 10-15 ingredient limit per recipe for 4-6 servings, usage of common household ingredients, 10 or fewer simple steps, a suggested total preparation time of 60 minutes or less, and a recommendation of fewer than 400 calories per serving. After recipes were received, they were tested and evaluated by research staff and volunteers. Evaluation forms were created to ensure quality control during recipe testing. Recipes were standardized to US measures (cups, tbsp, etc) and changes were made to enhance recipe quality, taste, and/or nutrition. These adjustments were communicated to the recipe author before being added to the cookbook. Final versions of the recipes were tasted and evaluated by staff; patients also evaluated select dishes. Each recipe was photographed. Research staff wrote instructions and descriptions, and each recipe was marked for inclusion in various search categories. The MDACC graphics department and the MDACC core facility, e-Health Technology, created the layout and presentation of the public interface, allowing users to search for, view, and alter recipes, as well as access other media.

Figure 1. Recipe inclusion process: scheme depicting how recipes were collected, tested, and uploaded into the “@TheTable” database. Abbreviations: SQL:Structured Query Language; NDSR: Nutrient Database; MDACC: MD Anderson Cancer Center; USDA: United States Department of Agriculture.



Data entry of recipes and caloric information was facilitated by the e-Health Technology group. A recipe database was provided to researchers, which calculated nutrition information using the

US Department of Agriculture National Nutrient Database for Standard Reference [11] for macronutrient content. Many recipes were also analyzed using Nutrition Data System for

Research software (2013) developed by the Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN [12] for micronutrient composition.

The e-Health Technology back-end system included a structured query language (SQL) server database, interactive user interface design, and a secure network for data collection/transfer. The SQL server database was designed to maintain user information for researchers, recipe details, searchable recipe tags, user ratings, user comments, and resource links. Researchers with administrative access to the database had the ability to input, change and alter recipe information, add new searchable tags, upload videos and pictures, and upload tip sheets. The public user interface of the system allows for users to navigate the recipe bank with searchable tags, interactively customize recipe ingredients, rate recipes, comment on recipes, share recipes through social media, and access all other media content including tip sheets and videos. The website was designed to be fully functional with tablets and mobile phones with Internet access capability.

In order to provide a resource that was both useful and unique to patients and survivors, we sought out the advice and personal experiences of the MDA-CCH Family Advisory and Adolescent/Young Adult Advisory Council members, which included current patients, parents, and CCS. Feedback included adding nutrition analysis for each recipe, an interactive search feature, colorful designs, and the ability to alter ingredients and have the changes reflected in the nutrition facts label. The council members also provided valuable feedback regarding search categories that may be important to CCS and patients including color, texture, taste, and specific nutrients.

Nutrition tip sheets were developed based on advice from council members and staff from several disease-specific sections within the MDA-CCH. Videos demonstrating recipes were created by research staff in collaboration with University of Texas-Television and uploaded to the website, as well as to YouTube. The video “chefs” include research staff, volunteers, and patients. These videos and tip sheets are publically available on the Internet.

Presenting the Cookbook

A media tour was planned and executed to disseminate the cookbook including 11 radio interviews and meetings with reporters at three top-tier parenting publications. Further, research staff went to each MDA-CCH disease-specific section to present the cookbook and gather feedback for its

improvement. The cookbook was also presented at several conferences and promoted at hospital events.

To determine if similar resources existed and to allow “@TheTable” to be unique in its format, other Web-based cookbooks were researched. Websites such as “Eat to Beat”; “Cook for Your Life”; and the National Heart, Lung, and Blood Institute’s (NHLBI) healthy eating cookbook all provide healthy recipes, cooking tips, and cooking demonstration videos [13-15]. The “Eat to Beat” website focuses on the prevention of cancer, while the “Cook for Your Life” website provides recipes for the cancer patient [13,15]. The NHLBI Web-based cookbook provides heart healthy recipes for the family [14]. However, none of these cookbooks offer healthy recipes tailored specifically to the pediatric cancer patient or survivor and their families. They do not have as many search options inclusive of symptoms, food textures, and meal preparation time, nor do they offer real time nutrition content adjustment of recipes.

Results

“@TheTable” Website Recipes

Initial planning and decision making for the cookbook began in summer 2010. The first hundred recipes were tested and entered into the database by midsummer 2012. The “@TheTable” website officially launched in the fall of 2012. To date, over 400 recipes have been indexed on the “@TheTable” website, which is freely available on the Internet [16]. A registered dietitian at MDA-CCH has analyzed all included recipes. Nutritional information is available for each recipe and automatically adjusts when users change ingredient amounts (Figure 2 shows this).

Specifically, the ingredients list can be manipulated by altering ingredient amounts (double, half, or quarter recipe) or by deleting ingredients completely. For example, by clicking on the blue pencil icon illustrated in Figure 2, ingredient amounts can be doubled, halved, or quartered. The blue trash bin icon in Figure 2 will delete the ingredient completely. Ingredient alterations immediately change the accompanying nutrition information panel. This allows users to observe how certain ingredients contribute to a recipe’s nutrition profile. Recipes are tagged across several categories so they are searchable by type of dish, ingredient, color, nutrition, cooking time, taste, and texture. Descriptions and examples of search terms are available in Table 1. All search terms were chosen based on feedback from MDA-CCH patient and family advisory councils.

Figure 2. Screenshot of a recipe from "@TheTable" cookbook website.

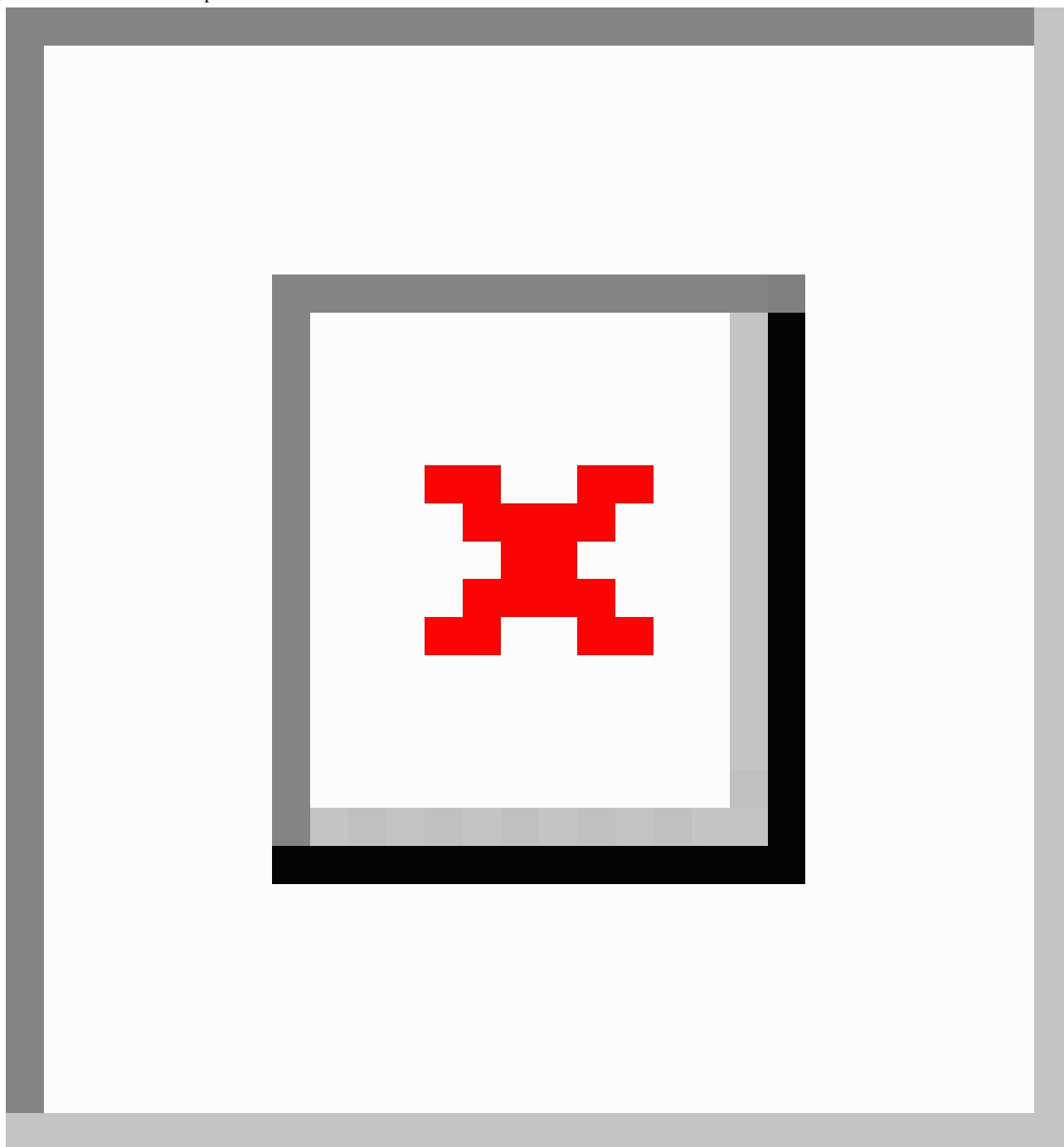


Table 1. Detailed search terms and descriptions available for the “@TheTable” cookbook website.

Search category title	Description/reasoning	Available search terms
Type of dish	Describes meal courses and specific foods	Breakfast, appetizers/snacks, soups/stews, sandwiches/burgers, main dishes, meatless main dishes, side dishes/salads, desserts, dips/sauces/gravies, beverages/smoothies
Color	Overall color of the dish; feedback provided that children may prefer foods of certain colors	Red/orange, green, blue/purple, white/yellow
Nutrition related recipes	Terms that define the health of the dish; patients requested finding dishes that tailored to a specific nutrient need	Low sodium low fat, fiber, iron, protein, vitamin K, low cholesterol, zinc, calcium, vitamin C, magnesium
Quick meals	Total amount of time to complete a recipe	4 time ranges, under 15 minutes, 15-30 minutes, 30-45 minutes, 45-60 minutes
Symptom related recipes	Recipes that contain foods with potential for alleviating side effects	Neutropenia, diarrhea, constipation, weight gain, nausea/vomiting, dry mouth/mouth sores, fatigue, platelets
Taste	Patients reported preferences for certain sensory foods during treatment	Salty/savory, sweet, sour/tangy, spicy, strong flavor/aroma
Texture	Children have preferences toward foods of a specific consistency	Crunchy, smooth/creamy, soft, dry, chewy

Cooking Videos

In addition to healthy recipes, social media functionality and cooking videos are also built into the website. Specifically, users are able to rate and comment on each recipe or share their favorite recipe on Facebook, Twitter, or Pinterest. Cooking videos featuring local chefs, staff, and pediatric cancer patients/survivors demonstrating recipes found in the cookbook were filmed onsite at MDA-CCH.

The “@TheTable” website is also a nutrition information resource. The website has 26 nutrition and cooking tip sheets available with topics ranging from cooking, shopping, and food storage suggestions to more general nutritional information. The website is continuously updated with new recipes, videos, and nutrition information and maintained by research staff in collaboration with the MDA-CCH site managers.

Discussion

“@TheTable” as a Resource for Interventions

With over 400 recipes in the database, and ongoing efforts to include more, “@TheTable” is a unique resource for promoting healthy lifestyles spanning pediatric oncology prevention, treatment, and survivorship. Several research projects in various stages of completion are utilizing the Web-based cookbook. During the cookbook’s infancy stage, a personalized monthly weight management counseling intervention for pediatric cancer patients was developed. This intervention utilized recipes from the cookbook to provide healthy cooking tips and nutrition

advice to patients and their families, who reported the website was helpful for finding recipes tailored to a specific symptom.

The “@TheTable” website is also being used as a cancer prevention resource for patients, survivors, and the general public. Recipes from the website are used for employee wellness programs and monthly cooking classes for optimal health. While currently just a resource and not an evaluation tool, the Web-based cookbook could be incorporated into assessment-oriented interventions. This is a major emphasis of future studies by our group. For example, a community weight management program for overweight children was designed using an entire curriculum of recipes from “@TheTable”, as a cancer prevention intervention. Participants were encouraged to visit the website to find recipes that were demonstrated during each weekly cooking class. Feedback from this program is currently being analyzed.

Future Goals

In addition, video game-based behavioral interventions that integrate the cookbook with gameplay are underway. Another future goal is to increase accessibility of this resource to Hispanic populations. Recipes and tip sheets in Spanish are currently limited in availability on the website; however, there are plans to incorporate more Spanish recipes, videos, and resources.

Through evaluations of the website’s current and future use, as well as incorporation of the website into interventions designed to promote energy balance, we will adapt and build this resource to serve cancer patients, survivors, and the general public.

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Conflicts of Interest

None declared.

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Abbreviations

CCS: childhood cancer survivors

MDACC: University of Texas MD Anderson

MDA-CCH: University of Texas MD Anderson Children's Cancer Hospital

NHLBI: National Heart, Lung, and Blood Institute

SQL: structured query language

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Protocol

Cross-Sectional Study of 24-Hour Urinary Electrolyte Excretion and Associated Health Outcomes in a Convenience Sample of Australian Primary Schoolchildren: The Salt and Other Nutrients in Children (SONIC) Study Protocol

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Abstract

Background: Dietary sodium and potassium are involved in the pathogenesis of cardiovascular disease. Data exploring the cardiovascular outcomes associated with these electrolytes within Australian children is sparse. Furthermore, an objective measure of sodium and potassium intake within this group is lacking.

Objective: The primary aim of the Salt and Other Nutrient Intakes in Children ("SONIC") study was to measure sodium and potassium intakes in a sample of primary schoolchildren located in Victoria, Australia, using 24-hour urine collections. Secondary aims were to identify the dietary sources of sodium and potassium, examine the association between these electrolytes and cardiovascular risk factors, and assess children's taste preferences and saltiness perception of manufactured foods.

Methods: A cross-sectional study was conducted in a convenience sample of schoolchildren attending primary schools in Victoria, Australia. Participants completed one 24-hour urine collection, which was analyzed for sodium, potassium, and creatinine. Completeness of collections was assessed using collection time, total volume, and urinary creatinine. One 24-hour dietary recall was completed to assess dietary intake. Other data collected included blood pressure, body weight, height, waist and hip circumference. Children were also presented with high and low sodium variants of food products and asked to discriminate salt level and choose their preferred variant. Parents provided demographic information and information on use of discretionary salt. Descriptive statistics will be used to describe sodium and potassium intakes. Linear and logistic regression models with clustered robust standard errors will be used to assess the association between electrolyte intake and health outcomes (blood pressure and body mass index/BMI z-score and waist circumference) and to assess differences in taste preference and discrimination between high and low sodium foods, and correlations between preference, sodium intake, and covariates.

Results: A total of 780 children across 43 schools participated. The results from this study are expected at the end of 2015.

Conclusions: This study will provide the first objective measure of sodium and potassium intake in Australian schoolchildren and improve our understanding of the relationship of these electrolytes to cardiovascular risk factors. Furthermore, this study will provide insight into child taste preferences and explore related factors. Given the cardiovascular implications of consuming too much sodium and too little potassium, monitoring of these nutrients during childhood is an important public health initiative.

KEYWORDS

sodium, dietary; sodium chloride, dietary; potassium, dietary; child; urine specimen collection; blood pressure; obesity; taste; Australia

Introduction

Background

In most developed countries, salt (sodium chloride) is commonly added to the food supply [1]. Consequently, children frequently consume more dietary sodium than recommended [2], as sodium chloride is the main contributor to sodium intake (~90%) [3]. Consuming too much sodium during childhood is associated with raised blood pressure [4], which is a risk factor for future cardiovascular disease [5]. There is also some evidence to suggest that the combination of sodium and potassium in the diet is an important determinant of blood pressure levels during childhood [6]. For long-term gains in public health, it is important that dietary intakes of sodium and potassium are monitored in the pediatric population. This information can be used to guide future dietary interventions that aim to maintain healthy blood pressure levels across the lifespan and in turn reduce the burden of cardiovascular disease.

Measuring Sodium and Potassium Intake

Overview

The use of 24-hour urinary electrolyte excretion is a reliable, objective method to estimate group intakes of sodium and potassium [7,8] and overcomes a number of limitations associated with self-reported dietary assessment methodologies.

Sodium Intake

Approximately 90-95% of ingested sodium is excreted in the urine [9]. Some sodium is lost through sweat; the amount is dependent on level of physical activity and exposure to heat [3]. Because of the high recovery of dietary sodium via urinary losses, 24-hour urine collection is considered the “gold-standard” method to determine sodium intake and its use is recommended in sodium assessment studies [10]. Due to the large intra-individual fluctuations in day-to-day sodium intake, it is necessary to complete at least seven 24-hour urine collections to assess an individual's intake of sodium [11]. However, larger population studies generally utilize one 24-hour urine collection when attempting to describe the average sodium (salt) intake of groups [12] or to monitor changes in sodium intake in a study population [13].

Despite the robustness of 24-hour urine samples to objectively determine dietary sodium intake, it is difficult to get a representative number of people to complete due to the associated participant burden and logistical challenges. Alternatively, many studies, particularly large national nutrition surveys, assess sodium intake from 24-hour dietary recalls [14]. As with other nutrients, dietary assessment has a range of limitations including respondent bias and reliance on memory to recall food intake [15]. In the case of sodium, dietary recall assessment is further limited by the quality of food composition databases and the inability to quantify the amount of salt added

during cooking and at the table [14]. For these reasons, dietary records tend to underestimate total sodium intake [16,17]. In developed countries, where the majority of salt comes from processed foods, the daily underestimation of sodium in adults has been described as 15-22% [16] and, in children, 7% [17].

Potassium Intake

The recovery of dietary potassium via urinary excretion is lower than for sodium, with approximately 80-85% of ingested potassium excreted in the urine [18]. Like sodium, some potassium is lost through sweat, but most (~10-15%) is lost via fecal excretion [19,20]. With increased dietary fiber intake, fecal losses of potassium increase [21]. Despite these larger losses, the use of 24-hour urinary potassium excretion is routinely used in population studies to obtain a reliable measure of average potassium intake [7]. Furthermore, assessment of both sodium and potassium via 24-hour urine collection enables the molar ratio of sodium to potassium to be determined.

Sodium Intake in Children

Internationally, most studies that have utilized a 24-hour urine collection to assess sodium intake were conducted in the 1980s in Europe and in relatively small sample sizes [2]. However, more recent estimates using this robust methodology in larger samples of children come from the United Kingdom (n=340) [22] and Germany (n=364) [17]. In view of the importance of using a reliable measure to monitor population sodium intake, the most recent 2008/09 to 2011/12 UK National Diet and Nutrition Survey included 24-hour urine collections within a sub-sample of children aged 4 years and over [23]. With the exception of one very small study (n=12) completed in 1982 [24], to our knowledge there has been no other attempt to objectively measure sodium intake in Australian schoolchildren using 24-hour urine collection.

The most recent national estimates of sodium intake in Australian children come from 24-hour dietary recall data collected within the 2011-13 Australian Health Survey [25]. In this study, average intakes of sodium from food and beverage sources were high: 2058 mg/d, 2462 mg/d, and 2761 mg/d in 4-8 year olds, 9-13 year olds, and 14-16 year olds, respectively. These intakes exceed the recommended Upper Level (UL) for daily sodium intake [3]. Importantly, as the 24-hour recall measure does not include discretionary salt use [25], it is likely that the total daily sodium intake of Australian schoolchildren is higher. To obtain an accurate assessment of total sodium intake in Australian schoolchildren, the collection of 24-hour urine samples is required.

Potassium Intake in Children

Very few studies have reported potassium intake in children obtained from 24-hour urine collections [26,27]. Furthermore, to our knowledge, no Australian study has utilized this methodology. Most information relating to potassium intake

comes from 24-hour dietary recall data collected during national nutrition surveys [25,28,29]. In Australia, the 2011-13 Australian Health Survey reported average intakes of potassium were 4-8 years: 2138 mg/d; 9-13 years, boys: 2690 mg/d, and girls: 2433 mg/d; 14-18 years, boys: 2830 mg/d, and girls: 2466 mg/d [25]. Overall, average intake falls below the recommended Adequate Intake (AI) for potassium. Of note, due to insufficient data regarding the requirements for potassium in children, the AI was based on population intake estimates from previous national nutrition surveys [3].

Association Between Sodium and Potassium Intake and Cardiovascular Risk Factors

The dietary electrolytes, sodium and potassium, are both involved in the development of high blood pressure [30]. In adults, excess dietary sodium has a detrimental effect on blood pressure [7] and cardiovascular health [31], whereas higher intake of potassium has been shown to be protective [32]. The interplay between these two electrolytes is important, with the sodium to potassium ratio associated with blood pressure [33,34] and a predictor of cardiovascular disease (CVD) risk [35]. During childhood, sodium and potassium are also important moderators of blood pressure. The evidence for the effects of sodium intake on blood pressure in children and adolescents is strong. Population studies from the United Kingdom [36] and the United States [37,38] have reported a positive association between sodium intake and blood pressure. Furthermore, findings from meta-analyses have shown that reductions in sodium intake lead to modest reductions in blood pressure [4,39].

Findings relating to the effects of potassium alone on blood pressure in children and adolescents are less consistent. For example, some cross-sectional studies have found either a positive association [11,40] or inconsistent findings by gender [41] between potassium intake and blood pressure. Conversely, longitudinal studies have found that a higher intake of potassium is associated with lower systolic blood pressure [6,42]. A recent meta-analysis, which included three intervention trials and one cohort study, found no association between potassium intake and blood pressure levels in children [43]. The World Health Organization's most recent guideline for potassium intake in children acknowledges the inconsistencies across studies in children. However, given the protective effects of potassium on blood pressure and CVD risk in adults, it is recommended that children's potassium intake be in line with the recommendation for adults (ie, at least 90 mmol/d or 3510 mg/d) with adjustment for energy requirements [44]. Most studies in children have examined the effects of either sodium or potassium on blood pressure in isolation. One longitudinal study in Dutch children found that although sodium alone was not related to blood pressure, a higher sodium to potassium ratio was predictive of higher systolic blood pressure levels [6].

Raised blood pressure during childhood is associated with target organ damage [45], as well as greater risk of hypertension during adulthood [46]. This emphasizes the need to monitor intake of sodium and potassium during childhood and gain a better understanding of the relationship between these electrolytes and blood pressure levels. Currently, there is no country-specific

data assessing the association between an objective measure of sodium and potassium intake with blood pressure levels in Australian schoolchildren.

Additional Risks of High Sodium Intake During Childhood

Beyond the concerns of high sodium diets raising blood pressure, there is evidence in children to indicate that higher intake of sodium is associated with increased risk of overweight and obesity. There are now data from three large population-based nutrition surveys in children and adolescents (ie, Great Britain [47], Australia [48], and the United States [49]) that support the link between dietary sodium intake and obesity via greater consumption of sugar-sweetened beverages (SSBs). Remarkably similar results have been observed across each country whereby sodium intake was positively associated with SSB consumption, which in turn is an important risk factor for obesity [50]. However, more recent evidence suggests that sodium intake is associated with adiposity, independent of energy intake [51]. To date, no study has utilized a reliable marker of sodium intake (24-hour urinary sodium excretion) to examine the association between sodium intake and measures of adiposity in Australian children. As overweight and obesity follows a trajectory over the life course [52], it is important to understand the association between these risk factors and 24-hour urinary sodium excretion in Australian children.

Preference for Salt Taste in Children

Taste is an important influence on food choice, particularly in children [53], but there are very few studies worldwide that describe children's taste preferences for foods with varying levels of sodium. Existing studies with children that included food tasting have used a small number of non-commercial foods, with salt added during preparation [54-57]. Since processed foods contribute a large proportion of dietary sodium [58], and there is variation in preferred saltiness between different food types [59,60], further data across a range of processed foods is needed. This is particularly important as Australia and other countries have categories of food with nominated sodium-reduction targets [61] and consumer acceptance of lower sodium food reformulation is fundamental to achieve sustainable population-wide reductions in sodium. To our knowledge, there is no published research examining the impact of salt on taste preferences in Australian school-age children.

The Salt and Other Nutrient Intakes in Children (SONIC) Study

The primary aim of the SONIC study was to obtain an accurate measure of total dietary sodium intake using 24-hour urinary excretion in a sample of primary schoolchildren in Victoria, Australia. Secondary aims within this sample of primary schoolchildren were: (1) to objectively measure potassium intake and the sodium to potassium ratio using 24-hour urinary electrolyte excretion, (2) to identify the dietary sources of sodium and potassium, (3) to assess the association between 24-hour urinary sodium and potassium excretion and blood pressure, (4) to assess the association between 24-hour urinary sodium excretion and body mass index (BMI) z-score and waist circumference, and (5) to identify children's taste preferences

and saltiness perception using high and low sodium variants across a range of manufactured foods, which are major dietary sources of salt.

The purpose of this paper is to describe the study design and data collection methods used within the SONIC study. In addition, we report on the recruitment outcomes and data processing procedures for determining completeness of 24-hour urine samples within the study population.

Methods

Study Design

The SONIC study was a cross-sectional study conducted within primary schools located in Victoria, Australia from 2009-2013. Ethics approval was obtained by the Deakin University Human Research Ethics Committee (Project No: EC 62-2009). Recruitment and data collection occurred in two phases. The first phase (Phase 1) of the study was conducted within non-government (ie, private) schools during June 2010 to June 2011. Findings from Phase 1 have previously been reported [62]. The second phase (Phase 2) of the study was conducted within government schools during November 2011 to May 2013.

Rationale for Phase 1 and Phase 2

To enable a representative sample of children across different socioeconomic stratum, this study was initially designed to take place in government schools. However, as this was the first Australian study to propose the collection of 24-hour urine collections within the school sector, there were difficulties in obtaining approval from the governing education authority to conduct the study in government schools. Therefore, to demonstrate the feasibility of collecting 24-hour urines, the study was piloted in a smaller sample of children within the non-government school sector. This was possible as permission to conduct research within non-government schools is granted on a school-by-school basis by either the school board or principal. After the successful completion of Phase 1 within non-government schools, permission to enter government schools was granted by the Victorian Department of Education and Early Childhood Development (2011_001151). Due to the overall difficulties in recruiting schools to participate, we utilized a convenience sampling framework.

Participants

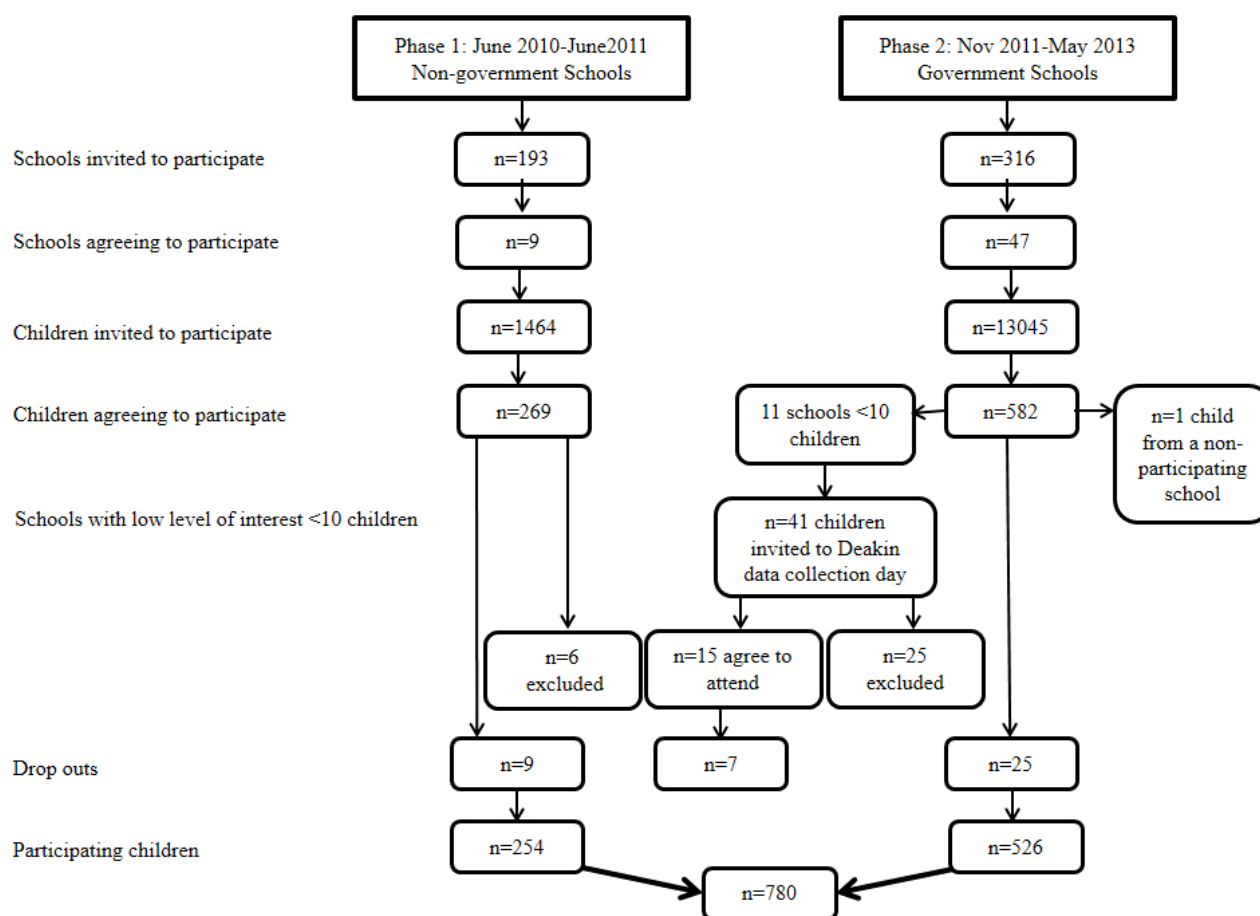
Participants were children attending non-government and government primary schools in Victoria, Australia. Primary school-aged children were targeted, as opposed to adolescents

in high school, as findings from the 2007 Children's Nutrition and Physical Activity Survey (CNPAS) revealed younger children had particularly high sodium intake compared to dietary recommendations [3,63]. To maximize recruitment, participation was open to all children attending the primary school. However, in some instances, the school principal thought it was inappropriate for very young children (eg, prep classes or grade 1) to participate in the study. Therefore, to respect the requests of individual schools, the grades invited to participate varied across schools. To help engage families to participate in the study, parents of participating children had the option of completing a 24-hour urine collection. Children were excluded from the food tasting session if they had food-related anaphylaxis. Those children with food specific allergies (eg, gluten intolerant) were not permitted to taste relevant food products (eg, bread).

Recruitment

Phase 1

Non-government privately funded schools located in Victoria were targeted for recruitment. A Web-based school locator search engine was used to identify all those non-government Victorian schools with enrollments of primary school children ($n=193$) [64]. A convenience sample of schools was selected from the list, and principals were contacted via an official letter or email of invitation and a phone call, inviting school participation in the study. In total, 104 schools were invited, of which 9 agreed to participate in the study (response rate=8.7%) (Figure 1). A short presentation, outlining the purpose of the study, was presented to students at the school assembly, after which students were provided with study information packs containing written materials, addressed to parents, inviting them to take part in the study. Reminder notices, outlining the purpose of the study and the procedure to participate, were also included in school newsletters. Of the potential 1464 students, 269 agreed to participate (response rate=18.4%); nine of these children later dropped out of the study. Reasons for attrition included no longer interested in participating ($n=3$), being absent on the day of data collection ($n=5$), or no longer attending the school ($n=1$). Data from six participating children were excluded from analysis as they were 13-14 years of age (ie, in grade 8 of high school) and the target group for this study was primary school. These children were invited to participate as they were enrolled at a unique school that included children from grade preparatory-10. Written consent was obtained from the child, as well as the child's parent/caretaker. To thank children for their participation time, an AU \$20 book voucher was provided.

Figure 1. Flow and response rates of participants in the SONIC Study.

Phase 2

Victorian government schools with enrollments for primary schoolchildren were identified using the Department of Education and Early Childhood Development online school locator (n=649) [65]. At the commencement of recruitment in September 2011, Victorian government schools were divided into four regions (Northern, Eastern, Southern, and Western Metropolitan regions); since the time of recruitment, these regions have changed slightly. A convenience sample of schools was selected, starting within the Eastern Metropolitan region, due to the proximity to Deakin University Burwood Campus. Once school recruitment was exhausted within the Eastern region, the Southern Metropolitan region was sampled, followed by the Northern Metropolitan region. No schools in the Western Metropolitan region were contacted as the study had reached its funding capacity. As per Phase 1, principals were contacted via an official letter or email of invitation and a phone call, inviting school participation in the study. In total, 316 were invited, of which 47 agreed to participate (response rate=14.9%) (Figure 1).

The recruitment strategy for children differed between participating government schools, due to constraints placed on the amount of access the project officer could have within the schools. For example, it was not always possible to do the short presentation outlining the study at all schools. Furthermore, study information packs were not distributed to all children at

the school. Instead, a “recruitment starter pack”, which contained study information packs, was delivered by the project officer to the school principal, who then organized distribution of the packs to school children. Across all schools, the study was advertised in the school newsletter and parents could then contact the project officer via email or phone expressing their interest in the study and request an information pack. Of the potential 13,045 students enrolled at schools and invited to participate, 582 agreed to participate (response rate=4.5%). To avoid high costs associated with travelling to schools with only a few participants, data collection procedures occurred only at schools with ≥ 10 participants. In schools (n=11) with < 10 participants, children were advised that to participate they would have to travel to Deakin University in Burwood, Melbourne to complete data collection procedures on a Saturday. Of the 41 children that this applied to, 15 agreed to visit Deakin University; however, 7 of these did not attend (ie, dropouts) on the scheduled day of data collection. The remaining 25 were excluded from the study as they were not willing to come to Deakin University. A further 25 children dropped out of the study; reasons for attrition included no longer interested in participating (n=7) or being absent on the day of data collection (n=18). Finally, one child from a school that refused to participate attended the Deakin University data collection day. This child was aware of the study as their mother worked at Deakin University. Written consent was obtained from the child, as well as the child’s parent/caretaker. Due to guidelines for

inducements for study participation in government schools, either a book voucher to the value of AU \$20 per participant or \$100 per school was issued to the school library to thank the children for their participation.

Data Collection

With the exception of the one day of data collection completed at Deakin University, testing procedures were completed at schools by a team of research staff. In Phase 1 of the study, data

was collected at participating schools across two time blocks, June-December 2010 and May-June 2011. In Phase 2 of the study, data was collected as schools were recruited between November 2011 and May 2013.

Testing Procedures

An overview of data procedures completed is shown in [Table 1](#).

Table 1. Overview of data collected.

Item	Description
Health and medical question-naire	Child’s date of birth, gender, birth weight, health conditions, medications, dietary supplements, discretionary salt use habits, parent’s highest level of education attained
Anthropometry	Height, weight, body mass index, waist and hip circumference
Blood pressure	Systolic and diastolic blood pressure
24-hour urine collection	Urinary sodium, potassium, creatinine, total volume
24-hour dietary recall	Food and beverage intake, table salt use
Taste testing	Preference and discrimination with high vs lower salt food item
Parental component (optional)	
Demographics	Date of birth, gender
24-hour urine collection	Urinary sodium, potassium, creatinine, total volume

Demographic Characteristics

The parent of each child completed a health information questionnaire (see [Multimedia Appendix 1](#)). The questionnaire collected information on the child’s age, gender, birth weight, existing medical conditions, and use of medications or dietary supplements. In Phase 2 of the study, the questionnaire was modified to include an additional question relating to the parent’s highest level of education attained and information on this was retrospectively collected from parents with children participating in Phase 1.

Discretionary Salt Use

Both parents and children were asked to report on the frequency of discretionary salt use. For parents, three questions were included on the health information questionnaire, two of which applied to the parent’s use of salt, “Q1: Do you add salt during cooking?” (used previously in 2007 CNPAS [66]) and “Q2: Do you place a salt shaker on your table at meal times?”, and one question that related to the child’s own use of salt at meal times, “Q3: Does your child add salt to their meal at the table or sandwich preparation?” For each of these questions, parents could respond “yes usually”, “yes sometimes”, “no”, or “don’t know”. At school on the day of data collection, the study child was also questioned about their own use of table salt. Children were asked, “Does the person who prepares your meal add salt when cooking?” and “Do you add salt to your meal at the table?” (used previously in 2007 CNPAS [66]), to which they could respond “yes, usually”, “yes, sometimes”, “no”, or “Don’t know”.

Anthropometry

Height, body weight, waist, and hip circumference were measured according to the protocols of the International Society

for Advancement of Kinanthropometry [67]. For all measures, children were wearing light clothing with shoes removed. Height was measured to the nearest 0.1 cm using a calibrated portable stadiometer SECA (mod 220) (Hamburg, Germany). Weight was measured to the nearest 0.1 kg using a calibrated FS-127-BRW portable electronic scale (Bradman, MA, USA). A minimum of two measurements were taken for height and weight. If the two measurements were not within 5 mm for height or 0.1 kg for weight, a third measurement was taken. The mean value was used as the final score if two measurements were taken. The median value was used as the final measure if three measurements were taken. BMI was calculated as body weight (kg) divided by the square of body height (m²). Age and gender adjusted BMI z-scores will be calculated using the LMS method [68] with the 2000 US Centers for Disease Control and Prevention (CDC) Growth Charts acting as the reference population [69]. Participants will be grouped into weight categories (very underweight, underweight, healthy weight, overweight, obese) using the age and gender-specific International Obesity Task Force BMI reference cut-offs for children [70,71].

Waist and hip circumference was measured to the nearest 0.1 cm using a Lufkin Executive Thinline W606PM pocket tape (Sparks, MD, USA). Waist circumference was taken at the end of a normal expiration at the narrowest point between the lower costal border and the top of the iliac crest. Hip circumference was measured at the level of the maximum protrusion of the gluteal muscles. A minimum of two measurements were taken for waist and hip circumference. If the two measurements were not within 10 mm of the first, a third measurement was taken. The mean value was used as the final score if two measurements were taken. The median value was used as the final measure if three measurements were taken.

Blood Pressure

Blood pressure was measured using an automatic vital signs monitor (OMRON HEM-907) machine according to the US National Heart Lung and Blood Institute Guidelines [72]. Measurements were completed in the sitting position after 10 minutes of rest with the child's arm positioned at the level of the heart on a rested table. Children were instructed to refrain from talking or coughing during the measurements. To determine the appropriate cuff size, the child's upper arm (midpoint between the acromion and olecranon) circumference was measured and from this one of three cuff sizes (small 17-22 cm, medium 22-32 cm, large 32-42 cm) was selected for use. The cuff was positioned on the child's arm by aligning the marked cuff artery indicator with the brachial artery. Once wrapped firmly on the arm, the cuff size was checked by ensuring the marked index line fit within the specified range line on the cuff. If the cuff was noted as being too small or too large, the size up or down was fitted. Three blood pressure readings were taken on the right arm at 1-minute intervals. The average of the last two measurements will be used for analysis.

Dietary Recall

A three-pass 24-hour dietary recall was used to determine all food and beverages consumed from midnight to midnight on the day prior to the interview. To be consistent with the protocols used in the 2007 CNPAS survey, we utilized the three-pass method. This method includes the following stages: (1) provide a quick list of all foods and beverages, (2) a series of probe questions relevant to each quick list item to gather more detailed information including quantifying the amount consumed, the time and place of consumption, any additions to the food item, brand name, and meal occasion (ie, breakfast, morning tea, lunch, afternoon tea, dinner or supper), and (3) finally, a recall review to validate information and make any necessary adjustments. Portion sizes were estimated using a validated food model booklet and standard household measures. All items were hand-recorded on a food intake form by research staff with a nutrition background and who had received training from an Accredited Practising Dietitian. It is recognized that children aged 8 years and above have the cognitive ability to recall their own food and beverage intake, whereas in younger children there is a need for a proxy (eg, parent) to help recall intake [73]. In this study, 24-hour recalls were completed on the day of testing at an allocated space within the school. Up to six children were present within each testing session, with children rotating across data collection stations. To avoid young children feeling excluded from certain collection procedures, all children completed the 24-hour dietary recall. However, in

analyses related to dietary assessment only recalls in children aged 8 years and above will be utilized. The 24-hour food and beverage intakes will be converted into nutrient intakes, using FoodWorks Version 8, which is linked to the Australian nutrient composition database AUSNUT 2011-13 [74]. Daily sodium (g) intake will be converted to the salt equivalent (g) using the conversion factor 2.543 [18].

The Goldberg cut-off method [75], adjusted for use within the pediatric population [76], will be used to identify participants with implausible energy intakes. Child-specific physical activity levels (PAL) [77] will be used to calculate age and gender-specific Goldberg cut-offs. Schofield equations, specifying age, gender, body weight, and height [78], will be used to calculate each participant's estimated basal metabolic rate (estBMR). The ratio of each participant's reported energy intake to estBMR (EI:estBMR) will be compared to the appropriate calculated age and gender-specific Goldberg cut-off value. A participant with an EI:estBMR below the cut-off value will be classified as a low energy reporter.

Taste Testing Procedures

Tastings were conducted in one-to-one sessions using pre-packed, commercially available high and low salt variants of processed foods that have been identified as major sources of dietary sodium in Australian children (Table 2) [79]. A variety of different core food items such as bread, cereals, and cheese were evaluated. Within core food types tested, the difference in sodium content of the two samples varied between 27% and 84%. For example, one brand of bread with a sodium level of 202mg/100g was compared to another with 511mg/100g (60% difference). There were also differences in the percentage sodium variation within food categories, for example, processed meats varied between 25% and 40%, while for snack foods, potato crisps varied by 94% and tomato sauce by 27%. Differences in sodium content were calculated based on sodium levels provided on package nutrition information panels. To assess taste preference, children were asked to taste high and low salt samples of a food (Figure 2), and asked which they preferred using a forced choice methodology previously shown to be appropriate for use with children [80]. After this, they were asked which of the samples they thought tasted saltier. Participants were then asked to drink some water, and the same process was repeated with a second food type. The two food types tested, with two samples for each, were presented in unmarked wrapping in randomized order. Pairs of low and higher sodium foods were matched as closely as possible for appearance and nutritional composition other than sodium level.

Table 2. Foods tested in sensory component.

Bread and cereal	Sandwich fillings	Snack foods
Bread: sourdough white; sourdough wholemeal ^b	Cheese, sliced cheddar ^a	Crisps, potato ^a
Wraps, multigrain ^a	Ham: sliced ^a	Corn chips, plain ^a
Cornflakes ^b	Chicken, sliced roast ^a	Rice crackers, plain ^a
Wheat cereal biscuits ^a		Baked beans ^a
		Tomato sauce ^a

^aOne-paired comparison, using low/high salt food variants.

^bTwo-paired comparisons, using low/high salt and medium/high salt food variants.

Figure 2. SONIC study participant completing data collection procedures.

24-Hour Urine Collection

Collection Protocol

Participants could commence the 24-hour urine collection either at school or at home over the weekend. Written instructions, tailored for either a school or weekend day collection, were provided for parents, and simplified pictorial instructions were provided for children. All children were instructed to commence the collection by emptying their bladder, discarding this urine, and noting this as the 24-hour collection start time. During the 24 hours following this, all urine voided was collected. Children finished the collection with a final void at the corresponding 24-hour finish time. Urine was collected in 2.5 L wide-mouth,

rimmed polypropylene bottles. To assist with urine collection, an additional 500 mL plastic handled jug was provided. Children were asked to report any missed collections or spillages on a urine collection slip, which was returned with the 24-hour urine sample.

School day collections commenced during school hours and at the end of the school day children collected their materials to continue the collection at home. On the following school day, children returned to research staff and finished the collection by providing a final void. Children completing the collection on a weekend day were able to commence the urine collection at any suitable 24-hour period over the weekend, parents recorded start and finish times on the 24-hour urine bottle and

a urine collection slip, children were instructed to return completed samples to research staff at school on the following Monday morning.

Urinalyses

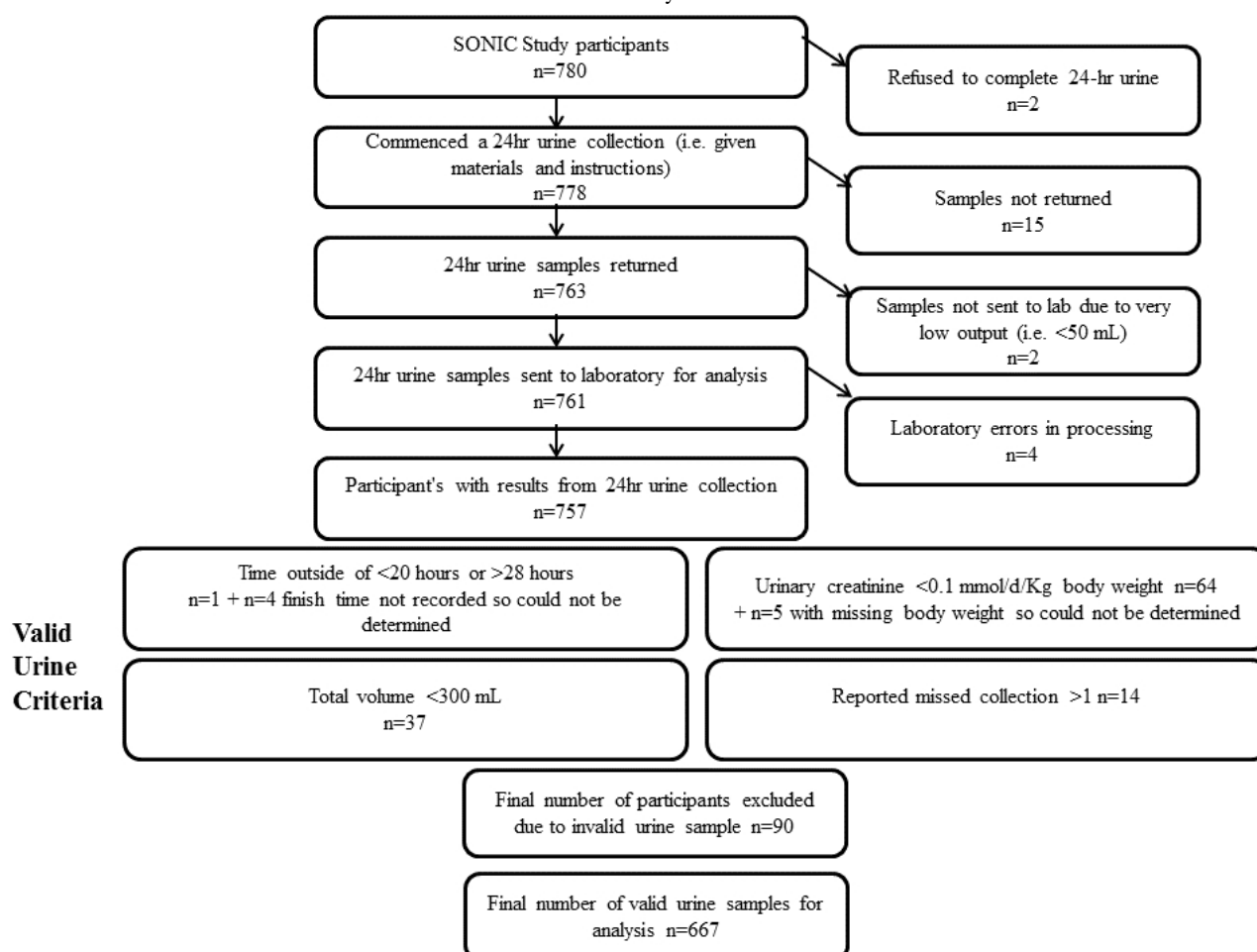
Urinary sodium and potassium concentration was assessed using indirect ion selective electrodes and urinary creatinine concentration was assessed using the Jaffe reaction [81] on the Siemens Advia 2400 analyzer (Dorevitch Pathology, Melbourne, Vic, National Association of Testing Authorities and Royal College of Pathologists of Australia accredited pathology laboratory). Per participant 2 x 10 mL aliquots were taken for storage and transferred to -80°C conditions. The molecular weights of sodium (23 g/mol), sodium chloride (58.5 g/mol), and potassium (39.1 g/mol) will be used to convert laboratory of mmol to mg [18].

Criteria for Assessing Completeness of 24-Hour Urine Samples

If the duration of the collection was not exactly 24 hours (but within 20-28 hours), urinary sodium, potassium, creatinine, and

total volume were normalized to a 24-hour period. Following this, urine collections will be considered incomplete and excluded if (1) the timing of the collection was <20 hours or >28 hours, (2) total volume was <300 mL, (3) the participant reported missing more than one collection, or (4) urinary creatinine excretion was less than 0.1 mmol/Kg body weight/day [22,41,82]. A total of 15 participants did not return their urine collection slip, so it was not possible to confirm if they had missed collections or spillages. In these children, the completeness of the 24-hour urine collection was assessed based on the other three criteria. Of the 780 participants, 757 (97.1%) had available results from the 24-hour urine collection (Figure 3). Based on the completeness criteria, 90 participants (11.5%) were classified as providing invalid 24-hour urine samples and will be excluded from analyses. Note the number of invalid urines based on the four criteria ($n=125$) is greater than the final number of excluded urines ($n=90$) as some participants' 24-hour urine collection met more than one of the criteria for invalid urine (Figure 3).

Figure 3. Flow chart of assessment of valid 24-hour urine collections for analysis.



Sample Size

To estimate mean sodium intake within a 95% confidence interval of ± 4 mmol/d and assuming a standard deviation of 37 mmol/d (unpublished 24-hour urine pilot data from UK children) [83], a sample size of 329 children was required. We

anticipated recruiting 10 children from each school (ie, cluster size $n=10$) and assumed an intra-cluster correlation (ICC) of .01, giving a design effect ($DEFF = 1 - (n-1) ICC$) of 1.09. Therefore the sample size after adjusting for clustering was 359 children. Allowing for a 10% loss due to dropout and incomplete urine samples, the target sample size was therefore 395. Given

gender differences in sodium intake, we aimed to recruit 395 boys and 395 girls (ie, total n=790).

Data Analysis

Descriptive statistics will be used to describe sodium and potassium intakes. Dietary sources of sodium and potassium will be determined at the individual level using the mean ratio method [84]. Linear and logistic regression models will be used to assess the association between electrolyte intake and health outcomes (blood pressure and BMI z-score and waist circumference) and to assess differences in taste preference and saltiness discrimination between food types, and correlations between taste preference, sodium intake, and covariates. To account for clustering of students within schools, clustered robust standard errors will be used. Analyses will be adjusted for covariates (age, gender, socioeconomic status).

Results

Data collection was completed in May 2013. A total of 780 children across 43 schools participated. Data analysis is currently underway and results are expected at the end of 2015.

Discussion

Strengths and Limitations

This study will provide the first objective measure of sodium and potassium intakes in Australian schoolchildren. The major strength of this study is the use of 24-hour urine collections to assess total daily sodium intake in a large sample of schoolchildren. Furthermore, a well-devised 24-hour urine collection protocol, tailored specifically to children was used. Limitations of the study include the convenience sampling framework and the low response rate, which limits the generalizability of the study findings. In addition, dietary recall data is only available on those children aged 8 years and above and only 1 day of recall data was collected.

Conclusion

Given the cardiovascular implications of consuming too much sodium and too little potassium, monitoring of these nutrients during childhood is an important public health initiative. The methods described within provide a platform for other research groups and public health organizations to conduct 24-hour urinary sodium and potassium measurements in wide-ranging children and potentially adolescent populations, thus adding to the evidence base exploring the intake of these important electrolytes, their implications of health in the early stages of life, and the potential impact on food choice.

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Authors' Contributions

CAG drafted the manuscript and co-ordinated comments from co-authors. JRB wrote the sections specific to sensory components. CAG and JRB developed study protocols. CAN, KJC, LJR, GL, RK, and FH secured funding for the project. CAN, KJC, LJR, GL, RK, FH, CAG, and JRB all contributed to the study design and methodology. CAG was responsible for recruitment and data collection within Phase 1 of the study. MR and JB were responsible for recruitment and data collection within Phase 2 of the study. All authors contributed to drafts of this manuscript and read and approved the final manuscript.

Conflicts of Interest

Authors CAG, JRB, LJR, KJC, GL, and MR declare that they have no conflicts of interest to declare. FJH and CAN are members of Consensus Action on Salt & Health (CASH) and World Action on Salt & Health (WASH). Both CASH and WASH are non-profit charitable organizations and FJH and CAN do not receive any financial support from CASH or WASH. CAN has received remuneration from Meat & Livestock Australia and Nestle Health Science. These payments are unrelated to the submitted work.

Multimedia Appendix 1

Health information questionnaire.

[PDF File (Adobe PDF File), 469KB - [resprot_v4i1e7_app1.pdf](#)]

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Abbreviations

AI: adequate intake
BMI: body mass index
CNPAS: Children's Nutrition and Physical Activity Survey
CVD: cardiovascular disease
EI: estBMR: energy intake:estimated basal metabolic rate
estBMR: estimated basal metabolic rate
ICC: intra-cluster correlation
SONIC: Salt and Other Nutrient Intakes in Children study
SSB: sugar-sweetened beverage

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Protocol

Secondary Care Clinic for Chronic Disease: Protocol

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Abstract

Background: The complexity of chronic disease management activities and the associated financial burden have prompted the development of organizational models, based on the integration of care and services, which rely on primary care services. However, since the institutions providing these services are continually undergoing reorganization, the Centre hospitalier affilié universitaire de Québec wanted to innovate by adapting the Chronic Care Model to create a clinic for the integrated follow-up of chronic disease that relies on hospital-based specialty care.

Objective: The aim of the study is to follow the project in order to contribute to knowledge about the way in which professional and management practices are organized to ensure better care coordination and the successful integration of the various follow-ups implemented.

Methods: The research strategy adopted is based on the longitudinal comparative case study with embedded units of analysis. The case study uses a mixed research method.

Results: We are currently in the analysis phase of the project. The results will be available in 2015.

Conclusions: The project's originality lies in its consideration of the macro, meso, and micro contexts structuring the creation of the clinic in order to ensure the integration process is successful and to allow a theoretical generalization of the reorganization of practices to be developed.

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KEYWORDS

delivery of health care; integrated; chronic disease; secondary care; tertiary health care; ambulatory care; research design; models; theoretical

Introduction

Context

In Canada and around the world, the growing complexity and financial burden of chronic disease prevention and management are increasingly prompting the development of organizational

models based on interdisciplinarity and integrated care networks. Most of these models were meant to be implemented at the primary health care services organization level [1-6]. However, during recent years in the province of Quebec, the primary care level has been impacted by many changes, including institutional mergers, service pathway redesign, and increased responsibilities. All these changes have still not yet been fully

absorbed today [7]. In this context and following on from the “National Consultation on Health Services and Policy Issues 2007-2010” [8], which suggests that innovative models should take particular geographic contexts and existing resources into account, the Centre hospitalier affilié universitaire de Québec, a specialty and subspecialty care facility, plans to open a clinic dedicated to chronic disease. The Centre will work with the existing clinics at the two hospitals that treat diabetes, heart failure, chronic obstructive pulmonary disease, and inflammatory bowel disease to improve care organization and management and, ultimately, ensure greater coordination and integration of the different follow-ups required for each of these diseases. The latter are generally recognized as priorities by the Public Health Agency of Canada [9], Quebec’s Ministère de la santé et des services sociaux [10,11], and the Regional Health Agency [12].

The Centre’s objectives are to reduce complications in the treatment of chronic disease, improve the quality of life of the chronically ill, create a pathway that will help alleviate overcrowding in emergency departments, and reduce the costs of treating these diseases. In the context of a hierarchy of care and services, the clinic set up by the Centre’s two hospitals (secondary and tertiary care) will have linkages to primary care services. Given the systemic challenges involved in creating the clinic, the Centre’s directors, through its Care and Services Coordination Committee, called on the expertise of researchers from Université Laval. The challenge is to reorganize activities based on current knowledge of the chronic care organization while also ensuring the initiative is a success by taking into account the imperatives underpinning the existing professional and management practices concerned. A preliminary study was therefore conducted by the research team, which obtained a training award in summer 2010 that was used to do a literature review as well as a grant from the Canadian Institutes of Health Research in April 2011 that was used to determine the components of the project to be implemented, identify the initial clinics and follow-ups to be set up with all the organizational and professional partners involved in the project, and prepare an overview of the situation.

Chronic Diseases

Chronic diseases are pathologies that are often characterized by a long period of latency and a prolonged course causing functional impairment and multiple disabilities [13]. While incurable, these diseases are distinctive in that their symptoms and progression can be controlled, in particular through prevention, healthy lifestyle choices, and appropriate medical follow-up [7,11,14,15].

The leading cause of death worldwide [16], chronic diseases have devastating consequences both for patients and their families, but also for health care systems [14,17-19]. The decline in quality of life due to the inability to perform daily activities, absenteeism, productivity losses [18,20-22], as well as the personal, emotional, and social burden for those affected are among the costs associated with these diseases. On a structural level, the cost of disability, morbidity, and death due to chronic disease in Canada is over CAN \$80 billion [22]. For instance, patients with chronic diseases are among the most frequent users

of emergency departments and are also known for their recurrent hospitalizations [23,24]. Given these findings, similar to various international bodies, the Canadian Health Council acknowledges that current approaches to chronic disease organization and management are contributing to ever-increasing costs and wait times [18,19,23]. Within Canada and internationally, care pathways are inadequate and access to care and services is difficult [7,18,25-27]. These problems are attributed to the fact that the current culture and structure of health care services delivery are reactive, since they are designed to systematically relieve symptoms and treat acute episodes [1,17,25,28-37]. Consequently, many authors [1,2,4,7,10,37-39] believe health care transformation must be achieved by introducing a system that adopts an integrated prevention and management strategy where patients are followed long term and play an active role in their health, and that is based on a systematized, proactive, and coordinated approach.

Chronic Care Management Models

Many countries have recently proposed various effective projects [17,33,40-48] for chronic disease management that are based on care management [49]. Improved health outcomes can be achieved by reducing the risks of complications, while people’s functional abilities can be maintained and their professional care requirements reduced by more clearly identifying the care and services needed [6,7,25,27,28]. To achieve this, management must be coherent and coordinated in order to provide assistance and therapeutic management for the person in the long term [4,7,10,19,37,38]. While the emphasis is at times placed on early screening and adapted management (Kaiser Permanente, Guided Care, EverCare, Pfizer) [7,27,29,30,50,51], at times on making patients take more responsibility for their health combined with case management by specialized nurses rather than medical specialists (Community Matrons, Social Care Model) [7,51], and at times on multidisciplinary work (Veterans Health Administration) [5,38,51], the Chronic Care Model [36] remains the most comprehensive and widely used of these integrated management models [8,24,28,38,47].

Taking a holistic approach, the Chronic Care Model [52] encompasses six areas for concerted action: (1) delivery system redesign, (2) support for patient self-management, (3) clinical information systems, (4) clinical decision support, (5) community partnerships, and (6) health care organization and leadership. It is based on a clearly established partnership between informed, proactive people living with chronic conditions and trained, supported health care teams [6,17,25,28,35,51,53]. Numerous studies have documented the positive effects of implementing the six components of the Chronic Care Model, including reduced costs and improved client satisfaction, quality, and clinical outcomes [39,51,54]. However, since a number of barriers related to professional practices and management methods appear to prevent the desired approach from being established, Sunaert et al [47] point out that it is crucial to highlight the complementary and unique nature of the contributions and tasks of each of the stakeholders involved in the care process. To do so, they suggest implementing the components of the model progressively to allow stakeholders to fully absorb the changes. These findings have also been confirmed by various studies that suggest that

it is not necessary to implement all the components of the Chronic Care Model at once for it to be effective [6,7,17,38,39,51,52].

The Centre Hospitalier Affilié Universitaire de Québec Project

At the Centre, therefore, the decision will be to implement those components that would be most likely to ensure the initiative is a success by harmonizing the different practices in the participating hospitals, beginning with two specific clinics.

The components were selected based on Si and Bailie's study [55] that, following a review of 69 projects featuring elements of the Chronic Care Model, identified the four components an organization can focus on to ensure stakeholders make the model their own and implement the underlying elements. These components are delivery system redesign, support for patient self-management, clinical information systems, and clinical decision support.

Delivery system redesign involves defining the roles of care providers in the division of tasks [28,32,35,44,56,57], creating interdisciplinary teams, as well as coordinating patient follow-up and access to services [56,58]. In this respect, the Centre plans to clarify the roles of professionals—physicians, nurses, nutritionists, pharmacists, psychologists—in the assessment of the patient's initial condition, patient education, and types of follow-up. Activities already set up will be consolidated by adding specialized nurses, establishing a point-of-access for clients, and possibly by introducing walk-in access to medical specialists. At the Centre, the stakeholder also plans to develop linkages with family physicians who provide primary care by systematically informing them of the patient's condition in a manner that is acceptable to all.

Self-management support involves encouraging patients to make behavior and lifestyle changes [35,38,44,56,57] while providing them with the tools they need to perform the necessary monitoring and to seek care in specific situations [6,15,17,28,55,57,59]. For the Centre, this means strengthening support activities for patients, organizing support activities for the patients' families at group meetings, and developing a follow-up plan that will be reviewed periodically.

Clinical decision support involves offering continuing education activities to providers, developing various consultation mechanisms for specialists, ensuring easy and rapid access to specialist expertise, as well as producing evidence-based interdisciplinary practice guidelines and protocols [7,28,34,35,38,44,47]. At the Centre, bringing various professionals from the two hospitals under the same roof in the chronic disease clinic and promoting evidence-based practices are the two prerequisites needed to develop support activities.

Clinical information systems development involves creating a system accessible to professionals that contains clinical information about patients and the various parameters monitored and required to adjust care [6,15,17,28,35,55,57,60]. To this end, driven by the concerns of physicians, a patient registry could be created at the Centre hospitalier affilié universitaire de Québec so that all care providers can rapidly input and share basic clinical data on the patient's condition, enter reminders

for periodic follow-ups, and access certain patient data. The introduction of patient assessment and follow-up tools is also being considered by the physicians to facilitate intra- and interdisciplinary work.

To ensure the feasibility of the project, existing clinical and organizational realities took precedence when selecting the clinics and conditions to be followed. Thus, diabetes and inflammatory bowel disease will lay the groundwork for the Centre hospitalier affilié universitaire de Québec's chronic disease clinic. The selection of diabetes came from the Centre's directors, while inflammatory bowel disease came from the professionals themselves. In the case of diabetes, the directors' decision to restructure the two hospitals under their jurisdiction prevailed in order to strengthen each site's mission, namely, to develop ambulatory care at a single site. This decision was made to better address the specific needs of clients by providing access to integrated ambulatory services rather than having clients use emergency services and thereby make more efficient use of professional resources, space, and technical platforms. In the case of inflammatory bowel disease, the physician who leads the department of gastroenterology, using funding obtained to provide the services of a specialized nurse, submitted a request to the Centre's directors to introduce a more integrated follow-up. This would involve redesigning the pathway of patients who systematically go to the emergency department. In addition to improving patients' quality of life and their satisfaction with care, the objective of this initiative is to bring down the costs of repeated hospitalizations, decrease the number of tests currently ordered by emergency physicians due to their inability to access records, and reduce the use of costly medications.

These two initial clinics that will be set up within the same hospital will provide complementary internal and external services (primary care services), while relying on the fact that the latter are currently integrating various services, including community services, long-term residential services, and certain ambulatory services. This study is therefore contributing to the development of the local services networks that have been created to promote collaboration between the various care professionals in a given territory [61].

Conceptual Framework and Objectives

Since the creation of the chronic disease clinics must be approached in a strategic manner, the research project is based on an analysis of practices in the different groups of stakeholders concerned (clinical and organizational practices of managers, medical specialists, nurses, and other professionals—pharmacists, psychologists, nutritionists—and primary care physicians). It involves analyzing existing dynamics and those that might ensue from the implementation of the four selected components of the Chronic Care Model within the continuum of services [62–65]. Figure 1 provides a summary of the framework that will be used in the research.

The general objectives of the research project are (1) to produce knowledge that will allow what is learned from the two diabetes and inflammatory bowel disease projects to be used in a complementary manner to set up a clinic at some point in the future that will treat a wider range of chronic diseases, and (2)

to build on this knowledge to construct an explanatory theoretical model that will contribute to the development of similar programs or projects in other regions of Quebec, Canada,

and other countries, including Brazil, the country of origin of one of the researchers involved in this research project. The specific objectives are shown in [Textbox 1](#).

Textbox 1. Objectives of the research project.

Objective 1. For each of the two clinics to be set up:

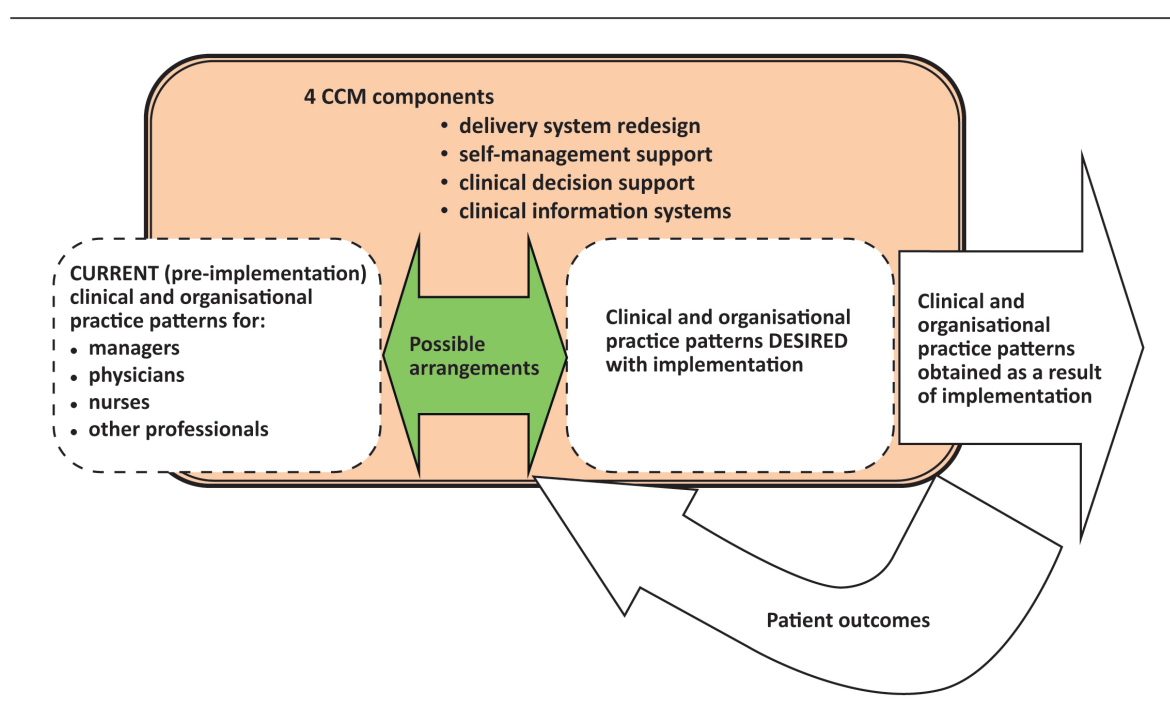
- 1.1 To describe and analyze current practice patterns and the arrangements that may be used by each of the groups of stakeholders involved in the activities underlying the four components of the Chronic Care Model.
- 1.2 To understand the clinical and organizational practices that result from these practice patterns and arrangements during implementation.
- 1.3 To assess patient outcomes for each of the diseases studied.

Objective 2. For both clinics:

To compare and contrast clinical and organizational practices for the diseases studied in order to assess their impact.

Objective 3. To develop a model to redesign the delivery of services to people with chronic diseases.

Figure 1. Framework of the chronic disease clinic.



Methods

Research Strategy

The strategy adopted is based on the longitudinal comparative case study method with embedded units of analysis [66]. This strategy is especially relevant when studying contemporary events over which the researcher has little or no control. Moreover, a case study is the preferred strategy, since it allows the implementation of follow-ups to be studied in depth and in the real-life context of a university hospital center where multiple factors come into play when effecting clinical and organizational changes. More specifically, a case study will allow clinical and organizational practices related to the project to implement two chronic disease clinics and follow-ups to be detailed based on the expertise used to carry out activities

(knowledge, know-how), the roles played (tasks and function), the powers deployed (influence, capacity for action), and supporting organizational methods [65]. Thus, the underlying conditions of the follow-ups and their impact on the implementation of the four components of the Chronic Care Model will be documented. This approach will allow us to study how the Chronic Care Model can be adapted to the clinical and organizational practices in a specific organization and how, from there, insight can be gained into the organization of chronic disease management.

To meet the specific objectives of the research project, namely, to analyze clinical and organizational practices while taking into account their impact on patients, the case study will include a mixed research method [67]. A descriptive, explanatory, and comprehension-oriented qualitative approach will be used to

gain a better understanding of the dynamics at work in the redesigns in question (Objectives 1.1, 1.2, and 2) in order to produce a redesign model that takes these dynamics into account (Objective 3). Quantitative methodology will be used to complete the qualitative component in order to assess patient outcomes following implementation (Objective 1.3).

Sources of Data

To achieve Objectives 1.1 and 1.2, data will be collected by consulting management documents, conducting individual and group interviews, and by observation.

The management documents consulted for the chronic diseases studied will include specific documents used in the management of each of the diseases studied (policies, practice guidelines, minutes of meetings) and administrative documents (planning statements, action plans, reports, minutes). This literature search will be performed, in particular, to put the general context in which the two chronic disease clinics will be created into perspective (linkages with other partners in the local network, decisions and negotiations with regional and central bodies, decisions made by the Centre, key individuals, and resources allocated).

Semi-structured individual and group interviews with members of work groups from the Centre associated with the reorganization of chronic disease management and other managers, physicians, and professionals directly involved in implementing the follow-ups will also be held. These interviews will be conducted at four points in time: (1) at the start of implementation, (2) during implementation (6 months later), (3) 1 year after implementation, and (4) 18 months after the start of implementation. These four points in time were selected to take into account a possible difference in the implementation or rate of implementation between the two clinics. The interviews will be conducted using a checklist that documents (1) stakeholders' roles depending on the nature of the work to be carried out (initial patient assessment, diagnosis, treatment, teaching, and types of patient follow-ups), (2) the expertise required depending on the nature of activities, self-management of care, and interprofessional and interorganizational communications, (3) the powers deployed with respect to the coordination of care and services with and between professionals, and (4) organizational supports for delivery, self-management, education, and information system activities.

Last, non-participant observation will be used within the management committees involved in setting up each clinic. Activities implemented to provide the follow-up for the two chronic diseases (education sessions, interventions of professionals who provide follow-ups and those of managers involved in implementation) will also be observed. This data collection will complete the information collected in the interviews throughout implementation and will be used to prepare subsequent interviews. This data will also be used to document the dynamics between managers and professionals and between professionals with respect to the possible clinical and organizational arrangements.

It should be noted that the preliminary data collection, carried out using the grant obtained from the Canadian Institutes of

Health Research in 2011, revealed a number of barriers to the implementation of follow-ups, some related to the resources to be mobilized and others to clinical practices, which provides starting points for more extensive data collection.

To achieve Objective 1.3, data collection will involve consulting patient registries and distributing standardized questionnaires to patients. This data collection will begin 1 year after implementation and will extend over an 18-month period to take into account the arrival of new patients and the planned length of follow-up for each patient. In cases where follow-up is planned for the person's life span, data will be collected at two points in time: 1 year after the start of implementation and 18 months later in order to document the impact of the follow-up provided on the person's condition.

In addition to demographic data, the information collected from registries will include the patient's state of health (main diagnosis, comorbidities, medication), the professional(s) consulted, the diagnosis or reason for consulting, the type of intervention, the intensity of services provided (number of contacts, their duration, and the length of follow-up), referral to a specialist or other professional, and, where applicable, the reason for terminating follow-up or destination following discharge. The patient registry should also document the impact on patients. Certain information will be collected in this regard, including test results (eg, repeat blood glucose tests, weight).

The impact will also be assessed by distributing standardized questionnaires to patients. These assessments will be used to study physical, social, family, and emotional functioning and will be completed during follow-up activities. Since the questionnaires will be administered by professionals, they will be designed to take into account the manner in which they will be used to assess patients' functional capacities depending on the follow-up provided. Particular attention will be paid to the quality of teaching and information provided to facilitate self-management of care, as well as the intention to terminate follow-up. To do this, standardized questionnaires that are used with hospitalized patients will be adapted, in particular for the scales that assess difficulties adapting following discharge from hospital and the quality of discharge teaching. The scale used to assess difficulties adapting is divided into four attributes used to assess readiness based on personal status, knowledge, ability to self-manage, and support expected. It is a self-administered questionnaire that uses a Likert scale of 0 to 10. The scale used to assess the quality of teaching is divided into two subscales: one for content and the other for nurses' teaching skills. The content assessment evaluates perception of the content required, the content received, and the difference between the two. For nurses' skills, sensitivity to personal beliefs and values, the use of understandable language, and the choice of the best time to give the patient and his/her family the teaching are evaluated. This questionnaire is also self-administered and uses a Likert scale of 0 to 10.

Recruitment of Participants

The project was submitted to and approved by the ethics committee of the site where the study will be conducted. It was agreed that all participants would be recruited on a voluntary basis.

Professionals and managers will first be recruited from among the initial contacts made by the researchers when they participated in the various committees involved in setting up the two clinics. All the other stakeholders directly involved in setting up these clinics will then be contacted personally by a member of the research team to invite them to participate. Patients will be recruited by someone who is neither involved in clinical follow-ups, nor part of the research team. Once they have agreed to participate, one of the members of the research team will contact them to explain the study.

All participants will be required to give their consent to participate in the research project by signing a form that guarantees the right to withdraw at any time during the process without prejudice. For patient consent to the use of their data, the rules proposed by the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council will be followed [68]. The confidentiality of the data collected will be safeguarded by creating a coding system to ensure participants' anonymity. All confidential data will be kept under lock and key. In accordance with applicable retention rules, documents relating to the project will be kept for 7 years after completion of the study [69].

Data Analysis

Data analysis will be organized in accordance with the above-mentioned research objectives and guided by the dimensions of the conceptual framework (see Figure 1), the current (pre-implementation) clinical and organizational practices, the desired practices based on the Chronic Care Model, the possible arrangements between the two, and the results obtained in terms of practices implemented and patient outcomes. The data studied will include interview transcripts, data from observation, and data from the literature review; the resulting set of data will be transferred onto a computerized platform and analyzed using qualitative analysis software specially designed for mixed methods research (QDA miner: Provalis Research).

The qualitative data for Objectives 1.1 and 1.2 as well as 2 and 3 will be analyzed using Miles and Huberman's methods [70].

First, for Objectives 1.1 and 1.2, the data collected will undergo an initial classification, after time 1, according to the dimensions of the conceptual framework. The data will then be reduced by grouping meanings according to the themes that emerge. Matrices and diagrams will then be used to highlight the patterns in the data. This operation will serve to establish associations between the different constructs of interest in the clinical and organizational practice patterns. Subsequently, at times 2, 3, and 4, the data will contribute to the themes already constructed and possibly reveal other explanatory patterns.

Objectives 2 and 3 concern, respectively, cross-sectional analyses of the practices at each clinic studied and the development of a model to redesign the delivery of services to people living with chronic diseases. For Objective 2, the different patterns of clinical and organizational practices will be taken, merged, and compared in order to produce a synthesis. Last, the model that must be constructed to meet Objective 3

will require the use of what Nizet [71] calls the double hermeneutic. Thus, the interpretations of the two analyses must be compared with the interpretations of managers and professionals at the clinics in order to achieve a global understanding of the situation.

Objective 1.3 will be achieved by conducting a quantitative data analysis using descriptive statistical analyses such as the mean, standard deviation, minimum and maximum and the quartiles of length of follow-ups, the number of professionals involved, the type of intervention, and the intensity of interventions. The analyses will explore the distribution of these variables. In addition to the impact on patients, the quantitative analysis of this data will complete Objective 2 and thus allow the quantifiable aspects of the two types of follow-up to be compared and contrasted, in particular the number of professionals involved and the intensity of interventions, the duration, and the variety of the types of interventions used.

Last, the validity of the analytical approach used in the study will be strengthened by using a variety of sources of data and building a "chain of evidence" starting with this data and ending with the construction of the explanations concerning clinical and organizational practices associated with delivery system redesign, self-management support, clinical decision support, and information systems. These explanations will form the basis of a cross-sectional explanation for the construction of a more comprehensive redesign model.

Results

We are currently in the analysis phase of the project. The results will be available in 2015.

Discussion

Contributions and Limitations

The contributions of the research will be threefold: the first is to consider specialized services as the linchpin for the creation of chronic disease clinic; the second is to adapt an organizational model for chronic disease management to existing resources and practices; while the third is to provide a theoretical explanation that goes beyond the local example.

In the literature, the implementation of a model for the follow-up of chronic diseases is based on primary health care services. However, according to studies by Lévesque et al [7,38], the latter are still not sufficiently organized in Quebec to support such an initiative alone. The significant changes these services have undergone in recent years (institutional mergers, service pathway redesign, the creation of local services networks, increased responsibilities) have not yet all been absorbed such that linkages can be made between the multiple partners (hospital centers, medical specialist groups, health and social services centers, medical clinics) required to set up these clinics. This organizational reality combined with the fact that chronic diseases are often followed by hospital-based medical specialists suggest that the desired complementarities can be sought outside primary care services. Another form of care organization must be considered, which can only increase the possibility of improving chronic disease management.

Similarly, beyond the idea of implementing an organizational model created elsewhere, it is a question of basing implementation on actual practices and existing resources so that these practices and resources can be taken into account and the organizational model adapted to the organizational reality. Thus, the opposite approach is taken: instead of practices adapting to the model, the model adapts to practices in order to ensure implementation is successful and to ensure the long-term sustainability of the clinic in the follow-up of chronic diseases. This approach leads us to identify explanatory elements by describing and highlighting the dynamics at work that can improve our understanding of approaches to implementation that retain existing elements, to use them, and to add elements modelled on the literature and research evidence. This method is consistent with approaches to change where the emphasis is shifted from managing change to managing the capacity to change [72].

Last, such empirical perspectives are necessarily reflected on a scientific level. This research project therefore aims to develop a new theory of care organization. Since the dimensions of the Chronic Care Model already form the basis of stakeholders' existing practices (delivery system redesign, self-management support, clinical decision support, and clinical information systems), but little is said about how to build on pre-implementation practices when new organizational models are introduced, developing a framework for the approach seems relevant. The intention is to go beyond the local example, to develop a model at a level that will allow generalizations of a theoretical nature. Developing knowledge of how to implement an integrated model for chronic disease follow-up is therefore highly relevant for the Canadian health care system and other systems around the world, service providers, and the chronically ill. Carrying out a project that can be used to document the adaptations that must be made to an intervention model based on evidence can only help improve the chances of success when setting up chronic disease clinics and thereby ensure their sustainability.

The main limitation of this study is that only one case is considered. However, this is minimized by the nature of the study and the possibility of making a theoretical generalization. While the description of the implementation cannot be generalized to other situations, the development of

cross-sectional proposals of rationalization of the phenomenon of care organization and management for the chronically ill could possibly be validated in other health system organizations.

Application of Integrated Knowledge

Collaboration between managers/decision makers, researchers, and professionals has existed for several years in the context of other projects. From the earliest planning stages of the ambulatory clinic at the Centre hospitalier affilié universitaire de Québec, the managers called on the expertise and support of researchers, for they wanted to reorganize follow-up activities for chronic diseases based on current knowledge. They also wanted to ensure the initiative was a success by taking professional practices and their specific context into account.

Thus, the knowledge application process is integrated into the research itself and consists of mutual exchanges throughout the study. The researchers participate in the Care and Services Coordination Committee, and the various other committees formed with professionals and managers involved in implementing the two follow-ups. The participation of a Brazilian researcher will contribute a point of view that will enrich local analysis perspectives, since services integration is an integral part of Brazil's health system. To this end, discussions will also be held by videoconference with a consultation committee made up of decision makers and researchers associated with this researcher's university and thereby contribute to the transfer of knowledge.

A workshop will be organized to which experts, decision makers, and researchers will be invited in order to discuss the findings of the study and the resultant service delivery redesign model. Moreover, various means of transferring knowledge, such as scientific and popular communications and publications, will be used to reach the research project's target audience. Dissemination of the results in decision making, administrative, and professional circles will be planned, taking their specific characteristics into account. The results will be documented in the form of short notes, brief reports, and summaries. This information will be available at conferences attended by managers (Association des gestionnaires des établissements de santé et de services sociaux, Association des cadres de la santé et des services sociaux du Québec, Association des Directeurs généraux des Services de Santé et Sociaux du Québec).

Conflicts of Interest

None declared.

Multimedia Appendix 1

CIHR decision letter.

[[PDF File \(Adobe PDF File\), 25KB - resprot_v4i1e12_app1.pdf](#)]

Multimedia Appendix 2

CIHR ranking.

[[PDF File \(Adobe PDF File\), 195KB - resprot_v4i1e12_app2.pdf](#)]

Multimedia Appendix 3

CIHR peer-reviewer 1.

[PDF File (Adobe PDF File), 53KB - [resprot_v4ile12_app3.pdf](#)]

Multimedia Appendix 4

CIHR peer-reviewer 2.

[PDF File (Adobe PDF File), 55KB - [resprot_v4ile12_app4.pdf](#)]

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Protocol

Auditory Brainstem Response as a Diagnostic Tool for Patients Suffering From Schizophrenia, Attention Deficit Hyperactivity Disorder, and Bipolar Disorder: Protocol

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Abstract

Background: Psychiatric disorders, such as schizophrenia, attention deficit hyperactivity disorder (ADHD), and bipolar disorder, may sometimes be difficult to diagnose. There is a great need for a valid and reliable diagnostic tool to aid clinicians in arriving at the diagnoses in a timely and accurate manner. Prior studies have suggested that patients suffering from schizophrenia and ADHD may process certain sound stimuli in the brainstem in an unusual manner. When these patient groups have been examined with the electrophysiological method of brainstem audiometry, some studies have found illness-specific aberrations. Such aberrations may also exist for patients suffering from bipolar disorder.

Objective: In this study, we will examine whether the method of brainstem audiometry can be used as a diagnostic tool for patients suffering from schizophrenia, ADHD, and bipolar disorder.

Methods: The method includes three steps: (1) auditory stimulation with specific sound stimuli, (2) simultaneous measurement of brainstem activity, and (3) automated interpretation of the resulting brain stem audiograms with data-based signal analysis. We will compare three groups of 12 individuals with confirmed diagnoses of schizophrenia, ADHD, or bipolar disorder with 12 healthy subjects under blinded conditions for a total of 48 participants. The extent to which the method can be used to reach the correct diagnosis will be investigated.

Results: The project is now in a recruiting phase. When all patients and controls have been recruited and the measurements have been performed, the data will be analyzed according to a previously arranged algorithm. We expect the recruiting phase and measurements to be completed in early 2015, the analyses to be performed in mid-2015, and the results of the study to be published in early 2016.

Conclusions: If the results support previous findings, this will lend strength to the idea that brainstem audiometry can offer objective diagnostic support for patients suffering from schizophrenia, ADHD, and bipolar disorder. A positive result from the study could imply that brainstem audiometry could become an important supportive tool for clinicians in their efforts to diagnose patients with these disorders in a timely and accurate manner.

Trial Registration: ClinicalTrials.gov NCT01629355; <https://clinicaltrials.gov/ct2/show/NCT01629355> (Archived by WebCite at <http://www.webcitation.org/6VBfTw5H>).

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KEYWORDS

brainstem audiometry; diagnosis; schizophrenia; ADHD; bipolar disorder

Introduction

Psychiatric disorders, such as schizophrenia, attention deficit hyperactivity disorder (ADHD), and bipolar disorder, may sometimes be difficult to diagnose [1]. The diagnostic criteria are complex and the disorders may present themselves in a wide variety of manners in clinical practice. The diagnoses are made primarily by comparing symptoms to sets of diagnostic criteria, often with the help of structured interviews [2]. Clinicians may use somatic examinations, various biochemical tests, electroencephalography, radiological examinations, etc, as aids in the diagnostic process. The investigations preceding the setting of these diagnoses are often extensive and time-consuming. There is a need for a valid and reliable diagnostic tool that can help clinicians in their efforts to diagnose these disorders in a timely and accurate manner. A diagnostic tool that could simplify the diagnostic process could free up resources that could be used to examine and treat more patients.

The brainstem is a hub for traffic in the central nervous system, including auditory activity. Evoked response audiometry is an electrophysiological method that records electrical signals—referred to as evoked potentials—that occur in the auditory system following acoustic stimulation [3–8]. By varying different elements in the examination, such as the time span of the examination, the acoustic properties of stimulation, the electrode placement and design, the number of signals forming the mean value, and the electrical filtering, different potentials may be studied. Areas of testing may involve masking functions (filters), habituation, lateralization (lateral asymmetry), and topographic patterns (eg, comparison between the peripheral activity and the thalamus activity) [9].

The early responses are studied with brainstem audiometry, also referred to as auditory brainstem response (ABR). This examination procedure has been used for many years in audiology departments, mainly for establishing the hearing threshold of patients, for aiding in the diagnosis of sensorineural hearing loss, and in the diagnosis of lesions and tumors in the brainstem. In this study, we will be drawing on a method that represents a further development of the standard ABR, referred to as SensoDetect Brainstem Evoked Response Audiometry (SD-BERA). It uses a wider array of acoustic stimuli, including complex sounds such as masking noises. The method consists of three parts: (1) auditory stimulation with specially designed sounds, involving functional and dysfunctional neuronal networks, (2) simultaneous reading of activity in the brainstem via electrodes, and (3) automated interpretation of the measurements with computer-based signal analysis.

Prior studies have suggested that patients suffering from schizophrenia and ADHD may process certain sound stimuli in the brainstem in an unusual or aberrant manner [3–20]. Some studies have suggested that when these patient groups have been examined with brainstem audiometry, the resulting brainstem audiograms have displayed illness-specific aberrations

[9,14,17,21]. These aberrations have also been noted in unpublished observations. Previous studies have aimed to associate details in the audiograms with specific anatomical structures. This will be one of the first systematic studies drawing on this method to include patients with bipolar disorder.

In this study, we will examine whether the method of high-resolution brainstem audiometry can be used as a diagnostic tool for patients suffering from schizophrenia, ADHD, and bipolar disorder. We will study the use of a short (25 to 30 minutes) examination procedure. We will test the following hypotheses: (1) patients with schizophrenia, ADHD, and bipolar disorder differ from healthy subjects with respect to brainstem response measured with brainstem audiometry, (2) the diagnoses mentioned above may be reached in a blinded study, and (3) the method has sufficient sensitivity and specificity to be applied as a tool for diagnostic support for these illnesses.

Methods

Inclusion Criteria, Exclusion Criteria, and Recruitment

Patients aged 18 to 70 years that have received a best-practice diagnosis—according to the 10th revision of the International Classification of Diseases (ICD-10) criteria [1]—of schizophrenia (section F20), ADHD (section F90), or bipolar disorder (section F31), at least one year prior to enrollment, may be included in the study.

Patients who are incapable of giving consent, who suffer from serious hearing loss, who have serious ongoing alcohol abuse or drug abuse issues, who have diagnosed psychiatric comorbidity, or who have a history of brain injury following cranial trauma will be excluded.

The patients will be recruited from the psychiatric departments at the University Hospital of North Norway (UNN) and from the registry at the General Practitioner Office in Storsteinnes, Balsfjord, Norway. Healthy control subjects of matching gender and age will be recruited from the population of the district of Troms, primarily students and employees at the psychiatric departments at UNN and from the General Practitioner Office in Balsfjord, Norway.

Information regarding the patients' diagnoses and medications will be collected from their medical records.

The study has been approved by the Regional Medical Ethics Committee for North Norway (REC North 2011/2149).

Study Design

This is a blinded study with brainstem audiometry, with the purpose of evaluating the predictive value of the test. A total of 48 individuals will participate in the study—a patient group consisting of 36 individuals with the above diagnoses (ie, three groups of 12 patients with each diagnosis) and 12 healthy individuals will undergo measurements. The resulting data will be analyzed under blinded conditions, according to a previously

arranged data algorithm. This clinical trial has been registered at ClinicalTrials.gov (Identifier NCT01629355).

Measurements

The actual measurement procedure is noninvasive. The examination takes 25 to 30 minutes and no preparation or active patient participation is required during the procedure. Five surface electrodes are attached to the skin on the forehead and behind the ears on the mastoid process. The examination

involves the patient sitting comfortably reclined in an armchair in a quiet and dimmed room with headphones, listening to an array of acoustic stimuli not exceeding 70 dB (Figure 1). The method registers evoked potentials resulting from neural activity in the brainstem. These potentials occur within 10 msec following acoustic stimulation, are registered by the surface electrodes, and stored digitally. The method is European Conformity (CE) marked.

Figure 1. Demonstration of brainstem audiometry measurement equipment (first author pictured).



Analysis

The resulting wave pattern consists of seven peaks, which are interpreted with respect to latencies and amplitudes (Figure 2). From this pattern, abnormalities in the brainstem are detected

and disease-specific patterns can be matched. A data algorithm is used in the analysis. In this study, the audiograms are anonymized and subsequently analyzed with paid assistance from SensoDetect, a company based in Lund, Sweden.

Figure 2. Illustrative photo of equipment used, demonstrating recorded waves.



Statistics and Power

Based on prior findings, we expect a sensitivity and specificity of 80%. A power calculation suggests that 12 patients in each patient category will be sufficient to detect statistical differences at the $P < .05$ level (ie, Fischer's exact test for the analysis of difference in the percentage of population response between groups, the Mann-Whitney test, or Wilcoxon test for the analysis of differences in values between groups).

Results

This project is now in a recruiting phase. When all patients and controls have been recruited and the measurements performed, the data will be analyzed according to a previously arranged algorithm. This analysis will be performed blindly by the company SensoDetect (ie, they will not know the diagnoses of the patients from which individual measurements were taken).

We expect the recruiting phase and measurements to be completed in early 2015, the analyses to be performed in mid-2015, and the results of the study to be published in early 2016.

Discussion

The aim of this study is to evaluate whether the method is useful with respect to reaching a diagnosis of schizophrenia, ADHD, or bipolar disorder, and to assess, in a blinded study, the validity of the method for diagnosing these illnesses. The long-term benefit of this method could be to ensure a fast and accurate diagnosis for individuals suffering from schizophrenia, ADHD, or bipolar disorder, and thus be able to provide the patients with timely and adequate attention. Should the results confirm that the method represents a valid and reliable diagnostic support tool for these disorders, it may be significant to the field of psychiatry.

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Conflicts of Interest

None declared.

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Abbreviations

ADHD: attention deficit hyperactivity disorder

ABR: auditory brainstem response

CE: European Conformity

ICD-10: 10th revision of the International Classification of Diseases

SD-BERA: SensoDetect Brainstem Evoked Response Audiometry

UNN: the University Hospital of North Norway

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Original Paper

Do Extreme Values of Daily-Life Gait Characteristics Provide More Information About Fall Risk Than Median Values?

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Abstract

Background: Gait characteristics estimated from daily-life trunk accelerations reflect gait quality and are associated with fall incidence in older adults. While associations are based on median values of these gait characteristics, their extreme values may reflect either high-risk situations or steady-state gait and may thus be more informative in relation to fall risk.

Objective: The objective of this study was to improve fall-risk prediction models by examining whether the use of extreme values strengthens the associations with falls.

Methods: Trunk acceleration data (Dynaport MoveMonitor) were collected from 202 older adults over a full week. From all walking episodes, we estimated the median and, as reliable estimates of the extremes, the 10th and 90th percentiles of gait characteristics, all over 10-second epochs. In addition, the amount of daily activities was derived from the acceleration data, and participants completed fall-risk questionnaires. Participants were classified as fallers based on one or more falls during 6 months of follow-up. Univariate analyses were performed to investigate whether associations with falls were stronger for the extremes than for the medians. Subsequently, three fall-risk models were compared: (1) using questionnaire data only, (2) adding the amount of activities and medians of gait characteristics, and (3) using extreme values instead of medians in the case of stronger univariate associations of the extremes.

Results: Stronger associations were found for the extreme characteristics reflecting high regularity, low frequency variability, and low local instability in anterior-posterior direction, for high symmetry in all directions and for low entropy in anterior-posterior and vertical directions. The questionnaire-only model improved significantly by adding activities and gait characteristics' medians. Replacing medians by extremes with stronger associations did improve the fall prediction model, but not significantly.

Conclusions: Associations were stronger for extreme values, indicating "high gait quality" situations (ie, 10th and 90th percentiles in case of positive and negative associations, respectively) and not for "low gait quality" situations. This suggests that gait characteristics during optimal performance gait provide more information about the risk of falling than high-risk situations. However, their added value over medians in prediction is limited.

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KEYWORDS

accidental falls; risk assessment; accelerometry; activities of daily living; gait; walking; logistic models; aged

Introduction

Identifying persons with a high risk of falling can facilitate effective prevention of falls. Several ways of assessing fall risk have been investigated, including questionnaires, physical tests, gait analysis, and physical activity measurements [1-4]. Yet the predictive value of these models is still limited.

A promising way to assess fall risk is by means of body-worn sensors in daily life. Trunk accelerations during walking can provide information about personal risk factors for falls related to physical capacity and health status. This information is typically assessed by gait analysis in controlled settings, which has shown that high variability, low stability, and low symmetry of gait are associated with falling [5,6]. The use of body-worn sensors in daily life can add information about physical activity [7], as well as situational fall-risk factors related to one's behavior and environment [8]. This new approach has demonstrated the potential to make an important contribution to fall-risk assessment, as shown by daily-life gait characteristics' associations with falls and the added value of gait characteristics in fall prediction over commonly used methods [9-11].

Even though the previously developed fall-risk model based on daily-life gait characteristics showed a very promising performance (ie, an area under the receiver operator curve [AUC] of 0.82) [10], there may still be room for improvement. One aspect to consider is the selection of specific gait episodes in daily life that contain the most relevant information for fall-risk prediction. Previous studies used the mean or median of a gait characteristic over the analyzed epochs of gait, based on the assumption that this would be the most representative estimate for that characteristic [9-11]. However, as situations in daily life vary, gait characteristics obtained in particular situations may better reflect a person's fall risk than the median of those obtained in all analyzed epochs of gait. On the one hand, episodes with "low gait quality" may contain information about taking risks or responding to risks in such situations. High-risk situations may be expected to show high variability and low stability and symmetry, as these gait characteristics are associated with falling [5,6,9-15]. On the other hand, situations where people show "high gait quality" might be informative about the best possible performance they can achieve, which

may be closely related to personal risk factors or the performance in a lab or on a treadmill. We expected these two extreme situational effects, high-risk situations and optimal gait performance, to be reflected in the extreme values of gait characteristics calculated over 1 week. Therefore, we investigated whether extreme values of gait characteristics obtained in daily life had stronger associations with falls and predicted these falls better than their median values.

Methods

Participants

The 202 individuals who participated in this study were part of the larger Fall Risk in Old Age (FARAO) cohort study conducted at VU University Amsterdam. They were mainly community dwelling older adults, and inclusion criteria were having a mini mental state examination (MMSE) of at least 19 (out of 30 points), age between 65 and 99, and the ability to walk 20 meters continuously, with the aid of an assistive device if needed. All participants provided written informed consent and the medical ethical committee of the VU University Medical Hospital approved the protocol (number 2010/290).

Protocol

At the start of the study, participants were interviewed and trunk accelerations were recorded over a full week, after which their fall incidence was monitored for 6 months. During the interview, demographic information was collected (Table 1), as well as fall history and the geriatric depression score (GDS) [16], since these were previously shown to be associated with future falls [10]. Following the interview, participants wore a tri-axial accelerometer (MoveMonitor, McRoberts, The Hague, Netherlands; sampling range -6g to 6g; sampling rate 100 Hz) for 1 week continuously, except during water-related activities that could damage the device. Participants were instructed to wear the accelerometer with an elastic band around their waist at the mid-back, at the level of their lumbar spine. After the interview and measurements, participants' falls were monitored for 6 months by monthly telephone contact in addition to a daily diary. If participants had fallen at least once during the 6-month follow-up, they were classified as fallers; if not, they were classified as non-fallers.

Table 1. Participant demographics.

	Fallers (n=70)	Non-fallers (n=132)	<i>P</i> (<i>t</i> test)
Age (years), mean (SD)	75.6 (6.1)	75.1 (6.6)	.59
Gender (male), %	47	50	.73
Community dwelling, %	94	94	.93
Weight (kg), mean (SD)	75 (14)	74 (14)	.45
Height (m), mean (SD)	1.71 (0.09)	1.70 (0.09)	.46
BMI (kg/m ²)	25.6 (3.7)	25.3 (3.6)	.57
Use of walking aid, %	26	22	.66
MMSE (max 30), mean (SD)	27.7 (2.3)	27.8 (2.1)	.78

Physical Activities and Gait Characteristics

The accelerations recorded during the measurement week were used to estimate the average amounts of physical activities as well as a comprehensive set of gait characteristics. Table 2 (gait characteristics) and Table 3 (physical activities) cover the complete set of derived parameters. The parameters in question were estimated as described in previous papers (see [7,10] for physical activity and [9,17] for gait characteristics). We added the estimation of sample entropy [18,19] in view of its potential to discriminate fallers from non-fallers [10,20]. We used 5 consecutive data points and 0.3 as the radius of tolerance, based on the determination of auto-regressive process orders and relative errors of sample entropy for our data as proposed by Lake et al [21]. In order to focus solely on regular walking, we discarded locomotion episodes suspected to reflect running. These episodes, which caused severe outliers for some participants, were identified by a low stride time (<0.8 s) and/or a high vertical (VT) acceleration root-mean-square (RMS) (>5 ms⁻²).

As in previous studies, median values of gait characteristics were estimated from all 10-second walking epochs recorded during the measurement week. In addition, the extremes were estimated as the parameter values of the 10th and 90th percentiles of the gait characteristics derived. We used the 10th and 90th percentile values as best estimates of the extremes themselves, since the reliability of the extremes appeared to be insufficient; when using the data and procedures as described in previous work [9], but now for extremes instead of medians, more than 90% of the between-weeks intraclass correlations (ICC) were below 0.7. For the 10th and 90th percentile values, more than 90% had an ICC above 0.7, similar to the medians.

Statistical Analysis

Univariate Regression

We assessed the added value of extreme values of gait characteristics over median values by comparing their association with fall incidence through univariate logistic regression. A percentile value (10th, 50th, or 90th) was considered to have a stronger association over the other two percentile values when its regression P value was lowest and below .05.

Generating Fall Prediction Models

Three fall-risk models were generated. Model 1 was based on the participant's fall history (yes/no) and the GDS score. Other data obtained through the interview were not used for the fall prediction models because these were not associated with falling in a previous study [10]. In Model 2, all amounts of physical activities were added, as well as the median values of all gait characteristics. In Model 3, we replaced the median value of a given gait characteristic by its extreme value, provided that the latter had a stronger association with falls according to the univariate analysis. The outcome variable for all three models was whether or not participants had fallen at least once during the 6 months of follow-up. The fall prediction models were

generated by means of stepwise forward logistic regression. In every step, the parameter with the lowest P value below .05 when added to the parameters in previous steps was selected, provided that the parameter did not have an absolute Spearman correlation higher than .7 with any of the previously selected parameters. The models were tested for inadequate calibration between predicted probabilities and observed fall incidences using the Hosmer-Lemeshow test.

Comparing Fall Prediction Models

When evaluating the added value of new parameters for a prediction model, it is not trivial to determine the significance of added parameters while considering the number of parameters that were available for selection. Commonly used tests typically compare pre-determined prediction parameters (eg, [22,23]) and do not account for the freedom of parameter selection or the setting of regression coefficients. In this study, to estimate a P value for the improvement of the models when adding or replacing parameters, we required a test that could handle models with different numbers of parameters and could select parameters from subsets of different numbers of potential parameters. Since we found no analytical test that satisfied these requirements, we used a Monte Carlo permutation test. All parameters as obtained from the week of acceleration data collected from one participant were permuted with the data of another randomly selected participant. Since all gait characteristics and amounts of activities were taken from the same week of accelerations of another participant, correlations between these parameters remained the same. Questionnaire data and fall incidence were not permuted between participants. We generated models for 1000 differently permuted datasets and estimated the P value for the improvement between models as the ratio of permutations having a larger increase of the area under the receiver operator curve (AUC) between the models than the increase of the AUC between the models obtained with the original dataset. The first model, being based exclusively on questionnaire data, was not affected by the permutations.

Results

Univariate regression showed significant associations ($P<.05$) with falling for 14 out of 30 gait characteristic medians (Table 2). High stride regularity anterior-posterior (AP), high harmonic ratio VT and AP, low local dynamic stability AP, and low sample entropy VT had a stronger association than the medians of these characteristics. When using extremes, the associations of low frequency variability AP, high harmonic ratio mediolateral (ML), and low sample entropy AP with falls were significant, whereas they were not significant when using the median values. All stronger associations for extremes were found for the extremes related to optimal performance gait, that is, the 10th percentile (lower extreme) in case of positive associations with falls, and the 90th percentile (higher extreme) in case of negative associations. Regression results of questionnaire data and amounts of activities showed significant associations for fall history, GDS depression scale, and lying duration (Table 3).

Table 2. Univariate logistic regression of gait characteristics' 10th, 50th, and 90th percentile values, with future falls (B values [*P* values] are based on *z*-transformed data).

Characteristics	10th perc. B (<i>P</i>)	Median B (<i>P</i>)	90th perc. B (<i>P</i>)
Gait speed	-0.36 (.03)	-0.38 (.02) ^a	-0.32 (.04)
Speed variability	0.26 (.10)	0.19 (.21)	-0.08 (.60)
Stride frequency	-0.21 (.15)	-0.31 (.04) ^a	-0.15 (.41)
Frequency variability VT	0.25 (.09)	0.26 (.08)	-0.12 (.41)
Frequency variability ML	0.25 (.10)	0.21 (.15)	0.01 (.96)
Frequency variability AP	0.33 (.03) ^a	0.27 (.07)	0.07 (.61)
Stride regularity VT	-0.23 (.14)	-0.34 (.03) ^a	-0.26 (.08)
Stride regularity ML	0.07 (.65)	-0.08 (.58)	-0.06 (.70)
Stride regularity AP	-0.24 (.12)	-0.32 (.04) ^a	-0.37 (.02) ^a
RMS VT	-0.29 (.07)	-0.50 (.004) ^a	-0.41 (.009)
RMS ML	0.09 (.53)	-0.08 (.60)	-0.06 (.67)
RMS AP	-0.20 (.19)	-0.37 (.02) ^a	-0.25 (.11)
Low frequency percentage VT <0.7 Hz	0.20 (.18)	0.38 (.01) ^a	0.23 (.11)
Low frequency percentage ML <10 Hz	0.24 (.12)	0.33 (.04) ^a	0.15 (.32)
Low frequency percentage AP <0.7 Hz	0.28 (.06)	0.37 (.01) ^a	0.27 (.07)
Index of harmonicity VT	-0.16 (.30)	-0.23 (.12)	-0.20 (.17)
Index of harmonicity ML	0.27 (.07)	0.24 (.11)	0.13 (.37)
Index of harmonicity AP	0.11 (.45)	0.18 (.23)	0.28 (.07)
Harmonic ratio VT	-0.03 (.83)	-0.43 (.009) ^a	-0.51 (.003) ^a
Harmonic ratio ML	0.11 (.46)	-0.25 (.11)	-0.32 (.048) ^a
Harmonic ratio AP	-0.05 (.76)	-0.41 (.01) ^a	-0.53 (.002) ^a
Local dynamic stability VT	0.29 (.053)	0.33 (.03) ^a	0.22 (.16)
Local dynamic stability ML	0.10 (.51)	0.08 (.58)	0.03 (.86)
Local dynamic stability AP	0.38 (.02) ^a	0.34 (.03) ^a	0.27 (.08)
Sample entropy VT	0.60 (<.001) ^a	0.41 (.02) ^a	0.14 (.35)
Sample entropy ML	-0.09 (.54)	-0.12 (.43)	-0.16 (.31)
Sample entropy AP	0.39 (.01) ^a	0.22 (.15)	0.02 (.87)
Dominant frequency's amplitude VT	-0.22 (.16)	-0.29 (.06)	-0.19 (.21)
Dominant frequency's amplitude ML	0.16 (.28)	0.14 (.34)	0.15 (.31)
Dominant frequency's amplitude AP	-0.13 (.37)	-0.06 (.71)	0.07 (.63)

^aSignificant associations of medians and stronger associations of extremes.

Table 3. Univariate logistic regression of questionnaire parameters and amounts of physical activities with future falls (B values [*P* values] are based on *z*-transformed data).

	B (<i>P</i>)
Fall history	0.55 (<.001) ^a
GDS depression scale	0.45 (.003) ^a
Lying duration	-0.40 (.02) ^a
Sitting duration	0.27 (.09)
Standing duration	0.24 (.11)
Locomotion duration	-0.01 (.96)
Shuffling duration	0.23 (.12)
Number of transitions ^b	0.15 (.30)
Number of steps	-0.05 (.76)

^aSignificant associations.^bDirect transitions from sedentary (lying and sitting) to non-sedentary (standing, locomotion, and shuffling) activities.

Fall history was selected as a parameter in all models. GDS depression score was selected in the questionnaires-only model but not in the models including acceleration data. In both models that included acceleration data, lying duration as well as low frequency percentage below 0.7 Hz in the VT and sample

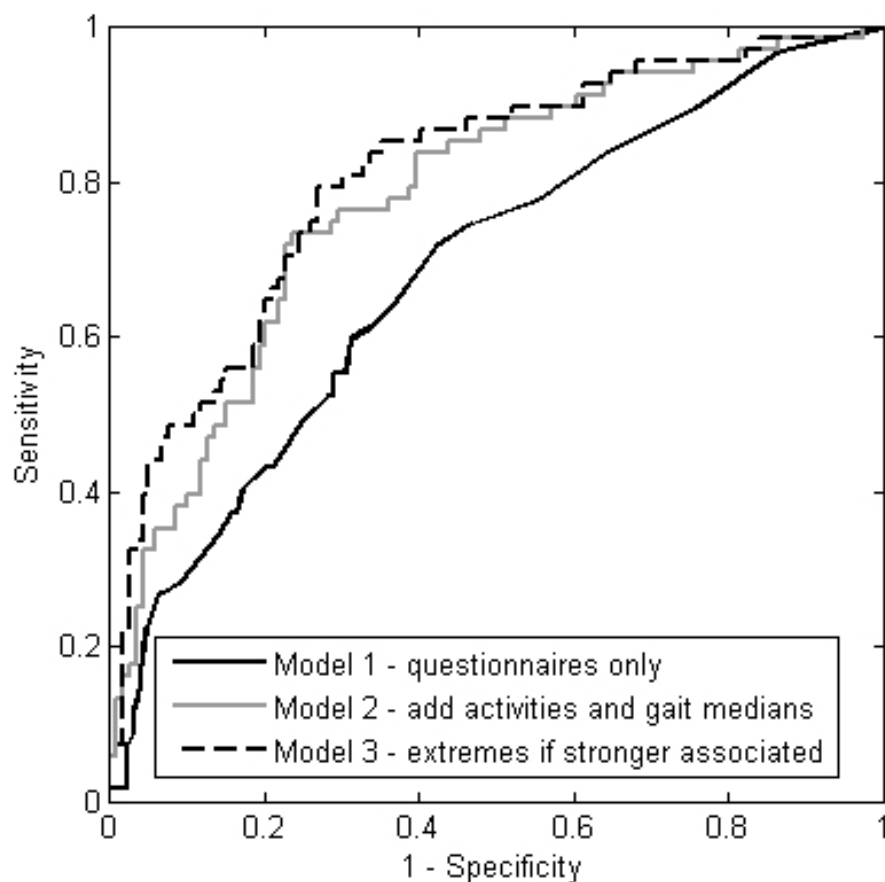
entropy in both the VT and ML direction were selected (Table 4). For Model 3, only one extreme value (10th percentile of Sample Entropy VT) was selected as a parameter. The Hosmer-Lemeshow test revealed no indications of inadequate calibration (*P*=.58, .41, and .76 for Models 1-3, respectively).

Table 4. Fall prediction models with parameter coefficients and *P* values.

Models	B	<i>P</i> value	Parameters
Model 1: questionnaires only			
	-0.70	<.001	Constant
	0.46	.004	Fall history
	0.33	.04	GDS depression score
Model 2: add activities and gait characteristics' medians			
	-0.66	<.001	Constant
	0.67	<.001	Fall history
	0.41	.04	Low frequency percentage VT <0.7 Hz
	-0.43	.02	Lying duration
	0.86	.002	Sample entropy VT
	-0.53	.03	Sample entropy ML
Model 3: replace gait characteristics' median if extreme has stronger association			
	-0.68	<.001	Constant
	0.69	<.001	Fall history
	1.02	<.001	Sample entropy VT (Low extreme)
	0.61	.002	Low frequency percentage VT <0.7 Hz
	-0.60	.004	Lying duration
	-0.47	.03	Sample entropy ML

Receiver operating characteristic (ROC) curves of the 3 prediction models are shown in Figure 1. The AUC for the prediction Models 1-3 were 0.684, 0.781, and 0.808, respectively. Models 2 and 3, which both involved daily-life acceleration parameters, performed significantly better than

Model 1 (*P* values for the improvements were .01 and .003, respectively). Model 3 with extremes did not improve significantly with respect to Model 2 based exclusively on median values (*P*=.19).

Figure 1. ROC curves for the 3 prediction models.

Discussion

Principal Findings

This study investigated whether extreme values of gait characteristics as observed during a single week in daily life are more strongly associated with fall risk than their median values. In particular, we determined the added value for fall-risk assessment of such extreme values of gait characteristics above the median values.

The characteristics with an extreme that had a univariate association stronger than the median, that is, high regularity and harmonic ratio, and low frequency variability, local dynamic stability and entropy, seemed to share a strong dependency on situational effects, as indicated for example by their systematic difference between treadmill and daily-life walking [8]. For all of these characteristics, the strongest associations with fall risk were found for the extremes related to a lower fall risk, which indicates that they were the “high gait quality” extremes. This suggests that for these characteristics the optimal performance in daily-life situations provided more information about fall risk than performance in more demanding situations. These optimal performance gait episodes may be recorded in situations that are more comparable between subjects and may consequently provide a better assessment of an individual’s capacities than the median. However, the most representative values in daily life, as quantified by the median, still had stronger associations for most of the characteristics. The fact

that none of the “low gait quality” extremes were found to have a stronger association than the medians suggests that the presence of irregular gait episodes in daily life is not an indication of situations with higher fall risk, but rather an indication of situations that require or permit gait adaptations. Low gait quality extremes may reflect the exposure to environmental constraints, such as imposed by a winding forest track compared to a paved footpath. Moreover, exposed individuals may be those who can cope with such environmental constraints, whereas these are avoided by individuals with acknowledged lower gait quality.

The expected added value of the gait characteristics’ extreme values in daily life above the medians in a fall-risk prediction model was not demonstrated. Although the model including the extremes (Model 3) had a higher AUC than the model with the medians (Model 2), the Monte Carlo permutation test indicated that this difference may have resulted from a combination of chance and an expected improvement due to the replacement of medians with more strongly associated extremes; the *P* value for the improvement found was .19. The improvement of univariate associations found may have been too small to yield a significant effect on the predictive value of the models. Perhaps the high-quality extremes are merely a more accurate estimation of the individual’s capacities and do not provide information about a new concept such as risk-taking behavior. However, the Monte Carlo permutation tests did confirm the previously reported finding that information from trunk

accelerations recorded during a week in daily life significantly improves fall prediction models based on questionnaire data alone [10].

Limitations

The reported AUC and the Monte Carlo permutation test have their limitations. The AUC we reported may have been biased since the AUC was estimated from the same dataset used for the model generation. The presented models should be validated with new or other data, in order to obtain an unbiased AUC. The Monte Carlo permutation test is a method for testing the significance of model improvement by increasing the set of optional parameters. However, in the comparison of Models 2 and 3, we did not add parameters, but rather replaced parameters. It was therefore necessary to compare the change in AUC between permuted and non-permuted data, rather than the AUC itself. This comparison assumed that probability of the improvement of 0.027 (ie, the difference in AUC between Models 2 and 3) is similar for different starting values of the AUC. However, one may assume that such an improvement is less probable when starting with a higher AUC. We can therefore consider the estimated *P* value of .19 as a conservative estimate, since the starting AUC (Model 2) of the permuted data was typically lower than that of the non-permuted data.

Comparison With Previous Studies

The parameters that were incorporated in the model comparison have been previously linked to falling [1,9,10,20], except for lying duration. Lying duration was negatively associated with fall risk, which might be explained by an elevated risk of falling when one is not well rested, assuming that less lying implies

being less well-rested. It may also reflect high fall risk when leaving the bed during the night. Sample entropy was previously found to be associated with falling for the AP direction, but not for the ML direction [20]. Also in this study sample entropy in ML direction was not univariately associated with falling. This hampers the interpretation of its contribution to the model and of its meaning for fall risk in general.

When comparing the results in this study with those reported previously [10], one would expect to find quite similar results since most of the participants (169 out of our 202) participated in both studies. This was indeed the case for the univariate associations. With one exception (local dynamic stability or logarithmic divergence rate in mediolateral direction), all differences in significant associations were still nearly significant with $P < .10$. However, Model 2, which included physical activities and gait characteristics' medians, contained different parameters than the model derived in the previous study [10]. Apparently, the selection of model parameters was sensitive to slight changes in population. The models were in agreement in that both included fall history and a combination of physical activity parameters and gait characteristics.

Conclusions

Several "good gait quality" extremes of gait characteristics were estimated to have a stronger association with future falls than their medians. In particular, epochs with low frequency variability and high regularity, symmetry, and stability may be of particular interest for fall-risk prediction. However, using gait characteristics' extremes in addition to medians did not significantly improve fall prediction models.

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Conflicts of Interest

Since November 2014, Sietse Rispens has been employed by Philips Research Europe, Eindhoven, The Netherlands, which has an interest in the field of fall-risk monitoring.

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Abbreviations

AP: anterior-posterior
AUC: area under the receiver-operator curve
GDS: Geriatric Depression Score
ICC: intraclass correlation
ML: mediolateral
MMSE: Mini Mental State Examination
ROC: receiver operating characteristic
RMS: root mean square
VT: vertical

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Do Extreme Values of Daily-Life Gait Characteristics Provide More Information About Fall Risk Than Median Values?

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Short Paper

Focus Groups Move Online: Feasibility of Tumblr Use for eHealth Curriculum Development

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Abstract

Background: Constructing successful online programs requires engaging potential users in development. However, assembling focus groups can be costly and time consuming.

Objective: The aim of this study is to assess whether Tumblr can be used to prioritize activities for an online younger worker risk reduction and health promotion program.

Methods: Younger summer parks and recreation employees were encouraged to visit Tumblr using weekly announcements and competitions. Each week, new activities were posted on Tumblr with linked survey questions. Responses were downloaded and analyzed.

Results: An average of 36 young workers rated each activity on its likeability and perceived educational value. The method was feasible, efficient, and sustainable across the summer weeks. Ratings indicated significant differences in likeability among activities ($P<.005$).

Conclusions: Tumblr is a means to crowdsource formative feedback on potential curricular components when assembling an online intervention. This paper describes its initial use as well as suggestions for future refinements.

(*JMIR Res Protoc* 2015;4(1):e34) doi:[10.2196/resprot.3432](https://doi.org/10.2196/resprot.3432)

KEYWORDS

Tumblr; focus group; crowdsourcing; curriculum development; Internet

Introduction

Online health promotion programs have been successful in improving understanding and altering behaviors of adults [1-3] and adolescents [4,5]. Previously, Web-based behavior-change technology had not been applied to enhancing the safety and health promotion of younger worker safety. Teenagers and younger adults, aged 14 to 24 years, account for 13.0% (18.1 million/140.2 million) of the US labor force, and their injury rate is approximately twice that of older workers [6,7]. The majority receive little or no training as to safety and their rights

as workers [8]. The National Institute for Occupational Safety and Health (NIOSH)-developed training for this worker group, Youth @ Work: Talking Safety [9], is formatted as a classroom-based curriculum. The PUSH (Promoting U through Safety & Health) project is a NIOSH-funded efficacy trial to move that content online and incorporate a wellness component to extend its reach and achieve the dimensions of Total Worker Health [10].

When online programs are used with tech-savvy teenagers and young adults, the ability to incorporate graphics and interactivity may be particularly important [11,12]. Successful

technology-enabled health promotion programs have engaged their prospective participants in development, using focus groups, interviews, and advisory panels [13,14], aspects especially essential for younger users [15-17]. However, assembling convenience samples of young potential users can be challenging, costly, and time consuming [18].

Tumblr is a free, easily modifiable feature-rich platform that offers features of popular social networking and blogging sites, with easy posting of content, including images and videos. We asked whether Tumblr could be used to present and prioritize components for a younger worker online health protection and promotion program. We present the identified advantages, challenges, and potential future refinements of this technique.

Methods

Participants

Younger workers employed as staff in the aquatics division of a large city parks and recreation program were recruited during the summer of 2012. A letter describing the PUSH study was provided during staff orientation, and all pool workers were offered an opportunity to provide anonymous online feedback concerning different e-learning activities (brief videos, games, written content, and quizzes), with a new Tumblr activity

featured each week. At weekly briefings during their employment period, pool staff supervisors reminded potential participants about Tumblr activities by providing business cards with the website address and prompting workers by offering a healthy food reward each week to the pool with the highest percent participation.

Tumblr Use

Three research assistants explored the Internet to identify brief interactive e-learning activities relevant to worker safety, communication, and healthy lifestyles, such as videos, interactive quizzes, and online games. Potential sites were reviewed and selected to provide a variety of potentially useful formats. Research assistants tracked the time required to select and post Tumblr activities.

Once chosen, activities were embedded on the PUSH project's Tumblr page (Figures 1 and 2). Beneath the activity were open survey items powered by Survey Gizmo, an online survey hosting website. The activity was followed by instructions that survey items were for parks and recreation workers and should only be completed once per individual. The two survey questions were (1) I enjoyed the activity, (2) I learned something new. Both questions were rated on a seven-point agreement scale, from 1 = strongly disagree to 7 = strongly agree. Other than their assigned pool, responses were anonymous.

Figure 1. PUSH Tumblr site with different activities, one of which would be highlighted for assessment each week.

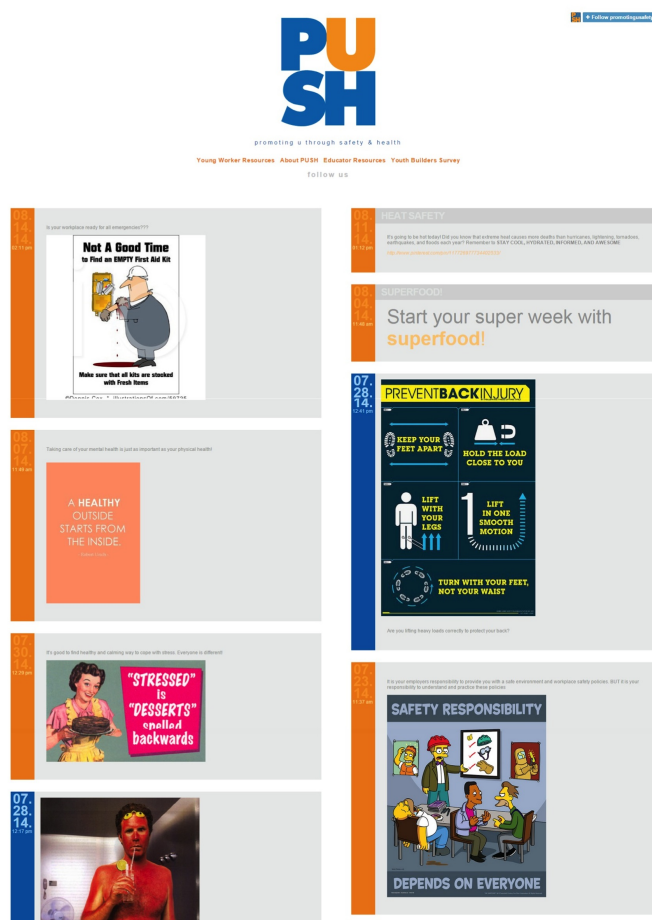



Figure 2. Example of Social Jet Lag video for viewing on Tumblr, with the attached segment from the linked survey that younger workers used to assess the activity.

W4- Buckman, Creston, and Mt. Scott Page One

Social jetlag and its consequences



Using an agreement scale from strongly agree to strongly disagree:

- 1. The daytime sleepiness scale was helpful.**

Strongly Agree Agree Somewhat Agree Don't Agree or Disagree Somewhat Disagree Disagree Strongly disagree
- 2. I enjoyed the "Social jet lag" video.**

Strongly Agree Agree Somewhat Agree Don't Agree or Disagree Somewhat Disagree Disagree Strongly disagree
- 3. I learned something new.**

Analysis

Data for each activity were exported to SPSS, Version 21. Descriptive statistics were compiled, and ratings among activities were compared with ANOVA.

This project was a sub-study of a larger assessment that involved an additional confidential online survey completed by participants [19]. The overarching objective was to develop content that would enhance development of the PUSH online curriculum, a Web-based worker safety and health promotion program for younger workers. The Oregon Health & Science University Institutional Review Board approved the study materials and procedures.

Results

Participant Demographics and Technology Use

Tumblr assessments were a component of a larger project to identify the current habits and educational needs of younger workers, and those findings have been reported [19]. The participants were a convenient sub-sample of that study. For

the entire group, the mean age was 17.9 (SD 2.3), 87.2% (163/187) were white, and 65.2% (122/167) were female. As a group, 96.8% (181/187) used the Internet daily, 73.8% (138/187) checked Facebook each day, and 13.9% (26/187) visited Tumblr daily.

Activities Assembly and Likability and Learning Ratings

The seven assessed activities are shown in [Textbox 1](#) in the order that they were presented across the summer weeks. The three research assistants estimated each allowed 60 minutes per week to search for potential sites, and another 20 minutes comparing their best finds to decide on that week's activity. Thirty minutes was needed to post the activity and survey questions, and another 30 minutes to download and analyze that week's results. Pool recreation workers were reminded about that week's activity and contest during their usual Monday supervisor briefing. Another two hours per week was needed to determine pool participation and provide the healthy food offering to the winning pool. The total time needed each week was approximately 6.5 hours.

Textbox 1. The seven assessed activities.

Assessed activities

- Communication style self-assessment quiz
- Violence: news story about workplace shooting
- Self-assessment quiz about definition and types of harassment
- Speaking up: animated video about worker rights, responsibility, and self-advocacy
- Stress comical video
- Brief documentary-style video about jet lag and sleep debt
- Animated comical video highlighting workplace injuries

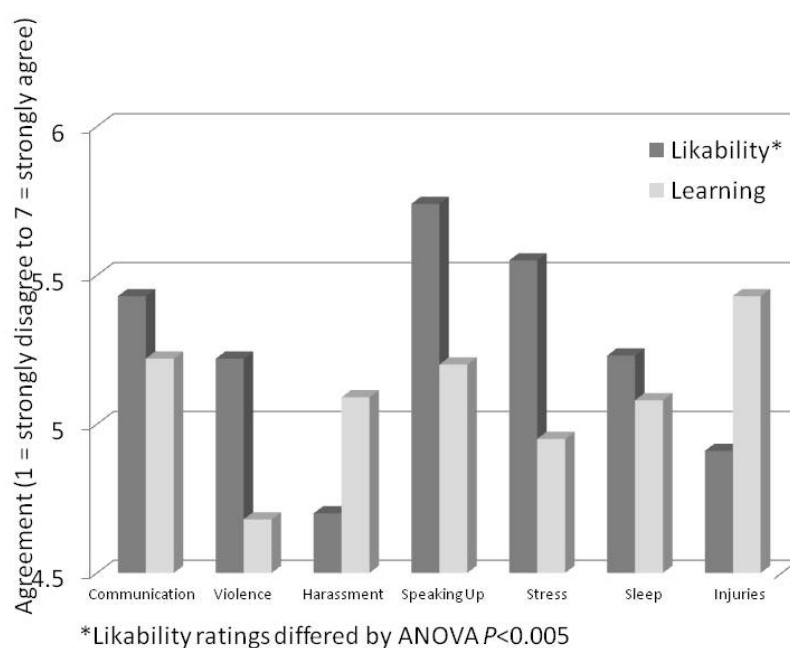
A mean of number 36.1 (SD 17.6) assessments (range 22-63) were received for each of the seven activities. The mean percentage of workers present at the weekly briefings was 30.0% (SD 18), and the range was wide at 7.0-71.0% across the 13 pools. Having access to a computer at the pool appeared to

facilitate participation. For the activities, mean likability and learning varied, and the two scores did not parallel each other (Table 2 and Figure 3). Although there was no significant difference among the perceived learning ($F_{6,251}=0.96$, $P=.45$), likability differed among activities ($F_{6,246}=3.35$, $P<.005$).

Table 2. Mean likeability and perceived learning.

Activity	Likability ^a mean (SD)	Learning mean (SD)
Communication	5.43 (1.04)	5.22 (1.57)
Violence	5.22 (1.48)	4.68 (1.82)
Harassment	4.70 (1.52)	5.09 (1.26)
Speaking Up	5.74 (0.97)	5.20 (1.03)
Stress	5.55 (1.23)	4.95 (1.63)
Sleep	5.23 (1.42)	5.08 (1.78)
Injuries	4.9 (1.72)	5.43 (1.16)

^aDifferences among ratings by ANOVA $P<.005$

Figure 3. Likeability and learning ratings for Tumblr posted activities.

Discussion

Principal Results

This is the first description of using Tumblr and a linked survey to obtain formative information for online curriculum development. The method was feasible and easily implemented with limited resources. Feedback was acquired using a method that simulated how the activities ultimately would be used in an online Total Worker Health enhancement program for younger workers.

Our planned intervention platform is a cTRAIN system that uses self-paced informational screens and periodic learning self-assessments [20]. Although the system has been shown to increase knowledge, a concern was that its relatively static images would not engage younger workers to complete the program. Tumblr was used to identify more dynamic and engaging activities to punctuate the curriculum. Ratings for likability differed significantly among posted activities, which allowed prioritizing their use in the online worker health protection and promotion program.

Using this method required access to a group with computer access that was motivated to repeatedly visit the site and comparable to those targeted in the intervention. The survey responses allowed activities to be ranked and identified significant differences in likability. The time required to assemble, post, and analyze activities was much less than would have been needed to recruit, conduct, and analyze group interviews with this number of respondents. Three refinements would enhance this method's future use. Response rate was relatively low, and individual incentives, used in other aspects of this project, may have been more effective than the pool-wide

competitions. In addition, although ratings allowed for sites to be prioritized, presenting more than one activity simultaneously and asking participants to rank rather than individually score offerings may have been more discriminatory. Finally, although inexpensive and efficient, findings lacked the richness of a facilitated discussion and adding a blog feature and chat wall might have provided more formative data. However, our goal was to select among existing components rather develop new content, and for that purpose, this method was acceptable.

Limitations

This novel use of Tumblr for curriculum development has limitations. Our sample was younger than older adults who may visit the Web less often, and this process may not be as applicable with other less technology savvy groups. In addition, the process worked well for selecting among activities rather than designing formats. For the latter, the ability to query focus group participants would be useful. However, Tumblr use was an efficient means to obtain feedback from a range of participants without the time and expense needed to convene, conduct and analyze multiple focus groups.

Conclusion

Tumblr use might be considered a type of crowdsourcing, a term used to describe when online tasks are performed by a network of people responding to an open call [21]. Initially used for computer-coding tasks, it has expanded to product development and marketing research [22]. Data gathered in these ways are comparable to more traditional paradigms, while being cheaper, easier and faster [23-25]. As interventions are developed and moved online, using the same vehicle to virtually focus group input is a logical extension. These novel findings provide a guide to that process.

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Conflicts of Interest

The e-learning software mentioned, cTRAIN, is distributed through the Northwest Educational Training & Assessment Center. Dr Rohlman has a financial interest from the commercial sale of technologies used in this research. This potential conflict of interest has been reviewed and managed by the OHSU Conflict of Interest in Research Committee.

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Abbreviations

NIOSH: National Institute for Occupational Safety and Health

PUSH: Promoting U through Safety & Health

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Letter to the Editor

“What Is eHealth”: Time for An Update?

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Abstract

The annual number of articles reporting on eHealth interventions has increased over the last 10 years. In contrast, the last article in this journal on the definition of eHealth was published in 2006. This leads to the question whether the field itself has reached consensus about the definition and description of eHealth or whether it is in need for a new review of the literature and a new description of the rapidly changing field of eHealth. Since the JMIR community has successfully collaborated on the “CONSORT-eHealth” in the past, we would like to use the same strategy to explore the need for a new definition of eHealth and the creation of a taxonomy for this field. Therefore, we hereby submit a call to all JMIR-readers, to fill out a 4-question survey on their ideas about a refined eHealth definition. Based on these results, we will decide whether or not to engage in a systematic review. Logically, the entire JMIR community is invited to join us in our attempt to further elucidate the field of eHealth.

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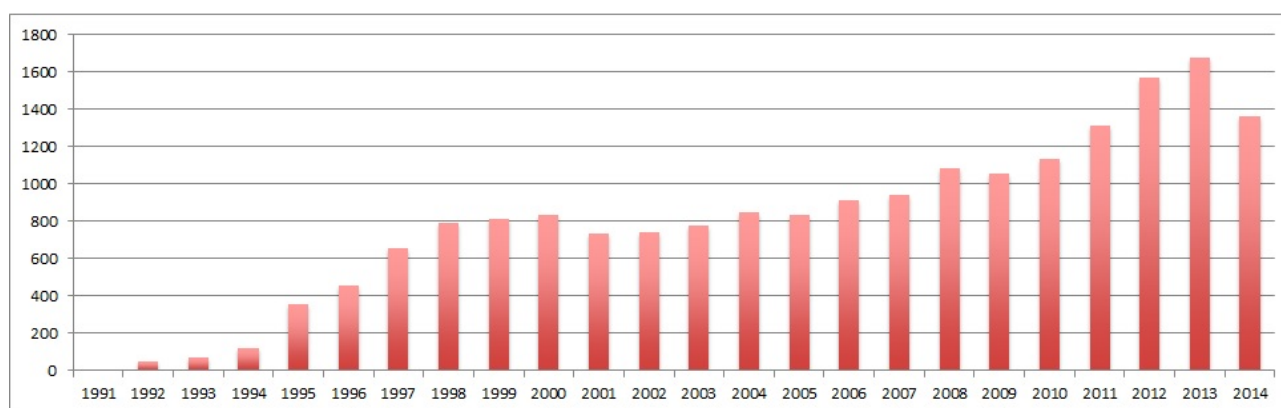
In 2001, the editor of the Journal of Medical Internet Research, Gunther Eysenbach, reported on the need for defining eHealth [1]. In what would be the first article of the “What is eHealth” series, he defined eHealth as follows:

eHealth is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and

worldwide by using information and communication technology.

Subsequently, Eysenbach invited researchers to explicate their views on the definition of, which together would elucidate the realm of eHealth. This invitation led to a series of papers reporting about definitions concerning eHealth.

In reaction to Eysenbach’s invitation, Della Mea [2] described eHealth as a popular term which scientists have adopted from the fields of commerce and economics. Instead of providing a uniform definition, Della Mea described eHealth as a broad term that encompasses multiple domains. In the following years, the field of eHealth expanded and the number of eHealth related studies increased (Figure 1).

Figure 1. Number of papers mentioning eHealth per year in Pubmed (search conducted in fall 2014, 2014 is therefore incomplete).

However, except for Eysenbach's broad definition of 2001, a clear uniform and comprehensive definition of eHealth and its domains was still lacking. Four years had passed when, in 2005, Oh et al [3] pointed at the problem which arose from the lack of a definition for eHealth: How can we communicate about a phenomenon when that phenomenon is not clearly defined? In a qualitative, systematic review, they found 51 unique definitions for eHealth. Although health and technology were mentioned in all 51 definitions, a uniform description of these general terms were missing. In 2005, Pagliari et al [4] referred to the same problem (the lack of a clear and uniform definition) in the light of archiving and retrieving eHealth studies. In their qualitative study, Pagliari and colleagues found 36 different definitions. They discovered that most definitions applied to the functional scope of eHealth rather than to specific applications. Based on their findings, the authors concluded that the definition posted by Eysenbach sufficed, although they made some adjustments:

eHealth is an emerging field of medical informatics, referring to the organization and delivery of health services and information using the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a new way of working, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology.

In contrast to their fellow "What is eHealth?" contributors, who concentrated on the definition of eHealth, Jones et al [5] published an article in 2005, in which they described stakeholders' views on the concerns and promise of eHealth in future research. They discovered that the views of the various stakeholders were, surprisingly, not that different; their main recommendations were that the scope of eHealth research should be on using, processing, sharing, and controlling information. Unfortunately, it did not lead to a new definition, which was

also noticed by Ahern et al [6]. In this most recent article in the "What is eHealth" series, which was published in 2006, the authors clearly underscore the need for a more coordinated and rigorous attempt to define the field of eHealth [6].

In addition to the wish for a uniform definition of eHealth, the availability of related terms such as Medicine 2.0, Web 2.0, Health 2.0, mHealth, Telecare and Telehealth may be confusing. Although not identical, there seems to be a lot of overlap, and different terms are used interchangeably throughout literature [6]. The articles in the "What is eHealth" series, point out that eHealth related research encompasses a broad field that ranges from theory development to large randomized controlled trials. What's more, usage of eHealth differs per health care setting or even per person, varying from interventions or services such as apps, websites, online discussion groups to real-life medical data collection, for instance by using wearables. This supports the need for a clear uniform description of eHealth and an attempt to compose a comprehensive overview of the various domains in the eHealth field. As such, it would be very interesting to investigate whether a taxonomy of the broad field of eHealth, including related topics, would lead to a better definition of the various domains within eHealth.

The annual number of articles reporting on eHealth interventions has increased over the last 10 years (see Figure 1). In contrast, the last article in this journal on the definition of eHealth was published in 2006. This leads to the question whether the field itself has reached consensus about the definition and description of eHealth or whether it is in need for a new review of the literature and a new description of the rapidly changing field of eHealth. Since the JMIR community has successfully collaborated on the "CONSORT-eHealth" in the past, we would like to use the same strategy to explore the need for a new definition of eHealth and the creation of a taxonomy for this field. Therefore, we hereby submit a call to all JMIR-readers, to fill out a 4-question survey on their ideas about a refined eHealth definition. The results of this survey will be published in the Journal of Medical Internet Research. Based on these

results, we will decide whether or not to engage in a systematic review. Logically, the entire JMIR community is invited to join us in our attempt to further elucidate the field of eHealth.

Survey

<http://tinyurl.com/eHealthdef>

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Original Paper

Care Models of eHealth Services: A Case Study on the Design of a Business Model for an Online Precare Service

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Abstract

Background: With a growing population of health care clients in the future, the organization of high-quality and cost-effective service providing becomes an increasing challenge. New online eHealth services are proposed as innovative options for the future. Yet, a major barrier to these services appears to be the lack of new business model designs. Although design efforts generally result in visual models, no such artifacts have been found in the literature on business model design. This paper investigates business model design in eHealth service practices from a design perspective. It adopts a research by design approach and seeks to unravel what characteristics of business models determine an online service and what are important value exchanges between health professionals and clients.

Objective: The objective of the study was to analyze the construction of care models in-depth, framing the essential elements of a business model, and design a new care model that structures these elements for the particular context of an online pre-care service in practice.

Methods: This research employs a qualitative method of an in-depth case study in which different perspectives on constructing a care model are investigated. Data are collected by using the visual business modeling toolkit, designed to cocreate and visualize the business model. The cocreated models are transcribed and analyzed per actor perspective, transactions, and value attributes.

Results: We revealed eight new actors in the business model for providing the service. Essential actors are: the intermediary network coordinator connecting companies, the service dedicated information technology specialists, and the service dedicated health specialist. In the transactions for every service providing we found a certain type of contract, such as a license contract and service contracts for precare services and software products. In addition to the efficiency, quality, and convenience, important value attributes appeared to be: timelines, privacy and credibility, availability, pleasantness, and social interaction. Based on the in-depth insights from the actor perspectives, the business model for online precare services is modeled with a visual design. A new care model of the online precare service is designed and compiled of building blocks for the business model.

Conclusions: For the construction of a care model, actors, transactions, and value attributes are essential elements. The design of a care model structures these elements in a visual way. Guided by the business modeling toolkit, the care model design artifact is visualized in the context of an online precare service. Important building blocks include: provision of an online flow of information with regular interactions to the client stimulates self-management of personal health and service-dedicated health expert ensure an increase of the perceived quality of the eHealth service.

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KEYWORDS

eHealth; business model innovation; strategic design; precare; service design; visual modeling method; care model

Introduction

Implementation Barrier of eHealth Services

Innovative eHealth technologies have the potential to provide solutions for several challenges within health care, including the growing number of chronic diseases, rising shortage of health staff, and the pressure to increase cost savings within healthcare [1-4]. An illustrative example is an eHealth service for diabetes that provides state-of-the-art technologies that have the potential to assist health care professionals, patients, and informal carers to better manage diabetes insulin therapy, help patients understand their disease, support self-management, and provide a safe environment. Yet, in order to realize these potential benefits, new designs of care models are required [5-7].

A growing number of scholars at the intersection of medical informatics, public health, and business are investigating eHealth and related technologies [3]. The Internet and mobile applications inspire new business model innovations. These Internet technologies lead to drastic changes in the way that organizations interact [8]. Despite the growing awareness of the importance of business model design, the nature of business model design has received little attention. To date, research has concentrated on piloting Internet and related technologies in diverse care and cure contexts, with less attention paid to the business interactions between organizations. There is a lack of in-depth knowledge on the network organizations influencing eHealth services. Most studies have targeted the care and cure phase of the health care chain. So far, academic research has not emphasized business model design in this early phase of the health care chain. To contribute to this research area, the present paper aims to generate an improved understanding of how to design a business model in order to overcome the implementation barrier of eHealth services; in particular, we seek to arrive at an in-depth understanding of the value exchanges within precare service interactions. This paper adopts the following definition of precare, “health-protective behavior before the actual care phase” [9].

Theoretical Background on Business Model Design

Business model design was conceived when online services such as those provided by Amazon were established, and new constructs were needed for the purpose of explaining and improving the understanding of this phenomenon of eBusiness [10]. At that time, eBusiness start-ups even patented a number of business model innovations, confirming that this was a new locus of innovation that went beyond advanced information and communication technology (ICT) systems and the service itself [11,12]. Since then, the theoretical understanding of business models has advanced in the field of strategic management. Different streams of research have been established with different orientations. For example, McGrath [13] emphasizes a discovery-driven rather than analytical approach in which new insights are created by engaging in significant experimentation and learning. Casadesus-Masanell and Ricart have pointed out that “the exercise of designing new business models is closer to an art than to a science” [14]. Few approaches have appealed more to the abilities of strategic designers than this strategy approach of “modeling, experimentation, prototyping, and

discovery” of business models. However, artifact examples of business models are hard to find, and there is a lack of modeling approaches. This study provides a design perspective that pays specific attention to the visual nature and artifact design of a business model for an online service. Our objective is *to analyze and design a business model for precare services*. To design a model, it is vital to have an understanding of care model characteristics. Internet technologies have created new opportunities in health care and changed the way in which actors within these business models interact. The construction of care models is studied in-depth by framing the essential elements of a business model, and design a care model that structures these elements for the particular Internet technology-enabled precare service context.

Design Challenge

Internet technologies create new opportunities for eHealth service provision and change the way in which actors interact within new models of value exchange. Although the clinical results of eHealth innovations have proved to be very promising, their implementation is not so straightforward. In fact, problems have been encountered in the adoption of most eHealth innovations [15]. To decrease the failure rate of eHealth service innovations, business model innovation should be given high priority at the start of a project and further developed in iterative loops [16]. The main barrier in adopting online service innovations, besides budgetary limitations, is the organizational model; eHealth services appear not to fit with the organizations of the health care providers. At the organizational level, research has found a gap in understanding the network organization needed between health care providers, receivers, and technology-oriented companies [15]. Prior studies, from a design perspective, have explored eHealth services and their business models, and found that most of the value propositions of eHealth services do not match the real needs of medical professionals and clients [8]. When asked to deliberate on how eHealth could enable them to work more effectively, efficiently, and professionally, both general practitioners and specialists first mentioned quality as the most important value of business model innovation in eHealth. In addition, they expect eHealth technologies to enable better, clearer, and easier communication between different health professionals and care organizations, thereby increasing the level of convenience [17]. Whereas current propositions focus on costs and efficiency, health professionals prefer an emphasis on performance quality and convenience from their perspective of professional practice [18]. The design challenge is to define the properties of these values and model the structure and the design of transactions between actors in order to create such values [8].

Essential Characteristics of Business Model Design

Network Structure

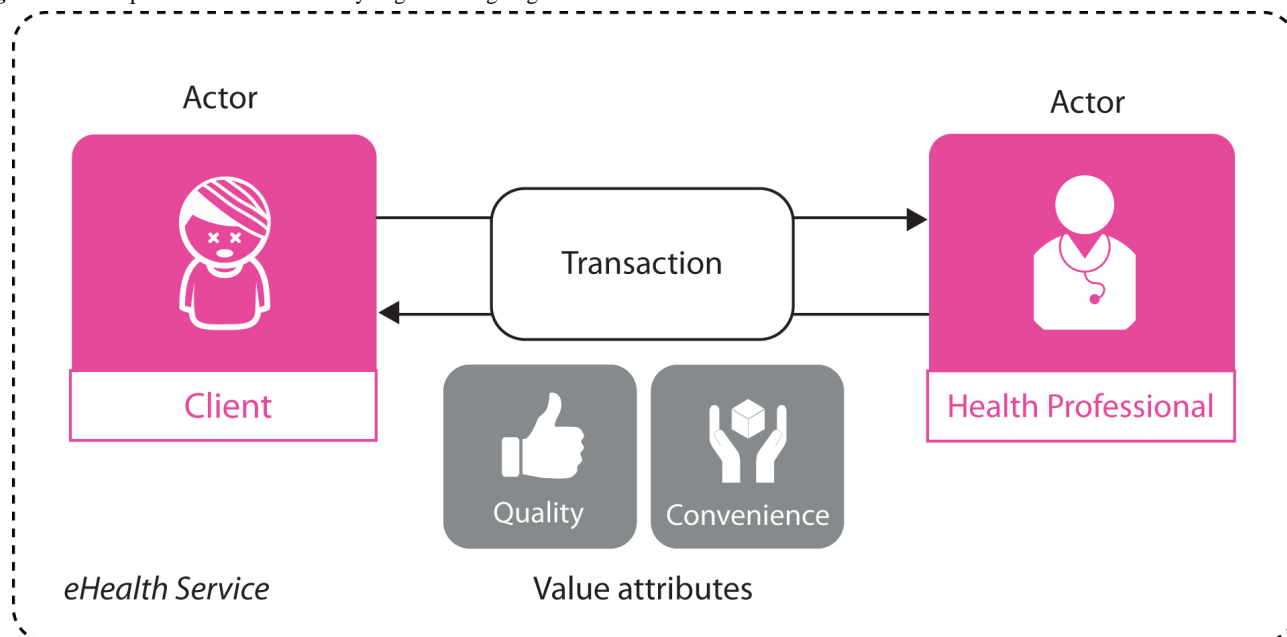
For designing a business model, it is essential to understand its characteristics. First, the business model should be an integrative network model, integrating a network organization with network technology [11,12,19]. The source of innovation is the information and communication technology that enables new models of networked business organization. The network organization includes resources from partner organizations,

including customers at home and nonprofit organizations [8]. Such an intrafirm network structure of the business model mediates between technology and economic value, which is an important characteristic of constructing a business model [20]. For the design of a business model, the unit of analysis is the network structure that includes social, technical, and economic elements: The social element is the *network organization*, integrated with the technical element of *Internet and mobile technology*, and in exchange with the economic element of *financing*. The network structure is inherent to a business model, and according to Amit and Zott [21], does not relate to one organization, but to strategic networks [22] and connecting across the boundaries of one organization [16,23]. Furthermore, in considering the business model as unit of analysis and design, it is interesting to distinguish it from what a business model is not. A business model is not a marketing model or only a pricing or revenue model. Nor is its business component in isolation, such as only a value proposition or network structure. Neither is a business model a policy or strategy, such as a corporate strategy, market adoption strategy, or product market strategy. A business model is not even a business process [24]. Although business models are generated for a single firm context, many practitioners used the “business model canvas” [25] for this purpose; the real design challenge is to connect the value propositions and finance in a network structure design [23,26]. The business model canvas frames the standardized elements of a business model. However, just as a SWOT (strengths / weaknesses / opportunities / threats)-canvas does not model a strategy, neither does this canvas model the business model, in the sense of providing an artifact design of the model. The standardized building block elements are neither connected by transactions, nor visualized by a model structure of the network that uniquely identifies the business model. To some extent this canvas appears to be useful, for example, for the analysis and overview of business model elements of the individual firm perspective, but for the design and modeling of a business model, it is not well equipped [8]. The design challenge in our case is using the network structure with an

additional toolkit to construct the business models. Second, we extract, as essential elements, from the most cited definition of a business model by Amit and Zott [21], “A business model depicts the content, structure, and governance of transactions designed so as to create value through the exploitation of business opportunities”: (1) “transactions” refer to the network exchanges between organizations; and (2) “value”, which seems to be the most essential element, refers to the purpose of the business model, that is, creating value for customers in transaction with business partners. When we consider the network structure as the unit of analysis of the business model, the core properties that appear to be relevant are the transactions and the value. Teece [27] describes value creation and value delivery as essential properties of a business model. For him, the essence of a business model is in defining the manner by which the enterprise delivers value to customers, entices customers to pay for value, and converts those payments to profit. Chesbrough and Roosenboom [20] indicate that a business model provides a structure of the value chain and describe the position of the firms within the value network. The firms’ organizations and the person representing the organizations are the actors in the value network of service providing. With regard to the modelling challenge of designers, we postulate to model the network structure of actors and value transactions. Using and advancing these essential business model characteristics, the design of a business model can be reframed as, *visually modeling a network structure of actors and value transactions*.

The conceptual framework visualizes the essential elements for analyzing and designing a care model (Figure 1 shows this). The framework focuses on the values of convenience and quality for the clients who make use of the eHealth service offered by the health professional. The most essential transaction in an eHealth service proposition that creates value by providing quality and convenience occurs between these two actors, and thus we frame this transaction as the starting point of business model design.

Figure 1. Conceptual framework for analyzing and designing a care model.



Actors

We follow Herzlinger, who suggests putting the client in charge of health care in order to generate more freedom of choice, openness, and transparency in the design of business models [28]. Designing from a client perspective can give insight into the tighter relationship between actors who create and deliver value to the client. The client is therefore placed in the center of the conceptual framework. We define the client actor as, “a person using the services of a professional organization” [29]. These services are provided by the health care professional, the second actor in the conceptual framework. The health professional can be the specialist, the general practitioner, nurses, etc. When designing a business model, additional interactions with other actors need to be investigated further.

Transactions

We follow Amit and Zott, who relate transactions to both the economic theory of transactions and the network theory in organizational behavior [21]. The primary, most important transaction in the conceptual framework is the customer value proposition defined by Johnson et al as, “how the health professional creates value for the client by providing a solution for a fundamental problem in a given situation” [30]. By definition, the transactions are reciprocal in nature. In return for the value proposition, the client pays a fee, subscribes to an insurance policy, and pays tax to the government for public health facilities and services. This part of the transaction in the conceptual framework is the monetization, concerning when and how money is raised, as defined by Baden-Fuller and Mangemartin, “Monetization involves more than just pricing (the economists concern), but includes systems determining timings of payments and methods of collecting revenues” [31]. This financial exchange part of the transaction builds on the market innovation approach of Kim and Mauborgne, who

analyzed pricing in relation to cost targets and partner capabilities in the value network relations. The types of monetization they introduced include direct selling, leasing, time share, slice-share, and equity payment [32].

Value Attributes

Value attributes can be attached to transactions. These attributes—the potential properties of transactions—can add value to both the perceived quality and convenience of the eHealth service for the client. For instance, “quality value” is focused on improving the product or service performance, and “convenience value” is defined as “making products or services more convenient and easier to use” [25]. When designing a business model, it is essential to create value for the customer. Ostenwalder identified three types of customer value. The first, use value, is provided by the actual use of a product or service (eg, driving a car) when its attributes (eg, features, design, support, etc) correspond to the client’s needs and expectations. The second, risk reduction value, reduces the client’s risks (eg, car insurance), such as by alleviating financial fears and providing buy-back guarantees. Insurance contracts provide this value. The third, effort value, makes the client’s life easier (eg, home delivery of groceries); by reducing efforts that are time consuming and/or require specific skills [25]. In eBusiness, this last type of effort value also works the other way around. When the customer fills out the order forms and other administrative details, this reduces the effort of the eBusiness firm. This Internet-enabled efficiency makes it possible to lower the price (cost value) and also provides great potential for lowering the organizational health care cost. In prior research, medical professionals have stated that they favor performance quality and convenience value over cost and efficiency value. The medical professionals showed the least interest in novelty, design, and brand value [8].

Table 1. Care model constructs.

Element	Construct	Definition
Actor		In the value network of service providing, the firm, the organization [33], and the person(s) representing the organization.
	Health professional	A professional working at a health care providing service organization, such as the medical specialist, the general practitioner, specialized nurse, etc.
	Client	A person using the services of a professional organization [29].
Transaction		Reciprocal exchange of value. Core transaction, value proposition in return for monetization.
	eHealth value proposition	Providing a solution for a fundamental problem in a given situation [30] of online service providing of health care by Internet- and mobile-based applications and technologies [3].
	Monetization	When and how is money raised? Monetization involves pricing including the systems determining timings of payments and methods of collecting revenues [34]. Such as direct selling, leasing, time share, slice-share, and equity payment [35].
Value attributes		Properties of transactions, that add value to the use, effort experience, and risk reduction [25] of the eHealth service.
	Quality	Value of improving the product or eHealth service performance [25].
	Convenience	Value of making products or services more convenient and easier to use [25].

Research Question

In this study, we further investigate the construction of business models in depth by framing the essential elements of actors, transactions, and value attributes. In order to design a business model that structures these elements specifically for the Internet technology-enabled precare service context, we address the following research question, “What characteristics of business model design in precare contribute to the convenience and quality of eHealth services provided by a health professional to a client?”.

To deconstruct the service relationship between the client and the health professional, a designerly modeling approach is valuable in locating the different actors, transactions, and value attributes that fit the preferred value proposition focusing on the convenience and quality of eHealth services. These elements of a business model are a steppingstone in the creation of building blocks; compositions of actors, transactions, and attributes that are valuable in the design of business models of eHealth services within the precare phase.

The next section addresses the Methods in which we report on the research method and the toolkit developed for the visual design of business models. Then the Results section provides an empirical analysis of the actors’ perspectives on the business model for a precare service and presents the newly designed business model artifact for this precare service. In the final section, we draw conclusions and discuss the research limitations and suggestions for future research.

Methods

Case Study

Selection

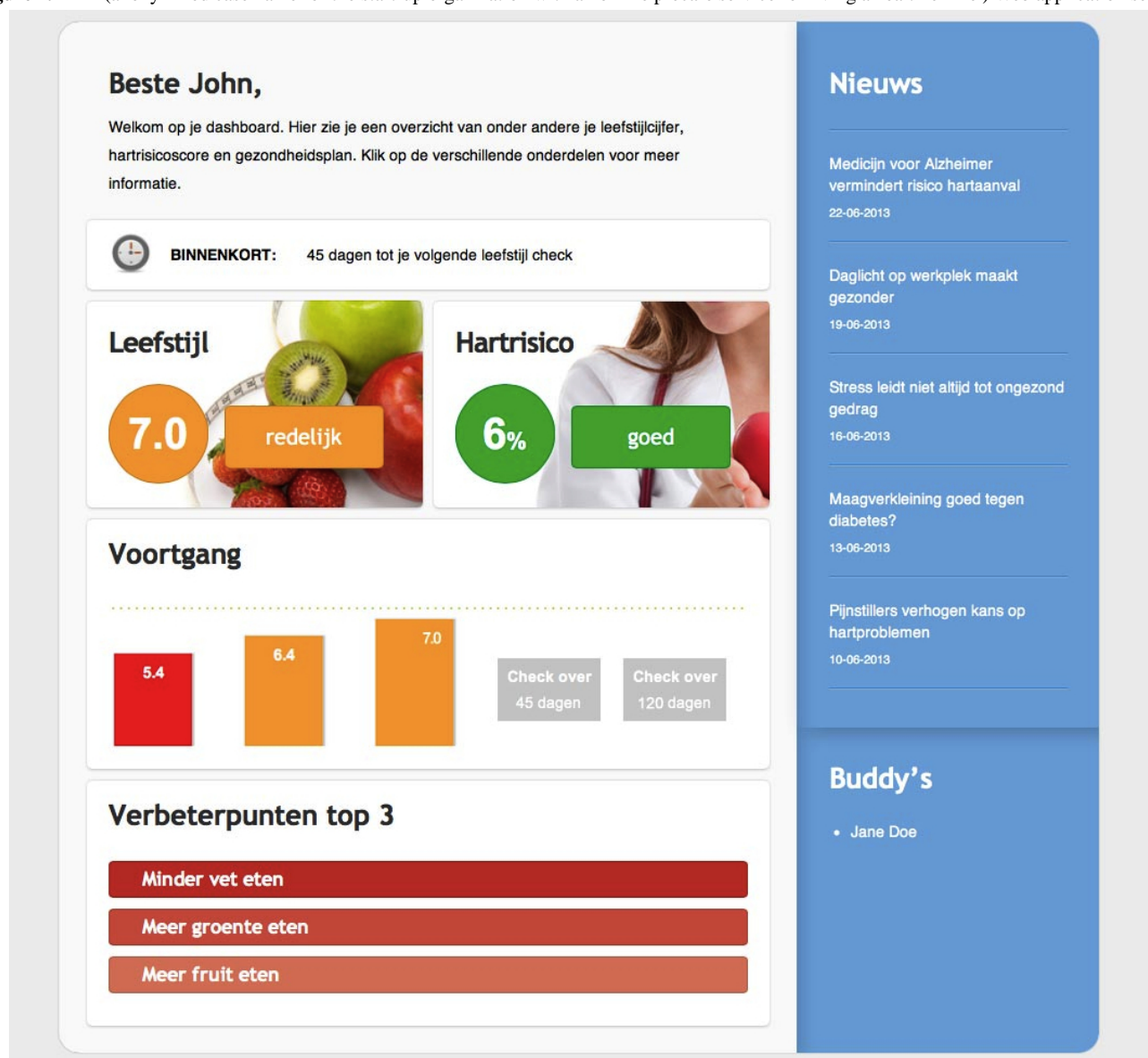
To arrive at a better in-depth understanding of the business-modeling phenomenon within its real-life context, we adopted a case study method [34]. Case study research, when it is convincingly grounded in the evidence, can generate frame-breaking insights [34]. We selected an innovative eHealth

case, PRE (anonymized case name for the start-up organization with an online precare service for living a healthier life), an online precare service that fits the purpose of the research. As a baseline for the point of departure, we define the relationship between the two actors: the client and the health professional (Figure 1). The client actor in a precare context is the person who engages in some type of health-protective behavior [9]. According to Haris and Guten [9], the major concerns are the health beliefs of individuals (clients) and their settings, and the environmental cues to action or characteristics of the health care delivered to them that can be modified in the design of a business model. Health-protective activities include direct contact with a health care professional, the second actor in the conceptual framework. Exploring this transaction relation in practice from different viewpoints, and by further deconstructing the details, helped in the identification of valuable care model characteristics. We used a visualization method to turn the implicit business model into an explicit model. In a structured and visual way, we collected data on the actors, transactions, and performance attributes of the online precare service. We then conducted a within case analysis, including the different perspectives involved in the e-service. Based on the analysis, we constructed the design for the business model.

Case PRE

PRE is a start-up organization launched by a professional cardiologist. The purpose of PRE is to make clients aware of their lifestyle and heart risk by supporting them with an online service for living a healthier life. On the PRE Web application, a client creates a personal online account and gets feedback information, including a grade for his or her personal lifestyle and a percentage chance of heart failure. These results are based on an online questionnaire (up to 300 questions), and a small physical examination (taking blood for glucose levels). PRE regularly gives advice on how the client can improve his or her lifestyle, and provides the client with a lifestyle score, updated bimonthly (Figure 2 illustrates an example screen of PRE’s Web-based services).

Figure 2. PRE (anonymized case name for the start-up organization with an online precare service for living a healthier life) Web application service.



Data Collection

Purposeful sampling was used to take a closer look at a relevant eHealth situation, the PRE case. An in-depth investigation of different perspectives was conducted in order to study a variety of views, rather than the mean or average. The sample of data collection (Table 2) includes the capturing of the individual perspectives of five respondents involved in the online health protection service. In total, five respondents were consulted, and six visual models were created.

The PRE service has been implemented as a full operational service after a pilot implementation to ensure the quality of the online service. There were two clients that experienced the system for a minimum of two months that were invited to join an interactive session. Furthermore, a cardiologist (owner of PRE), a manager, and a precare specialist participated in an interactive session. The data were collected over a time span of three weeks. With interactive sessions, participants were guided to deconstruct business models associated with the PRE service.

Table 2. Sample of participants in interactive sessions.

Network actor	Respondent	Interview	Visual model
PRE care service provider	CEO ^a /cardiologist	1	1
Intermediar	Manager	1	1
Occupational health	Precare specialist	1	2
Client	Client X	1	1
	Client Y	1	1
Total	5	5	6

^aCEO = Chief Executive Officer

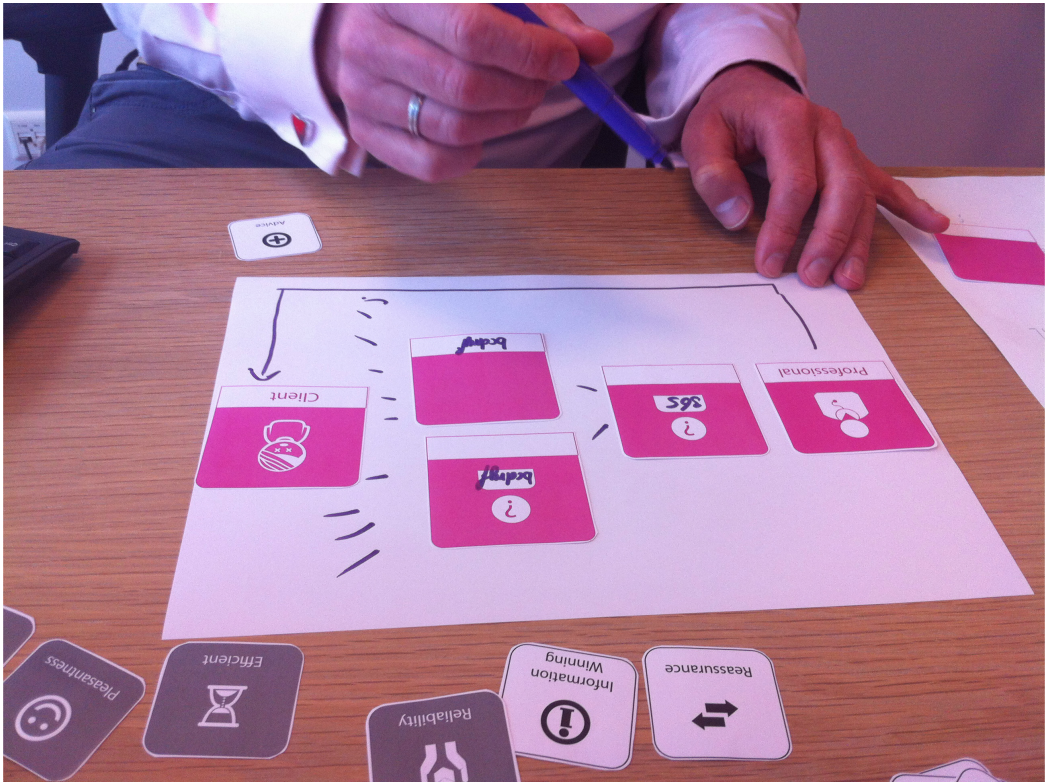
Visual Business Modeling Method

In the data collection, a visual modeling method was used to support the participant in deconstructing the business model into separate actors, transactions, and valuable attributes. The researchers developed this toolset by combining the toolsets of the visual brainstorm method of the Board of Innovation [36] with the Netmap method used for field studies [33]. This type of actor map toolset is interview-based, and aims to visually capture the connections with many stakeholders and evaluate the types of interactions [8]. The visual business modeling method is a tool that consists of 16 different icons to visualize all types of business ideas, adjusted to the scope of the study by the researchers. The toolset consists of preprinted and “open” cards that can be filled in by the respondent. The preprinted cards are based on the conceptual framework (Figure 1). These cards, starting with two cards for the actors (the client and health professional), contain eight types of transactions and nine attributes that could contribute to the perceived quality and convenience of the eHealth service. Blank cards were included

to allow the participants to identify important actors, transactions, or attributes that were not on the tool’s predefined cards. Figure 3 shows one of the participants using the cards during an interactive session.

Each participant was asked to visualize the business models concerning the PRE service by using blank sheets of paper, markers, and the mapping toolset (Figure 3). These interactive sessions were guided by an interview protocol consisting of five subtopics. First, the different actors involved in the business models were allocated to roles by asking the interviewee to pick the corresponding actor cards or write new actors on the blank cards. The second part focused on the connections between those actors, and the third part on the characteristics of these connections, that is, the transactions. Fourth, if applicable, values that contribute to the perceived convenience and quality of the service were ascribed to the related transactions. The visual modeling method made use of red flags to mark the most important attributes. All interviews were recorded. Within-case evidence was acquired by analyzing the records, taking notes, and combining the notes with the created visual models.

Figure 3. Impression of the use of the visual business modeling method during the interactive sessions.



Data Analysis

There were three types of data that were analyzed: (1) visual modeling data, (2) interview data, and (3) documented data. All the types of qualitative data were combined to frame, analyze, and synthesize the business model view of each respondent. The visual business models created by the participants were analyzed by means of a comparative analysis. The in-depth analysis of different perspectives meant that a variety of views, rather than the mean or average, were investigated. By analyzing the different visual models created from the different perspectives, the created models were transcribed into digitalized models. When comparing these models and extracting valuable actors, transactions, and attributes, conclusions were drawn regarding the elements contributing to the convenience and quality of the service. Based on these insights, building blocks were created that can be used in the design of an eHealth service. For the building block design, the actor-transaction toolset was used as a basis for designing the new business model for the precare phase of care.

Results

New Identified Actors

The framing of all business model views resulted in the identification of important actors, transactions, and value attributes. In addition to the two client and health professional actors in the conceptual framework, eight new actors were identified, framed with eight different types of transactions and six additional value attributes.

There were three actor perspectives that were synthesized from the six individual business model views. Figures 4 and 5 show the evidence of two of these business model views that have been cocreated and digitalized. The generated insights from the comparative analysis of these visual business models are presented in the following paragraphs. For each of the three perspectives, the new insights are described regarding the type of transactions between newly identified actors, and their perceived valued attributes from online PRE service. The first perspective is from the online service provider, the second from the network coordinator, the intermediate organization in occupational health services, and the third perspective is from the clients working at a company that has contracted the occupational health services.

Figure 4. Business model view A from client perspective.

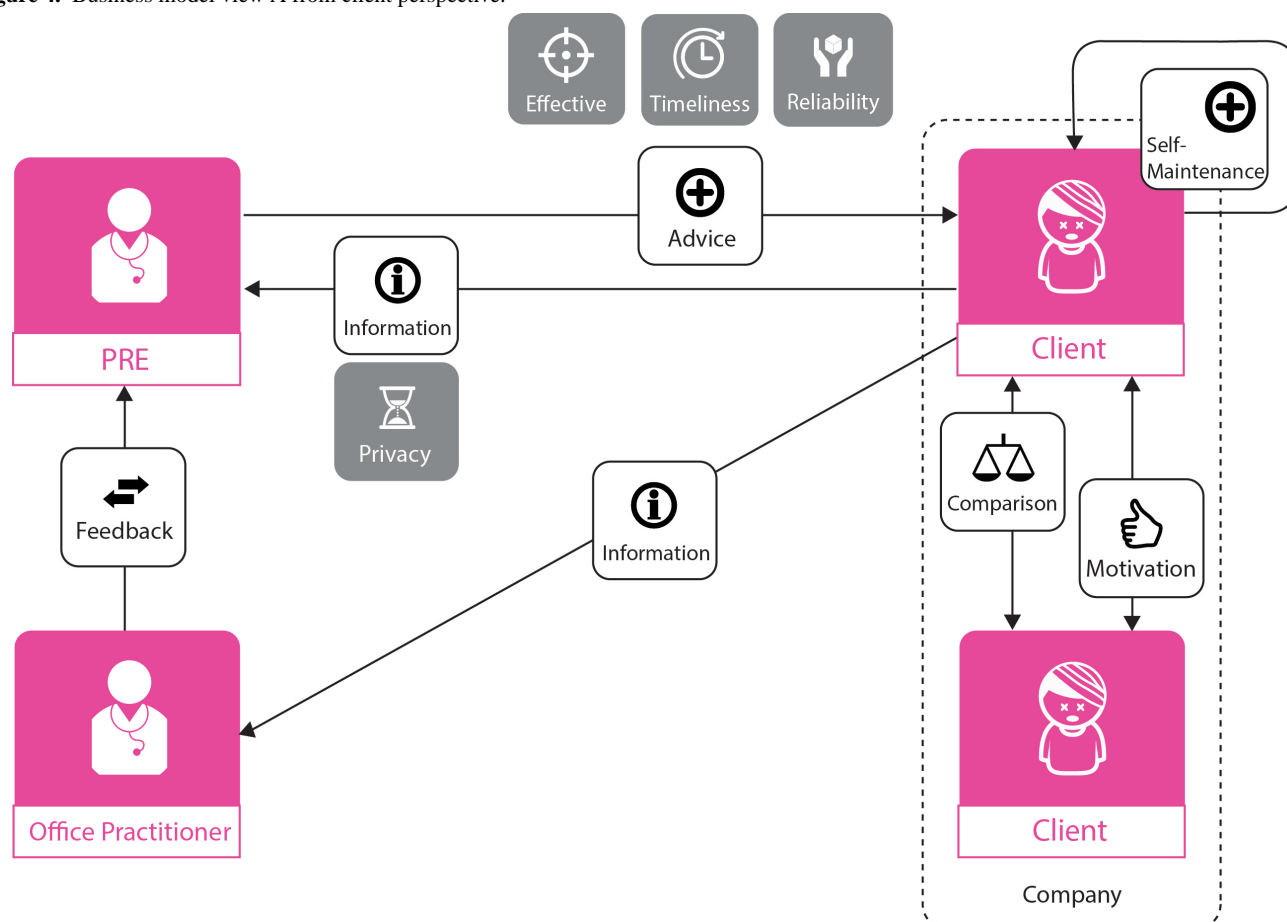
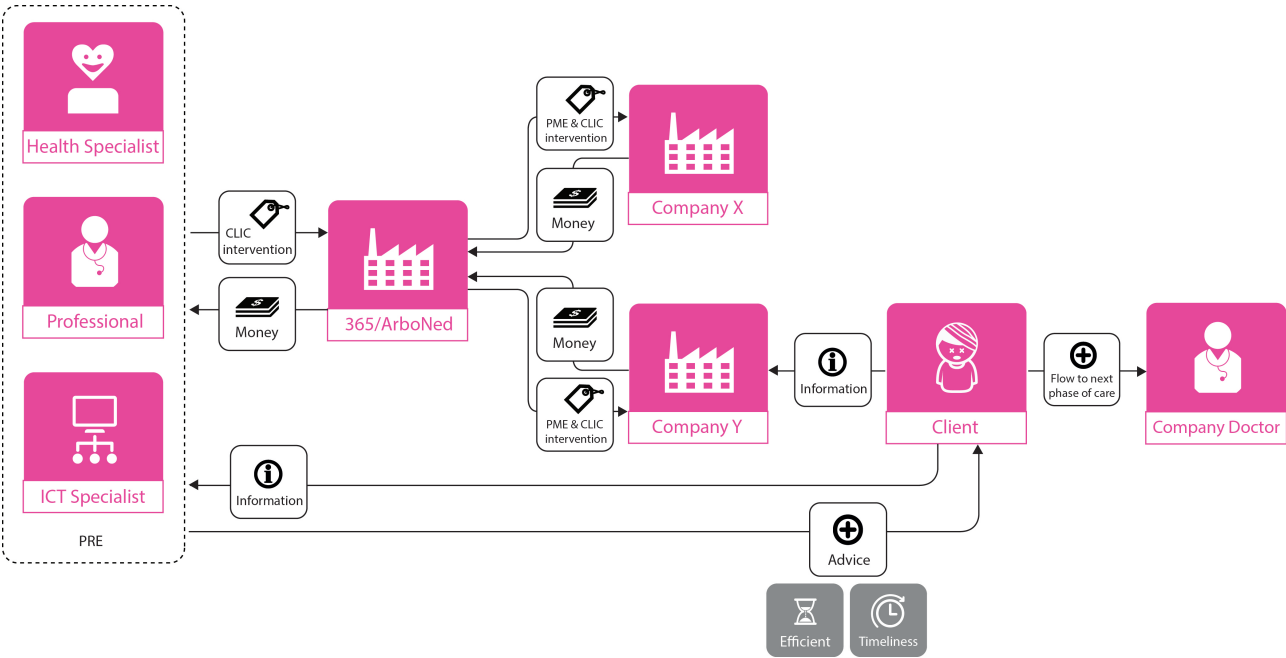


Figure 5. Business model view B from PRE (anonymized case name for the start-up organization with an online precare service for living a healthier life) health professional perspective. PME:preventive medical examinations.



Online Service Provider Perspective

Overview

The first perspective analyzed in the deconstruction of the PRE care model is the perspective of the online service provider. The

health care professional is the developer and owner of the service. Table 3 categorizes the actors, transactions, and value attributes of the care model that are of importance for the online service provider.

Table 3. Online service provider overview of actors, transactions, and value attributes.

Actors	Transactions	Value attributes
ICT specialist	Online precare service, PRE health protection	
Health specialist	Recommendations	Timeliness
Intermediate organization, 365/ArboNed ^a	License for precare software products	Efficient

Actors

From the health professional perspective, three new actors were identified as an essential part in the care model. These essential actors are key developers and a partner to deliver the service to the client. First, the *ICT specialist* was mentioned as an important actor in the development of the service. He transforms the regular precare service into a new online service. Second, a *health specialist* contributes to the professionalization of the content of the health recommendations. Third, as most important customer actor was identified, the 365/ArboNed organization, this is the *intermediate organization* dedicated to occupational health and safety of employees, the 365/ArboNed organization. To extend the reach of the service, PRE has partnered with this organization. For 365/ArboNed, PRE is a unique selling point, increasing the quality of the services offered to the companies within its network. 365/ArboNed, situated in the Netherlands, is “an occupational health service that is contracted by more than 72,000 companies nationwide to provide their employees with occupational health care” [37].

Transactions

1. Online precare service, health protection recommendations

In framing the relation between the client and the health professional, PRE is an online precare service providing professional lifestyle advice. The PRE service consists of a “flow” of digital triggers and recommendations, including weekly tips and tricks, video messages from the health professional, and extensive bimonthly advice. This transaction in which the service provides health protection recommendations only takes place if the client’s heart risk and lifestyle score are below seven on a scale of ten. These scores are based on the client’s responses to several questions regarding his or her lifestyle, which are included in the yearly Preventive Medical Examinations (PME) of the occupational health service. Employers in the Netherlands are legally obligated to offer PME to their employees.

2. License for precare software products

The software products in the transaction between the health professional and the intermediate organization provide the basis for the pricing and licensing of the business model. The precare

software modules are paid for by the intermediate organization with a license fee. The license covers the use of the online heart risk and lifestyle assessment services (including the estimation of scores and recommendation messages) from PRE software modules in its online PME questionnaire. The precare intervention service is an additional option in the contract provided by the intermediate organization to the companies.

Value Attributes

The aim of the health professional in the design of the PRE service is to disseminate lifestyle advice to as many clients as possible. Therefore, *efficiency* is one of the main attributes of the online precare service transaction. In addition, the health professional noted the importance of the *timeliness* of the service, which provides a continuous flow of advice to the client by means of weekly tips and tricks, video messages, and recurrent questionnaires. The health professional considers the digital characteristics of an online eHealth service as an opportunity to create personal, automated advice in precare. The system behind the service constructs this advice by combining short text passages—entered in the system by the professional—based on the outcome of the PRE questionnaire.

Network Coordinator Perspective

Overview

The second perspective, from which insights are derived, is the perspective of the coordinator of the PRE service within the 365/ArboNed network of business-to-business customers. In

protecting health within the firm environment, the network coordinator pointed out the existence of two different situations: (1) the normal situation when the client is at low risk and thus no intervention is needed, and (2) the service situation where intervention from PRE is needed (Table 4).

Actors

From the network coordinator perspective, zooming in on how the organization delivers the online precare service to the clients identified three additional new actors. First, *the marketing department of 365/ArboNed* is an actor that integrates the precare service in service package contracts for the second identified actor, *the companies within its network*. Third, the occupational health service employs a precare specialist, a so-called *vitality and health expert*. This actor has a direct relation with PRE regarding the information and content of the precare service, and has a coaching relation with certain clients, with whom this dedicated precare specialist holds face-to-face meetings. This last actor evidences that the delivery of the online service on a computer device comes with personal contact for a certain group of clients requiring coaching on precare. This situation corresponds to the situation when, due to high heart risk and a low lifestyle score, PRE intervention is required. In this situation, another new actor is involved, *the office practitioner*, who is involved when a PRE intervention is started. The client's heart risk and lifestyle scores are complemented with heart rate and cholesterol level measurements. The client, therefore, needs to schedule an appointment with his or her office practitioner to take a blood sample.

Table 4. Network coordinator's overview of actors, transactions, and value attributes.

Actors	Transactions	Value attributes
Marketing department	Service contract	Reliability
Companies within network	Software products transaction, PME digital feedback report	Privacy
Office practitioner	Check-up measurement	Availability
Vitality health specialist	Personal coaching	Privacy
	Product support feedback	Personal interaction

Transactions

3. Service contract for precare services and software products transaction

The relation between the health professional and the intermediate organization involves a value transaction, as the software modules are paid with a license fee. The precare software products are embedded in the PME. 365/ArboNed has incorporated the heart risk and lifestyle scores in the PME assessment as a unique selling point in its service package proposition to companies. In addition to providing feedback to the client regarding the outcome of the test, 365/ArboNed gives feedback concerning the preventive medical results to his or her employer. The employer can optionally request a report on the lifestyle scores of different departments in the company.

Within the company contract packages, the PRE intervention service based on employees' heart risk and lifestyle scores is optional. When a company chooses to include the PRE

intervention service in its contract with 365/ArboNed, and one of the clients in its employ needs intervention coaching—when the PME results show high risk—direct contact is made between the client and PRE. This transaction is described in the health professional's perspective.

4. Preventive Medical Examinations Digital Feedback Report

The PME is a questionnaire that consists of three hundred questions assessing a client's everyday lifestyle and behavior. The client receives a summary of the outcome of the questionnaire in the form of a digital feedback report. If the client's lifestyle score is below seven, and his or her employer has included the PRE service in its precare service package, a PRE intervention is initiated. Besides the intervention transaction between PRE and the client, this also entails a personal start-up meeting between the precare specialist and the client, and an appointment with the office practitioner.

5. Personal coaching and check-up measurement

If the client’s lifestyle score is below seven on a scale of ten, a PRE intervention transaction will be started. To establish this intervention transaction, two new transactions are initiated. First, direct and personal contact between the precare specialist and the client is established, and second, between the precare specialist and the office practitioner. In a face-to-face start-up meeting, the vitality and health expert (VHE) can support the advice the client receives from PRE, and motivate the client to improve his or her lifestyle. The office practitioner has to measure the client’s heart rate and take a blood sample to determine cholesterol levels.

6. Product support feedback transaction

The VHE provides the developers of the precare service (the PRE team) with feedback in order to improve the overall quality of the service. The feedback is related to the process coordination of the PRE service, and how the ICT architecture behind the service can be improved. Although this transaction can be valuable in the design of any eHealth service, in this case the experience of the VHE with PRE is of importance because the incorporation of PRE in the PME’s of 365/ArboNed only started toward the end of the year in 2012.

Value Attributes

In addition to the attributes of efficiency and timeliness, the managers of the intermediate organization came up with four new value attributes in the care model of precare services. First, the client’s *privacy* needs to be ensured when entering personal information into an online system. Second, within the digital feedback report transaction, *reliability* is a necessary attribute,

contributing to how the client perceives the quality and convenience of the service. Third, in the transaction in which the health professional intervene, the *availability* of the advice has been identified as a valuable element that contributes to the perceived usability of the precare service. The *personal interaction* of the face-to-face start-up meetings increases the convenience of the service. In addition to these meetings with the vitality health specialist, this type of direct contact also takes place in the check-up measurement appointment with the office practitioner.

Clients’ Perspective

Overview

To explore the transactions from the clients’ point of view, two clients, client X and client Y, were interviewed. The created care models showed many similarities, and only differed on a few attributes of the transactions between PRE and the client (Table 5).

Actors

From the client perspective, one new group of actors was identified. This group of actors comprises the other clients making use of the professional intervention service. These “coclients” can vary from familiar colleagues to anonymous users. Close contact between coclients can help motivate clients to improve their lifestyle and their heart risk and lifestyle scores. According to client Y, the business-related context of the interaction among clients provides a supportive boost in sharing and comparing heart risk percentages and lifestyle scores, information that is generally perceived as highly personal.

Table 5. Client’s overview of actors, transactions, and value attributes.

Actors	Transactions	Value attributes
Coclients	Self-management	Pleasantness, reliability, privacy
	Flow to next care stage	Timeliness, effectiveness

Transactions

7. Self-management of health protection by the client

In the deconstruction of the care model by the clients, self-management was identified as a new transaction. Self-management refers to the interventions, training, and skills by which patients can effectively take care of themselves, and learn how to do so. In contrast to the other transactions, which involve an exchange of activities between two actors, this transaction is the client’s relation with himself or herself in the self-management of his or her state of health. The earlier identified transactions of a personal tailored feedback report, a professional intervention service, personal coaching and check-up measurement, and online social sharing serve to support the self-management of the client.

8. Online social sharing transaction

In the interaction with other clients, comparison and motivation were mentioned when the interviewed clients deliberated about

their health-protection activities. Clients compare their scores and thereby motivate each other.

Value Attributes

Within the transactions between the PRE online service and the client, client X identified *pleasantness*, *timeliness*, and *reliability* as the core value attributes contributing to self-management and the quality and convenience of the intervention service. Like client X, client Y stated that timeliness and reliability are core value attributes in this transaction. *Timeliness* is a result of the continuous flow of information that keeps encouraging the client to adjust his or her lifestyle. However, instead of pleasantness, client Y stressed *effectiveness* as another element contributing to the perceived convenience and quality of PRE. In addition, client Y emphasized that guaranteeing *privacy* is critical when entering personal information into the online system. For this client, the privacy issue in the PRE service is solved by the involvement of a professional health care provider in the development of the service. Both clients perceived PRE

as a reliable service for the same reason, because a professional cardiologist developed it.

Design

Synthesis

When comparing the different business models created from the different actor perspectives, conclusions can be drawn regarding the elements of a business model that contribute to the convenience and quality of the eHealth service in precare. These elements can be divided into actors, transactions, and attributes. Only when both actors confirmed the transactions or relating attributes took place between them, the transactions or relating attributes were validated.

Actors

Concerning the positioning of actors, three major insights emerged from the analysis results. First, a professional such as a health care provider should be involved in the development of an eHealth service in order to ensure that the client feels secure when entering personal information into an online system. Moreover, the professional qualifications of the involved health care provider ensure the reliability of the advice provided to the client. Second, an intermediate organization with a large network can be valuable in connecting the provided service with potential clients. Third, face-to-face contact, such as with the precare specialist or office practitioner, has an influence on how the client perceives the quality and convenience of the service. This direct contact serves to support the client's self-management. The actual presence of the precare specialist is important, since the transaction between this actor and the client, the actual support, has a lesser influence in the minds of the client's on the perception of the service.

Transactions

From the deconstructed care models, we derived three insights with regard to the transactions contributing to a valuable eHealth service. The first transaction is the aim of any eHealth service in precare, and entails self-management of the client. This transaction is supported by the second interaction between the client and the eHealth service. This connection needs to consist of a flow of information from the client to the service, and, based on this information, a flow of advice from the service to the client. A distinctive characteristic of the interaction between the client and an eHealth service is the digital nature of both flows. Another transaction positively influencing the self-management of the client is the motivational boost provided by interaction with other clients when they compare scores and share tips.

Value Attributes

Finally, insights can be derived from the attributes the participants attached to the transactions. Based on the results, we can conclude that four attributes contribute to the convenience and quality of online services, and thereby influence the design of eHealth services. These attributes are the client's privacy when providing the service with personal information, the reliability of the advice received by the client,

the timeliness of the advice received by the client, and the preferred type of contact with a precare specialist. Both privacy and reliability are perceived values of the client when a professional health care provider is involved in the development of an eHealth service. Direct contact with a precare specialist or office practitioner positively influences the perceived quality and convenience of an eHealth service. Timeliness involves the time management of the advice transaction between service and client; a continuous flow contributes to the convenience and quality of the service.

Constructing Building Blocks

Overview

Based on these insights, we constructed five building blocks. These building blocks—elements of a business model consisting of actors, transactions, and value attributes—contribute to the convenience and quality of an eHealth service. Together these building blocks form a business model that can be used in the design of any eHealth service in the precare phase. [Figure 6](#) shows this model, consisting of the five building blocks.

Building Block 1

The involvement of a health professional, involving a professional health care provider in the development of an eHealth service will ensure privacy and reliability in the transactions between client and service.

Building Block 2

Interaction with the health professional, information flow from the client to the service, and a continuous flow of advice back to the client are needed in accomplishing self-management of the client.

Building Block 3

Coordinating network organization, involving an intermediate organization with a large network can assist in extending the service's reach, connecting the service with potential clients. However, on the basis of the results, no conclusions can be drawn concerning the nature of the transaction between the organization and the client.

Building Block 4

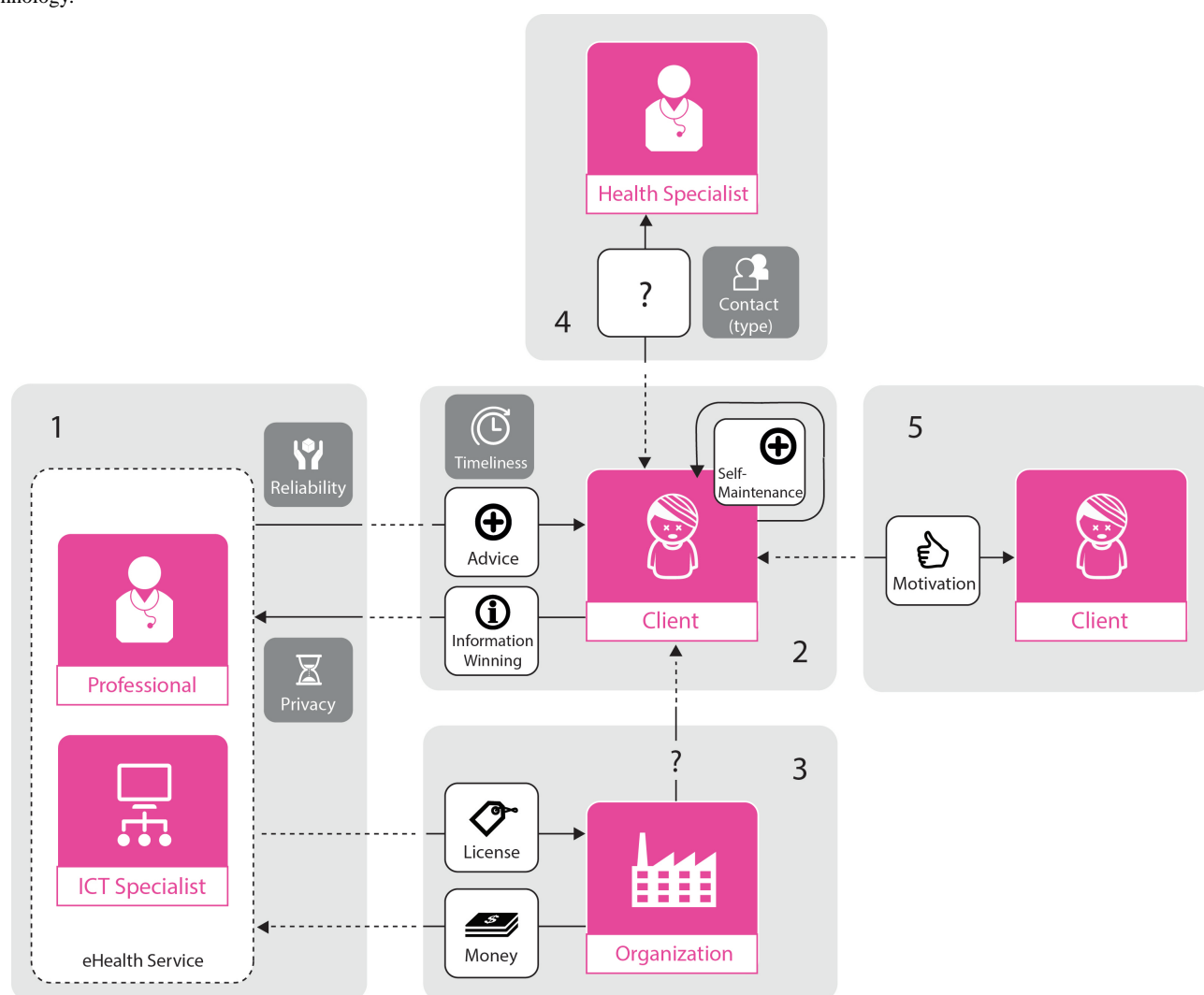
Direct contact, face-to-face contact between the client and a precare specialist supports self-management of the client and his or her perception of the eHealth service. The type of transaction has less influence, and is therefore labeled with a question mark.

Building Block 5

Interaction with other clients, the presence of other clients making use of the same eHealth service has the potential to motivate the client and support his or her self-management.

In order to design an effective business model for eHealth service solutions, all building blocks need to be integrated. All building blocks are of equal importance; the combinations of actors, transactions, and attributes all contribute to the convenience and quality of an eHealth service.

Figure 6. The five building blocks integrated in the business model design for eHealth services in precare. ICT: information and communication technology.



Discussion

Principal Findings

Taking up the design challenge of creating an innovative business model for an eHealth service, we framed the characteristics of a business model and constructed a care model that structures the actors, transactions, and value attributes for the particular context of an online precare service. Based on in-depth insights on which value exchanges between a health professional and a client are important, we constructed the building blocks of a care model for precare eHealth services. From five actor perspectives, we identified and defined the care model actors, transactions, and attributes that contribute to the perceived convenience and quality of this particular eHealth service. The generated insights and design contribute to this situation, but also have broader relevance for comparable online eHealth services. As more generic implications for the design and implementation of eHealth innovations, we propose to: (1) involve a health professional, since this will ensure privacy and reliability in the transactions between the client and the service; (2) provide an online flow of information with regular interactions to the client in order to stimulate self-management of personal health; (3) involve an intermediate organization

with a large customer base to extend the service's reach; (4) involve a service-dedicated health expert for personal face-to-face contact with clients in order to ensure and increase the perceived quality of the eHealth service; and (5) include social interaction with other clients of the online service with a view to motivating and supporting the self-management of personal health.

As more generic implications for the design and implementation of *care models*, we propose to: (1) investigate role perspectives, first by uncovering all the actors involved, then analyze, together with each actor, their own positioning in exchange with other actors, unraveling the value exchange of the transactions between actors in the network; (2) visualize the care model situation guided by the visual modeling toolkit, which helped actors to structure their thoughts, and provide knowledge on organizational conditions that are relevant for the design of the care model; (3) design building blocks from a deconstruction of the (visual) role perspectives on an organizational network model of value exchange; and (4) create artifacts of care model designs to communicate about the implementation of business model innovation for eHealth services (involve strategic designers).

Limitations and Further Research Suggestions

Although the study was executed in depth and from multiple role perspectives, the choice of a single case study method comes with limitations. These include the two clients who used the precare service for different lengths of time; one client tested the service for two months, and the other for one year. Also both clients had a low heart failure risk and high lifestyle score. These differences influenced their perception of the service, but overall the ways in which they visualized the care models had more commonalities than differences. A first suggestion for further research is to conduct a multiple case study with more interviewees per role perspective. A second research suggestion is related to the visual business modeling method, in which the participants could freely modify and add actor, transaction, and attribute cards. Permitting this degree of flexibility and creativity in codesigning could have positively affected the participants' openness to the implementation of the care model innovation. This research by design method required reflection on action, demonstrated with the deconstruction part of this study. Further research experiments on the visual elements in the business modelling kit and on the codesigning situation can bring the modelling method to a next level of intervention. Another relevant direction for further research would be to quantitatively validate the influence of the separate building blocks on the convenience and quality of the service, in contribution to the knowledge field of care models in eHealth. Also further quantitative research on monetization (eg, cost structures and revenue streams) is worthwhile to investigate. Furthermore, an interesting related avenue for further research in complex value network structures is the in-depth analysis to overcome the key barriers for the integration and adoption of eHealth services. Concerning the monetization barriers, such as willingness to pay, issue of having no financial reimbursement structure for eHealth services, requires further research. A final consideration

in this case study relates to the venture context. The eHealth service was studied in a business start-up context. The importance of building blocks might change or new blocks could appear in different phases of the service's life cycle. Understanding the developments a business model in eHealth goes through enables forward-looking design of business models for eHealth services. In addition, our final research suggestion is to study the influence of the different stages of a service's life cycle on the design of its business model.

Conclusions

This study provides an overall business model that is informative and serves as a source of inspiration for the creation of eHealth services in the precare phase of care that provide convenience and quality to the end user. By using a visual modeling method in codesign with the actors involved, the essential actors, transactions, and value attributes of a business model were discovered in the context of the PRE case study. We revealed eight actors in the business model of the precare service. Essential for providing the service are: the intermediary network coordinator connecting companies, the service dedicated ICT-specialists, and the service dedicated health specialist. In the transactions we found a certain type of contract, such as a license contract and service contracts for precare services and software products. In addition to the efficiency, quality, and convenience value attributes, important value attributes appeared to be: (1) timeliness, (2) privacy and credibility, (3) availability, (4) pleasantness, and (5) social interaction. As such, the final business model emphasizes the importance of real-time contact between the client and a health care provider in online interactive intervention programs. Moreover, larger groups of clients could be treated in the precare stage at the same time, thereby educating and helping clients to self-manage healthier behavior, while also stimulating dialogue and support between clients.

Conflicts of Interest

None declared.

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Abbreviations

ICT: information and communication technology

PME: preventive medical examinations

PRE: anonymized case name for the start-up organization with an online precare service for living a healthier life

VHE: vitality and health expert

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