JMIR Research Protocols

Ongoing Trials, Grant Proposals, Formative Research, Methods, Early Results
Volume 3 (2014), Issue 2 ISSN: 1929-0748

Contents

Protocols

Original Papers

Corrigenda and Addenda

Protocol

The Cost Effectiveness of a Tailored, Web-Based Care Program to Enhance Postoperative Recovery in Gynecologic Patients in Comparison With Usual Care: Protocol of a Stepped Wedge Cluster Randomized Controlled Trial

Esther VA Bouwsma[1,2,3], MD; Johannes R Anema[2,3], MD, PhD; Antonie Vonk Noordegraaf[1,2,3], MD; Dirk L Knol[4], PhD; Judith E Bosmans[3,5], PhD; Steven E Schraffordt Koops[6], MD, PhD; Paul JM van Kesteren[7], MD, PhD; W Marchien van Baal[8], MD, PhD; Jos P Lips[9], MD, PhD; Mark H Emanuel[10], MD, PhD; Petrus C Scholten[11], MD, PhD; Alexander Mozes[12], MD; Albert H Adriaanse[13], MD, PhD; Hans AM Brölmann[1,3], MD, PhD; Judith AF Huirne[1,3], MD, PhD

[1]Department of Obstetrics and Gynecology, VU University Medical Center, Amsterdam, Netherlands
[2]Department of Public and Occupational Health, VU University Medical Center, Amsterdam, Netherlands
[3]EMGO Institute for Health and Care Research, Amsterdam, Netherlands
[4]Department of Epidemiology and Statistics, VU University Medical Center, Amsterdam, Netherlands
[5]Department of Health Sciences, Faculty of Earth and Life Sciences, VU University, Amsterdam, Netherlands
[6]Department of Obstetrics and Gynecology, Meander Medical Center, Amersfoort, Netherlands
[7]Department of Obstetrics and Gynecology, Onze Lieve Vrouwe Gasthuis, Amsterdam, Netherlands
[8]Department of Obstetrics and Gynecology, Flevo Hospital, Almere, Netherlands
[9]Department of Obstetrics and Gynecology, Kennemer Gasthuis, Haarlem, Netherlands
[10]Department of Obstetrics and Gynaecology, Spaarne Hospital, Hoofddorp, Netherlands
[11]Department of Obstetrics and Gynaecology, Diakonessenhuis, Utrecht, Netherlands
[12]Department of Obstetrics and Gynecology, Amstelland Hospital, Amstelveen, Netherlands
[13]Department of Obstetrics and Gynecology, Medical Center Alkmaar, Alkmaar, Netherlands

Corresponding Author:
Judith AF Huirne, MD, PhD
Department of Obstetrics and Gynecology
VU University Medical Center
De Boelelaan 1117
Amsterdam,
Netherlands
Phone: 31 20444 4827
Fax: 31 204444811
Email: j.huirne@vumc.nl

Abstract

Background: The length of recovery after benign gynecological surgery and return to work frequently exceeds the period that is recommended or expected by specialists. A prolonged recovery is associated with a poorer quality of life. In addition, costs due to prolonged sick leave following gynecological surgery cause a significant financial burden on society.

Objective: The objective of our study was to present the protocol of a stepped wedge cluster randomized controlled trial to evaluate the cost effectiveness of a new care program for patients undergoing hysterectomy and/or adnexal surgery for benign disease, compared to the usual care.

Methods: The care program under study, designed to improve convalescence and to prevent delayed return to work, targets two levels. At the hospital level, guidelines will be distributed among clinical staff in order to stimulate evidence-based patient education. At the patient level, additional perioperative guidance is provided by means of an eHealth intervention, equipping patients with tailored convalescence advice, and an occupational intervention is available for those patients at risk of prolonged sick leave. Due to the stepped wedge design of the trial, the care program will be sequentially rolled out among the 9 participating

hospitals, from which the patients are recruited. Eligible for this study are employed women, 18-65 years of age, who are scheduled for hysterectomy and/or laparoscopic adnexal surgery. The primary outcome is full sustainable return to work. The secondary outcomes include general recovery, quality of life, self-efficacy, coping, and pain. The data will be collected by means of self-reported electronic questionnaires before surgery and at 2, 6, 12, 26, and 52 weeks after surgery. Sick leave and cost data are measured by monthly sick leave calendars, and cost diaries during the 12 month follow-up period. The economic evaluation will be performed from the societal perspective. All statistical analyses will be conducted according to the intention-to-treat principle.

Results: The enrollment of the patients started October 2011. The follow-up period will be completed in August 2014. Data cleaning or analysis has not begun as of this article's submission.

Conclusions: We hypothesize the care program to be effective by means of improving convalescence and reducing costs associated with productivity losses following gynecological surgery. The results of this study will enable health care policy makers to decide about future implementation of this care program on a broad scale.

Trial Registration: Netherlands Trial Register: NTR2933; http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=2933 (Archived by WebCite at http://www.webcitation.org/6Q7exPG84).

(JMIR Res Protoc 2014;3(2):e30) doi:10.2196/resprot.3236

KEYWORDS

gynecology; Internet; telemedicine; convalescence; return to work; economic evaluation

Introduction

Early Discharge From the Hospital

In the last two decades, the hospital stay following surgical procedures has been shortened drastically, due to recovery-enhancing strategies such as the use of minimally invasive techniques and the implementation of fast-track programs [1-4]. The advantages of early postoperative discharge include increased patient satisfaction, low hospital-acquired infection rates, and reduced hospitalization costs [5]. However, a major disadvantage of minimizing the length of a hospitalization is that patient contact becomes very brief, which is often at the expense of time spent on patient education. Ironically, the lack of detailed convalescence instructions at the time of discharge increases the risk of an unnecessary prolonged recovery [6-11]. Therefore, as long as the organization of perioperative care has not fully anticipated the transition of postoperative recovery to the home setting, early discharge does not necessarily translate into accelerated recovery and earlier resumption of (work) activities [12-14].

In gynecology, the postoperative convalescence after discharge from the hospital has not received much attention in research and practice. Yet, there is considerable evidence that the length of recovery time after a gynecological surgery systematically exceeds the period considered as appropriate by specialists [5,10,12-17]. In a prospective study performed by our own study group among 148 patients receiving gynecological surgery for a benign disease, median time to return to work (RTW) exceeded the recommended sick leave of 6 weeks by approximately 3 weeks. The median time to RTW following an intermediate surgery (eg, laparoscopic or vaginal hysterectomy) was 60 days (interquartile range, IQR 56-135) and following a major surgery (eg, abdominal hysterectomy) 69 days (IQR 56-135) [10].

Prolonged Recovery at Home

An unnecessary prolonged recovery is associated with poorer quality of life [18,19]. In addition, work related problems have also been associated with an increase in health care consumption [20]. Furthermore, taken into account that about 14,000 hysterectomies are performed annually in the Netherlands alone [21], the financial burden on society due to delayed convalescence after a gynecological surgery is substantial.

In order to reduce unnecessary delayed recovery, and concurrently decrease costs associated with prolonged sick leave and increased health care utilization following gynecological surgery, our research group started working on an innovative strategy to optimize perioperative care in 2008. Since the beginning of the project several goals were achieved, starting with the development of detailed convalescence recommendations following 4 types of benign gynecological surgery, using a modified Delphi method [22]. Simultaneously, a multidisciplinary care program was developed [23,24] consisting of an interactive eHealth intervention and—for those patients at risk of prolonged sick leave—an occupational intervention. The care program provides guidance to patients from the moment the surgery is planned, until the full resumption of all activities—including return to work—and encourages patients to take an active role in their own recovery. The care program was subject to an effect evaluation as well as a process evaluation in 2010 [25]. While the effectiveness study among 215 patients showed a positive effect on the outcomes: (1) RTW, (2) quality of life, and (3) perceived pain [26], the process evaluation showed some room for improvement [27].

Besides evaluating the effectiveness of a study, it is of equal importance to conduct an economic evaluation, especially considering the high economic burden of extended time to convalescence after a gynecologic surgery. The economic evaluations are necessary to gain insight into the costs of an intervention in relation to its effects. Health care policy makers can use these results to decide how resources should optimally be allocated to maximize health or welfare [28].

Therefore, the primary objective of the current study is to conduct an economic evaluation of the care program compared to the usual care. This economic evaluation will be conducted

alongside a randomized trial, as the intervention concerns a further developed version of the care program, which has not yet been subject to an effect evaluation. In addition, this construction enables the systematic collection of relevant effect and cost data under "real life" conditions. As the intervention care program targets two levels (the hospital level and the patient level), a cluster design was chosen in order to prevent contamination between the study arms. The primary outcome duration until full sustainable RTW will be assessed on the level of the individual participant. On the level of the participating hospitals, we will investigate to what extent the guidelines on convalescence recommendations are adopted, and how future implementation of the guidelines and care program can be facilitated.

Methods

The Standard Protocol Items

The Standard Protocol Items, Recommendations for Interventional Trials statement [29], and CONsolidated Standards Of Reporting Trials (CONSORT) statement [30,31], were used in order to describe the design of this study. In addition, we used the extension to cluster randomized trials [32] and the CONSORT eHealth checklist [33].

Ethical Issues

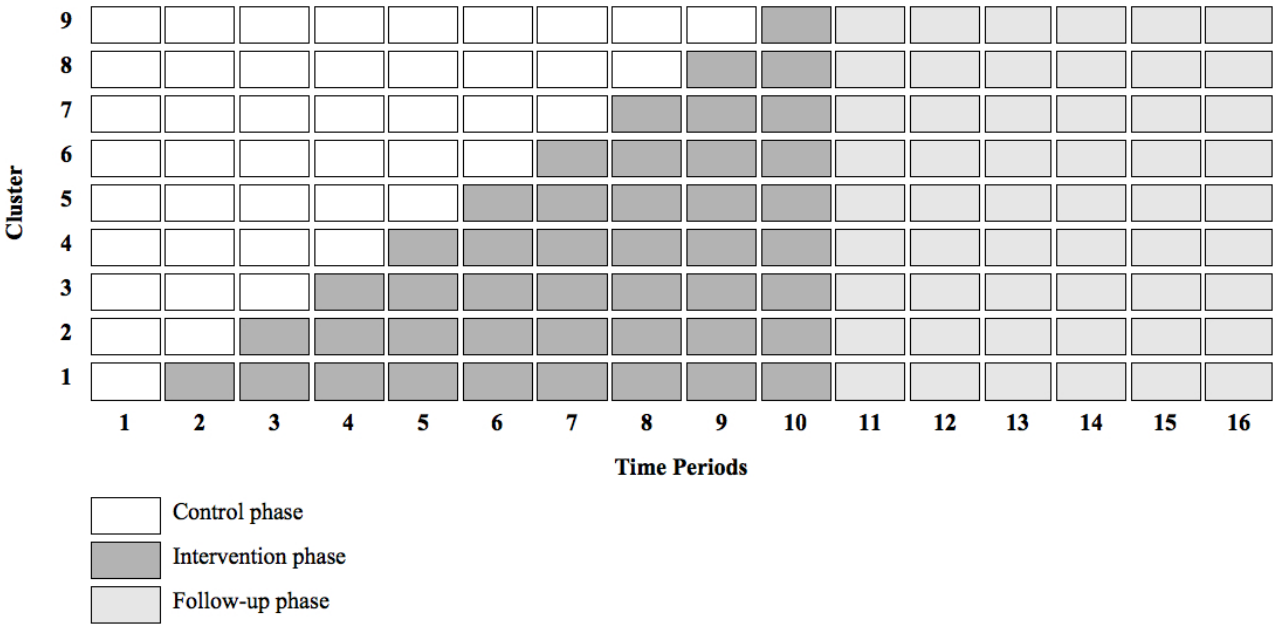
The Institutional Review Boards of all participating hospitals approved this study protocol. Informed consent was obtained from all of the patients.

Trial Design

This trial is designed as a cluster, randomized controlled, stepped wedge trial, which involves a sequential rollout of the intervention in the participating clusters over several time periods. In our study, clusters are the departments of obstetrics and gynecology in nine different hospitals in the Netherlands. Each time period (TP) takes 2 months. At the start of the trial (TP_1), all of the patients scheduled for a surgery in all of the participating hospitals receive usual care (control phase). After two months (TP_2), the intervention is implemented in the first cluster, and from now on the patients scheduled for a surgery in this hospital will receive the intervention program, while in all of the other hospitals the patients still receive usual care. The patients in cluster 2 who underwent surgery during TP_1 remain in the control group until they finish the 12 month follow-up. During TP_3, the intervention program continues in cluster 1, and the intervention is implemented in cluster 2 as well, resulting in the deliverance of the intervention program to the patients in clusters 1 and 2 that will undergo surgery from this point onward, while patients in clusters 3 to 9 serve as the control group. At the beginning of TP_4, cluster 3 starts with the intervention, etc. This is repeated until the intervention is implemented in all clusters (TP_{10}). Figure 1 illustrates the study design.

A cluster design was chosen to minimize the risk of contamination, as our intervention targets both health care providers and patients. A stepped wedge approach was employed because of the unique feature of an unidirectional crossover, preventing the intervention to be withdrawn from the hospital during the trial [34-36]. Because there is substantial evidence from our previous trial that the care program under study will be effective, this is particularly convenient, as hospitals will be able to keep using the intervention after the trial. Moreover, it enables us to study the implementation process carefully, giving valuable insight into barriers and facilitators for future broader implementation.

Figure 1. Trial design.



Selection of Clusters

The clusters in this trial consist of nine hospitals in the surroundings of Amsterdam, the capital of the Netherlands. The hospitals were eligible if they performed at least 100 hysterectomies or laparoscopic adnexal surgeries yearly, and were located within 50 km of the Vrije Universiteit Medical Center (VUmc). The research team enrolled the clusters before the start of the trial. In an attempt to select a heterogeneous sample of hospitals, we included 1 university hospital, 7 teaching hospitals, and 1 nonteaching hospital.

Study Population

The eligible participants for this study are women 18-65 years of age, employed for at least 8 hours per week (salary employed, self employed, or voluntary work), and scheduled for a surgery for a benign gynecological disease in one of the nine participating hospitals. The types of surgeries that are included are: (1) total abdominal hysterectomy (TAH), (2) vaginal hysterectomy (VH), (3) total laparoscopic hysterectomy or laparoscopic assisted vaginal hysterectomy (TLH), or (4) laparoscopic adnexal surgery (LAS). The factors that are possibly complicating the postoperative course (eg, severe comorbidity, malignancy, pregnancy), the factors that are interfering with the eHealth intervention (computer or Internet illiteracy), or with the occupational intervention (conflict with employer, prolonged sick leave, or disability) serve as the exclusion criteria. Table 1 lists an overview of all eligibility criteria.

Table 1. Eligibility criteria.

Inclusion criteria	Exclusion criteria
Women scheduled for:	(Suspicion of) malignancy
Laparoscopic adnexal surgery	(Ectopic) pregnancy
Total laparoscopic hysterectomy	Deep infiltrating endometriosis
Vaginal hysterectomy	Concomitant health problems affecting daily activities
Total abdominal hysterectomy	Psychiatric disorders affecting daily activities
18-65 years of age	Legal conflict with employer
Employed ≥ 8 hours/week	Being sick listed >4 weeks, or when reason of sick leave is related to gynecological surgery > 2 months
	Inability to understand or complete Dutch questionnaires
	Computer or Internet illiteracy

Recruitment of Patients

The recruitment of patients will take place in all participating hospitals. When the patients are scheduled for a hysterectomy or laparoscopic adnexal surgery, they will receive a letter about the study on behalf of their gynecologist. The letter includes detailed information about the trial. In addition, it is explained that someone from the research team will make contact by telephone after one week to evaluate the patients' willingness to participate and answer questions if necessary. If the patient does not wish to be contacted, she can return an included reply card, or send an email to a specified email address.

When contact is made and the patient is willing to participate, eligibility is assessed. The eligible patients are then requested to return a signed informed consent, which is also attached to the information letter. The participants will not receive any financial or nonfinancial incentives.

Randomization

The randomization takes place at the level of the clusters and determines the order in which the intervention program is implemented in the participating hospitals. The randomization will be performed by a statistician using a computer generated list of random numbers.

The patients are informed about the allocation of treatment by the research team after the patient's informed consent and the completion of the first questionnaire before surgery. As the treatment allocation depends on the scheduled date of the surgery, and the implementation phase of the hospital in which they are being operated, it is predetermined for each participant, potentially causing selection bias. To minimize the risk of selection bias, the participants will not be informed about the study design, and will be counseled as if they have equal chances between receiving the usual care or the intervention program. For this reason, counseling will be done by the research team, rather than by their own physician, who might be, for example, more willing to include patients during the intervention phase than during the control phase. Moreover, physicians will be blinded to the randomization schedule, and will only be informed about the start of the intervention phase approximately one month before the actual implementation. Once the intervention phase has started, the importance of not communicating this information with the potential patients will be emphasized.

Interventions

Usual Care

Before the implementation of the intervention program, the participants receive the usual perioperative care as provided in the hospital in which they are scheduled for surgery. Although considerable variation exists in the Netherlands, in most cases patients get verbal (general) instructions at discharge by a nurse and/or physician, often followed—but not necessarily—by a letter or brochure. In general, an outpatient postoperative consultation is scheduled 4 to 6 weeks following the surgery. Between discharge and the postoperative consultation, medical

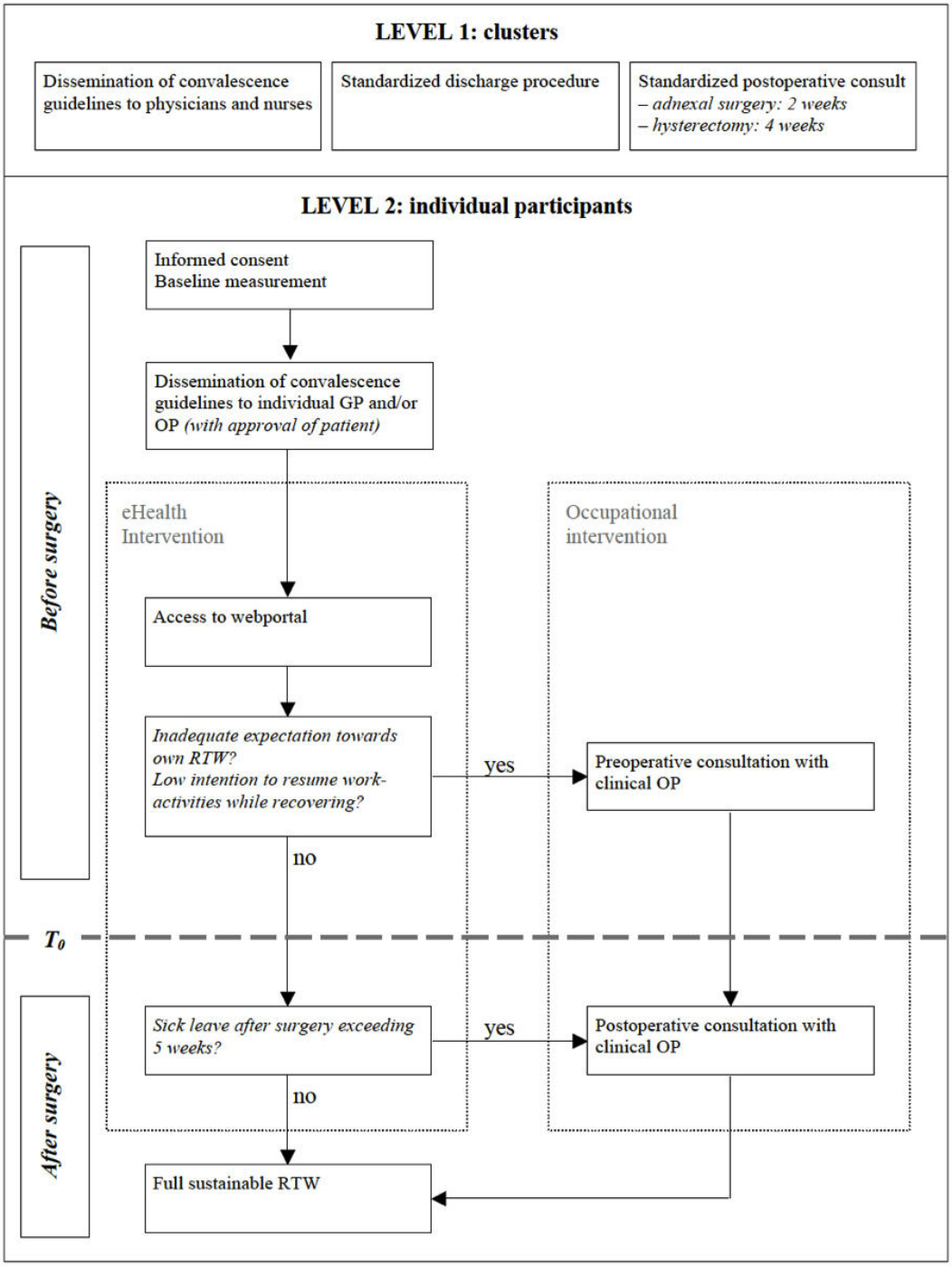
care is only initiated by the patient, who can consult her general physician (GP) or gynecologist, if necessary. Employed workers who have not resumed work within 6 weeks after the surgical procedure will be invited for a consultation with their occupational physician (OP), as required by law in the Netherlands.

Intervention

The systematic development of the care program using the principles of Intervention Mapping is described in more detail elsewhere [23]. Both theory and practice were combined, and all stakeholders were involved in the process. The engagement of the patients was prompted through focus groups [24]. The Attitude, Social influence, and Self-efficacy model was used as a theoretical framework for determinants of behavior regarding return to work [37,38].

The care program targets two levels, which are described below. Figure 2 shows an overview of the intervention care program.

Figure 2. Overview of the care program. GP=general physician; OP= occupational physician; RTW=return to work.



Cluster Level

At the cluster level, the intervention care program aims to structure and stimulate evidence-based perioperative care. Approximately two months before a cluster shifts from the control to the intervention phase, the principle researcher will approach the head of the department to arrange logistics. A minimum of two meetings is planned one or two weeks before the actual implementation with physicians and nurses to provide and explain the new convalescence recommendations that should be communicated to the patients. In addition, all health professionals involved in the clinical care receive a pocket card on which these recommendations are summarized for quick reference. The residents involved in the discharge communication are instructed to explain the convalescence recommendations to their patients before they are discharged. Visual reminders in the patient records will help the residents do so. With the secretary of the department, a strategy is developed to prompt the standard postoperative consultation at 4 weeks following a hysterectomy, and 2 weeks following adnexal surgery. During the trial, newsletters will be spread regularly to reinforce the different aspects of the intervention care program.

Patient Level

Individual Tailored Guidance

At the patient level, the care program aims to provide individual tailored guidance to patients from the moment the surgery is planned until the full resumption of all activities. It consists of two steps: (1) access to an interactive eHealth intervention for all patients, and (2) an additional occupational intervention for those patients at risk for prolonged sick leave.

eHealth Intervention

The patient webportal (Figure 3, [39] aims at empowering its users and improving communication between patients and their employers, as well as improving the communication between the involved health care professionals during the perioperative period. Access to the webportal will be given to the patients approximately 2 to 4 weeks prior to surgery by the research team, by providing a username and temporary password. The instructions are given by email, and it is explained that if patients require assistance, they can contact the research team by phone or email. If patients fail to log in, an automatic reminder is sent to them one week before their surgery to remind them about the webportal and its functionalities. User authentication will make it possible to analyze website activity for each individual participant (visit duration, number of sessions, number and details of pages visited).

The most important tool of the webportal is the possibility to generate a tailored convalescence plan. In the instruction email, patients are encouraged to generate such a plan at least once, preferably before surgery. Having access to detailed convalescence advice will enable the patients to develop realistic expectations about their own recovery, and plan the resumption of their activities and work reintegration accordingly. Moreover, a tailored convalescence plan will help the patients gain insight into potential recovery problems and find solutions at an early stage, preferably before surgery. Because the convalescence plan is composed before surgery, gynecologists are asked to approve the plan electronically on the first postoperative day. In the case of an uncomplicated procedure, the plan is turned into a definite convalescence plan, and the patients are instructed to follow the recommendations in it. In the case of a converted procedure, the plan is adjusted to the type of surgery that was actually performed. In the event of severe complications, the gynecologist can choose not to approve the convalescence plan, and the patients then receive a message that the convalescence plan is not valid anymore, and that they should follow up with the specific instructions given to them at discharge. With the consent of the patient, the approved convalescence plan is also disclosed to the GP and/or OP of the patient. This last feature was added since the prior evaluation of the webportal, and was developed to facilitate the involvement of other health care professionals during the perioperative period in order to stimulate a multidisciplinary approach. In addition, the webportal was equipped with a tool that enables the patients to generate a recovery report, a graphic presentation of their own recovery, allowing them to track their progress.

During the trial, the content of the website will be frozen, except from the dynamic component (forum). Table 2 summarizes the most important tools of the eHealth intervention. Screenshots of the webportal are included as a Multimedia Appendix (see Multimedia Appendix 1).

Figure 3. Screenshot of ikherstel.

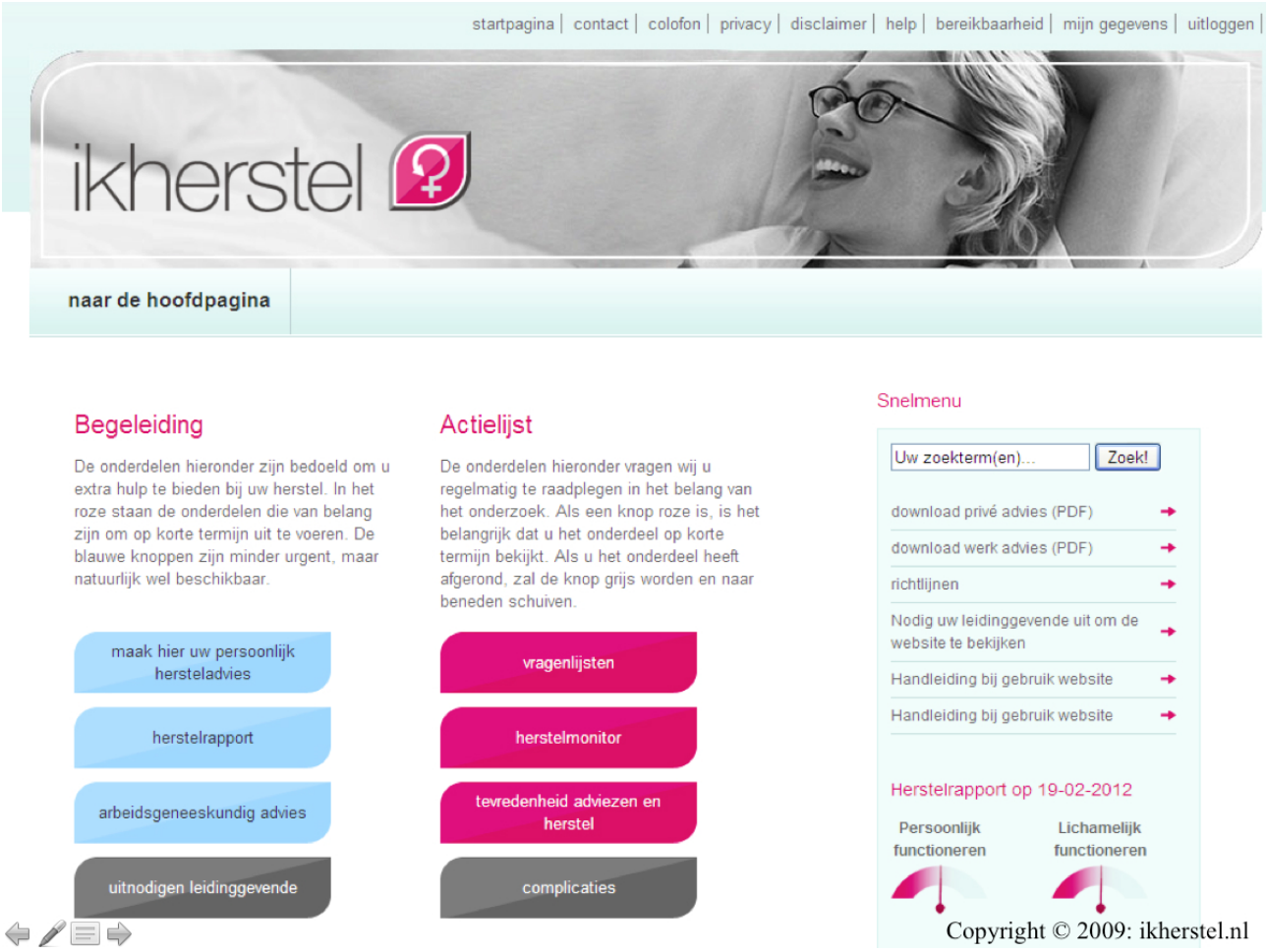


Table 2. Content of the eHealth intervention.

Tool	Description
Personalized convalescence plan[a]	The tool allows patients to generate detailed tailored instructions on the resumption of activities after the surgery, allowing preoperative planning of (work) activities. The convalescence plan is approved electronically on the first postoperative day by the surgeon who performed the surgery, resulting in a definitive convalescence plan. With the consent of the patient, the approved convalescence plan is shared with GP and/or OP.[a]
Recovery monitor + recovery report[a]	The tool makes an inventory of the resumption of activities at 2, 4, 7, 14, 28, 56, and 84 days after surgery. Results are graphically displayed in a recovery report, allowing the patient to track their progress.[a] In case the patients fall behind, an alerting system advises them to contact a specific health care professional, depending on the underlying problem.
Invitation of employer	The tool allows patients to invite an employer to an anonymous section of the webportal to stimulate a dialogue. The development of a reintegration plan preoperatively will help them gain insight into potential RTW problems.
Video	There is a 9-minute film illustrating the common pitfalls during the postoperative period.
Knowledge	There are several tools to find additional information, such as an extended list with answers to frequently asked questions, a glossary, and links to other useful websites.
Forum	The tool allows the patients to interact (privately or publicly) with other patients.

[a]Tools that were modified since the last evaluation of the webportal

Occupational Intervention

The occupational intervention is developed to provide additional guidance to those patients at risk for prolonged sick leave. The occupational intervention will be delivered by a group of six independent OPs, who will be trained as RTW coordinators before the start of the trial. There are two types of consultations: (1) a preoperative, and (2) a postoperative consultation. All consultations will be delivered by telephone, unless the OP and the patient decide together otherwise.

The patients who have an inadequate expectation about their own recovery (longer than 3 weeks for LAS, longer than 6 weeks for VH/TLH, or longer than 8 weeks for TAH), or have a low intention to resume work activities while still recovering, are offered a preoperative consultation, as expectations about RTW and intention to resume work have been identified as two predictors for RTW in recent studies [10,40,41]. During the preoperative consultation, the OP explains the importance of a prosperous recovery in terms of improving quality of life and preventing long term sickness. In addition, the OP tries to identify and—if necessary—alter attitudes and (irrational) beliefs about recovery.

The patients who exceed 5 weeks of sick leave receive a postoperative consultation, during which, the OP assesses the underlying mechanism for the delayed recovery. The OP gives advice to improve the reintegration process. Moreover, as a RTW coordinator, the OP has an excellent position to communicate with the patient's gynecologist, GP, OP, and employer, if necessary, and of course, with the consent of the patient, stimulating an integrated care approach. In addition, the OP has the possibility to initiate a participatory workplace intervention, aimed at finding consensus between the patient and her employer concerning solutions for identified obstacles for RTW with the help of an occupational therapist (OT) [42,43].

The occupational intervention described above differs from the intervention as delivered during the first trial, due to the insight gained during the process evaluation. Originally, contact with the clinical OP took place in the 10thor 11thweek, however, this turned out to be too late in order to be able to alter attitudes and beliefs, and influence the development of a solid RTW plan. Therefore, in the current trial, contact will be made much earlier, at 5 weeks, and on indication already before surgery. In addition, the patients will receive the details of the postoperative appointments before surgery in order to prepare them that the occupational intervention is part of the care program they receive, as in the prior trial, almost half of the patients declined additional occupational care. In the case of full RTW, the postoperative appointment will be cancelled.

Outcomes

Effect Measures

The effects of the intervention will be assessed on the level of the patient. The primary outcome of the study is the sick leave duration until full sustainable RTW, defined as the duration of the sick leave in calendar days from the day of surgery until full RTW, in their own work or other work with equal earnings, for at least 4 weeks without (partial or full) recurrence [44]. The recurrence of sick leave due to the gynecologic surgery within the four week period after initial full RTW will be added to the preceding period of the sick leave. The RTW will be assessed by a monthly electronic sick leave calendar.

Secondary outcomes that will be assessed are:

1. Recovery, measured by the Recovery Index-10 (RI-10) a validated recovery-specific questionnaire [45];
2. Self-reported quality of life, assessed by the Dutch versions of the EuroQol-5D (EQ-5D) [46] and the Short-Form Health Survey (SF-36) [47,48];
3. Duration of sick leave until first RTW, and total duration of sick leave due to the gynecological surgery for the entire follow-up period, both measured by the monthly sick leave calendars;
4. Self-efficacy, assessed by the Dutch adaptation of the General Self-Efficacy Scale (GSES) [49];
5. Coping, assessed by the Pearlin Mastery Scale (PMS) [50];
6. Pain intensity, measured by the Von Korff questionnaire (VAS) [51]; and
7. (Post) operative complications both assessed through self-report and by the review of surgical reports. Complications include: (1) enlargement of the wound (≥ 8cm), (2) unintended injury to other structures (eg, bowel, bladder, ureter), (3) unexpected blood loss requiring transfusion, (4) prolonged hospital stay, (5) readmission within 72 hours (overnight), (6) repeat surgery within 2 weeks, and (7) postoperative infection requiring antibiotics.

Prognostic Factors

Before surgery, data about potential prognostic factors will be collected. In case of coincidental and meaningful differences, analyses will be adjusted for the following characteristics: (1) sociodemographic data such as age, education level, and ethnicity; (2) personal factors such as expectation, motivation, and intention toward RTW, duration of sick leave in the past 3 months; and (3) work related factors such as physical workload and potential work related psychosocial factors, assessed by the Dutch Musculoskeletal Questionnaire (DMQ) [52] and the Job Content Questionnaire (JCQ) [53].

In case of an unequal distribution of severe complications (defined as: wound enlargement with more than 8cm or repeat surgery within 2 weeks), between the two study arms, the analyses will be adjusted for these surgery-related characteristics as well.

Cost Measures

The costs will be measured from a societal perspective and consist of: (1) costs of the intervention, (2) health care utilization, and (3) costs associated with lost productivity. All of the costs will be converted to the year 2014 using consumer price indices [54]. The discounting of costs will not be necessary because the follow-up period is limited to one year.

The intervention costs are those that are related to implementing and operating the new care program, and will be estimated using a bottom-up approach. The detailed information regarding the quantity and unit prices of the following resources will be collected: (1) training of involved health care professionals (clinical staff, OP, OT), (2) the eHealth intervention (hosting of webportal, administrator time), and (3) the occupational intervention (number and duration of consultations).

The health care utilization will be assessed on a monthly basis using a retrospective electronic questionnaire. Only the health care costs related to the gynecological surgery will be collected and include: (1) surgery and hospitalization; (2) visit is to health care professionals in primary or secondary care and visits to

alternative medicine therapists; (3) medication; and (4) home care and informal help. If available, Dutch guideline prices will be used to value health care utilization. If cost guidelines are not available, costs will be estimated using real prices or population-based estimates if available in the literature. The prices of the Royal Dutch Society for Pharmacy will be used to value medication [55].

The costs associated with productivity loss consist of absenteeism and presenteeism costs. The absenteeism will be assessed by monthly sick leave calendars. The human capital approach will be used to calculate the costs of losses to production as a result of sick leave due to the gynecologic surgery (net number of days on sick leave during follow-up, multiplied by the estimated prices of production loss of a worker per day of sick leave). The presenteeism (reduced productivity while at work) will be assessed with two items of the Productivity and Disease Questionnaire [56]. A decline in the amount or quality of work performed due to the gynecologic surgery compared to the level at which the patient normally performs, will be considered as presenteeism. The costs associated with presenteeism will be calculated by multiplying the presenteeism score during follow-up by the estimated price of production loss per day.

Process Measures

A process evaluation will be conducted to evaluate the implementation process of the intervention [57]. The assessment of the extent to which the intervention program was applied as intended will provide valuable insight into the facilitators and barriers for future implementation. The process evaluation will take place both on the level of the cluster as well as the patient, and both quantitative and qualitative methods will be used. An automatically generated weblog will enable the analysis of the website activity for each individual participant, giving more insight into which patients used the eHealth intervention, and how it is being used. The appointment system and patient records of the OP will enable us to analyze the number of consultations that have taken place, as well as the reasons for cancellations, and the occurrence of any protocol deviations. By means of an Internet questionnaire at the end of the follow-up period, patient satisfaction, perceived effectiveness, and any usage barriers will be assessed. The principle investigator will continuously collect reasons for exclusion and dropout during the trial. In accordance to the prior process evaluation conducted [27], the following process measures are included: (1) reach, extent to which the intervention reaches the target population; (2) dose delivered, extent to which the intervention is delivered to the target population; (3) dose received, extent to which the participants used the intervention; (4) fidelity, extent to which the intervention was delivered as planned; and (5) attitudes, satisfaction, perceived effectiveness, and usage barriers.

Cointerventions and Contamination

Cointerventions during the intervention period cannot always be avoided. However, we will be able to determine whether patients received cointerventions by means of the monthly cost diaries. The risk of contamination is reduced by the cluster design of the trial. To assess whether contamination occurred, the patients in both groups are asked about the instructions they received at discharge, which will then be compared to the convalescence recommendations implemented during the intervention phase of the study.

Data Collection

The surgery is considered T_0. The data will be collected by means of self-reported electronic questionnaires [58] before surgery and 2 weeks (T_1), 6 weeks (T_2), 12 weeks (T_3), 26 weeks (T_4), and 52 weeks (T_5) after surgery. In addition, all of the participants will be requested to fill out a monthly electronic sick leave calendar and cost diary. The patients that are not sick listed, and do not have medical costs during 3 consecutive months, receive a shortened version of the monthly questionnaire. In the case of no response, the patients receive an electronic reminder after 1 and, if necessary, 2 weeks. Every 3 months an attempt will be made to complete missing data regarding RTW, sick leave, and health care usage per email, post, and/or telephone. Table 3 provides an overview of all outcome measures and assessment instruments used in this trial. Not all of the instruments have been validated for Internet use.

Table 3. Assessment of study outcomes.

Outcome measures		–		+	+	+	+	+
		± 4 weeks	Surgery (T_0)	2 weeks (T_1)	6 weeks (T_2)	3 months (T_3)	6 months (T_4)	12 months (T_5)
Primary								
	Duration of sick leave until full sustainable RTW	Monthly sick leave calendar[a]						
Secondary								
	Duration of sick leave until first RTW	Monthly sick leave calendar[a]						
	Total duration of sick leave	Monthly sick leave calendar[a]						
	Recovery (RI-10)	x		x	x	x	x	x
	Quality of life (EQ-5D)	x		x	x	x	x	x
	Quality of life (SF-36)	x				x	x	x
	Self-efficacy (GSES)			x		x		x
	Coping (PMS)			x		x		x
	Pain intensity (VAS)			x	x	x	x	x
	(Post) operative complications			x	x			x[b]
Prognostic factors								
	Social demographic variables	x						
	Personal factors	x						
	Work related factors (DMQ, JCQ)	x						
	Type of surgery/complications		x					
Cost								
	Care program	Bottom-up approach[c]						
	Health care utilization	Monthly cost diary[a]						
	Productivity loss	Monthly sick leave calendar[a]						
Process [d]								
	Compliance (dose received)	Continuously by weblog						
	Attitudes (satisfaction, perceived effectiveness, usage barriers)					x		x
	Satisfaction Patient Satisfaction with Occupational Health Services Questionnaire					x		x

[a]short version after 3 consecutive months without sick leave or health care usage

[b]review of surgical reports

[c]calculated by research team

[d]only intervention group

Blinding

The participants, care providers, and researchers cannot be blinded for the allocated treatment. However, analysis of the data by the researcher will be blind, as all of the patients receive their own study code, under which their data is stored in the database. The assessment of the outcomes is measured through self-reported questionnaires.

Sample Size

We calculated the sample size needed with the method described by Hussey and Hughes [35]. Based on the previous study, we expect a hazard ratio of 1.5 on the primary outcome full sustainable RTW. To achieve a power of 0.8 with a two-tailed alpha of .05, and taking into account a dropout rate of 10%, a

total of 212 patients will be needed when using the log-rank test.

With an intracluster correlation of .05, 9 clusters, and 10 time periods, the design effect is calculated to be 2.14 [35]. By multiplying the design effect by the sample size without a correction for a stepped wedge design, a sample size of 454 women is needed. Assuming that all of the hospitals will include the same amount of participants, each hospital should include approximately 50 patients (5 patients per time period per hospital).

Statistical Analyses

Effect Evaluation

All further described analyses will be performed at the patient level, according to the intention-to-treat principle. In addition, for all tests, a two-tailed significance level of $P \leq .05$ will be considered statistically significant. The statistical software packages that will be used include SPSS (version 16.0) and STATA (version 11.2).

The baseline characteristics will be summarized using descriptive statistics, and compared between the experimental and control group to verify prognostic comparability. In case of coincidental and meaningful differences, these variables will be used as covariates in the further described models.

For the primary outcome, the duration of sick leave until full sustainable RTW, Cox regression analyses will be used to investigate the intervention effect. Both the crude and adjusted analyses will be performed. In the adjusted analyses, the following variables will be used as covariates: (1) hospital, to adjust for clustering (random gamma effect); (2) type of surgery performed; (3) time period, to adjust for naturally occurring changes over time irrespective of the intervention; and (4) optionally, (time period) x (intervention) interaction term, to adjust for time effects (the longer the care program is implemented, the more effective it might be).

The differences in secondary outcomes will be assessed using generalized linear longitudinal mixed models. All of the available measurements (2 weeks, 6 weeks, 12 weeks, 26 weeks, and 52 weeks) will be used, and the baseline scores will be used as covariates, as well as the hospital and the type of surgery (random effect).

To assess whether protocol deviations caused bias, a per protocol analysis will be performed, and the results will be compared to the intention-to-treat analyses. In addition, several subgroup analyses will be performed. The predefined subgroups will be: (1) hysterectomy (TAH, VH, TLH); (2) minimally invasive hysterectomy (VH, TLH); (3) abdominal hysterectomy only; and (4) laparoscopic adnexal surgery only.

Economic Evaluation

Both a cost-effectiveness analysis and a cost-utility analysis will be performed from the societal perspective. The analyses will be performed according to the intention-to-treat principle. The missing cost and effect data will be imputed using multiple imputation [59]. The imputation will include variables that are related to the missing data or the outcome measure, and variables that differ at baseline between the groups. To account for the skewed distribution of costs, predictive mean matching will be used in the multiple imputation. The number of imputed datasets to be created will be determined based on the fraction of missing information [60]. 'All of the datasets will be analyzed separately, and the results of these analyses will be pooled using Rubin's rules [61]. The incremental cost effectiveness ratios (ICERs) will be calculated by dividing the differences in mean total costs between both treatment groups, by the difference in mean effects between both treatment groups. To avoid double counting, the productivity costs due to sick leave will be excluded in the ICER, with sick leave as the effect measure. The incremental cost utility ratio will be calculated by dividing the incremental costs by the difference in the quality adjusted life years between both treatment groups. To account for the typically skewed distribution of costs, bias corrected and accelerated bootstrapping (5000 replications) will be used to estimate the 95% confidence intervals around the mean cost differences, and the uncertainty surrounding the ICERs. The bootstrapped ICERs will be graphically presented in cost effectiveness planes [62]. The cost effectiveness acceptability curves will be estimated to show the probability of the intervention program to be cost effective in comparison with the usual care for a range of different ceiling ratios, thereby showing decision uncertainty [63]. To assess the robustness of results, several secondary economic analyses will be performed: (1) complete case analysis, (2) per protocol analysis, (3) analysis with costs calculated according to the friction cost approach, and (4) analysis from the health care perspective.

Results

The enrollment of the patients started October 2011. The follow-up period will be completed in August 2014. Data cleaning or analysis has not begun as of this article's submission.

Discussion

Targeting Two Levels

This paper outlines the methodology of a stepped wedge cluster randomized trial to evaluate the cost effectiveness of a care program designed to improve postoperative recovery compared to the usual care. The intervention care program targets two levels: (1) the level of the hospital, and (2) the level of the patient. At the level of the hospital, the newly developed guidelines will be distributed among the clinical staff in order to stimulate evidence-based patient education at the time of discharge. At the patient level, access to an eHealth intervention is provided with tailored convalescence recommendations, and an occupational intervention is available, for those patients at risk of prolonged sick leave, for additional guidance.

What This Study Will Add

The combination of increasing demands on the health care system and the limited health care budget designates a need to enhance the cost effectiveness of our health care system. The introduction of minimally invasive techniques in the last two decades has led to savings in in-hospital care due to shorter lengths of hospital stay, despite higher operative costs, longer

operation time, and more expensive equipment [64-66]. However, early discharge does not necessarily lead to enhanced recovery, as postoperative recovery at home requires a different organization of perioperative care as well, such as preoperative patient education, including the deliverance of evidence-based standardized convalescence recommendations [6,8,9,12,67-70]. As far as we know, our care program is the first intervention developed, and being thoroughly evaluated, that anticipates this transition of perioperative care to the home setting. Second, the utilization of innovative eHealth technologies will limit the workload of involved health care professionals, anticipating a personnel shortage in the health care sector due to a shrinkage of the working population in the near future [71]. Finally, our trial will be one of few that conducted an economic evaluation from a societal perspective, not only taking into account solely direct medical costs—which are important for the hospital perspective—but also including costs associated with postoperative health care utilization and productivity losses due to absenteeism and presenteeism after discharge.

Strengths and Limitations

The main strength of the present study is the choice for a stepped wedge cluster randomized trial. The contamination between study arms is prevented by the cluster design. In addition, the stepped wedge approach enables us to study the implementation process carefully, and gain valuable insight into the facilitators and barriers toward future implementation of the intervention program [72]. Because the crossover of the design is unidirectional, the intervention is not withdrawn from the hospitals during the trial. This is particularly convenient, as our previous trial supports our hypothesis that the care program will lead to enhanced postoperative recovery [73]. Finally, there is a statistical advantage to the stepped wedge approach because the intervention effect is estimated not only by between cluster comparisons, as in a parallel group design, but also by within cluster comparisons, limiting the risk of confounding and increasing statistical power [36,74].

This study also has limitations. First of all, randomized studies without blinding have higher risks of (selection) bias. A second limitation of this study might be the fact that some of the hospitals have already participated in the earlier trial in 2010. The existing knowledge about the convalescence recommendations could be a source of contamination for the current study, and could lead to an under estimation of the care program effect.

Generalizability

The generalizability of this study will be high, due to the pragmatic study design. In order for procedures to be similar to clinical practice, interference of the research team will be minimized during the trial. The wide diversity of participating (7 teaching, 1 academic, and 1 nonteaching) hospitals, will also contribute to a heterogeneous sample of patients being enrolled in this study, enhancing generalizability. However, we should also be aware of factors that could possibly limit the external validity. A typical feature of eHealth interventions is the risk of selection bias toward the higher educated participants as compared to the general population. Moreover, as the care program was developed in the Dutch setting, and especially tailored to Dutch patients, generalizability of the results of this trial to other countries will be unknown, due to differences in social and health care systems.

Policy Implications

The results of this cost effectiveness study will enable health care policy makers to decide about future implementation of the care program on a broad scale in the Netherlands. In the case that the care program under study is proven to be cost effective, this will have considerable impact. Most importantly, the financial burden on society due to prolonged sick leave following benign gynecological surgery will be substantially reduced. Also, the individual patients will benefit through increased quality of life, and employers will profit because of a decline in absenteeism rates. Moreover, for health care professionals, the care program will be an asset, as it will lead to better organized and more efficient care. Finally, the care program has the potential to maximize the beneficial effects of other recovery enhancing strategies, such as the use of minimally invasive surgery.

Acknowledgments

This study was funded by ZonMw, an organization for health research and development in the Netherlands (project numbers 150020037, 171102015, and 92003590).

Conflicts of Interest

EVB, AVN, HAB, JRA, and JAH are the developers of the care program under study.

Multimedia Appendix 1

Screenshots of ikherstel.

[PPT File (Microsoft PowerPoint Presentation), 1MB - resprot_v3i2e30_app1.ppt]

Multimedia Appendix 2

CONSORT-EHEALTH checklist V1.6.2 [34].

[PDF File (Adobe PDF File), 984KB - resprot_v3i2e30_app2.pdf]

Multimedia Appendix 3

Grant Proposal.

[PDF File (Adobe PDF File), 150KB - resprot_v3i2e30_app3.pdf]

Multimedia Appendix 4

Letter of Grant Approval.

[PDF File (Adobe PDF File), 41KB - resprot_v3i2e30_app4.pdf]

References

1. Kehlet H, Wilmore DW. Multimodal strategies to improve surgical outcome. Am J Surg 2002 Jun;183(6):630-641. [Medline: 12095591]
2. Wodlin NB, Nilsson L. The development of fast-track principles in gynecological surgery. Acta Obstet Gynecol Scand 2013 Jan;92(1):17-27. [doi: 10.1111/j.1600-0412.2012.01525.x] [Medline: 22880948]
3. Kjølhede P, Borendal Wodlin N, Nilsson L, Fredrikson M, Wijma K. Impact of stress coping capacity on recovery from abdominal hysterectomy in a fast-track programme: A prospective longitudinal study. BJOG 2012 Jul;119(8):998-1006; discussion 1006. [doi: 10.1111/j.1471-0528.2012.03342.x] [Medline: 22568450]
4. Gilmartin J. Contemporary day surgery: Patients' experience of discharge and recovery. J Clin Nurs 2007 Jun;16(6):1109-1117. [doi: 10.1111/j.1365-2702.2007.01548.x] [Medline: 17518885]
5. Horvath KJ. Postoperative recovery at home after ambulatory gynecologic laparoscopic surgery. J Perianesth Nurs 2003 Oct;18(5):324-334. [Medline: 14569542]
6. Bisgaard T, Klarskov B, Rosenberg J, Kehlet H. Factors determining convalescence after uncomplicated laparoscopic cholecystectomy. Arch Surg 2001 Aug;136(8):917-921. [Medline: 11485527]
7. Møller C, Ottesen M, Kehlet H, Ottesen BS. Convalescence recommendations after hysterectomy. A study of opinions among Danish physicians. Ugeskr Laeger 2001 Dec 10;163(50):7043-7047. [Medline: 11794035]
8. Naidu M, Sultan AH, Thakar R. Convalescence advice following gynaecological surgery. J Obstet Gynaecol 2012 Aug;32(6):556-559. [doi: 10.3109/01443615.2012.693983] [Medline: 22779961]
9. Ottesen M, Møller C, Kehlet H, Ottesen B. Substantial variability in postoperative treatment, and convalescence recommendations following vaginal repair. A nationwide questionnaire study. Acta Obstet Gynecol Scand 2001 Nov;80(11):1062-1068. [Medline: 11703209]
10. Vonk Noordegraaf A, Anema JR, Louwerse MD, Heymans MW, van Mechelen W, Brölmann HA, et al. Prediction of time to return to work after gynaecological surgery: A prospective cohort study in the Netherlands. BJOG 2014 Mar;121(4):487-497. [doi: 10.1111/1471-0528.12494] [Medline: 24245993]
11. Well A, Ijsseldijk A, Bonjer J, Vrijland W, Brouwer K. Medisch Contact. 2002. Boer Kd. Onnodig thuis; ziekteverzuim na liesbreukoperatie URL: http://medischcontact.artsennet.nl/archief-6/tijdschriftartikel/05311/onnodig-thuis.htm [accessed 2014-06-05] [WebCite Cache ID 6Q6M43leM]
12. Carter E. Ready for home? Nurs Times 1981 May 7;77(19):826-829. [Medline: 6909791]
13. Evenson M, Payne D, Nygaard I. Recovery at home after major gynecologic surgery: How do our patients fare? Obstet Gynecol 2012 Apr;119(4):780-784. [doi: 10.1097/AOG.0b013e31824bb15e] [Medline: 22433341]
14. Majeed AW, Brown S, Williams N, Hannay DR, Johnson AG. Variations in medical attitudes to postoperative recovery period. BMJ 1995 Jul 29;311(7000):296 [FREE Full text] [Medline: 7633239]
15. Easton K, Read MD, Woodman NM. Influence of early discharge after hysterectomy on patient outcome and GP workloads. J Obstet Gynaecol 2003 May;23(3):271-275. [Medline: 12850859]
16. Johansen P, Al-Khafagi SK, Thøstesen LM, Lauszus FF, Rasmussen KL. Analysis of need for sick leave after hysterectomy. Ugeskr Laeger 2008 Apr 21;170(17):1465-1468. [Medline: 18462627]
17. Rasmussen KL, Hansen V, Madzak F, Ljungstrøm B, Lauszus FF. Feeling of illness after hysterectomy. Women's own assessment. Ugeskr Laeger 2001 Dec 10;163(50):7040-7042. [Medline: 11794034]
18. van Oostrom SH, Driessen MT, de Vet HC, Franche RL, Schonstein E, Loisel P, et al. Workplace interventions for preventing work disability. Cochrane Database Syst Rev 2009(2):CD006955. [doi: 10.1002/14651858.CD006955.pub2] [Medline: 19370664]
19. Waddell G, Burton AK. Is work good for your health and well-being?. 2006 URL: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/214326/hwwb-is-work-good-for-you.pdf [accessed 2014-03-03] [WebCite Cache ID 6NnRlwNCh]
20. Reeuwijk KG, Robroek SJ, Hakkaart L, Burdorf A. How work impairments and reduced work ability are associated with health care use in workers with musculoskeletal disorders, cardiovascular disorders or mental disorders. J Occup Rehabil 2014 Jan 4. [doi: 10.1007/s10926-013-9492-3] [Medline: 24390780]
21. Statline Databank. Surgeries in the Netherlands. 2014 February URL: http://www.webcitation.org/6Nm4SznjS

22. Vonk Noordegraaf A, Huirne JA, Brölmann HA, van Mechelen W, Anema JR. Multidisciplinary convalescence recommendations after gynaecological surgery: A modified Delphi method among experts. BJOG 2011 Dec;118(13):1557-1567. [doi: 10.1111/j.1471-0528.2011.03091.x] [Medline: 21895950]
23. Vonk Noordegraaf A, Huirne JA, Pittens CA, van Mechelen W, Broerse JE, Brölmann HA, et al. eHealth program to empower patients in returning to normal activities and work after gynecological surgery: Intervention mapping as a useful method for development. J Med Internet Res 2012;14(5):e124 [FREE Full text] [doi: 10.2196/jmir.1915] [Medline: 23086834]
24. Pittens CA, Vonk Noordegraaf A, van Veen SC, Anema JR, Huirne JA, Broerse JE. The involvement of gynaecological patients in the development of a clinical guideline for resumption of (work) activities in the Netherlands. Health Expect 2013 Aug 29. [doi: 10.1111/hex.12121] [Medline: 23992108]
25. Vonk Noordegraaf A, Huirne JA, Brölmann HA, Emanuel MH, van Kesteren PJ, Kleiverda G, et al. Effectiveness of a multidisciplinary care program on recovery and return to work of patients after gynaecological surgery; design of a randomized controlled trial. BMC Health Serv Res 2012;12:29 [FREE Full text] [doi: 10.1186/1472-6963-12-29] [Medline: 22296950]
26. Vonk Noordegraaf A, Anema J, van Mechelen W, Knol D, van Baal W, van Kesteren P, et al. A personalised eHealth programme reduces the duration until return to work after gynaecological surgery: Results of a multicentre randomised trial. BJOG 2014 Feb 11. [doi: 10.1111/1471-0528.12661] [Medline: 24511914]
27. Bouwsma EV, Vonk Noordegraaf A, Szlávik Z, Brölmann HA, Emanuel MH, Lips JP, et al. Process evaluation of a multidisciplinary care program for patients undergoing gynaecological surgery. J Occup Rehabil 2013 Sep 22. [doi: 10.1007/s10926-013-9475-4] [Medline: 24057871]
28. Drummond MF, Sculpher MJ, Torrance GW, O'Brien BJ, Stoddart GL. Methods for the economic evaluation of health care programmes. Oxford: Oxford University Press; 2005.
29. Chan AW, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin JA, et al. SPIRIT 2013 explanation and elaboration: Guidance for protocols of clinical trials. BMJ 2013;346:e7586 [FREE Full text] [Medline: 23303884]
30. Schulz KF, Altman DG, Moher D, CONSORT Group. CONSORT 2010 statement: Updated guidelines for reporting parallel group randomized trials. Obstet Gynecol 2010 May;115(5):1063-1070. [doi: 10.1097/AOG.0b013e3181d9d421] [Medline: 20410783]
31. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: Updated guidelines for reporting parallel group randomised trials. BMJ 2010;340:c869 [FREE Full text] [Medline: 20332511]
32. Campbell MK, Piaggio G, Elbourne DR, Altman DG, CONSORT Group. Consort 2010 statement: Extension to cluster randomised trials. BMJ 2012;345:e5661. [Medline: 22951546]
33. Eysenbach G, CONSORT-EHEALTH Group. CONSORT-EHEALTH: Improving and standardizing evaluation reports of Web-based and mobile health interventions. J Med Internet Res 2011;13(4):e126 [FREE Full text] [doi: 10.2196/jmir.1923] [Medline: 22209829]
34. Brown CA, Lilford RJ. The stepped wedge trial design: A systematic review. BMC Med Res Methodol 2006;6:54 [FREE Full text] [doi: 10.1186/1471-2288-6-54] [Medline: 17092344]
35. Hussey MA, Hughes JP. Design and analysis of stepped wedge cluster randomized trials. Contemp Clin Trials 2007 Feb;28(2):182-191. [doi: 10.1016/j.cct.2006.05.007] [Medline: 16829207]
36. Mdege ND, Man MS, Taylor Nee Brown CA, Torgerson DJ. Systematic review of stepped wedge cluster randomized trials shows that design is particularly used to evaluate interventions during routine implementation. J Clin Epidemiol 2011 Sep;64(9):936-948. [doi: 10.1016/j.jclinepi.2010.12.003] [Medline: 21411284]
37. de Vries H, Dijkstra M, Kuhlman P. Self-efficacy: The third factor besides attitude and subjective norm as a predictor of behavioural intentions. Health Educ Res 1988;3(3):273-282. [doi: 10.1093/her/3.3.273]
38. Lechner L, Kremers S, Meertens R, de Vries H. Determinanten van gedrag. In: Gezondheidsvoorlichting en gedragsverandering Health Education and Behavioral Change. 8 ed. Assen: van Gorcum; 2012:75-106.
39. ikherstel. Welkom bij ikherstel.nl URL: http://www.ikherstel.nl./ [accessed 2014-06-04] [WebCite Cache ID 6Q5N3xli7]
40. van Oostrom SH, van Mechelen W, Terluin B, de Vet HC, Knol DL, Anema JR. A workplace intervention for sick-listed employees with distress: Results of a randomised controlled trial. Occup Environ Med 2010 Sep;67(9):596-602. [doi: 10.1136/oem.2009.050849] [Medline: 20363809]
41. Vermeulen SJ, Anema JR, Schellart AJ, Knol DL, van Mechelen W, van der Beek AJ. A participatory return-to-work intervention for temporary agency workers and unemployed workers sick-listed due to musculoskeletal disorders: Results of a randomized controlled trial. J Occup Rehabil 2011 Sep;21(3):313-324 [FREE Full text] [doi: 10.1007/s10926-011-9291-7] [Medline: 21336673]
42. Anema JR, Steenstra IA, Urlings IJ, Bongers PM, de Vroome EM, van Mechelen W. Participatory ergonomics as a return-to-work intervention: A future challenge? Am J Ind Med 2003 Sep;44(3):273-281. [doi: 10.1002/ajim.10259] [Medline: 12929147]
43. de Jong AM, Vink P. Participatory ergonomics applied in installation work. Appl Ergon 2002 Sep;33(5):439-448. [Medline: 12236653]

44. de Vet HC, Heymans MW, Dunn KM, Pope DP, van der Beek AJ, Macfarlane GJ, et al. Episodes of low back pain: A proposal for uniform definitions to be used in research. Spine (Phila Pa 1976) 2002 Nov 1;27(21):2409-2416. [doi: 10.1097/01.BRS.0000030307.34002.BE] [Medline: 12438991]
45. Kluivers KB, Hendriks JC, Mol BW, Bongers MY, Vierhout ME, Brölmann HA, et al. Clinimetric properties of 3 instruments measuring postoperative recovery in a gynecologic surgical population. Surgery 2008 Jul;144(1):12-21. [doi: 10.1016/j.surg.2008.03.027] [Medline: 18571580]
46. Dolan P. Modeling valuations for EuroQol health states. Med Care 1997 Nov;35(11):1095-1108. [Medline: 9366889]
47. Aaronson NK, Muller M, Cohen PD, Essink-Bot ML, Fekkes M, Sanderman R, et al. Translation, validation, and norming of the Dutch language version of the SF-36 health survey in community and chronic disease populations. J Clin Epidemiol 1998 Nov;51(11):1055-1068. [Medline: 9817123]
48. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992 Jun;30(6):473-483. [Medline: 1593914]
49. Teeuw B, Schwarzer R, Jerusalem M. Dutch adaptation of the general self-efficacy scale. 1994 URL: http://userpage.fu-berlin.de/~gesund/publicat/ehps_cd/health/dutch.htm [accessed 2014-03-03] [WebCite Cache ID 6NnSKKgm3]
50. Pearlin LI, Schooler C. The structure of coping. J Health Soc Behav 1978 Mar;19(1):2-21. [Medline: 649936]
51. Von Korff M, Ormel J, Keefe FJ, Dworkin SF. Grading the severity of chronic pain. Pain 1992 Aug;50(2):133-149. [Medline: 1408309]
52. Hildebrandt VH, Bongers PM, van Dijk FJ, Kemper HC, Dul J. Dutch musculoskeletal questionnaire: Description and basic qualities. Ergonomics 2001 Oct 10;44(12):1038-1055. [doi: 10.1080/00140130110087437] [Medline: 11780727]
53. Karasek R, Brisson C, Kawakami N, Houtman I, Bongers P, Amick B. The job content questionnaire (JCQ): An instrument for internationally comparative assessments of psychosocial job characteristics. J Occup Health Psychol 1998 Oct;3(4):322-355. [Medline: 9805280]
54. Statline Databank. Consumer prices. URL: http://www.cbs.nl/nl-NL/menu/themas/inkomen-bestedingen/cijfers/default.htm [accessed 2014-03-02] [WebCite Cache ID 6NluSnQ0M]
55. Z-index. G-standaard. URL: http://www.z-index.nl/g-standaard/g-standaard [accessed 2014-03-03] [WebCite Cache ID 6NnSqbHJW]
56. Koopmanschap MA. PRODISQ: A modular questionnaire on productivity and disease for economic evaluation studies. Expert Rev Pharmacoecon Outcomes Res 2005 Feb;5(1):23-28. [doi: 10.1586/14737167.5.1.23] [Medline: 19807557]
57. Steckler AB, Linnan L. Process evaluation for public health interventions and research: An overview. In: Process evaluation for public health interventions and research. USA: Jossey-Bass; 2002.
58. Net Q. Utrecht, The Netherlands: NetQuestionnaires Nederland BV; 2011. Software for creating assessment of internet surveys. Computer program URL: http://www.netq-enquete.nl/nl [accessed 2014-06-07] [WebCite Cache ID 6QA6xaD7e]
59. van Buuren S, Boshuizen HC, Knook DL. Multiple imputation of missing blood pressure covariates in survival analysis. Stat Med 1999 Mar 30;18(6):681-694. [Medline: 10204197]
60. White IR, Royston P, Wood AM. Multiple imputation using chained equations: Issues and guidance for practice. Stat Med 2011 Feb 20;30(4):377-399. [doi: 10.1002/sim.4067] [Medline: 21225900]
61. Rubin DB. Multiple imputation for nonresponse in surveys. New York: Wiley; 1987.
62. Black WC. The CE plane: A graphic representation of cost-effectiveness. Med Decis Making 1990;10(3):212-214. [Medline: 2115096]
63. Fenwick E, O'Brien BJ, Briggs A. Cost-effectiveness acceptability curves--facts, fallacies and frequently asked questions. Health Econ 2004 May;13(5):405-415. [doi: 10.1002/hec.903] [Medline: 15127421]
64. Bijen CB, Vermeulen KM, Mourits MJ, de Bock GH. Costs and effects of abdominal versus laparoscopic hysterectomy: Systematic review of controlled trials. PLoS One 2009;4(10):e7340 [FREE Full text] [doi: 10.1371/journal.pone.0007340] [Medline: 19806210]
65. Nieboer TE, Johnson N, Lethaby A, Tavender E, Curr E, Garry R, et al. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev 2009(3):CD003677. [doi: 10.1002/14651858.CD003677.pub4] [Medline: 19588344]
66. Sculpher M, Manca A, Abbott J, Fountain J, Mason S, Garry R. Cost effectiveness analysis of laparoscopic hysterectomy compared with standard hysterectomy: Results from a randomised trial. BMJ 2004 Jan 17;328(7432):134 [FREE Full text] [doi: 10.1136/bmj.37942.601331.EE] [Medline: 14711748]
67. Bay-Nielsen M, Bisgaard T. Convalescence and sick leave following inguinal hernia repair. Ugeskr Laeger 2009 Sep 28;171(40):2899-2901. [Medline: 19814936]
68. Callesen T, Klarskov B, Bech K, Kehlet H. Short convalescence after inguinal herniorrhaphy with standardised recommendations: Duration and reasons for delayed return to work. Eur J Surg 1999 Mar;165(3):236-241. [doi: 10.1080/110241599750007108] [Medline: 10231657]
69. Clayton M, Verow P. Advice given to patients about return to work and driving following surgery. Occup Med (Lond) 2007 Oct;57(7):488-491 [FREE Full text] [doi: 10.1093/occmed/kqm063] [Medline: 17906266]

70. Berendsen AJ, de Jong GM, Meyboom-de Jong B, Dekker JH, Schuling J. Transition of care: Experiences and preferences of patients across the primary/secondary interface - a qualitative study. BMC Health Serv Res 2009;9:62 [FREE Full text] [doi: 10.1186/1472-6963-9-62] [Medline: 19351407]
71. Noteboom A, Blankers I, Goudriaan R, Groot W. E-health en zelfmanagement: een panacee voor arbeidstekorten en kostenoverschrijdingen in de zorg?. URL: http://www.ape.nl/include/downloadFile.asp?id=286 [accessed 2014-03-03] [WebCite Cache ID 6NnNevrIF]
72. Dekkers OM. The stepped wedge design. Ned Tijdschr Geneeskd 2012;156(9):A4069. [Medline: 22373553]
73. Edwards SJ, Braunholtz DA, Lilford RJ, Stevens AJ. Ethical issues in the design and conduct of cluster randomised controlled trials. BMJ 1999 May 22;318(7195):1407-1409 [FREE Full text] [Medline: 10334756]
74. Woertman W, de Hoop E, Moerbeek M, Zuidema SU, Gerritsen DL, Teerenstra S. Stepped wedge designs could reduce the required sample size in cluster randomized trials. J Clin Epidemiol 2013 Jul;66(7):752-758. [doi: 10.1016/j.jclinepi.2013.01.009] [Medline: 23523551]

Abbreviations

CONSORT: CONsolidated Standards Of Reporting Trials
DMQ: Dutch Musculoskeletal Questionnaire
EQ-5D: EuroQol-5D
GP: general physician
GSES: General Self-Efficacy Scale
ICER: incremental cost effectiveness ratio
IQR: interquartile range
JCQ: Job Content Questionnaire
LAS: laparoscopic adnexal surgery
OP: occupational physician
OT: occupational therapist
PMS: Pearlin Mastery Scale
RI-10: Recovery Index-10
RTW: return to work
SF-36: Short-Form Health Survey
TAH: total abdominal hysterectomy
TLH: total laparoscopic hysterectomy
TP: time period
VAS: Visual Analogue Scale
VH: vaginal hysterectomy

Edited by G Eysenbach; submitted 01.04.14; peer-reviewed by G Kok; comments to author 22.04.14; accepted 21.05.14; published 18.06.14.

Please cite as:
Bouwsma EVA, Anema JR, Vonk Noordegraaf A, Knol DL, Bosmans JE, Schraffordt Koops SE, van Kesteren PJM, van Baal WM, Lips JP, Emanuel MH, Scholten PC, Mozes A, Adriaanse AH, Brölmann HAM, Huirne JAF
The Cost Effectiveness of a Tailored, Web-Based Care Program to Enhance Postoperative Recovery in Gynecologic Patients in Comparison With Usual Care: Protocol of a Stepped Wedge Cluster Randomized Controlled Trial
JMIR Res Protoc 2014;3(2):e30
URL: http://www.researchprotocols.org/2014/2/e30/
doi:10.2196/resprot.3236
PMID:24943277

Protocol

Dabigatran Versus Warfarin After Bioprosthesis Valve Replacement for the Management of Atrial Fibrillation Postoperatively: Protocol

Andre Rodrigues Duraes[1], PhD; Pollianna DS Roriz[2], MD; Fabio V Bulhoes[2], MD; Bianca DA Nunes[2]; Juliana QV Muniz[2]; Italvar NDCR Neto[2]; Andre MS Fernandes[2], PdD Comp Sc; Francisco JFBD Reis[2], PhD; Edmundo JN Camara[2], PhD; Erenaldo DSR Junior[2]; Deusdeth TS Segundo[2]; Felipe Pinho E Albuquerque Silva[2]; Roque Aras[2], PhD

[1]Hospital Ana Nery, Serviço de Cardiologia, Universidade do Estado da Bahia, Salvador, Brazil

[2]Hospital Ana Nery, Serviço de Cardiologia, Universidade Federal da Bahia, Salvador, Brazil

Corresponding Author:
Andre Rodrigues Duraes, PhD
Hospital Ana Nery
Serviço de Cardiologia
Universidade do Estado da Bahia
Rua Saldanha Marinho - Caixa D´água, Salvador - BA, 40320-010
Salvador, 40320-010
Brazil
Phone: 55 7181489582
Fax: 55 7130174583
Email: andreduraes@gmail.com

Abstract

Background: Warfarin and similar vitamin K antagonists have been the standard therapy for patients with mechanical or biological valve prosthesis and atrial fibrillation (AF). Even with the appropriate use of therapy, some studies have reported that there is a high incidence of thromboembolic events, 1%-4% per year. Furthermore, a bleeding risk is significant, ranging from 2% to 9% per year, according to some studies.

Objective: The objective of our study was to examine the effect of dabigatran etexilate versus dose-adjusted warfarin for the prevention of intracardiac thrombus in persistent or permanent AF at least 3 months after aortic and/or mitral bioprosthesis replacement.

Methods: Dabigatran versus warfarin after bioprosthesis valve replacement for the management of atrial fibrillation postoperatively (DAWA) is a phase 2, prospective, open label, randomized exploratory pilot study. The main variable to be observed in this study is intracardiac thrombus. From August 2013 to April 2015, 100 patients, at least 3 months after aortic and/or mitral bioprosthesis replacement and permanent or persistent AF postoperatively, who match eligibility criteria will be selected from Ana Nery Hospital in Salvador-Bahia with a follow-up of three months. Patients were randomly assigned in a 1:1 ratio to receive either dabigatran etexilate or warfarin.

Results: Although the present study has no statistic power to proof non-inferiority, it is expected that the dabigatran etexilate group will be protected as well as the warfarin group from intracardiac thrombus, without increasing the bleeding rates, since we are using safer doses (110 mg bid). The lack of necessity of monitoring INR is also another factor that contributes to a better adherence to the new drug and it can make all the difference in the manner of doing anticoagulation for patients with similar clinical characteristics.

Conclusions: The study is in the recruitment phase. It is possible that dabigatran etexilate is as effective as warfarin in preventing the emergence of intracardiac thrombus in patients with AF and mitral and/or aortic bioprosthesis.

Trial Registration: Clinicaltrials.gov NCT01868243; http://clinicaltrials.gov/ct2/show/NCT01868243 (Archived by WebCite at http://www.webcitation/6OABiuasd).

(JMIR Res Protoc 2014;3(2):e21) doi:10.2196/resprot.3014

KEYWORDS

warfarin; dabigatran; anticoagulants; atrial fibrillation; stroke; hematologic agents

Introduction

Overview

Valvular heart disease affects over 100 million people worldwide. Its prevalence is rising due to the high incidence of rheumatic disease in developing countries and the growing impact of degenerative valve disease in elderly populations, a consequence of population ageing [1,2]. An estimated 4 million valve replacement procedures have been performed in the last 50 years, and it remains the only definitive treatment for most patients with advanced heart valve disease [3].

Warfarin

Warfarin and similar vitamin K antagonists (VKA) have been the standard therapy for patients with a prosthetic heart valve and atrial fibrillation (AF). Even with the appropriate use of therapy, the incidence of thromboembolic events is still substantial, 1%-4% per year. Furthermore, bleeding risk is significant, ranging from 2% to 9% per year [3-5]. VKA have a narrow therapeutic index and also a complex pharmacology, for example, a long pharmacologic inertia and common interaction with other drugs [6]. These features make the management of these drugs a challenge for physicians and their patients.

Dabigatran Etexilate

Dabigatran etexilate is the prodrug of dabigatran, a direct thrombin (factor IIa) inhibitor. After administration, it is rapidly converted by serum esterase to the active moiety, dabigatran, which is a nonpeptide, potent, competitive, and reversible inhibitor of thrombin. The pharmacokinetics and pharmacodynamics of dabigatran allow fixed dose administration without coagulation monitoring [7].

The US Food and Drug Administration (FDA) approved dabigatran on October 19, 2010, for the prevention of stroke and systemic embolism in patients with nonvalvular AF [8]. The Randomized Evaluation of Long-Term Anticoagulation Therapy (RE-LY) trial [9] was a noninferiority study that compared dabigatran at 2 fixed doses (150 mg twice daily and 110 mg twice daily) with dose-adjusted warfarin (target international normalized ratio, INR range = 2.0-3.0) reaching the criterion of noninferiority for the two doses tested (relative risk, RR = 0.66; 95% confidence interval, CI 0.53-0.82; *P*=.001; and RR=0.91; 95% CI 0.74-1.11; *P*=.34, respectively) [8]. The continued observation of 5851 dabigatran-treated RE-LY patients beyond the randomized trial's follow-up time suggests no significant difference between the two dosages in the trial's primary endpoint, stroke or systemic embolism, however, the 150 mg dosage showed higher rates of major and minor bleeding, without increasing the risk of hemorrhagic stroke [10].

Nevertheless, there are no studies in humans evaluating the efficacy and safety of dabigatran in patients with AF and mitral and/or aortic bioprosthetic valve. Among patients with mechanical heart valves, the randomized phase II study to evaluate the safety and pharmacokinetics of oral dabigatran etexilate in patients after heart valve replacement (RE-ALIGN) was terminated early because the dabigatran etexilate treatment arm had significantly more thromboembolic events (valve thrombosis, stroke, and myocardial infarction) and major bleeding (predominantly postoperative pericardial effusions requiring intervention for hemodynamic compromise) than did the warfarin treatment arm. These bleeding and thromboembolic events were reported in patients who were initiated on dabigatran etexilate postoperatively within 3 days after mechanical bileaflet valve implantation, and in patients whose valves had been implanted more than 3 months previously [11].

With this gap in mind, considering the complicated management of VKAs, the investigators of this study chose to conduct an open randomized controlled pilot trial to assess the efficacy and safety of dabigatran etexilate compared with warfarin in patients with persistent or permanent AF after bioprosthetic mitral and/or aortic replacement (DAWA).

Methods

Study Design

DAWA is a phase 2, prospective, open label randomized pilot study. The main variable to be observed in this study is intracardiac thrombus. There are no formal primary or secondary clinical efficacy or safety outcomes because it is a pilot study. Mortality and morbidity events (ischemic and hemorrhagic stroke, systemic embolism, major bleeding, prosthesis valve thrombosis, and any cause of death) will be evaluated in an exploratory manner and are considered as further endpoints in this trial. The inclusion and exclusion criteria are outlined in Textboxes 1 and 2.

The study will be performed in accordance with the ethical principles that have been laid down in the Declaration of Helsinki. They are consistent with the International Conference on Harmonization/Good Clinical Practice, and applicable regulatory requirements in Brazil where it was approved unreservedly by the local ethics and research committee´s under protocol number 14284813.9.0000.0045. A data monitoring committee will monitor patient safety and treatment efficacy every 2 months.

Textbox 1. DAWA inclusion criteria.

1. Age from 18 to 64 years at entry
2. Patients with mitral and/or aorthic valve bioprosthesis for at least 3 months postoperatively
3. There is 12-lead electrocardiogram documented AF on the day of screening or randomization; or a 24-hour Holter electrocardiogram recording showing AF episodes postoperatively
4. Brain computed tomography scan without hemorrhage or findings of acute cerebral infarction on the last 2 days of screening
5. Exclusion of atrial thrombus or valve prosthesis thrombosis by transesophageal echocardiograph on the last 2 days of screening
6. Written, informed consent

Textbox 2. DAWA exclusion criteria.

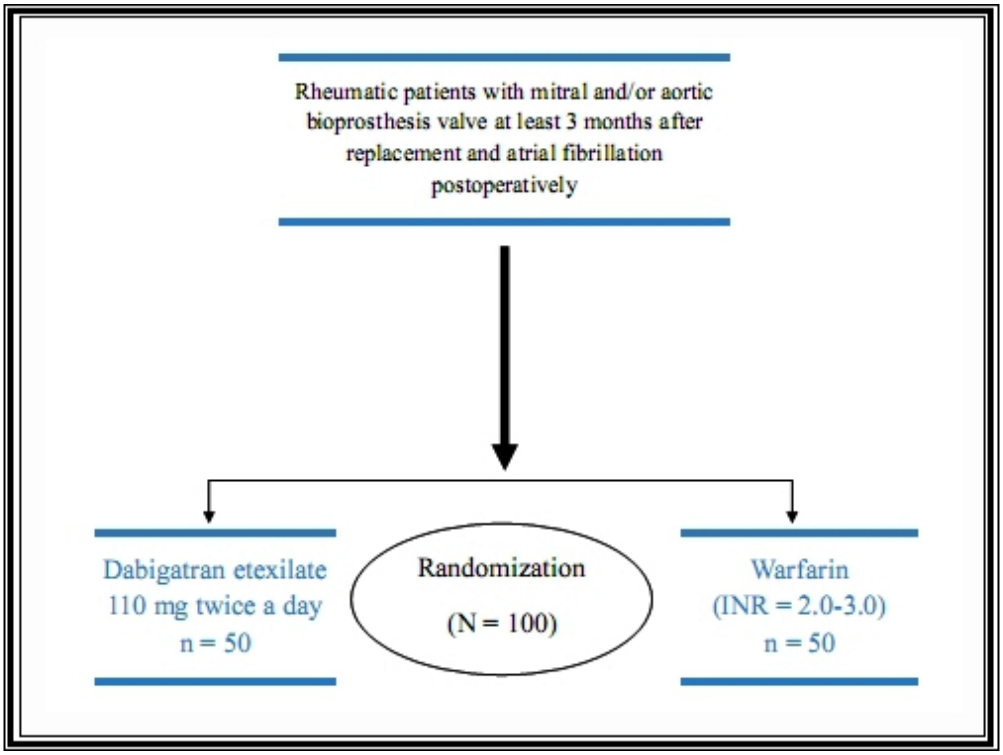
1. Previous hemorrhagic stroke
2. Ischemic stroke in the last 6 months
3. Severe renal impairment (creatinine clearance rates < 30 ml/min)
4. Active liver disease (any etiology)
5. Concomitant use of any antiplatelet (aspirin, clopidogrel, prasugrel, ticagrelor, ticlopidine, etc)
6. Increased risk of bleeding (congenital or acquired)
7. Uncontrolled hypertension
8. Gastrointestinal hemorrhage within the past year
9. Anemia (hemoglobin level <10 g/dL) or thrombocytopenia (platelet count < 100 × 109/L)
10. Active infective endocarditis
11. Pregnant or lactating women

Randomization and Follow-Up

Prospectively, from August 2013 to April 2015, 100 consecutive patients between 18 and 64 years old, at least 3 months after mitral and/or aortic bioprosthesis valve replacement, documented AF postoperatively, and who match the eligibility criteria are being recruited from Ana Nery Hospital in Salvador-Brazil after obtention of informed consent.

For the allocation of the participants, a computer generated list of random numbers including 1 to 100 was used [12]. Following that, the allocation sequence was concealed (in sequentially numbered, opaque, black, sealed, and stapled envelopes) from the researcher who was enrolling and assessing participants. By convention, every “even number” is being allocated to the dabigatran etexilate group and every “odd number” to the warfarin group, that was consecutively selected blindly from the previous list, thereby selecting exactly 50 patients in each group (1:1 allocation), (Figure 1 shows this grouping). After this randomization, patients had study visits scheduled at 7 days (via telephone) and at 30 days (personally). The enrollment period was 21 months with a planned minimum follow-up period of 3 months.

Figure 1. DAWA study.



Drug Administration Protocol

Dabigatran etexilate will be supplied as capsules containing 110 mg, which should be taken twice daily without the need of INR monitoring. All the patients randomized to use dabigatran etexilate will remain with that drug for the duration of the study. Any patients who used warfarin previously will do a drug washout, followed by an immediate introduction of dabigatran etexilate once the INR < 2.5.

The patients assigned to warfarin will require close coagulation monitoring to achieve the target INR (range, 2.0-3.0). Therefore, it will be necessary to follow a protocol of monitoring and dosage adjustment of this drug to ensure the safety and optimization of its use since each patient responds differently to the same doses. The warfarin dose adjustment algorithm was made according to the evidence-based guideline of the American College of Chest Physicians, and several other studies [6,13-18]. Doses between 5 mg and 10 mg were administered for the first days for most individuals, with subsequent dosing based on INR response. The patients should have a baseline prothrombin time/INR checked prior to initiating warfarin therapy, and rechecked 2-3 days after initiating therapy, and then checked again every 2-3 days until stable. After this, they will be rechecked after 15 days, and if they are stable, every 30 days.

Outcomes

The primary endpoint will be the appearance of an intracardiac thrombus in an esophageal echocardiogram to be held at the end of the follow-up. Other probable endpoints are the composite of stroke (ischemic or hemorrhagic), systemic embolism (to the central nervous system or peripheral), and prosthesis valve thrombosis. The safety endpoints will be any bleeding event (major or minor), elevated liver enzymes, or hepatic function abnormalities.

A thromboembolic event involving the central nervous system was defined as a sudden, focal neurological deficit of presumed vascular origin lasting 24 hours to 7 days (reversible ischemic neurological deficit) or enduring more than 7 days (stroke), as confirmed by computed tomographic or magnetic resonance scan imaging and evaluated by a skilled physician. A peripheral embolism was diagnosed when there was a sudden onset of arterial occlusion in the extremities (with or without cyanosis) and with reported absence of pulse, or sudden abdominal pain requiring urgent intervention (confirming acute intestinal ischemia during the surgical procedure). One of the criteria in the list below defined a major bleeding event [19]. All other bleeding will be considered minor and will also be computed.

Major bleeding criteria: (1) fatal bleeding, (2) symptomatic bleeding in a critical area or organ, such as intracranial, intraspinal, intraocular, retroperitoneal, intraarticular or pericardial, or intramuscular with compartment syndrome, and/or, (3) bleeding causing a fall in hemoglobin level of 20 g L^{-1}(1.24 mmol L^{-1}) or more, or leading to transfusion of two or more units of whole blood or red cells.

Safety Monitoring

Any patients with bleeding on dabigatran etexilate or warfarin therapy will be immediately hospitalized and screened for the severity of bleeding (mild, moderate, or life-threatening bleeding). The management of these complications will follow current guidelines and review articles [13-18].

All participants will have telephone visits scheduled weekly. After that period, study visits will be scheduled monthly. The telephone number of all the researchers will also be available to the patients. At any time, in any phase of the study, the patient will have the full right to request exclusion from the study.

Electrocardiography and laboratory tests (blood count, renal function, electrolytes, and liver function tests) will be performed monthly to monitor any changes that indicate bleeding or coagulopathy. Before the randomization and after the follow-up period, patients will undergo a brain computed tomography without contrast to exclude recent ischemic or previous hemorrhagic cerebrals events, and a transesophageal echocardiogram to check prosthesis function (including peak and mean gradient), and to check left atrial thrombus.

During the follow-up, if any unfavorable outcome with patients in the study is evidenced, an emergency meeting with the ethics committee will be held to evaluate the discontinuation of the study, regardless of their stage of recruitment. Other than that, every 2 months there will be a meeting with the same group with the intention of observing the progress of the study and the outcomes observed in each patient.

Statistical Considerations

The SPSS 17.0 (SPSS Inc) will be used to perform statistical analysis of the collected data. The primary analysis will be performed according to the intent-to-treat principle. A safety analysis will be performed on all patients treated regardless of any protocol violations. The quantitative variables will be described as mean and standard deviation. The mean comparison will be performed by the Student *t* test for independent populations or related populations, as appropriate. The qualitative and categorical variables will be presented as percentages and their comparisons will be made by $\chi 2$ test (chi-square) or the Fisher exact test when indicated.

Use of Concomitant Drugs

The use of drugs such as acetylsalicylic acid, clopidogrel, and other antiplatelet agents will not be allowed during the study period. The same applies to antiarrhythmic drugs that interact with dabigatran etexilate, such as quinidine.

Results

Although the present study has no statistic power to proof non-inferiority, it is expected that the dabigatran etexilate group will be protected as well as the warfarin group from intracardiac thrombus, without increasing the bleeding rates, since we are using safer doses (110 mg bid). The lack of necessity of monitoring INR is also another factor that contributes to a better adherence to the new drug and it can make all the difference in the manner of doing anticoagulation for patients with similar clinical characteristics. Enrollment for this study started in July 2013 and is expected to conclude in April 2015. Final results are expected in September 2015. The study is in the recruitment phase.

Discussion

Anticoagulant treatment reduces the incidence of death and cardioembolic events in patients with AF or a prosthetic heart valve, and the incidence of death and recurrences in patients with venous thromboembolism [18]. Warfarin works by binding to vitamin K epoxide reductase to inhibit vitamin K-dependent coagulation factors II, VII, IX, and X. For all its extensive use, warfarin has many clinical shortcomings, including variable pharmacokinetic and pharmacodynamics properties, a narrow therapeutic index range, and numerous interactions with certain foods and drugs. All of these factors contribute to the need for frequent coagulation laboratory monitoring and dosage adjustments.

Recently, direct thrombin inhibitors and factor Xa inhibitors have been added to the armamentarium for anticoagulation in AF. Dabigatran is an oral, reversible, direct competitive inhibitor of thrombin, which prevents the conversion of fibrinogen to fibrin within the coagulation cascade, thereby inhibiting thrombus formation [8]. The association of AF and bioprosthesis increases significantly the thromboembolic risk, making the use of dabigatran etexilate uncertain at this scenario. The RE-ALIGN trial [20] was the first clinical study to evaluate an oral direct thrombin inhibitor (dabigatran etexilate) as an alternative to warfarin for use in patients with mechanical heart valves requiring anticoagulation therapy. That study was prematurely interrupted because it showed increased rates of thromboembolic and bleeding events in the dabigatran etexilate treatment arm [20]. This report describes the rationale and design of the first clinical trial, to our knowledge, to test the hypothesis that dabigatran etexilate exhibits similar efficacy to warfarin with respect to prevention of intracardiac thrombus in patients with aortic and/or mitral bioprosthesis valve and AF postoperatively.

Acknowledgments

A special thanks to Sheila Oliveira, coordinator of the imaging center in Ana Nery Hospital, for her help.

Authors' Contributions

AD, PR, EJ, EC, FP, RAJ, FR, and AM conceived the study, participated in its design, and drafted the manuscript. BN, IN, and JM are coprinciple investigators of this project, and will do acquisition of data and revising.

Conflicts of Interest

None declared.

References

1. Carapetis JR, Steer AC, Mulholland EK, Weber M. The global burden of group A streptococcal diseases. Lancet Infect Dis 2005 Nov;5(11):685-694. [doi: 10.1016/S1473-3099(05)70267-X] [Medline: 16253886]
2. Nkomo VT, Gardin JM, Skelton TN, Gottdiener JS, Scott CG, Enriquez-Sarano M. Burden of valvular heart diseases: A population-based study. Lancet 2006 Sep 16;368(9540):1005-1011. [doi: 10.1016/S0140-6736(06)69208-8] [Medline: 16980116]
3. Sun JC, Davidson MJ, Lamy A, Eikelboom JW. Antithrombotic management of patients with prosthetic heart valves: Current evidence and future trends. Lancet 2009 Aug 15;374(9689):565-576. [doi: 10.1016/S0140-6736(09)60780-7] [Medline: 19683642]
4. Cannegieter SC, Rosendaal FR, Briët E. Thromboembolic and bleeding complications in patients with mechanical heart valve prostheses. Circulation 1994 Feb;89(2):635-641. [Medline: 8313552]
5. Cortelazzo S, Finazzi G, Viero P, Galli M, Remuzzi A, Parenzan L, et al. Thrombotic and hemorrhagic complications in patients with mechanical heart valve prosthesis attending an anticoagulation clinic. Thromb Haemost 1993 Apr 1;69(4):316-320. [Medline: 8497842]
6. Gage BF, Fihn SD, White RH. Management and dosing of warfarin therapy. Am J Med 2000 Oct 15;109(6):481-488. [Medline: 11042238]
7. Ezekowitz MD, Connolly S, Parekh A, Reilly PA, Varrone J, Wang S, et al. Rationale and design of RE-LY: Randomized evaluation of long-term anticoagulant therapy, warfarin, compared with dabigatran. Am Heart J 2009 May;157(5):805-810. [doi: 10.1016/j.ahj.2009.02.005] [Medline: 19376304]
8. O'Dell KM, Igawa D, Hsin J. New oral anticoagulants for atrial fibrillation: A review of clinical trials. Clin Ther 2012 Apr;34(4):894-901. [doi: 10.1016/j.clinthera.2012.01.019] [Medline: 22417716]
9. Connolly SJ, Ezekowitz MD, Yusuf S, Eikelboom J, Oldgren J, Parekh A, RE-LY Steering Committee and Investigators. Dabigatran versus warfarin in patients with atrial fibrillation. N Engl J Med 2009 Sep 17;361(12):1139-1151. [doi: 10.1056/NEJMoa0905561] [Medline: 19717844]
10. Connolly SJ, Wallentin L, Ezekowitz MD, Eikelboom J, Oldgren J, Reilly PA, et al. The long-term multicenter observational study of dabigatran treatment in patients with atrial fibrillation (RELY-ABLE) study. Circulation 2013 Jul 16;128(3):237-243. [doi: 10.1161/CIRCULATIONAHA.112.001139] [Medline: 23770747]
11. U.S. Department of Health and Human Services. FDA drug safety communication: Pradaxa (dabigatran etexilate mesylate) should not be used in patients with mechanical prosthetic heart valves URL: http://www.fda.gov/drugs/drugsafety/ucm332912.htm [accessed 2014-03-09] [WebCite Cache ID 6Nx7rjaQb]
12. Haahr M. Random.org. List randomizer URL: http://www.random.org/lists/ [accessed 2014-03-09] [WebCite Cache ID 6Nwio8W0q]
13. Ansell J, Hirsh J, Hylek E, Jacobson A, Crowther M, Palareti G, American College of Chest Physicians. Pharmacology and management of the vitamin K antagonists: American College of Chest Physicians evidence-based clinical practice guidelines (8th edition). Chest 2008 Jun;133(6 Suppl):160S-198S. [doi: 10.1378/chest.08-0670] [Medline: 18574265]
14. Tran HA, Chunilal SD, Harper PL, Tran H, Wood EM, Gallus AS, Australasian Society of Thrombosis and Haemostasis (ASTH). An update of consensus guidelines for warfarin reversal. Med J Aust 2013 Mar 4;198(4):198-199. [Medline: 23451962]
15. Peacock WF, Gearhart MM, Mills RM. Emergency management of bleeding associated with old and new oral anticoagulants. Clin Cardiol 2012 Dec;35(12):730-737. [doi: 10.1002/clc.22037] [Medline: 22811404]
16. Whitlock RP, Sun JC, Fremes SE, Rubens FD, Teoh KH, American College of Chest Physicians. Antithrombotic and thrombolytic therapy for valvular disease: Antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians evidence-based clinical practice guidelines. Chest 2012 Feb;141(2 Suppl):e576S-e600S [FREE Full text] [doi: 10.1378/chest.11-2305] [Medline: 22315272]
17. Wittkowsky AK, Spinler SA, Dager W, Gulseth MP, Nutescu EA. Dosing guidelines, not protocols, for managing warfarin therapy. Am J Health Syst Pharm 2010 Sep 15;67(18):1554-1556. [doi: 10.2146/ajhp100064] [Medline: 20811035]
18. Becattini C, Vedovati MC, Agnelli G. Old and new oral anticoagulants for venous thromboembolism and atrial fibrillation: A review of the literature. Thromb Res 2012 Mar;129(3):392-400. [doi: 10.1016/j.thromres.2011.12.014] [Medline: 22264937]
19. Schulman S, Kearon C, Subcommittee on Control of Anticoagulation of the Scientific and Standardization Committee of the International Society on Thrombosis and Haemostasis. Definition of major bleeding in clinical investigations of antihemostatic medicinal products in non-surgical patients. J Thromb Haemost 2005 Apr;3(4):692-694. [doi: 10.1111/j.1538-7836.2005.01204.x] [Medline: 15842354]
20. Eikelboom JW, Connolly SJ, Brueckmann M, Granger CB, Kappetein AP, Mack MJ, RE-ALIGN Investigators. Dabigatran versus warfarin in patients with mechanical heart valves. N Engl J Med 2013 Sep 26;369(13):1206-1214. [doi: 10.1056/NEJMoa1300615] [Medline: 23991661]

Abbreviations

AF: atrial fibrillation

CI: confidence interval
DAWA: dabigatran compared with warfarin in patients with persistent or permanent AF after bioprosthetic mitral and/or aortic replacement
FDA: US Food and Drug Administration
INR: international normalized ratio
RE-ALIGN: randomized, phase II study to evaluate the safety and pharmacokinetics of oral dabigatran etexilate in patients after heart valve replacement
RE-LY: randomized evaluation of long-term anticoagulation therapy
RR: relative risk
VKA: vitamin K antagonists

Edited by G Eysenbach; submitted 08.10.13; peer-reviewed by A Gómez-Outes; comments to author 07.03.14; revised version received 09.03.14; accepted 13.03.14; published 01.04.14.

Please cite as:
Duraes AR, Roriz PDS, Bulhoes FV, Nunes BDA, Muniz JQV, Neto INDCR, Fernandes AMS, Reis FJFBD, Camara EJN, Junior EDSR, Segundo DTS, Silva FPEA, Aras R
Dabigatran Versus Warfarin After Bioprosthesis Valve Replacement for the Management of Atrial Fibrillation Postoperatively: Protocol
JMIR Res Protoc 2014;3(2):e21
URL: http://www.researchprotocols.org/2014/2/e21/
doi:10.2196/resprot.3014
PMID:24691436

Original Paper

Feasibility and Preliminary Effects of a Virtual Environment for Adults With Type 2 Diabetes: Pilot Study

Constance Johnson[1], PhD; Mark Feinglos[1], MD; Katherine Pereira[1], DNP; Nancy Hassell[1]; Jim Blascovich[2], PhD; Janet Nicollerat[1], MSN; Henry F Beresford[1]; Janet Levy[1], PhD; Allison Vorderstrasse[1], MSN, DNSc

[1]Duke University, Durham, NC, United States

[2]University of California Santa Barbara, Santa Barbara, CA, United States

Corresponding Author:
Constance Johnson, PhD
Duke University
DUMC 3322
307 Trent Dr
Durham, NC,
United States
Phone: 1 6849332
Fax: 1 6818899
Email: constance.johnson@dm.duke.edu

Abstract

Background: Innovative interventions that empower patients in diabetes self-management (DSM) are needed to provide accessible, sustainable, cost-effective patient education and support that surpass current noninteractive interventions. Skills acquired in digital virtual environments (VEs) affect behaviors in the physical world. Some VEs are programmed as real-time three-dimensional representations of various settings via the Internet. For this research, a theoretically grounded VE that facilitates DSM was developed and pilot tested. It offered weekly synchronous DSM education classes, group meetings, and social networking in a community in which participants practiced real world skills such as grocery shopping, exercising, and dining out, allowing for interactive knowledge application. The VE was available 24/7 on the Internet, minimizing access barriers.

Objective: The objective of this study was to evaluate the feasibility and efficacy of participation in a VE for DSM education and support.

Methods: This study utilized a single group, pre-mid-post measure design. At 0, 3, and 6 months, we assessed participants' perceived VE usability and usefulness, self-efficacy, diabetes self-management behaviors, perceived social support, and diabetes knowledge using validated survey measures; and we recorded metabolic indicators (HbA1c, BP, BMI). Process data were continuously collected in the VE (log-ins, voice recordings, locations visited, objects interacted with, and movement). Data analysis included descriptive statistics, *t* tests to evaluate changes in mediators and outcomes over time, and depiction of utilization and movement data.

Results: We enrolled 20 participants (13/20, 65% white, 7/20, 35% black), with an age range of 39-72 years (mean age, 54 years) and diabetes duration from 3 months to 25 years. At baseline, 95% (18/19) and 79% (15/19) of participants rated usefulness and ease of use as high on validated surveys with no significant changes at 3 or 6 months. Participants logged into the site a mean of 2.5 hours/week over the course of 6 months. High DSM class attendance was reflected by the largest percentage of time spent in the classroom (48.6%). Self-efficacy, social support, and foot care showed significant improvement ($P<.05$). There were improvement trends in clinical outcomes that were clinically meaningful but did not reach statistical significance given the small sample size.

Conclusions: Because relatively little is known about usability, acceptability, and efficacy of health interventions in VEs, this study constitutes an important, innovative first step in exploring the potential of VEs for facilitating DSM. The preliminary data suggest that VEs provide a feasible and useful platform for patients and educators that affects self-management and related mediators. Flexible access to both synchronous and asynchronous diabetes education, skill building activities, and support from a home computer remove barriers to attending clinic-based meetings. This program has potential for improving DSM in an easily disseminated alternative model.

(JMIR Res Protoc 2014;3(2):e23) doi:10.2196/resprot.3045

KEYWORDS

diabetes mellitus, type 2; self-care; user-computer interface; virtual environments software; consumer health information; health communication

Introduction

Overview

"The medium is the message," a phrase coined over 40 years ago, signifies not only that the content of the message, but also the characteristics of the medium itself affect perception of the message [1]. Digital virtual environments (VE) allow messages to be embedded within realistic sensory scenarios and synchronous conversations among inhabitants affect the perception of the messages. Virtual environments, which promote social and educational interaction via repetition, practice, feedback, and application, may lead to superior learning [2]. Furthermore, virtual environments not only provide the context for the delivery of health messages, but also can potentially bring assistance and support to patients with chronic diseases like type 2 diabetes, to change behaviors needed for effective self-management.

Diabetes affects 23.6 million US adults, most of whom have type 2 diabetes (T2D) [3]. As the prevalence of T2D increases, health care providers and patients face the challenge of effective diabetes management and control to reduce complications and mortality [4-7]. Self-management is integral to the control of T2D, because patients provide 99% of their own care [8,9]. Effective self-management by patients requires informing and aiding patients via ongoing health professional facilitation of monitoring, support, and care, which are notably absent from current health care systems [10-12]. Diabetes self-management (DSM) interventions have demonstrated improvements in diabetes knowledge, self-management behaviors, and metabolic control; however, the interventions and their effects have been relatively short-lived [10,11,13]. The most effective interventions have incorporated interactive, somewhat individualized and frequent interactions among educators, providers, and patients [10]. However, frequent in-person interactions are costly and unsustainable. Ongoing diabetes education and support are necessary in a format that is more sustainable in health care systems [13,14]. Internet interventions, a logical approach to fill this need, have been used with T2D, resulting in increased support [15,16] and knowledge [16]; improvements in glycemic control [16] and self-management behaviors [17]; and more efficient use of primary care services [16] with decreased hospitalizations and emergency department visits [18]. In chronic disease, interactive health communication applications (computer-based information and support) have had a positive impact on knowledge, social support, clinical outcomes, and behavioral outcomes [19]. However, the heterogeneity of the effects of the Internet and technological interventions on metabolic control and self-management, ranging from small to large (and frequently not measured), may be due to a lack of interactivity in these interventions [20] and a drop in utilization of some technologies over time by clinicians and patients [18].

Currently, patients and providers with T2D face barriers to accessing even minimal self-management support or short-term diabetes self-management training (DSMT), including a lack of referral sources for DSMT, fear of losing patients to DSMT if offered outside their clinic, a belief that DSMT was not needed, inability to fit it into their schedule, cost, and transportation [21]. The flexibility of accessing both synchronous and asynchronous diabetes education, skill-building activities, and support via personal computer opens up doors to these aspects of diabetes care for many facing barriers (eg, location, time) to attending traditional clinic based meetings. Beyond these barriers to attending DSMT, VEs provide the potential platform for sustained education and interaction that is necessary throughout the trajectory of this chronic disease.

Digital VEs have the potential to solve the contextual disconnect between the clinic or other education-center based educational programs and the challenges of patients' daily lives [12] by simulating the community setting, allowing for knowledge application and role playing of self-management behaviors. Instead of being passive observers of computer images, users are active participants in computer-generated three-dimensional worlds. Digital VEs provide users with presence, immersion, and social interaction that can facilitate communication between patients and providers without physical limitations. Virtual environments have the capacity to profoundly change health care from "institution-centric" to "patient-centric" [22], yet further research is needed to determine the feasibility, usability, and outcomes of the technology. Virtual environments have been proposed and explored to address the need for transforming diabetes education and support, and addressing obesity; yet, to our knowledge, formal trials of their efficacy have not yet been conducted.

For this project, a Second Life [23] virtual diabetes community called SLIDES (second life impacts diabetes education & self-management) [24] was built with real-time interactions among adults with T2DM, health care professionals (HCP), and peers. The primary aim was to determine the feasibility and acceptability of an eHealth (a form of health information provided via the Internet [25]) program using a VE platform that provides DSMT and self-management support. A secondary aim was to determine preliminary effects of participation in the VE intervention on self-management and diabetes outcomes (HbA1c levels, blood pressure, and body mass index), as well as psychosocial outcomes or mediators (diabetes knowledge, self-management behaviors, self-efficacy, perceived support, presence, and copresence). The long-range goal is to build a tool for health care providers to not only disseminate information to health care consumers with chronic diseases, but also to promote skill building via interactive simulations and scenarios, provide social support, and offer individual educational consultation.

Theoretical Framework

Social cognitive theory [26] provides the theoretical framework for the behavioral intervention here, addressing interactive or reciprocal factors in relation to DSMT and support including environmental, personal, and behavioral factors. It was also necessary to incorporate constructs used in the VE literature and theory such as physical and behavioral realism, presence, copresence, and agency [27,28] to address the challenges and opportunities such environments provide compared to face-to-face ones. Details regarding this theoretical framework and how it was operationalized in the VE have been published elsewhere [29]. This integrated theoretical framework allowed us to capitalize on the strengths of successful self-management interventions (eg, the incorporation of social cognitive theory and frequent patient-provider interactions, peer support, feedback, and a multidisciplinary team) and enhance the intervention and participants' experiences by overcoming the weaknesses of current interventions (eg, a lack of interactivity, accessibility, and sustainability; resource intensiveness) [29].

Methods

Overview

This feasibility study involved a one-arm, pre-mid-post measure design. A convenience sample of adult participants with T2D was enrolled in the VE intervention with access to the site for 6 months. Pre-intervention measures at baseline, mid-intervention measures at 3 months, and post-intervention measures at 6 months provided data addressing the primary and secondary aims of the study.

Recruitment and Study Eligibility

Approval from the Duke University Institutional Review Board was obtained prior to study initiation. Endocrinologists and the study coordinator recruited a convenience sample within the endocrinology clinic at the Duke University Medical Center. Potential participants were identified by endocrinology providers either during scheduled visits or through medical record review. If recipients were interested in learning more or participating, letters were sent to them introducing the study and giving them the study coordinators' contact information. Eligible participants were those with a diagnosis of T2D who (1) were between 21 and 75 years old, (2) were able to speak and read English, (3) were computer literate (have used a computer for at least 6 months), (4) understood how to use the Internet (have accessed the Internet on at least 6 occasions), (5) had access to a computer with a non-dial-up Internet connection in a private location, (6) were mentally capable of informed consent, (7) were reachable by telephone, (8) had no comorbidities or severe diabetes-related complications that would interfere with study participation or measures (eg, renal failure, stage III hypertension, severe orthopedic conditions or joint replacement scheduled within 6 months, paralysis, bleeding disorders, or cancer), and (9) were able to travel to the clinic for follow-up appointments. Subjects at various stages of T2D with treatment regimens including both oral and injectable medications were included if the above criteria were met.

Intervention

User-Centered Design

The SLIDES community was developed using an iterative usability design, informed by the programmer, researchers, study team, and patients with diabetes [24]. This iterative user-centered design approach was informed by user, task, and environmental analyses [30]. The user analysis determined the characteristics of users such as age, computer literacy, social and cultural issues, and familiarity with Second Life. Hence, we built the environment for adult users who were VE novices, yet who were computer literate and possessed Internet skills. Furthermore, we considered the types of restaurants and types of food in the grocery store that should be included in the SLIDES site based on our user characteristics. The task analysis, which examined the goals of the users and the required tasks to meet these goals, informed the necessary task features of the VE community. For example, we considered that it was important for users to be able to purchase the books that they reviewed within our SLIDES site. Thus, if the user clicked on a book within the bookstore, a website where they could purchase the book directly appeared. In the environmental analysis, we considered types of machines used by the users and the specifications for use of the machines. We stayed within our specifications and did not require the users to purchase any special software to use the site. After we completed the build, we conducted a small-scale usability study with the first 5 participants in the study [31]. Small-scale usability studies are a way to validate the interface design decisions [30,32]. Using a talk-aloud methodology [33], we gave the users 12 most frequently used tasks and functions within the SLIDES environment (such as accessing a menu, navigation, and how to text) and asked them to complete these tasks under the observation of the investigator. The results of this study were used to make some minor changes within the SLIDES site (eg, added menus of popular chain fast-food restaurants, added a sign entitled Medications above the medications in the pharmacy). No major usability problems were found within our launched design.

SLIDES Site

The SLIDES site was designed to provide DSMT and support based on social cognitive theory, effective diabetes interventions, and American Diabetes Association and American Association of Diabetes Educator standards for diabetes care and education [34-36]. Classes, resources (grocery item feedback, menu feedback, weblinks, etc), and the infrastructure within Second Life were developed with enhancing patients' self-management skills and behaviors and interpersonal support in mind. The SLIDES community contained a bookstore with books and websites chosen by diabetes educators with links to purchase them; a grocery store with over 200 interactive grocery items with embedded information on nutritional content, suggested portions and substitutions; a pharmacy with items such as oral care products, glucometers, etc, which could be bought directly online, and information on related medications and over-the-counter applicable medications chosen by our diabetes educators; a clothing store where participants could individualize their avatar; a restaurant featuring the menus of popular chain

restaurants with embedded information on each menu item on nutrition, portions, and substitutions; a gym with exercise videos created by exercise physiologists that participants could mimic in their own home; and a community center with a classroom, slide projector, and a forum that allowed participants to cocreate information such as adding information on favorite recipes, restaurants, or personal experiences. This interactive VE incorporated many aspects of social cognitive theory, including cues to action and skill development [37-39]. Role-playing in this diabetes community allowed for immediate feedback and modeling of healthy behaviors. Brief health promotion and disease prevention messages were hung around the site (ie, signs) as cues to action.

Weekly 1-hour classes (using the American Diabetes Association/American Association of Diabetes Educators self-management training curriculum facilitated by nurse practitioners, diabetes educator or health professional guest presenters) were held [35,40] (Figure 1). Classes were offered during daytime and evening hours, allowing participants flexibility for attendance. Twelve classes rotated through the core AADE topics (healthy eating, being active, monitoring, taking medications, problem solving, healthy coping, and reducing risks). Classes allowed for delivery of information by the educators as well as opportunities for participant questions and interactions with one another. In addition, a weekly scheduled discussion/support group was moderated by a nurse practitioner.

Each participant had access to the SLIDES community site in Second Life 24 hours a day, 7 days per week. Access to SLIDES allowed participants to utilize resources and weblinks such as those in the bookstore or grocery store and to interact with other participants at their convenience. Participants were advised to consult their health care provider regarding any medication regimen changes or side effects, symptoms, or health status changes. Medical management remained outside the domain of this intervention.

Figure 1. Class session in SLIDES.

Measures

Demographics and Internet Experience

Demographic data included age, marital status, ethnicity, race, cohabitation, family history of diabetes, level of education, employment status, and household income range. We also assessed duration of diabetes, diabetes-related medications, attendance at prior diabetes education, and prior attendance at a diabetes support group. Finally, we assessed Internet use in general by hours per week, and then specifically hours per week using social networking sites, emailing, playing games, searching the Internet, and reading newspapers or magazines.

To meet our primary aim of developing a virtual diabetes community (SLIDES) and assessing its feasibility and acceptability, we tracked participation rates (number of log-ins, time spent in SLIDES) and use (locations visited in SLIDES, objects manipulated, voice and text tracking), perceived usefulness, perceived ease of use, and attitudes toward use.

Participation Rates and Usage

Process data were measured via the number of log-ins into SLIDES, duration of each log-in, locations visited in the site, and objects touched such as books, food items, etc. Additionally, all verbal and text communication during the duration of the study were recorded continuously (24/7). Process data were analyzed via average number of log-ins per month, average amount of time spent in the site, average amount of time spent in each location within the site, average number of objects touched, and a list of objects touched. Data points such as participant avatar location were collected every 15 seconds, or any time an object was “touched,” to ensure that object interactions were captured in the database.

Perceived Usefulness

Perceived usefulness was assessed using a verbal 7-point Likert scale based on work by Davis [41] (Cronbach alpha, 0.98). We averaged participants’ responses to the 6 questions to obtain a

perceived usefulness score. Lower scores indicated higher levels of perceived usefulness with responses ranging from 1 (extremely likely) to 7 (extremely unlikely). Questions were modified to fit outcomes related to VEs. The baseline version was modified to reflect participants' anticipated rating of usefulness of the VE, which could then be compared to the 2 later measures during and after their participation in the VE.

Perceived Ease of Use

Perceived ease of use was assessed based on work by Davis [41] (Cronbach alpha, 0.94). The questionnaire included 6 items using 7-point Likert scales that ranged from 1 (extremely likely) to 7 (extremely unlikely). These questions were modified to fit outcomes related to VEs. We averaged the 6 items into a single score of perceived ease of use. Again, the baseline version was modified to reflect participants' anticipated ease of use of the VE, which could then be compared to the two later measures during and after their participation.

Focus Group

The purpose of the focus group was program evaluation. Questions asked during the focus group included: What are your perceptions of the SLIDES site? What did you get out of the SLIDES site? What were positive and negative aspects of the SLIDES program? What changes would you make to the SLIDES program?

To meet our second aim of determining the preliminary effects of participation in the SLIDES intervention, we collected data on metabolic outcomes and potential psychosocial mediating variables as outlined below.

Physiological Outcomes

Metabolic control was measured by glycosylated hemoglobin (HbA1c), blood pressure (BP), and body mass index (BMI) obtained from medical records. HbA1c is a routine laboratory measure of metabolic control in clinical practice, obtained at 3-month intervals by diabetes care standards [36] and indicates average glucose levels over the prior 3 months. BP and BMI (calculated from height and weight) are clinical parameters associated with metabolic control and diabetes-related complications (heart disease, stroke) and influenced by self-management.

Self-Efficacy

Self-efficacy was assessed using the Diabetes Empowerment Scale-Short Form (DES-SF), an 8-item Likert scale that ranged from 1 (strongly disagree) to 5 (strongly agree), measuring participants' confidence in their ability to perform DSM behaviors and self-assess satisfaction with diabetes care. The DES-SF was created by choosing the item from the original 28 items with highest item to subscale correlation from each of the original eight conceptual domains (Cronbach alpha, 0.85) [42]. The total scale score was divided by 8 to provide a mean score for each participant.

Diabetes Knowledge

Diabetes knowledge was measured using a subset of the Assessment of Diabetes Knowledge [43] instrument. Twenty true/false items were utilized from this 114-item instrument, with representative items selected from the subcategories of treatment, sick days, hypoglycemia, effects of physical activity, reducing complication risks, smoking/alcohol effects, foot care, and diet. This scale was scored based on percentage of correct answers to the 20 items for each participant.

Self-Management Behaviors

The 11-item Summary of Diabetes Self-Care Activities [44] assessed the frequency of health behaviors over the previous week (number of days), including diet, exercise, blood sugar testing, foot care, and smoking. The instrument has acceptable internal consistency (mean, 0.47), and moderate test-retest correlations (mean *r*, 0.40) [44]. Responses were scored according to the authors' instructions, creating a mean score for each of the subscales of diet, exercise, blood sugar testing, and foot care [44].

Perceived Support for Diabetes Management

Perceived support for diabetes management was assessed using a 12-item survey with Likert scale items ranging from 1 (strongly disagree) to 7 (strongly agree). This diabetes support scale was developed specifically for assessment of social support in a diabetes Internet intervention. It has demonstrated internal consistency reliability of 0.90-0.93, sensitivity to intervention effects, and construct validity when compared to the Interpersonal Support Evaluation List and Chronic Illness Support Survey (*r*, 0.26-0.45) [15]. Each total score was divided by 12 to calculate a mean score with higher scores indicating more perceived support.

Presence

Presence (sense of actually being in the site) evaluation was based on the work of Witmer and Singer [45] (Cronbach alpha, 0.81). The original questionnaire included 32 items; however, we removed 5 items that were not applicable to this environment; 2 questions relating to the haptic subscale (tactile feedback), which is not available within this VE, and 3 questions regarding gaming experiences that were not related to any subscales. The subscales measured involved/control, natural, auditory, resolution, and interface quality. The involved/control subscale focuses on the reaction of the VE to user actions, users' perception of their control of actions in the VE, the degree of engagement of the visual aspects of the VE, and how engaged the participant felt [45]. Natural subscales assessed the perception of natural movement, the naturalness of the environment, and the participant's perceptions of natural interactions [45]. The auditory subscale addressed identifying and localizing sounds, and resolution addressed how well the participants could examine objects. Finally, the interface quality subscale assessed whether devices associated with the interaction in the environment interfered with the performance of tasks [45]. The presence questionnaire contained a 7-point scale with anchors based on the question stem from 1 (not) to 7 (very). We averaged each subscale, but do not provide an overall presence score because we eliminated 5 questions. However, each of the subscales should provide some measure of presence.

Copresence

Copresence (sense that others are actually present in the environment) [46] was measured based on the work of

Bailenson, Swinth, and Hoyt [47] (Cronbach alpha for subscales, 0.71-0.72). In addition to the 3-item scale measuring copresence, we measured embarrassment (3 items) and likability (4 items), both of which help to define copresence by showing social responses people have to others, such as liking others and willingness to perform embarrassing acts in front of others. All of the items were measured on a 7-point Likert scale from 1 (strongly disagree) to 7 (strongly agree). The means were obtained for copresence, embarrassment, and likability, respectively. Greater scores indicated higher levels of copresence, embarrassment, and likability. According to Bailenson et al [47], all three should be correlated: copresence and likability should be positively correlated and copresence/likability and embarrassment negatively correlated.

Study Procedures

During the baseline participant visit in a private room at our study office, the study coordinator obtained signed informed consent and administered surveys to assess demographic factors and psychosocial mediators as described above. The most recent height and weight, BMI, BP, and HbA1c were obtained from the participant's medical record by the study coordinator. During the baseline visit, subjects were oriented to the SLIDES site in Second Life and each subject's avatar was developed by the study staff with the participant's input and approval. Although participants could keep their individualized avatar indefinitely, they could only access the SLIDES site during the study period. Participants were given headphones with a microphone for home use to allow for synchronous voice communication. Online tutorials that were developed in Second Life helped to facilitate participant learning and integration into the VE. Written instructions for accessing the site were given to each participant along with their username and password during the initial, baseline visit. The initial baseline orientation with the study coordinator was approximately 60-90 minutes long. Most participants required at least 1 follow-up phone conversation with the coordinator to ensure that the application was set up and that they were able to use the basic functions on their home computer, which took about 30 minutes. Although periodic technical challenges required follow-up support, most were either related to Second Life server issues beyond our control or limitations of participant computers (processing capabilities, etc).

Individuals were told that they could visit the SLIDES site as frequently as they wanted, but were instructed to sign in to the SLIDES intervention at least twice a week for the first 4 weeks, after which they could log in to the SLIDES site at any time for the remaining 5 months. The rationale for the initial required log-ins were to encourage use and increase familiarity with the site, resources in the site, and to meet others and attend weekly diabetes education meetings. This was only "required" and participants received reminders from the study coordinator to log in if they did not meet this requirement for the first month so that their use of the site after that point could be observed for the remainder of the study as a part of feasibility testing. Three days after the baseline appointment, participants were telephoned to address any questions about Second Life or study procedures. A re-orientation was provided to those who continued to have difficulty with how to use the site, which was necessary for approximately 4 participants.

Weight, BP, and HbA1c at 3 and 6 months were obtained from medical records (with a 2-week window before or after the study follow-up time point). Subjects were sent a link via email to the follow-up surveys (as outlined above), which were administered online at 3 and 6 months through REDCap [48]. In the final week of the 6-month intervention period, all participants (including those who had withdrawn) were invited to attend an online focus group in the SLIDES site with the primary investigator and coinvestigator to discuss perceptions of the experience, positive and negative aspects of the intervention, technical difficulties, and suggested changes. Subjects who completed all visits and measures received $50 as compensation for their time, or prorated compensation depending on time spent in the study.

Statistical Analysis

All data, including the process data recorded in Second Life, were stored on a secure research server at the Duke University Office of Instructional Technology. Statistical data analysis was conducted in SAS software version 9.3 [49]. Data to test feasibility and acceptability of this eHealth intervention (primary aim) were descriptive and qualitative. Descriptive statistics were used to analyze the survey data on perceived usability and usefulness of the platform at 3 months and 6 months of study participation. In terms of the process data collected in the SLIDES site, descriptive statistics were used to provide frequencies, means, and standard deviations of the number of log-ins, number of minutes spent logged into the site, number and type of objects touched, and locations visited within the site. Heat mapping data were analyzed in R [50] by computer scientists to show locations visited. The focus group qualitative data were analyzed using content analysis, which is a data reduction technique that examines verbal data for recurring themes. Codes and themes were identified by the researchers based on participant discussion and responses. These focus group members' responses were categorized into four categories: expectations, positives, problems, and suggestions. These four categories were then coded into themes according to the constructs in our theoretical framework [29]. The text segments were analyzed for frequencies of themes. A second researcher reviewed the content of the focus groups for rigor of the findings.

Addressing our secondary aim, the preliminary effects of our VE program on measures of metabolic control (HbA1c levels, BP, and BMI) and potential psychosocial mediating variables (perceived support, self-efficacy, diabetes knowledge, diabetes self-management behaviors, presence, and copresence) were assessed. Means and standard deviations were used to describe these parameters at baseline. Paired *t* tests were used to assess pre-mid-post intervention differences in the study dependent variables (two-tailed tests, $\alpha<.05$). Given that this was a small pilot sample, with 61 missing follow-up data points out of 342 data points (18%), we did not attempt more sophisticated models accounting for missing data. In a larger trial and sample, we would have accounted for it in this manner.

Results

Demographic and Internet Experience

Of the 42 patients contacted, 20 (48%) agreed to participate in this feasibility study. Table 1 presents the sample characteristics. The average age of the sample was 53 years old (range, 39-72 years), with an average duration of diabetes of 12 years (range, 3 months to 25 years). Sixty-five percent (n=13) of the participants were white and 35% (n=7) were African American, 95% (n=19) were female, 55% (n=11) were married, and 25% (n=5) lived alone. In terms of socioeconomic status, 65% (13) had a bachelor's degree or higher and 20% (n=4) had less than a college degree, 55% (n=11) were employed full or part-time, and 70% (n=14) had annual incomes ≥ $50,000. Ninety percent (n=18) of the participants reported having a family history of diabetes, 25% (n=5) were using insulin, 45% (n=9) were on oral diabetes medications, 25% (n=5) were on both oral medications and insulin, and 70% (n=14) reported attending at least one diabetes class in the past. All participants reported spending 3 or more hours per week on the Internet, 75% reported spending greater than 3 hours/week using social networks such as Facebook, 60% reported spending greater than 3 hours/week emailing, 30% reported playing Internet games greater than 3 hours/week, and 85% reported searching online greater than 3 hours/week. See Figure 2 for types and amount of Internet use.

Figure 2. Type and amount of Internet use.

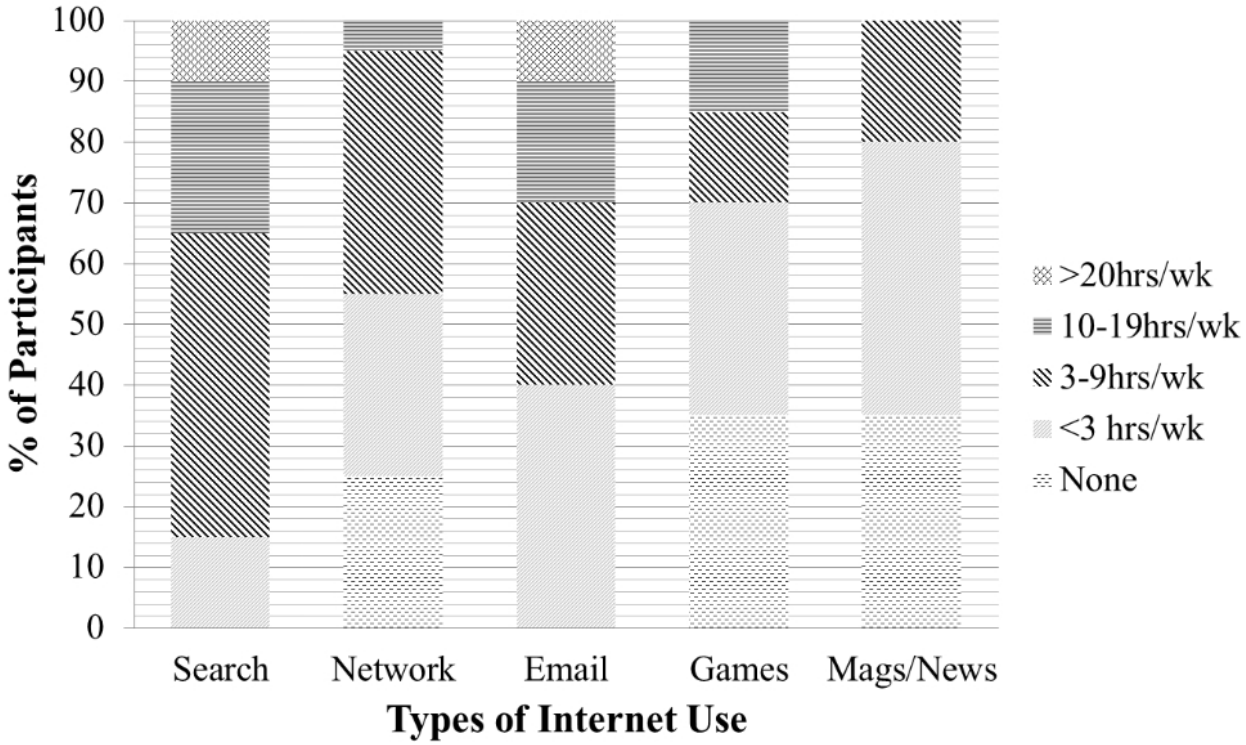


Table 1. Sample characteristics of participants in SLIDES (N=20).

Attribute		n (%)
Gender		
	Female	19 (95)
	Male	1 (5)
Age (yr)		
	<45	3 (15)
	45-54	7 (35)
	55-64	6 (30)
	65-74	3 (15)
	Missing	1 (5)
Race		
	White	13 (65)
	African American/black	7 (35)
Marital status		
	Single	7 (35)
	Married	11 (55)
	Divorced	2 (10)
Living with		
	Spouse/Partner	11 (55)
	Children	4 (20)
	Other relatives	2 (10)
	Other	2 (10)
	None of the above	5 (25)
Education		
	Technical/trade school	2 (10)
	Some college	2 (10)
	Associates degree	3 (15)
	Bachelor’s degree	4 (20)
	Master’s degree	9 (45)
Employment		
	Full-time	7 (35)
	Part-time	4 (20)
	Retired	4 (20)
	Not employed	5 (25)
Income level (US $)		
	25,000-34,999	4 (20)
	35,000-49,999	2 (10)
	≥50,000	14 (70)
Family history of diabetes		
	Mother	9 (45)
	Father	12 (60)
	Sister(s)	5 (25)
	Brother(s)	6 (30)

Attribute		n (%)
	Children	2 (10)
Medications		
	On oral medications	14 (70)
	On insulin	10 (50)
	On other medications	2 (10)
Ever attended diabetes support group		14 (70)

Participation Rates and Activity

Participants logged into SLIDES a total of 766 times with a mean of 38 times, a median of 35 times, and a range of 1-113 times per participant over the 6 months they were in the study. Seventy-five percent of the log-ins occurred in the first 3 months with the majority in the first month (Figure 3). Participants logged in for an average of 43 minutes per session with a median of 33 minutes per session. A subgroup of participants (n=14, 70%) were very active during the first 3 months in the study. This 3-month period represented one of the 12-week DSM class periods held in the site over the 6-month study period. These participants logged into the site a total of 712 times with a mean of 51 times, a median of 42 times, and a range of 19-113 times. On average, they logged into the site for 40 minutes per session. Most log-ins occurred around the times of scheduled classes or support sessions in SLIDES; however, some participants logged in on their own on other dates or times and interacted with the resources in the site (ie, grocery items, books, etc). In terms of communication, participants used voice communication a majority of the time when in the VE with others; text communication was only used during technical Second Life issues with voice functionality.

The participants in this study visited every location in the VE. However, they spent the majority of their time in the classroom (48.6%) because DSMT classes were held there twice weekly. The second most frequently visited area was the “outdoors” area on the site. As shown in the heat map (Figure 4), we discovered from our focus group that some of the participants used the outside area as a way to reduce stress because they could hear birds chirping or water in the background. The third most frequent area where the participants spent time was the social center (9.0%), a place they visited to socialize with other participants. Interestingly, the fourth most frequented area was the clothing store (5.6%), which allowed participants to individualize their avatars with clothing, hair, and general appearance.

A total of 297 of 394 (75%) objects such as food items, books, menus, websites, videos, and pharmacy items were “handled” by 19 of the participants while in SLIDES. Participants interacted with these 297 objects a total of 1180 times. Participant interaction with specific types of objects within these locations is delineated in Table 2.

Figure 3. Number of log-ins into the SLIDES site.

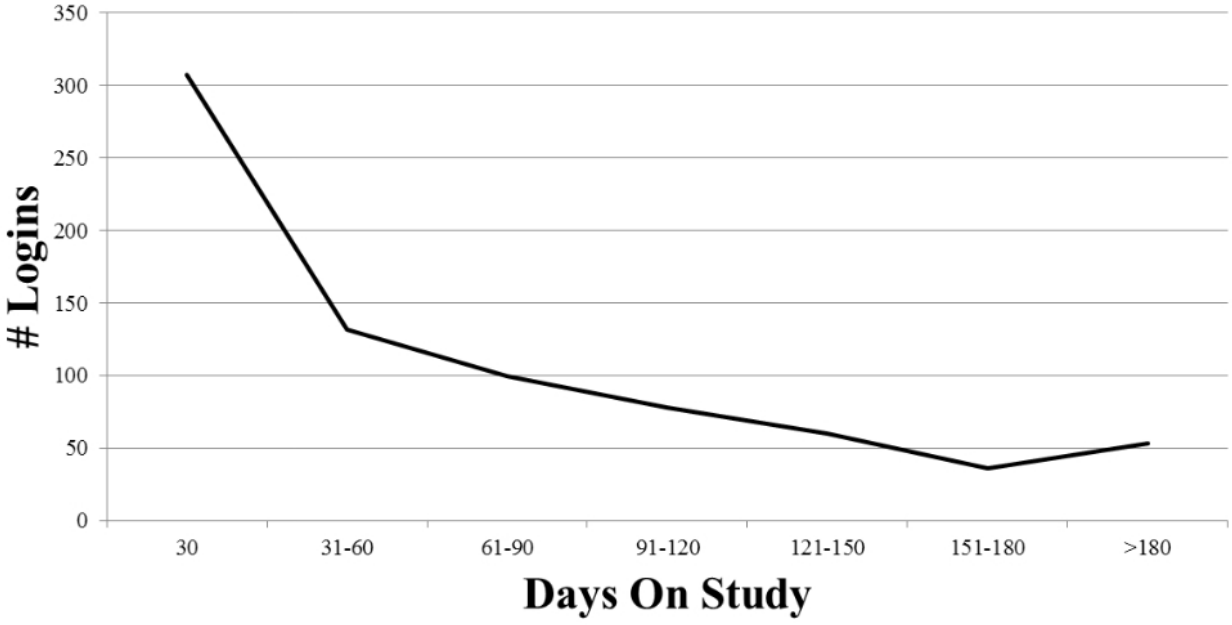
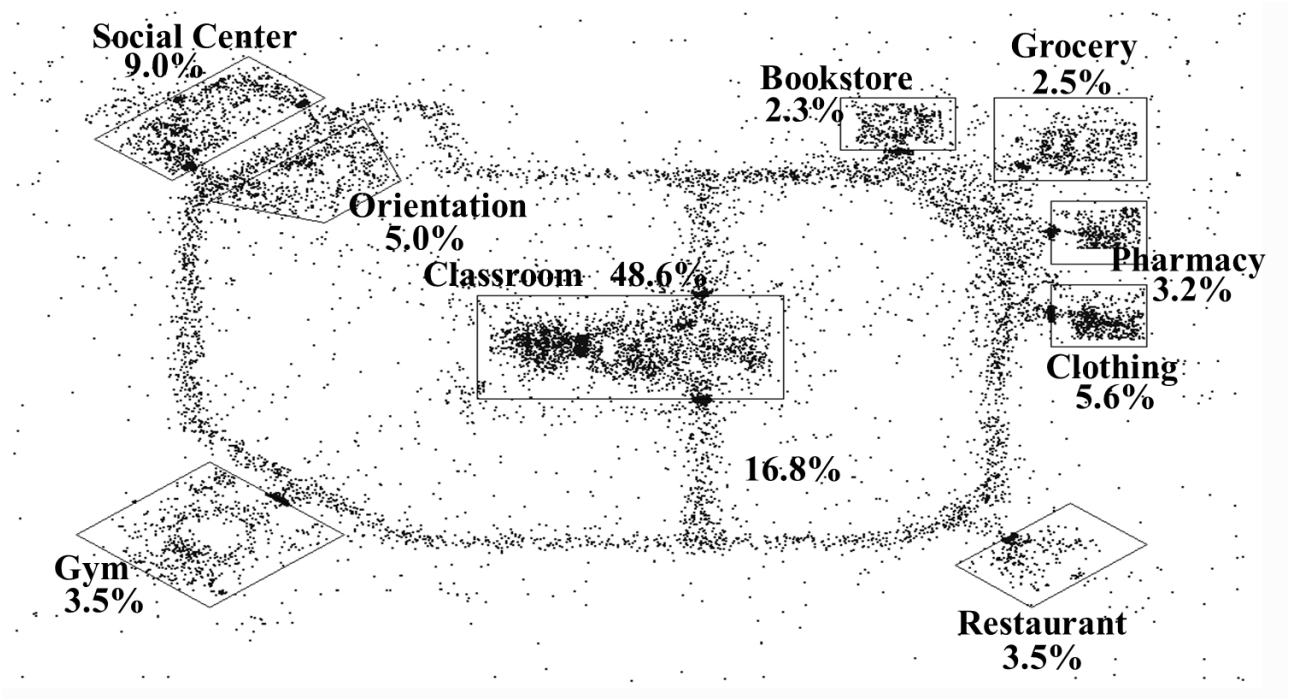


Figure 4. Heat map of locations visited.



Perceived Usefulness and Ease of Use

Overall, participants anticipated SLIDES to be useful at baseline (mean 2.14 SD 0.73) and this continued at 3 months (mean 2.02 SD 1.21) and at 6 months toward extremely likely (mean 1.68, SD 0.79). Although there was a trend toward extremely useful, there was not a statistically significant improvement (P=.07) between baseline and 6 months. With regard to ease of use, participants ranked SLIDES at baseline, 3, and 6 months between slightly and quite easy to use (baseline mean 2.48 SD 0.87; 3-month mean 2.73, SD 1.34; 6-month mean 2.33, SD 1.16). There were no statistically significant differences over time in ease of use; and baseline anticipations matched experiences during the study participation.

Table 2. Summary of all object interactions by participants.

Location of objects	Object category (items in store/items examined)	Object subcategory (number of interactions, %)	No. of participants who interacted with objects in location	Total no. of times object was interacted with by all participants	Number of interactions with objects per participant, mean (SD)
Grocery store	All food items (146/211)		19	408	22.66 (29.79)
		Meat, poultry, fish, nuts, beans (90, 22%)			
		Beverages (82, 20%)[a]			
		Fats, oils, sweets (61, 15%)[a]			
		Cereal/breads (33, 8%)[a]			
		Dairy (33, 8%)[a]			
		Vegetables (33, 8%)[a]			
		Frozen foods (33, 8%)[a]			
		Snack foods (20, 5%)[a]			
		Fruit (16, 4%)[a]			
		Rice/pasta (8, 2%)[a]			
Bookstore	Books (20/22)		15	63	4.2 (3.74)
		Nutrition (56, 89%)[a]			
		Diabetes management (4, 6%)[a]			
		Medication/treatment (3, 5%)[a]			
	Websites (self-care) (11/18)		15	105	7.0 (6.15)
Restaurant	Menus (56/64)		16	192	12 (18.46)
		Chain eat-in restaurants (106, 55%)[a]			
		Chain drive-through restaurants (86, 45%)[a]			
Pharmacy	All items (49/63)		15	104	6.93 (5.67)
		Blood glucose monitors (42, 40%)[a]			
		Dental, foot, skin care (25, 24%)[a]			
		Injection supplies (15, 14%)[a]			
		Mobility products, scales, diabetes specialty supplements (23, 22%)[a]			
	Medications (Rx) (10/11)[a]				
		Lipid lowering (21, 20%)			
		Oral antihyperglycemic (66, 63%)			
		Insulin (18, 17%)			
Gym	Exercise videos (cardio, yoga, strength training) (3/3)		17	134	7.88 (9.31)
Community center	Recorded classes (11/12)		16	73	6.63 (4.05)

Location of objects	Object category (items in store/items examined)	Object subcategory (number of interactions, %)	No. of participants who interacted with objects in location	Total no. of times object was interacted with by all participants	Number of interactions with objects per participant, mean (SD)
		Intro to diabetes (15, 21%)[a]			
		Healthy eating (10, 14%)[a]			
		Exercise (10, 14%)[a]			
	Forum		12	101	8.41 (10.1)

[a]Items reviewed most often.

Focus Groups

Eight of the participants attended the focus group. Six of these focus group participants were active users of the SLIDES VE and 2 were much less active participants. Four categories were discussed based on the focus group questions: expectations of the program, positive aspects of SLIDES, negative aspects of SLIDES, and suggestions for changes. The themes noted in the data coding were consistent with the theoretical framework (environmental factors, personal factors, and behavior) for the study approach, and are summarized in Table 3. The environmental factors were addressed in the participant comments through the themes of informational and community resources, social interaction, physical realism, and aspects of the usability of the site. The personal factors were addressed in the participant comments through the theme of diabetes knowledge, and behavior was addressed through self-management behavior change.

The focus group confirmed existing problems that we were aware of with the site and offered new insights for improvement of the site in future versions. With regard to the user expectations, all users thought that site provided resources that improved their knowledge of diabetes. The majority of the comments regarding the positive aspects of the site revolved around the informational resources and social interaction. The participants thought that the site provided a source of new information not only in the various locations in the site such as the grocery store, restaurant, and bookstore, but they also liked the interactive nature and informational aspects of the weekly classes. One participant stated that she learned something new every week. The majority of the positive comments on social interaction addressed their ability to interact with others synchronously and hearing about the experiences of others and learning through other participants "stories" about their disease. The majority of the comments about the negative aspects of the site were categorized as usability problems. For example, participants found the background noises made by other participants chewing food or just general home sounds, such as people talking or dogs barking, very annoying. Because the majority of conversations were synchronous, if the users did not mute their microphones, all of the sounds within their respective homes were heard by all participants and thus distracting. This required the moderators of social events such as the classes to ask participants to mute their individual microphones until they were ready to speak. Other problems identified by the participants had to do with the complex functionality of Second Life. These problems included navigational issues such as moving their avatar from one location to another, having difficulty with sound, and general computer problems that did not meet the specifications required by Second Life. Additionally, 1 participant who thought that there would be more participants in the site was referring to an age diversity issue. She was hoping for more people in her age group. Finally, the suggestions for future changes provided us with ideas on how to improve the site in the future. The majority of these suggestions were about how to improve social interaction such as including tasks to complete together as group such as homework, scavenger hunts, and in general group bonding activities. The participants thought that these types of activities would have helped them to bond earlier during their time in the site.

Table 3. Focus group results.

Categories	Themes (n, %)	Examples
Expectations (N=10)		
	Informational resources (3, 30%)	“The educational material was a plus too”
	Met expectations (2, 20%)	“Met expectations in terms of discussion”
	Diabetes knowledge (2, 20%)	“Learn a few things”
	No expectations (2, 20%)	“I had no expectations and was delighted”
	Social interactions (1, 10%)	“Intrigued by being with other people with diabetes”
Positive aspects of the site (N=55)		
	Informational resources (17, 31%)	"Liked the comments on the items in the grocery store"
	Social interaction (16, 29%)	“I did enjoy interacting with others”
	Diabetes knowledge (6, 11%)	“have had diabetes for 25 years, but learning new things”
	Usability (6, 11%)	“I am a click and find person—like things immediately at my disposal”
	Community resources (5, 9%)	“Liked the gym, helped me to exercise”
	Physical realism (3, 5%)	“Liked the seasons changing in the site”
	Self-management behavior change (2, 4%)	“Literally changed my life in terms of treatment with insulin—rarely now takes insulin during the day”
Negative aspects of the site (N=34)		
	Usability (26, 76%)	“background noises from others – home sounds, chewing”
	Social interactions (3, 9%)	“Expected larger group of participants”
	Informational resources (3, 9%)	“Need clarity on nutrition information by serving”
	Behavioral realism (2, 6%)	“Avoided gym ‘just like in real life’”
Suggestions for changes to site (N=31)		
	Social interaction (13, 42%)	“Would be good to have group exercises”
	Informational resources (9, 29%)	“More variety in the grocery store”
	Usability (5, 16%)	“Would like to hear (bots)and read feed-back”
	Diabetes knowledge (3, 10%)	“Would like nutritionist or other specialists at classes (podiatry, pharmacist)
	Community resources (1, 3%)	“Would like a walking path”

Physiological Outcomes

There were no changes noted from baseline to 6 months in systolic or diastolic blood pressure; however, overall the participants had good blood pressure control (Table 4). The changes that were noted were in weight and HbA1c. Although there was not a statistically significant change in either of these indicators, there was an average weight loss of 9.1 lb from baseline to 6 months. HbA1c also decreased from 7.51% (SD 1.15%) at baseline to 6.92% (SD 1.37%) at 6 months.

Table 4. Physiological and psychosocial outcomes.

Variable	Baseline (N=18) Mean (SD)	3 Months (N=14) Mean (SD)	Change at 3 months	6 Months (N=13) Mean (SD)	Change at 6 months
HbA1c (%)	7.51 (1.15)	7.14 (1.24)	t_{13}=0.54; *P*=.60	6.92 (1.37)	t_{11}=0.20; *P*=.85
Weight (lb)	217.5 (45.2)	215.7 (45.8)	$t_{.61}$=0.61; *P*=.55	208.4 (43.9)	t_{12}=1.04; *P*=.32
BMI (kg/m^2)	37.4 (7.9)	37.2 (8.3)	t_{14}=0.56; *P*=.58	36.2 (8.5)	t_{12}=1.14; *P*=.28
Systolic blood pressure (mm Hg)	131.3 (13.0)	129.6 (14.5)	t_{14}=0.47; *P*=.64	130.1 (10.5)	t_{12}=−0.38; *P*=.71
Diastolic blood pressure (mm Hg)	74.8 (10.8)	74.7 (11.2)	t_{14}=0.31; *P*=.76	78.1 (9.4)	t_{12}=−0.91; *P*=.38
Self-efficacy (score scale 1-5)	3.89 (0.81)	4.45 (0.67)	t_{13}=−2.3; *P*=.036	4.64 (0.39)	t_{11}=−2.73; *P*=.02
Social support (score scale 1-7)	4.61 (1.25)	5.45 (1.07)	t_{13}=−2.1; *P*=.056	6.35 (0.44)	t_{11}=−4.0; *P*=.002[a]
Diabetes knowledge (% score)	89.1 (4.04)	93.9 (5.25)	t_{13}=−1.73; *P*=.108	88.2 (15.0)	t_{10}=0.29; *P*=.77
Self-management (days per week)					
Dietary	4.13 (1.42)	4.5 (1.67)	t_{13}=0.51; *P*=.618	4.75 (1.45)	t_{11}=−0.69; *P*=.50
Exercise	3.07 (2.03)	2.43 (1.74)	t_{11}=0.00; *P*=1.00	2.79 (2.26)	t_{9}=−0.76; *P*=.46
Blood sugar testing	5.15 (2.04)	4.79 (2.08)	t_{13}=0.18; *P*=.859	4.83 (2.28)	t_{11}=0.70; *P*=.50
Foot care	3.68 (2.08)	4.61 (2.19)	t_{13}=−1.3; *P*=.213	6.17 (1.54)	t_{11}=−2.54; *P*=.03[a]

[a]Significant difference at *P*>.05 level.

Psychosocial and Behavioral Outcomes

Table 4 presents a summary of the effect of SLIDES on psychosocial diabetes outcomes including self-efficacy, social support, self-management behaviors, and diabetes knowledge. Participants were fairly knowledgeable about diabetes at baseline with a mean score of 89.1 (SD 4.04). There were no significant changes in knowledge level from baseline to 6 months post-intervention. At baseline, self-efficacy was neutral to moderate (mean 3.89, SD 0.81); however, this improved to moderate at 3 months (mean 4.45, SD 0.67) and then improved significantly toward high (*P*=.02) at 6 months (mean 4.64, SD 0.39). Similarly, participants ranked their social support for help in managing their diabetes between neutral and moderate (mean 4.61, SD 1.25) at baseline. However, their perception of social support changed at 3 months to moderate (mean 5.45, SD 1.07) and significantly (*P*=.002) increased at 6 months (mean 6.35, SD 0.44). For self-management behaviors, participants only showed statistically significant improvement in the number of days per week performing foot care (mean 3.68 SD 2.08 days per week to mean 6.17, SD 1.54 days per week at 6 months). No significant changes were noted in diet, exercise, or blood sugar testing. No participants reported smoking.

Presence

Participant perception of presence [45] (the feeling of “being there”) changed slightly from 3 months to 6 months. At 3 months, the mean response was somewhat or 4.44 (SD 0.73; mean range, 2.74-5.59) on a 7-point Likert scale. At 6 months, the mean response did not significantly change, but increased slightly to 4.64 (SD 46; mean range, 4.04-5.56). We examined the factors of control, sensory, distraction, and realism within the presence questionnaire, but found no significant differences between the overall mean and the individual factors.

Copresence

Copresence (the sense of being with other virtual humans) changed slightly from 3 months to 6 months. At 3 months, the mean score on a 7-point Likert scale for copresence was (slightly agree) 5.25 (SD 1.42) and at 6 months, the score was not significantly different (toward agree) at 5.78 (SD 1.35). Although a higher score indicates a greater level of copresence, and the participants average score did increase from 3 months to 6 months, there was not a statistically significance change. Embarrassment and likability are two other constructs to measure social response to others in a VE [47]. For embarrassment (degree of social influence), the mean score at 3 months was (slightly disagree) 3.44 (SD 2.08) and at 6 months, the score was (toward neutral) 3.99 (SD 2.03). Again, although a higher score shows a greater readiness to carry out embarrassing acts in front of others, there was no statistically significant difference between 3 and 6 months. These scores correlate well with how the participants acted while in the site. For example, when the participants lost their clothes while changing the clothes on their avatars, they were so embarrassed that they immediately left the site and the study coordinator had to intervene and redress their respective avatars. Likability (social response to others) was also measured into a single score at both 3 and 6 months. At 3 months, the composite score was (slightly agree) 5.4 (SD 1.23) and at 6 months, the score was (agree) 6.06 (SD 0.76); however, there was not a statistically significant difference between time points.

Discussion

Principal Results

This study examined the feasibility and acceptability of an eHealth program utilizing a digital VE platform that provided diabetes education and self-management support. In addition, we examined physiological outcomes (HbA1c levels, BP, BMI) and psychosocial outcomes or mediators (diabetes knowledge, self-management behaviors, self-efficacy, perceived support, presence, and copresence) to determine preliminary effects of participation in the VE intervention. To our knowledge, this is the first study to explore the feasibility of VEs as a medium to improve T2D self-management in patients. This study showed that not only was the VE easy to use even for our elderly participants (age >65), but the participants overall found the environment and the synchronous interaction with peers and educators useful.

Participants were very engaged in the VE particularly within the first 3 months or the total time of one diabetes class series (12 weeks). Once they completed the class series, they continued to come into the site, but not as frequently. There were two possible reasons for this: (1) the class series was completed, and (2) they had reviewed all informational resources on the site. A subgroup of 6 participants who had formed a supportive social group continued to return to the site to attend weekly group sessions. This ongoing group demonstrated that the classes and resources were important, but social support was very significant in their disease management, as we know from the literature to date [51]. Two factors may have facilitated this bonding between the participants; presence (the feeling of being there), copresence (the sense of being there with others), and the ability to communicate synchronously with other participants in real-time. The sense of presence is dependent upon immersion and interaction. Because our participants interacted synchronously with each other via voice, their virtual experience was more realistic and thus the greater sense of bonding among these participants. Additionally, the sense of presence and copresence prompted the participants to relate personal diabetes experiences and thus promoted a social learning situation. Social learning is based on the premise that understanding of content is socially constructed through conversations and interactions with others [52]. In addition to these potential reasons for drop off in utilization and persistent use by a subgroup of participants, we will conduct further analysis in our data visualization and case-based work, which is ongoing. This will allow us to address potential subgroup efficacy and participation characteristics as described by Eysenbach in VE and other Internet-based intervention research [53]. Although a cost analysis of this intervention was not within the scope of this study, sustainability of an intervention such as this one, we believe is directly linked to participant engagement. Keeping participants engaged requires not only a dynamic interface with sustained changes to the content, but also a supportive social group where individuals have the potential to bond over a period of time.

Participants spent the majority of their time in the classroom (48.6%), followed by the outside areas of the VE (16.8%), and the Social Center (9.0%). It was expected that the majority of participant time would be spent in the classroom because that is where they attended class once or twice a week. However, it was surprising to find that a significant amount of time was spent outside. The time spent moving from one location in the VE to another (see path around site on heat map Figure 3) was expected for transit. The activity on the “grassy areas” of the VE were unexpected, but clarity was obtained from our focus group, when we learned that participants used the site to help reduce anxiety or stress by sitting in the open outdoor areas and listening to the ambient sounds such as water lapping at the shore, birds chirping, or wind blowing. Virtual environments that are immersive provide both visual and auditory information [54]. This sensory information changes as the avatars move from place to place within the environment similar to real life, thus promoting a sense of presence or actually being there [54].

Participants also spent a significant amount of time interacting with objects. The top objects interacted with were food items in the grocery store. This is not surprising as people with diabetes find dietary issues and guidelines to be the most challenging [55]. Considering that social cognitive theory includes knowledge application, we embedded information in the virtual objects (user had to click on the object to see the information) such as nutritional feedback and suggestions for change in unhealthy food choices in each item in the grocery store. These external pieces of information served as cues to action to trigger good decision-making processes in terms of food choices. Participants in the focus group reported using this information to make healthier eating choices.

Statistically significant improvements were found in 3 behavioral and psychosocial outcomes at 6 months: social support, self-efficacy, and foot care. This was not expected given the small pilot sample size. However, we interpret these with caution given the sample size and heterogeneity in terms of baseline demographics and metabolic control. Although we did not find statistical significance in the physiological indicators, we did find some weight loss, and associated decrease in BMI. The mean weight loss of 9.1 lb is clinically relevant and we will need to explore case-based analysis further regarding improvements among subgroups by participation and behavioral outcomes characteristics. Interestingly, this weight loss occurred in the absence of significant dietary and physical activity changes, which could also indicate inaccuracy or variation in weight measurement in the clinic settings and needs to be interpreted with caution. Attaining higher quality and consistently collected measures are being studied in our current larger trial. HbA1c decreased from baseline to 6 months post-intervention, reaching a level of less than 7% at 6 months, although this is interpreted in the context that metabolic control was relatively good at baseline. It is thought that interactive health interventions exert their effects by a combination of enhanced self-efficacy and knowledge, enabling patients to change their health behaviors, leading in turn to changes in clinical outcomes [19]. Therefore, these findings are promising because significant improvements in self-efficacy and support may affect DSM and metabolic control in larger trials of VEs.

Limitations

Our findings are limited by the small pilot study sample and lack of comparison or control group, and will need to be tested in our future larger randomized controlled trial. This study primarily focused on feasibility and usability of VEs in the context of DSM and support. Although the study sample was diverse in terms of age and number of years with diabetes, it was primarily well-educated women with at least moderate income levels. We need to demonstrate the efficacy in a larger, more diverse sample. Broadening the locations and demographics of targeted participant recruitment in our larger trial, and ensuring that a VE is developed that appeals across age, race/ethnicity, and gender groups is a primary focus. We will also need to address the issue of enrolling a sample of activated participants who start with fairly good metabolic control in our future efficacy studies, and determine the ability to engage and improve outcomes among those with poor metabolic control who are less likely to participate in DSME in general. In terms of results, the reliance on clinical measures (weight, BP, HbA1c) from medical records due to the financial constraints of a pilot study resulted in some missing data and possible inconsistency in collection of these measures within the clinic setting. Therefore, the clinical outcomes must be interpreted with caution. Finally, participation within the site dropped after 12 weeks. We believe this was problematic because we did not keep the site content dynamic [56]. Our further study in this area will address these issues and attempt to explore participation and engagement over time.

Conclusions

e-Health applications such as SLIDES enable patients with chronic diseases such as diabetes to become more engaged with the self-management of their disease. Evidence shows that people who use e-Health resources have better social support for their disease, increased knowledge, and gains in self-efficacy [57]. This study clearly showed a difference in social support and self-efficacy after 6 months of participation that substantiates these previous findings. Because little is known about usability, acceptability, and efficacy of health interventions in a VE, this study constituted an important, innovative first step in exploring the potential of VEs in facilitating DSM. Using constructs from social cognitive theory and constructs from a VE theoretical framework in the development of this virtual community, we showed that developing environments such as these have the potential to motivate and support people to effectively self-manage their type 2 diabetes. The preliminary data demonstrated that VEs provide a feasible, useful, and effective platform for patients and educators. Flexible access to both synchronous and asynchronous diabetes education, skill building activities, and support from a home computer removed barriers to attending traditional clinic-based meetings. This program has potential for improving DSM in an easily disseminated alternative model on the Internet that may promote more effective resource utilization by reaching increased numbers of participants across geographic boundaries and potentially decreasing institutional diabetes education resources while maintaining the sense of personal interaction that has been shown to be important in successful diabetes self-management interventions.

Acknowledgments

This study was funded by the National Library of Medicine (1R21LM010727-01).

Conflicts of Interest

None declared.

References

1. McLuhan M. Understanding Media: The Extensions of Man. New York, NY: New American Library; 1964.
2. Okita S, Bailenson J, Schwartz D. The mere belief in social interaction improves learning. In: The proceedings of the 29th annual conference of the cognitive science society. 2007 Presented at: The 29th Annual Conference of the Cognitive Science Society; August 1-4, 2007; Nashville, TN p. 1355 URL: http://csjarchive.cogsci.rpi.edu/proceedings/2007/forms/authors3.htm#O
3. National Diabetes Statistics 2011. -10-24. 2013. National Diabetes Information Clearinghouse URL: http://diabetes.niddk.nih.gov/dm/pubs/statistics/ [accessed 2013-10-24] [WebCite Cache ID 6KbkomE4W]
4. Diabetes Control and Complications Trial Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. The Diabetes Control and Complications Trial Research Group. N Engl J Med 1993 Sep 30;329(14):977-986. [doi: 10.1056/NEJM199309303291401] [Medline: 8366922]
5. Franz M, Pastors J, Warshaw H, Daly A. Does "diet" fail? Clinical Diabetes 2000;18(4):162-167.
6. Lasker RD. The diabetes control and complications trial. Implications for policy and practice. N Engl J Med 1993 Sep 30;329(14):1035-1036. [doi: 10.1056/NEJM199309303291410] [Medline: 8366905]
7. Murphy SL, Xu J, Kochanek KD. National Center for Health Statistics. Hyattsville, MD; 2013. Deaths: Final Data for 2010, in National Vital Statistics Reports URL: http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_04.pdf [accessed 2014-03-27] [WebCite Cache ID 6OOYJpN09]

8. Funnell MM, Anderson RM. Patient empowerment: a look back, a look ahead. Diabetes Educ 2003;29(3):454-8, 460, 462 passim. [Medline: 12854337]
9. Glasgow RE, Funnell MM, Bonomi AE, Davis C, Beckham V, Wagner EH. Self-management aspects of the improving chronic illness care breakthrough series: implementation with diabetes and heart failure teams. Ann Behav Med 2002;24(2):80-87. [Medline: 12054323]
10. Norris SL, Engelgau MM, Narayan KM. Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials. Diabetes Care 2001 Mar;24(3):561-587. [Medline: 11289485]
11. Norris SL, Lau J, Smith SJ, Schmid CH, Engelgau MM. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control. Diabetes Care 2002 Jul;25(7):1159-1171. [Medline: 12087014]
12. Funnell MM, Anderson RM. Working toward the next generation of diabetes self-management education. Am J Prev Med 2002 May;22(4 Suppl):3-5. [Medline: 11985929]
13. Funnell MM, Anderson RM. Changing office practice and health care systems to facilitate diabetes self-management. Curr Diab Rep 2003 Apr;3(2):127-133. [Medline: 12728638]
14. Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, D.C: National Academy Press; 2001.
15. Barrera M, Glasgow RE, McKay HG, Boles SM, Feil EG. Do Internet-based support interventions change perceptions of social support?: An experimental trial of approaches for supporting diabetes self-management. Am J Community Psychol 2002 Oct;30(5):637-654. [Medline: 12188054]
16. Jackson CL, Bolen S, Brancati FL, Batts-Turner ML, Gary TL. A systematic review of interactive computer-assisted technology in diabetes care. Interactive information technology in diabetes care. J Gen Intern Med 2006 Feb;21(2):105-110 [FREE Full text] [doi: 10.1111/j.1525-1497.2005.00310.x] [Medline: 16390512]
17. Gottlieb S. Study explores Internet as a tool for care of diabetic patients. BMJ 2000 Apr 1;320(7239):892. [Medline: 10787248]
18. Welch G, Shayne R. Interactive behavioral technologies and diabetes self-management support: recent research findings from clinical trials. Curr Diab Rep 2006 Apr;6(2):130-136. [Medline: 16542624]
19. Murray, EJ, Burns, J, See, TS, Lai, R, Nazareth, I. Interactive Health Communication Applications for people with chronic disease. Cochrane Database Syst Rev 2004(4):CD004274. [doi: 10.1002/14651858.CD004274] [Medline: 15736316]
20. Bull SS, Gaglio B, McKay HG, Glasgow RE. Harnessing the potential of the internet to promote chronic illness self-management: diabetes as an example of how well we are doing. Chronic Illn 2005 Jun;1(2):143-155. [Medline: 17136920]
21. Peyrot M, Rubin RR, Funnell MM, Siminerio LM. Access to diabetes self-management education: results of national surveys of patients, educators, and physicians. Diabetes Educ 2009;35(2):246-263. [doi: 10.1177/0145721708329546] [Medline: 19208816]
22. Demiris G, Finkelstein SM, Speedie SM. Considerations for the design of a Web-based clinical monitoring and educational system for elderly patients. J Am Med Inform Assoc 2001;8(5):468-472 [FREE Full text] [Medline: 11522767]
23. Second Life. -10-24. 2013. Linden Labs URL: http://secondlife.com/?gclid=CKyj74q6r7oCFejm7AodHRkAVQ [accessed 2013-10-24] [WebCite Cache ID 6KbkVvpwp]
24. Johnson C, Feenan K, Setliff G, Pereira K, Shaw R, Hassell N, et al. Building a Virtual Environment for Diabetes Self-Management Education and Support. International Journal of Virtual Communities and Social Networking 2014 (forthcoming).
25. Oh H, Rizo C, Enkin M, Jadad A. What is eHealth (3): a systematic review of published definitions. J Med Internet Res 2005;7(1):e1 [FREE Full text] [doi: 10.2196/jmir.7.1.e1] [Medline: 15829471]
26. Bandura A. Social cognitive theory: an agentic perspective. Annu Rev Psychol 2001;52:1-26. [doi: 10.1146/annurev.psych.52.1.1] [Medline: 11148297]
27. Blascovich J, Loomis J, Beall AC, Swinth KR, Hoyt CL, Bailenson JN. Immersive virtual environments technology as a methodological tool for social psychology. Psychological Inquiry 2002;13(2):103-124.
28. Blascovich J. Social influence within immersive virtual environments. In: Schroeder R, editor. The Social Life of Avatars. Presence and Interaction in Shared Virtual Environments. London: Springer-Verlag; 2002.
29. Vorderstrasse A, Shaw RJ, Blascovich J, Johnson CM. A theoretical framework for a virtual diabetes self-management community intervention. West J Nurs Res 2014 Jan 21. [doi: 10.1177/0193945913518993] [Medline: 24451083]
30. Johnson CM, Johnson TR, Zhang J. A user-centered framework for redesigning health care interfaces. J Biomed Inform 2005 Feb;38(1):75-87. [doi: 10.1016/j.jbi.2004.11.005] [Medline: 15694887]
31. Faulkner L. Beyond the five-user assumption: benefits of increased sample sizes in usability testing. Behav Res Methods Instrum Comput 2003 Aug;35(3):379-383. [Medline: 14587545]
32. Tullis T, Albert B. Planning a usability study. In: Measuring the User Experience. Collecting, Analyzing, and Presenting Usability Metrics. Amsterdam: Morgan Kaufmann Publishers; 2008:45-62.
33. Ericcson A, Simon K. Protocol Analysis: Verbal Reports as Data, revised version. Cambridge, MA: MIT Press; 1993.
34. American Diabetes Association. Standards of medical care in diabetes--2014. Diabetes Care 2014 Jan;37 Suppl 1:S14-S80. [doi: 10.2337/dc14-S014] [Medline: 24357209]

35. Funnell MM, Brown TL, Childs BP, Haas LB, Hosey GM, Jensen B, et al. National standards for diabetes self-management education. Diabetes Care 2010;33(S1):S89-S96.
36. American Diabetes Association. Diabetes Care. 2013. Standards of medical care in diabetes--2013 URL: http://care.diabetesjournals.org/content/36/Supplement_1/S11.full [accessed 2014-03-27] [WebCite Cache ID 6OOgeuleA]
37. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. Psychol Rev 1977 Mar;84(2):191-215. [Medline: 847061]
38. Bandura A. Human agency in social cognitive theory. Am Psychol 1989 Sep;44(9):1175-1184. [Medline: 2782727]
39. Bandura A. The anatomy of stages of change. Am J Health Promot 1997;12(1):8-10. [Medline: 10170438]
40. American Association of Diabetes Educators. AADE 7 self-care behaviors. Diabetes Educ 2008;34(3):445-449.
41. Davis F. Perceived usefulness, perceived ease of use, and user acceptance of information technology. MIS Quarterly 1989;13:319-340.
42. Anderson RM, Fitzgerald JT, Gruppen LD, Funnell MM, Oh MS. The diabetes empowerment scale-short form (DES-SF). Diabetes Care 2003 May;26(5):1641-1642. [Medline: 12716841]
43. Speight J, Bradley C. The ADKnowl: identifying knowledge deficits in diabetes care. Diabet Med 2001 Aug;18(8):626-633. [Medline: 11553199]
44. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. Diabetes Care 2000 Jul;23(7):943-950 [FREE Full text] [Medline: 10895844]
45. Witmer BG, Singer MJ. Measuring presence in virtual environments: A presence questionnaire. Presence 1998;7(3):225-240.
46. Slater MA, Sadagic A, Usoh M, Schroeder R. Small-group behavior in a virtual and real environment: A comparative study. Presence 2000;9(1):37-51.
47. Bailenson J, Swinth K, Hoyt C, Persky S, Dimov A, Blascovich J. The independent and interactive effects of embodied-agent appearance and behavior on self-report, cognitive, and behavioral markers of copresence in immersive virtual environments. Presence 2005;14(4):379-393.
48. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009 Apr;42(2):377-381 [FREE Full text] [doi: 10.1016/j.jbi.2008.08.010] [Medline: 18929686]
49. Statistical Analysis Software. SAS. Cary, NC: SAS Institute; 2010.
50. The R Development Core Team. R: A language and environment for statistical computing.: R Foundation for Statistical Computing; 2010. URL: http://www.lsw.uni-heidelberg.de/users/christlieb/teaching/UKStaSS10/R-refman.pdf [accessed 2014-03-27] [WebCite Cache ID 6OOjUgBiw]
51. Strom JL, Egede LE. The impact of social support on outcomes in adult patients with type 2 diabetes: a systematic review. Curr Diab Rep 2012 Dec;12(6):769-781 [FREE Full text] [doi: 10.1007/s11892-012-0317-0] [Medline: 22949135]
52. Brown JS, Adler RP. Minds on fire: open education, the long tail, and learning 2.0. EDUCAUSE Review 2008;43(1):16-32.
53. Eysenbach G. The law of attrition. J Med Internet Res 2005;7(1):e11 [FREE Full text] [doi: 10.2196/jmir.7.1.e11] [Medline: 15829473]
54. Blascovich J. Social influence within immersive virtual environments. In: Schroeder R, editor. The Social Life of Avatars. Presence and Interaction in Shared Virtual Environments. London: Springer-Verlag; 2002.
55. Magkos F, Yannakoulia M, Chan JL, Mantzoros CS. Management of the metabolic syndrome and type 2 diabetes through lifestyle modification. Annu Rev Nutr 2009;29:223-256. [doi: 10.1146/annurev-nutr-080508-141200] [Medline: 19400751]
56. King J. 7 ways to keep customers coming back to your site. Targeted and engaging content encourages regular visitors URL: http://www.microsoft.com/canada/smallbiz/themes/marketing/article8.mspx [accessed 2013-10-24] [WebCite Cache ID 6KblY5dah]
57. Wicks P, Massagli M, Frost J, Brownstein C, Okun S, Vaughan T, et al. Sharing health data for better outcomes on PatientsLikeMe. J Med Internet Res 2010;12(2):e19.

Abbreviations

BMI: body mass index
BP: blood pressure
DES-SF: diabetes empowerment scale-short form
DSM: diabetes self-management
DSMT: diabetes self-management training
HbA1c: glycosylated hemoglobin
SLIDES: second life impacts diabetes education & self-management
T2D: type 2 diabetes
VE: virtual environment

Edited by G Eysenbach; submitted 24.10.13; peer-reviewed by J Brixey, L Ruggiero, B Gerber; comments to author 23.12.13; revised version received 03.02.14; accepted 13.03.14; published 08.04.14.

Please cite as:
Johnson C, Feinglos M, Pereira K, Hassell N, Blascovich J, Nicollerat J, Beresford HF, Levy J, Vorderstrasse A
Feasibility and Preliminary Effects of a Virtual Environment for Adults With Type 2 Diabetes: Pilot Study
JMIR Res Protoc 2014;3(2):e23
URL: http://www.researchprotocols.org/2014/2/e23/
doi:10.2196/resprot.3045
PMID:24713420

Original Paper

Analysis of Internet Usage Among Cancer Patients in a County Hospital Setting: A Quality Improvement Initiative

Lucy Wallace[1], MD; Lisa Lilley[2], RN; William Lodrigues[2], ARNP; Julie Dreadin-Pulliam[2], ARNP; Xian-Jin Xie[1], PhD; Sakshi Mathur[1], BS; Madhu Rao[1], MBA; Valorie Harvey[2], RN; Ann Marilyn Leitch[1], MD; Roshni Rao[1], MD

[1]University of Texas Southwestern, Dallas, TX, United States

[2]Parkland Memorial Hospital, Dallas, TX, United States

Corresponding Author:
Lucy Wallace, MD
University of Texas Southwestern
Harry Hines Blvd Blvd
Dallas, TX, 75390-8548
United States
Phone: 1 214 288 9955
Fax: 1 214 648 1118
Email: lucywallace77@yahoo.com

Abstract

Background: Cancer is one of the most common diseases that patients research on the Internet. The Commission on Cancer (CoC) recommended that Parkland Memorial Hospital (PMH) improve the oncology services website. PMH is Dallas County's public health care facility, serving a largely uninsured, minority population. Most research regarding patient Internet use has been conducted in insured, Caucasian populations, raising concerns that the needs of PMH patients may not be extrapolated from available data. The PMH Cancer Committee, therefore, adopted a quality improvement initiative to understand patients' Internet usage.

Objective: The objective of the study was to obtain and analyze data regarding patients' Internet usage in order to make targeted improvements to the oncology services section of the institutional website.

Methods: A task force developed an 11-question survey to ascertain what proportion of our patients have Internet access and use the Internet to obtain medical information as well as determine the specific information sought. Between April 2011 and August 2011, 300 surveys were administered to newly diagnosed cancer patients. Multivariate analyses were performed.

Results: Of 300 surveys, 291 were included. Minorities, primarily African-American and Hispanic, represented 78.0% (227/291) of patients. Only 37.1% (108/291) of patients had Internet access, most (256/291, 87.9%) having access at home. Younger patients more commonly had Internet access, with a mean age of 47 versus 58 years for those without (P<.001). Education beyond high school was associated with Internet access (P<.001). The most common reason for Internet research was to develop questions for discussion with one's physician. Patients most frequently sought information regarding cancer treatment options, outcomes, and side effects.

Conclusions: Less than one-half of PMH oncology patients have Internet access. This is influenced by age, educational level, and ethnicity. Those with access use it to obtain information related to their cancer diagnosis. The most effective way of addressing our patients' needs using the institutional website is to provide links to reputable disease-specific sites.

(JMIR Res Protoc 2014;3(2):e26) doi:10.2196/resprot.2806

KEYWORDS

Internet; cancer; quality; quality improvement; patient education

Introduction

Cancer is among the top three diseases that the public researches on the Internet [1]. Studies reveal that up to 63% of cancer patients search the Internet for information about their diagnosis [2]. Common reasons patients search the Internet are to develop questions to discuss with their physicians, verify information already received from their physicians, and seek alternative treatment options [2]. Research reveals significant differences

in Internet usage based on age [2], education [3], income [3], and ethnicity [3-6].

Hospitals are facing increasing pressure to initiate and maintain an Internet presence, particularly in competitive markets where consumers have the resources and ability to compare and select their preferred health care organizations [7]. Additionally, accrediting organizations, such as the American College of Surgeons Commission on Cancer (CoC), encourage participating members to create and maintain an Internet presence that includes patient education materials as well as information about the hospital itself.

Parkland Memorial Hospital (PMH) is Dallas County's public health care facility. It serves a largely uninsured, minority, and uneducated population, particularly with regard to cancer programs [8,9]. In March 2009, the CoC advised PMH to improve the presence of oncology services on the institutional website and include patient educational materials. A task force was subsequently formed, comprised of physicians, hospital administrators, nurses, and patient advocates, in order to oversee this quality improvement initiative.

A review of the literature was performed and revealed that the majority of research regarding patient Internet use was performed in insured, primarily Caucasian populations [2-4]. This raised concerns that the educational needs of these patients could not be extrapolated to the population that PMH serves. In addition, it was unclear what proportion of the PMH cancer patients actually had Internet access and would use it to seek medical information. Therefore, due to the paucity of data pertinent to the patterns of use and educational needs of the PMH patient population, a patient survey was developed. At the time of our study, prior surveys had been conducted, but in primarily Caucasian, insured populations. Therefore, the lack of such a survey in a minority, uninsured population prevented direct adoption of previously used instruments. It is worth noting that there were few investigations available for review that focused on the Internet use in the Hispanic population, which is the fastest growing demographic in the United States and a considerable segment of the PMH patient population. More recent studies of Internet usage in this rapidly growing segment of the population have focused primarily on mobile text messaging [5,6]. While insightful and compelling, these are not directly applicable to the CoC mandate for PMH to improve the oncology services presence and provide educational materials on the institutional website.

Prior to expending valuable resources, it was critical to understand how resources would be best applied. The goals of the survey were to ascertain rates of Internet access, rates of medical Internet use, and to understand the specific educational needs among the PMH cancer population. This information would be used to make targeted improvements to the oncology services section of the PMH institutional website.

Methods

Recruitment

After discussion with the institutional review board (IRB), because the primary focus of the study was quality improvement, this project was approved and initiated as an IRB-exempt protocol. From April 2011 to August 2011, 300 surveys were administered to newly diagnosed cancer patients presenting to PMH oncology clinics. Patients still without a known cancer diagnosis, those presenting for follow-up, and patients who were not yet 18-years old were excluded from the study. The surveys were administered in clinics focusing on breast, gastrointestinal, liver, lung, prostate, and gynecological cancers to provide broad representation and include the most commonly treated cancers at PMH. Survey administration was performed in the clinics by medical assistants, both in an attempt to ensure the surveys were completed as thoroughly as possible and so that illiterate and non-English speaking patients would not be inadvertently excluded. Patients who only spoke Spanish were administered the survey by Spanish speaking staff. During the months of survey administration, April through August of 2011, 864 patients were eligible to participate. These patients were approached during their initial oncology clinic visit and, of these, 300 patients agreed to participate, yielding a participation rate of 34.7% (300/864). Most of those who chose not to participate cited time constraints. No additional questioning or data collection was performed regarding reasons for nonparticipation.

Data Collection

The survey primarily focused on whether patients had Internet access, the location of Internet usage, and whether they attempted to obtain information on the Internet about their diagnosis. Demographic data including age, gender, race, and educational level was collected. Patients were asked to provide their specific cancer diagnosis. Additionally, to obtain guidance on the content of the PMH oncology services website, information regarding the patients' educational needs was also collected. Patients were asked if their primary reason for performing Internet research was to develop questions for discussion with their physician, verify information already received from their physician, investigate alternative treatments, or to learn about PMH. Patients were asked to select the type of information they were seeking and were given the following choices: cancer treatment options, cancer treatment outcomes, resources for coping with cancer, cancer clinical trials, cancer treatment side effects, and information about PMH. Patients were asked how many minutes per day were spent conducting Internet research. They were also asked if they would use the PMH site more if the content were offered in Spanish.

Statistical Analysis

De-identified patient information was collected and entered in an Excel spreadsheet for analysis. Fisher exact test was used for categorical data. Multivariate analyses were performed to determine which factors significantly impacted Internet access rates.

Results

Patient Surveys

Of the 300 surveys that were administered throughout PMH oncology clinics, 291 were sufficiently completed for inclusion into the study. Analysis revealed that 107/291 patients (36.8%)

had Internet access. The majority of these, 94/107 patients (87.9%), had Internet access at home. Of all patients with access to the Internet, 70/107 patients (65.4%), reported that they used the Internet to research their cancer diagnosis.

Demographics

Demographic data for the overall study population are depicted in Table 1. Most of the study population study population, 200/291 patients (68.7%), had obtained some or all of a high school education. Only 20/291 patients (6.9%) had graduated from college and an even fewer, 9/291 patients (3.1%), had obtained a graduate degree. The majority, 227/291 patients (78.0%), were minorities, primarily African-American and Hispanic.

The data were organized according to Internet access. Multivariate analyses were performed and the results are depicted in Table 2. Younger patients were more likely to have Internet access. The mean age of patients with Internet access was 47 versus 58 years for those without (P<.001). Patients with an educational level beyond high school had Internet access more often than those with a high school diploma or less (P<.001). There was no difference in Internet access rates among males and females. There was no statistically significant difference in rates of Internet access among the various races represented.

Table 1. Study population demographic data.

Demographics	n (%)
Gender	
Male	163 (56.0)
Female	118 (40.5)
Missing Data	110 (3.4)
Race	
African-American	108 (37.1)
Hispanic	96 (32.9)
Caucasian	54 (18.6)
Asian	16 (5.5)
Other	7 (2.4)
Missing Data	10 (3.4)
Educational Level	
High School	200 (68.7)
Beyond High School	78 (26.8)
Some College	48 (16.8)
Some Graduate School	20 (6.9)
Graduate Degree	9 (3.1)
Missing Data	13 (4.5)
Cancer Type	
Genitourinary Tract	51 (17.5)
Gynecologic	44 (15.1)
Gastrointestinal Tract	43 (14.8)
Breast	41 (14.1)
Lung	28 (9.6)
Other	56 (19.2)
Missing Data	28 (9.6)

Table 2. Multivariate analyses.

Factor/variable analysis	Odds ratio	95% CI	*P* value
Age			
Continuous	1.083	1.053-1.114	<.001
Gender			
Female	Reference[a]		
Male	2.491	1.043-5.951	.0399
Race			
Asian, Caucasian	0.475	0.232-0.971	.0414
African-American, Hispanic	Reference		
Education			
High School	Reference		
>High School	0.194	0.095-0.397	<.001
Cancer Type			
Breast	4.577	1.488-14.081	.008
Gastrointestinal	2.236	0.716-6.986	.1661
Lung	5.816	1.509-22.414	.0105
Gynecologic	Reference		
Genitourinary	1.480	0.399-5.490	.5578
Other	5.301	1.757-15.997	.0031

[a]The word reference is used to delineate the variable against which the others were compared to obtain the statistical data displayed.

Internet Usage

The qualitative data regarding patients' reasons and goals for their Internet use is represented in Table 3 and discussed herein. For the analysis of survey questions exploring the reasons for performing Internet research and the specific information that was sought, only the 107 surveys reporting positive Internet access were used. Also, multiple answers were allowed. There were 57.0% (61/107) of the patients who stated that the primary goal of their Internet research was to assist them in developing questions for discussion with their physician, this being the most common response. There were 38/107 (35.5%) patients who stated they used the Internet to verify information already received. Only 14.9% (16/107) patients stated their primary goal was to learn about PMH. The most common categories of information that patients are seeking on the Internet are information regarding cancer treatment options (42/67, 63%), cancer treatment outcomes (30/57, 53%), and cancer treatment side effects (23/49, 46%). Very few (7/28, 26%) were interested in learning about cancer trials. Even fewer (1/14, 13%) were seeking information specific to PMH.

When asked how many minutes were spent using the Internet daily, the most common response was 30 minutes. Of 107 patients, 25 (23.4%) stated that they would use the PMH oncology services website more if the information were also presented in Spanish. All of those patients were Hispanic and that number represents 61% (25/41) of the Hispanic patients who reported having Internet access.

Table 3. Patient goals for Internet use.

Patient goals	n (%)
Reason for performing Internet research	
Develop questions for discussion with physician	61 (57.0)
Learn about PMH	16 (14.9)
Investigate alternative treatments	37 (34.6)
Verify information already received	38 (35.5)
Specific information sought	
Cancer treatment options	67 (62.6)
Cancer treatment outcomes	57 (53.3)
Information about PMH	14 (13.1)
Coping with cancer	41 (38.3)
Cancer trials	28 (26.2)
Cancer treatment side effects	49 (45.8)

Discussion

Principal Findings

Less than one-half of PMH oncology patients have access to the Internet. This is lower than Internet access rates of 80% previously reported in study populations that are primarily Caucasian and insured [2]. However, the proportion of PMH patients with Internet access was greater than anticipated, supporting an effort to improve the oncology services presence on the PMH institutional website. This is especially true given that, of the patients with Internet access, the percentage who actually use the Internet to research their cancer diagnosis is comparable with that which has been reported in study populations that are primarily Caucasian and insured, 42% to 63% [2,3].

Regarding the portion of the survey that addressed content, a pattern emerged in the responses. Patients expressed little interest in information specific to PMH. It is believed that this likely speaks to the fact that PMH patients, being enrolled in Dallas County's public health care system, do not have other options for health care delivery, and therefore are not using the Internet to compare hospitals.

Patients' primary reason for performing Internet research was to develop questions for discussion with their physicians. They were most interested in finding information regarding cancer treatment options, outcomes, and side effects. This is what the task force has chosen to focus on, as changes have been made to the Oncology Services portion of the PMH institutional website. It was determined that the most efficient and cost-effective way to address the CoC recommendation, to provide educational materials on the institutional website, is to provide links to the websites of other reputable disease-specific organizations, such as American Cancer Society, National Institutes of Health, and Susan G Komen for the Cure.

Limitations

The inherent limitation of this and any study using a survey to gather data is that there is no way to account for recall bias on the part of the respondent. There were also surveys that were used but had some missing data. In other words, despite the survey being administered by a medical assistant in person, there were patients who did not complete every single question on the survey. An additional limitation of the survey format is that only the particular responses that are included in the answer choices can be analyzed. This survey did not include a section for free-form responses and, in the occasional instance of narrative response, there was no mechanism for analysis.

Conclusions

The findings of this quality improvement initiative will serve to assist other like institutions working to improve Internet resources for patients in an efficient and cost-effective manner. This is particularly true as it relates to other hospitals with a large and growing Hispanic population, as it has already been stated that this is the fastest growing demographic in the United States and was well represented in this study population.

In general, there is more pressure for health care systems to create and maintain a presence on the Internet, particularly in competitive markets in which patients have many choices. There is also the regulatory obligation for hospitals to implement and maintain an Internet presence, as the CoC mandate illustrates. However, this study has shown that in the county hospital setting, serving primarily minority, uninsured patients, valuable resources need not be dedicated to elaborate website interface implementation and maintenance. By conducting this survey and understanding the ways patients use the Internet and the specific information they are seeking, the PMH task force was able to successfully satisfy the CoC requirement using relatively few resources.

Acknowledgments

The authors wish to thank the David M Crowly Foundation for their support of this research.

Conflicts of Interest

None declared.

References

1. Larkin M. Online support groups gaining credibility. Lancet 2000;355(9217):1834. [doi: 10.1016/S0140-6736(05)73097-X] [Medline: 10832868]
2. Castleton K, Fong T, Wang-Gillam A, Waqar MA, Jeffe DB, Kehlenbrink L, et al. A survey of Internet utilization among patients with cancer. Support Care Cancer 2011;19(8):1183-1190. [doi: 10.1007/s00520-010-0935-5] [Medline: 20556435]
3. Fogel J, Albert SM, Schnabel F, Ditkoff BA, Neugut AI. Use of the Internet by women with breast cancer. J Med Internet Res 2002;4(2):e9 [FREE Full text] [doi: 10.2196/jmir.4.2.e9] [Medline: 12554556]
4. Fogel J, Albert SM, Schnabel F, Ditkoff BA, Neugut AI. Racial/ethnic differences and potential psychological benefits in use of the internet by women with breast cancer. Psychooncology 2003;12(2):107-117. [doi: 10.1002/pon.617] [Medline: 12619143]
5. Dang CM, Estrada S, Bresee C, Phillips EH. Exploring potential use of internet, E-mail, and instant text messaging to promote breast health and mammogram use among immigrant Hispanic women in Los Angeles County. Am Surg 2013;79(10):997-1000. [Medline: 24160786]
6. Kratzke C, Wilson S. Ethnic differences in breast cancer prevention information-seeking among rural women: will provider mobile messages work? [ePub ahead of print]. J Cancer Educ 2013 Oct 28. [doi: 10.1007/s13187-013-0576-8] [Medline: 24163017]
7. Revere L, Robinson L. How healthcare organizations use the Internet to market quality achievements. J Healthc Manag 2012;55:39-49. [doi: 10.1136/bmjqs-2012-000852]
8. Yorio JT, Xie Y, Yan J, Gerber DE. Lung cancer diagnostic and treatment intervals in the United States: a health care disparity? J Thorac Oncol 2009;4(11):1322-1330. [doi: 10.1097/JTO.0b013e3181bbb130] [Medline: 19752757]
9. Brazda A, Estroff J, Euhus D, Leitch AM, Huth J, Andrews V, et al. Delays in time to treatment and survival impact in breast cancer. Ann Surg Oncol 2012;17:S291-S296. [Medline: 20853049]

Abbreviations

CoC: Commission on Cancer
IRB: institutional review board
PMH: Parkland Memorial Hospital

Edited by G Eysenbach; submitted 19.07.13; peer-reviewed by KY Wen, K Gunn; comments to author 18.09.13; revised version received 18.11.13; accepted 13.03.14; published 09.05.14.

Please cite as:
Wallace L, Lilley L, Lodrigues W, Dreadin-Pulliam J, Xie XJ, Mathur S, Rao M, Harvey V, Leitch AM, Rao R
Analysis of Internet Usage Among Cancer Patients in a County Hospital Setting: A Quality Improvement Initiative
JMIR Res Protoc 2014;3(2):e26
URL: http://www.researchprotocols.org/2014/2/e26/
doi:10.2196/resprot.2806
PMID:24824330

Original Paper

Preventing Postpartum Smoking Relapse Among Inner City Women: Development of a Theory-Based and Evidence-Guided Text Messaging Intervention

Kuang-Yi Wen[1]; Suzanne M Miller[1]; Linda Kilby[2]; Linda Fleisher[3]; Tanisha D Belton[1]; Gem Roy[1]; Enrique Hernandez[4]

[1]Fox Chase Cancer Center/Temple University Health System, Cancer Prevention and Control, Philadelphia, PA, United States

[2]Manager of the Women, Infants and Children (WIC) Program in Philadelphia, Philadelphia, PA, United States

[3]The Center for Injury Research and Prevention, The Children's Hospital of Philadelphia, Philadelphia, PA, United States

[4]Temple University School of Medicine, Department of Obstetrics, Gynecology, and Reproductive Sciences, Philadelphia, PA, United States

Corresponding Author:
Suzanne M Miller
Fox Chase Cancer Center/Temple University Health System
Cancer Prevention and Control
333 Cottman Avenue
Philadelphia, PA, 19111
United States
Phone: 1 215 728 4069
Fax: 1 215 214 1651
Email: suzanne.miller@fccc.edu

Abstract

Background: Underserved women are at high risk for smoking relapse after childbirth due to their unique socioeconomic and postpartum stressors and barriers. Mobile text messaging technology allows delivery of relapse prevention programs targeted to their personal needs over time.

Objective: To describe the development of a social-cognitive theory-based and evidence-guided text messaging intervention for preventing postpartum smoking relapse among inner city women.

Methods: Guided by the cognitive-social health information processing framework, user-centered design, and health communication best practices, the intervention was developed through a systematic process that included needs assessment, followed by an iterative cycling through message drafting, health literacy evaluation and rewriting, review by target community members and a scientific advisory panel, and message revision, concluding with usability testing.

Results: All message content was theory-grounded, derived by needs assessment analysis and evidence-based materials, reviewed and revised by the target population, health literacy experts, and scientific advisors. The final program, "Txt2Commit," was developed as a fully automated system, designed to deliver 3 proactive messages per day for a 1-month postpartum smoking relapse intervention, with crave and lapse user-initiated message functions available when needed.

Conclusions: The developmental process suggests that the application of theory and best practices in the design of text messaging smoking cessation interventions is not only feasible but necessary for ensuring that the interventions are evidence based and user-centered.

(JMIR Res Protoc 2014;3(2):e20) doi:10.2196/resprot.3059

KEYWORDS

smoking relapse intervention; low-income women; mHealth; text messaging

Introduction

Tobacco use has remained the single most important modifiable cause of adverse pregnancy outcomes in the United States. Smoking accounts for 30% of deliveries of infants with low birth weights, 8% of preterm births, and 5% of all perinatal deaths [1-3]. Smoking during pregnancy and postpartum contributes to sudden infant death syndrome, changes in brain and nervous system development, and increased risk for infant ear and respiratory infections, in addition to cognitive and

behavioral deficits [4,5]. Motivational factors during pregnancy, including protection of the health of the unborn baby, social pressure, pregnancy nausea, and loss of taste for tobacco, often result in a "suspension of smoking behavior" [6-9]. However, many women relapse after giving birth, suggesting that their commitment to cessation is not permanent. Indeed, approximately 45% resume smoking after only 3 months and up to 80% relapse within 1 year [10]. Low-income women are more likely than their higher income counterparts to smoke during pregnancy and relapse after childbirth. Therefore, they represent an important target population for postpartum relapse prevention interventions, especially given that they are typically difficult to access and contact [11].

Although there are programs designed to motivate underserved women who are at increased risk for smoking relapse [12,13], underserved women are less likely to successfully participate in and/or complete a smoking cessation program in the first place [14,15]. Conflicts in scheduling, lack of transportation, and family priorities are barriers to attending smoking cessation interventions [15,16]. These personal barriers are compounded by postpartum responsibilities and roles of the new mother, including childcare burden, relationship issues, medical problems, coping with maternal weight gain, weaning issues, and attempts to return to a nonpregnant state that can trigger a return to smoking [17-22]. In general, few interventions focus on the critical transition from pregnancy to the postpartum period, where the focus shiftsfrom the time-limited barriers that undermine protecting the fetus's health to the psychosocial barriers that undermine the ongoing protection ofthe woman's and new infant's health [23,24]. Thus, there is a need for smoking relapse prevention interventions that are accessible to the target population and tailored to their specific psychosocial needs.

A key barrier that emerges for the delivery of evidence-based postpartum programs is access to the new mother.Encouragingly, due to the availability of modern technologies, one particularly well suited but under-utilized technology involves the use of mobile telephones to deliver health-related information to these hard-to-reach populations. Currently 90% of Americans own and use a mobile telephone with text messaging service and 47% of Americans use mobile phones to gain access to information on a daily basis [25]. Because mobile phones are also readily available to underserved women, text-based delivered interventions may benefit those who are most vulnerable and least readily accessible through alternative channels by providing intervention support and advice in a feasible and timely fashion [26]. Indeed, a recent Pew Research Center study found that African Americans and Latinos use mobile phones more than their white counterparts [27]. Furthermore, reading and sending text messages on a mobile phone are the most frequently engaged in activities [27]. In addition, mobile text messaging programs can be personalized, cost-effective, easily disseminated, and provide the anonymity that many people prefer [28,29]. Given that text messaging is available on all mobile phone platforms and with all providers, this technology demonstrates strong potential as a resource for behavior change interventions [29].

One successful example of using a text messaging program for pregnant women is the "Text4baby" program, which sends targeted health messages to promote healthy pregnancies and healthy babies [30]. Furthermore, studies show that text messages tailored to smoking habits and barriers to quitting have high usage, encourage quit attempts, and support smokers' coping with crave and relapse [28,31-33]. Yet, to our knowledge, no study has examined text messaging as an intervention channel for delivering postpartum smoking cessation interventions [34]. In fact, the number of interventions specifically designed to prevent postpartum smoking relapse is limited, and only a few have focused on underserved minority populations [35-38]. Despite the growing body of literature reporting the positive outcomes of text messaging-based interventions for behavior change, including smoking cessation [31,34,39-42], there is a gap in the literature related to the application and systematic description of the developmental steps that need to be undertaken to produce and test the feasibility of text messaging interventions [43,44], a critical component of producing and disseminating a successful behavior change intervention [45,46]. To fill this void, guided by our research team's cognitive-social health information processing (C-SHIP) model and health communication best practice principles, this paper describes an iterative user-centered developmental process of an evidence-based text messaging intervention designed to preventing smoking relapse among underserved inner city postpartum women.

Methods

Overview

With use of a user-centered approach, the intervention development followed a series of iterative steps to ensure that all content was understandable and evidence-based. Guided by the C-SHIP framework and health communication best practices, the text messaging intervention was developed through a systematic process that included needs assessment interviews, followed by an iterative cycling through text message drafting, revision through health literacy evaluation, review by target community interviews via cognitive response interviews, scientific advisory panel evaluation and feedback, and message revision, followed in turn by usability testing of the entire program.

The order of the development processes was established from our research team's multimedia intervention development experience [47,48] and the relevant literature [43,49] to ensure the integration of formative research, pretesting content, pilot testing,and the involvement of stakeholders. The following sections detail each phase of the developmental process. The final intervention product (Txt2commit) is also described. This study was approved by the Institutional Review Board at Fox Chase Cancer Center.

The Cognitive-Social Health Information Processing Model

Constructs from the C-SHIP model were used to guide the intervention development strategy and content. The C-SHIP model offers a unifying theoretical framework for assessing and

addressing the psychosocial relapse factors typically experienced by postpartum women [50-52]. The model is built on cumulative findings and theorizing from diverse relevant sub-areas of cognitive-behavioral science and evidence-based psychosocial interventions, and integrates key cognitive and affective processes. Guided by this model, we identified 5 areas of psychosocial relapse risk factors among low-income, minority women: (1) low knowledge and perceived risk for relapse, (2) inadequate decisional balance (low pros and high cons of cessation), (3) high affect (distress), (4) negative beliefs (low self-efficacy and fatalistic beliefs), and (5) lack of self-regulatory, practical, and social support strategies. Over the past decade, a sizable literature has accumulated to support the role of these factors in undermining smoking behavior, acting as barriers of self-initiated cessation and enrollment in smoking programs, and decreasing quit rates and maintenance of smoking abstinence [18,53-56]

Phase 1: Needs Assessment Individual Interviews

Participants (N=30) were recruited via flyers and staff referrals at 3 Women, Infants, and Children (WIC) clinics located in the inner city Philadelphia region. Interested women were invited to participate if they: (1) were 18 years of age or older, (2) had quit smoking for at least 1 pregnancy, and (3) had given birth to at least 1 child in the past 3 years. Interviews lasted approximately 20 minutes and included specific questions addressing the experiences, motivators, and techniques that had helped women maintain smoking abstinence after pregnancy, as well as personal, social, and environmental factors that triggered a postpartum relapse. Their mobile phone and text message use and preferences were also obtained. Upon completion of the interview, participants received a $20 gift card as compensation for their time and input.

Following an initial review of the interview transcripts, the research team developed a coding scheme based on the C-SHIP model. Responses categorized under C-SHIP were coded into 1 of the 5 psychosocial relapse risk factors. Subcategories in each domain were established as relevant themes emerged from the data. The intention behind coding responses into the C-SHIP processes was to systematically assess the major psychosocial relapse risk factors and identify the unique pattern of challenges faced by low-income, inner city women during the postpartum period.This information was used to guide the development of the Txt2commit intervention text message content.

Phase 2: Text Message Content Development

As reported above, text message content development was grounded in the C-SHIP theoretical model and guided by a formative research approach through a needs assessment interview phase with the target population. In addition, we conducted a comprehensive literature review, as well as an evidence-based guideline search for the potential adoption of existing materials to adapt to the target population. Content component constructs included factors such as messages for increasing awareness of the risks associated with smoking on infant's health (knowledge), techniques for controlling exposure to stressful cues that trigger the urge to lapse/relapse (affective distress), reinforcing beliefs about the woman's ability to sustain smoking absence (self-efficacy), considering the consequences of continued smoking (decisional balance), and identifying new behaviors to be substituted for smoking-related activities (self-regulatory skills). To respond effectively to situations in which the participant required an instant message to deal with craving or lapse situations, text messages were developed to offer strategies and emotional support to cope with craving/lapse situations and strategies for how to get back on track.

Phase 3: Health Literacy Evaluation

To ensure that the messages were designed for a low health-literate audience, 2 health literacy experts systematically evaluated all drafted messages using software and their health literacy expertise. The program Health Literacy Advisor (Health Literacy Innovations, LLC) was used to scan and highlight the text for complex terms, complex health terms, polysyllabic words (ie, words with more than 3 syllables), and long sentences (ie, sentences with 12 or more words).The findings from the health literacy analysis were then evaluated by the 2 health literacy experts and the research team to further revise the text messages to improve readability.

Phase 4: Message Review Cognitive Response Interviews

Following the revisions for health literacy, the messages were reviewed and vetted by participants (N=30) recruited at the 3 WIC offices with the same eligibility criteria identical to those of the needs assessment phase.Each participant reviewed 21 messages and was asked to think aloud about the messages, paraphrase the content, and respond to other inquiries and probes using the cognitive response technique [57]. Specifically, participants were asked if messages were relevant to them, understandable, and helpful in a stressful situation, as well as whether and how they would change the wording of the messages. Additionally, they rated each message from 1 (very poor) to 5 (very good) based on how helpful the message would be if they were inclined to smoke. Upon completion of the interview, participants received a $20 gift card as compensation for their time and input. The interview data and field notes were reviewed by the research team and messages were subsequently revised according to the participants' ratings and comments through a consensus process. Low-rated messages were flagged for possible removal.

Phase 5: Text Message Scientific Advisory Panel Review

A multidisciplinary scientific advisory panel was convened to provide further insight into the cultural sensitivity, appropriateness, and message appeal of the intervention for the target population. The panel (N=7) was composed of smoking cessation professionals, with expertise in psychosocial behavior, health communication, WIC management, and community perspectives. Panel members were provided with a list of messages (with information on revisions made in the health literacy evaluation process and suggestions made by participants), and the C-SHIP coding guide for each message. Members of the advisory panel evaluated the appropriateness of the content of each of the messages and provided their recommended revisions to the wording and readability of each message from their individual perspective and expertise. The

research team then reviewed the advisors' comments and made necessary modifications to produce the final program.

Phase 6: 1-Week Usability Testing

Ten participants, with the same eligibility criteria identical to those of the needs assessment phase, were recruited to pretest the program for usability testing following the scientific advisory review phase. The program was delivered over 1 week. Participants were provided with phones equipped with text messaging service and were instructed as follows: complete (open and confirm receipt of) 7 system-initiated messages (1 per day), and initiate 3 crave (described below) and 3 lapse message requests (described below) during the 1-week testing phase. Participants were debriefed individually by research staff at the conclusion of the usability testing and received a $20 gift card as compensation for their time and input. They were asked to provide the following overall feedback: system-initiated text message understandability, cultural appropriateness of text message wording, ease of use of crave and lapse functions, and problems encountered in use of the program. Each participant was also asked to provide additional comments concerning the intrusiveness, timing, and general burden imposed by using the program. Feedback was compiled and evaluated by the research team to determine whether adjustments in the messages, system, or study procedures warranted correction or adjustment, with subsequent implementation of necessary corrections and adjustments.

Results

Phase 1: Needs Assessment Interviews

The findings of the needs assessment interviews are reported elsewhere; participant characteristic information is presented in Table 1. In summary, participants (N=30) expressed the following reasons for why they resumed or refrained from smoking following childbirth: (1) motherhood demands (26/30, 87%), (2) partner and family relationships (22/30, 73%), and (3) the presence of other smokers in the environment (15/30, 50%). Participants reported 4 main strategies that helped them cope successfullywith postpartum cravings and relapses, including being informed of smoking risks (26/30, 86%), maintaining goal-oriented thoughts (18/30, 60%), thinking about the pros of quitting (26/30, 87%), and receiving positive social support from families and friends (27/30, 90%).

With regard to phone habits, most participants (21/30, 70%) had a home phone, but even more were mobile phone users (25/30, 83%). In addition, 93% (28/30) of participants reported that they used their mobile phones for texting, and 83% (25/30) reported that they texted on a daily basis. However, none of the participants in this population owned a smartphone. Therefore, our intervention only used text-messaging delivery, which is compatible with all models of mobile phones. Furthermore, when inquiring about their attitudes toward text message styles for a smoking cessation/relapse program, a more formal tone of content without the use of common text messaging abbreviations was preferred because it was thought to increase the creditability of the program. Information gathered from the needs assessment interviews was synthesized by the research team to guide the drafting of the text message content.

Phase 2: Message Development

A pool of 204 messages was initially developed based on the findings of the needs assessment and a review of the relevant literature.The emerging themes from the needs assessment content analysis were also integrated into the message drafting. The C-SHIP model provided a theoretical guide for message creation because this model indicates specific areas that are especially relevant for health interventions. Smoking facts from several evidence-based resources, including the National Cancer Institute's fact sheet concerning the harms of smoking, were identified and extracted to be included within the messages where appropriate.

The text messaging intervention developed included 3 main components: low-frequency messages to be sent during the third trimester (1 per week for engagement before the start of the main intervention), high-frequency messages to be sent after participants had given birth (1 message per day for 1 month), and messages available upon participant request when experiencing a craving for a cigarette or a lapse into having smoked one. The messages were systematically and comprehensively developed to address each component, so that some messages were specific to the prenatal or postpartum period and some to the situation of craving or lapsing. The drafted messages were coded across the 5 C-SHIP constructs by the research team.

Phase 3: Health Literacy Review

The initial assessment of the 204 text messages identified a number of issues, including the use of polysyllabic words, complex health terms, complex nonmedical terms, and long sentences. After the 2 health literacy experts reviewed and modified each message in collaboration with the research team, a second assessment using Health Literacy Advisor revealed a significant reduction in the following health literacy problems: a 72% reduction in polysyllabic words, 79% reduction in complex health terms, 91% reduction in complex nonmedical terms, and 47% reduction in long sentences. Most of the complex terms remaining in the text messages were words that pertained to the message content and the study, such as tobacco, smoking, and cancer. During the message review interview phase described below, these words were specifically tested and found to be readily recognized by study participants, indicating that they were not difficult to read or understand.

Phase 4: Message Review Cognitive Response Interviews

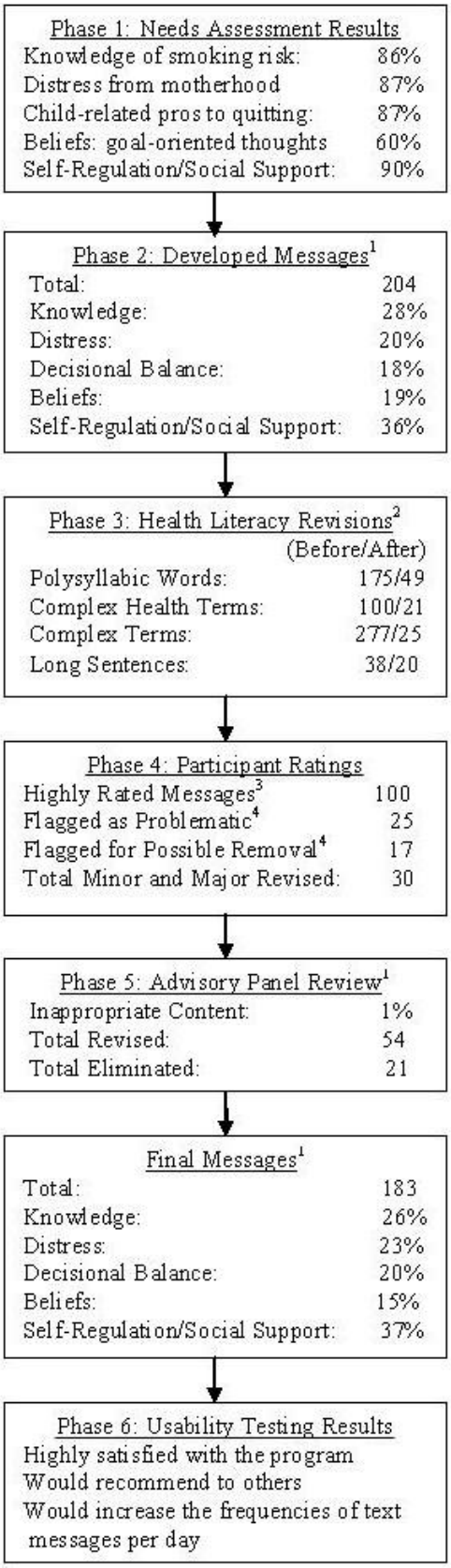
Messages were reviewed by 30 women at 3 different WIC clinic sites using the cognitive response interview technique. Table 1 displays the sample characteristics. Participants provided specific comments regarding improvements that could be made to the messages, as well as their general reaction to each message. This feedback was used to guide message revisions. For all but 1message, at least 67% (20/30) of participants found the messages to be understandable. Messages were generally viewed as helpful, obtaining a mean rating of 4.2 on a 5-point scale, and 50% of the messages were highly rated (>4.5). However, 25 messages received lower ratings, as summarized in Figure 1.These low-rated messages were subsequently either

revised (n=8) or eliminated (n=17). We also received universal agreement from the participants that 2-3 messages per day would be appropriate during the postpartum period.

Table 1. Background variables for needs assessment and message review interview sample (N=30).

Variable		Needs assessment n (%)	Message review n (%)
Race/ethnicity			
	Hispanic	6 (20)	6 (20)
	White	11 (37)	4 (13.3)
	African American	12 (40)	19 (63.3)
	Other	1 (3.3)	1 (3.3)
Marital status			
	Single	28 (93.3)	23 (76.7)
	Married/cohabiting	2 (6.7)	4 (13.3)
	Separated	0 (0)	2 (6.7)
	Divorced	0 (0)	1 (3.3)
Income			
	$0-15,000	17 (56.7)	18 (60)
	$15,000-30,000	10 (33.3)	11 (36.7)
	$30,000-45,000	3 (10)	0 (0)
	$45,000-60,000	0 (0)	1 (3.3)
Education			
	8-11 years	4 (13.3)	5 (16.7)
	H.S. grad/GED	14 (46.7)	16 (53.3)
	Vocational/tech	4 (13.3)	2 (6.7)
	Some college	6 (20)	7 (23.3)
	Bachelor’s degree	2 (6.7)	0 (0)
Health insurance			
	Medical assistance	28 (93.3)	24 (80)
	None	2 (6.7)	6 (20)
Employed		6 (20)	10 (33.3)
Home phone owner		21 (70)	14 (46.7)
Cell phone owner		25 (83.3)	25 (83.3)
Smoking frequency			
	Every day	17 (56.7)	12 (40)
	Some days	5 (16.7)	6 (20)
	None	8 (26.7)	12 (40)

Figure 1. Steps and results from each development phase. [1]Messages may fall under multiple categories; thus, percentages do not sum to 100%. [2]Eleven messages required additional revision to fit within the 159-character limit for text messages. [3]Highly rated messages received a mean rating over 4.5 (out of 5) for "Overall Helpful" and were found to be "Helpful If Stressed" by all raters. [4]Messages were flagged if they received a mean rating less than 4 (out of 5) for "Overall Helpful"; these were then identified for possible removal if two-thirds or more of raters found it "Not Helpful If Stressed," or designated "Problematic" in all other cases.



Phase 5: Text Message Scientific Advisory Panel Review

All messages were evaluated by the advisory panel in relation to the relevance of the messages to the population, as well as their coverage of factors involved in the C-SHIP framework. A final review of the advisory panel input by the research team resulted in slight modifications to 50% of the messages and 21 additional messages being eliminated.Table 2 provides examples of the message revision process and Table 3 provides samples of final text messages corresponding to the 5 C-SHIP constructs. For most messages, the basic content of the original message was retained, but revisions improved the readability and specificity of the message.

Table 2. Examples of message revision process.

Original message	Health literacy revision	Participant comment	Comment revision	After advisory panel
Research shows that female smokers lose an average of 14.5 years off their lives because of smoking.	Research shows that women who smoke lose about 14.5 years off their lives.	“It’s confusing. . . [when] it says this is about 14.5 years off their lives.”	Research shows that women who smoke live about 14.5 years less than those who don't.	Women who don't smoke live about 15 years more than women who do smoke.
The American Lung Association reports that smoking during pregnancy accounts for 10% of all infant deaths.	The American Lung Association reports that smoking during pregnancy is the reason for 10% of all infant deaths.	"Good message. Gives people info about the risks of smoking. It makes pregnant moms think about their unborn child."	None	The American Lung Association reports that smoking during pregnancy is the reason for 10% of all infant deaths.
Think about it. Would you rather feel tired and less energized, or healthy and rejuvenated? You're on the right path to a healthier you!	Think about it. Would you rather feel tired and have less energy, or healthy and rejuvenated? You're on the right path to a healthier you!	None	Would you rather feel tired and have less energy because you smoke? Or feel healthy and rejuvenated as a nonsmoker? Stay on the right path to a healthier you!	By not smoking, you will feel healthy and fresh instead of tired and drained. Stay on the right path to a healthier you!

Table 3. Samples of final text messages across 5 C-SHIP constructs.[a]

Knowledge	Decisional balance	Distress	Beliefs	Self-regulation /social support
Kids whose parents smoke get bronchitis and pneumonia much more often.	Caring for a baby takes a lot of energy! If you do not smoke, you will feel more active during the day to play with your baby.	Feeling extra stressed and grouchy today? Try playing soft music to help you relax. It may help calm any sudden urges and relax you and your fussy baby.	Smoking while pregnant puts your baby at higher risk for ear infections and asthma attacks. Be glad you chose to quit!	Put away ashtrays, matches, and lighters. Trade them for things that remind you not to smoke, like a list of reasons for quitting, or a family photo.
With each cigarette, you breathe in more than 4000 chemicals. Don’t be fooled, all forms of tobacco can hurt you and your baby.	If you hope to have more children, now is the time to quit. Smoking raises your chance of having trouble getting pregnant again.	It is normal to feel stressed with a new baby in the household. Remember to make “me” time!	At the end of each day, think about how you didn't smoke at all. Be thankful for that moment. It will make your thoughts of success stronger.	Make sure your car and home are smoke free. Do it for yourself and others, especially for your baby.
Babies whose mothers smoked during pregnancy are up to three times as likely to die from sudden infant death syndrome (SIDS) as babies of nonsmokers.	Not smoking makes you a better role model for your kids. A child raised by a nonsmoker is less likely to start smoking. Stay smoke free for your baby.	Do not worry if you are gaining a few pounds. Weight gain is normal when you stop smoking. Keep a healthy diet and talk to your doctor if you are concerned.	You quit smoking for a reason. Think about this reason often. It will never be less true, but it could become less important if you forget about it.	People who lift weights have spotters. You too should have a spotter! Pick someone you trust to support you and help you to stay smoke free.

[a]Some messages may fall under multiple categories.

Phase 6: 1-Week Usability Testing

Ten participants were recruited from the same 3 WIC clinic sites as in the interview phases to participate in a 1-week usability testing session. Each participant was provided with a mobile phone and instructions for mobile phone and message use. Each participant received 7 system-initiated messages over a 1-week period and was instructed to initiate 3 crave and 3 lapse message requests. Among the 10 enrolled participants, 8 successfully completed the testing and responded to the evaluation interview. All 8 participants identified the messages as helpful and reported being satisfied with the messages, as well as with the crave and lapse functions. They all stated that they would use the program and recommend it to others. They also suggested changes, including making the system-initiated messages more frequent (3 per day) and adding voice and video messages to the program. Based on participants’ feedback, the research team finalized the “Txt2commit” program, which provided: (1) 1 text message per week during the prenatal period

(27 weeks gestation and on) to enhance and sustain program engagement, (2) 3 text messages daily during the first postpartum month, and (3) crave and lapse functions so that participants could request additional messages when feeling the need. The final program was tested in a larger feasibility pilot study, results of which will be reported elsewhere for ease of communication. Figure 1 provides an illustration of the order and findings throughout different phases of the development, including the changes of the numbers of messages over time.

Discussion

The development of the Txt2commit mobile text messaging intervention relied on a combination of theory and evidence, systematic attention to health literacy issues, and integration of a user-centered approach throughout the developmental process. This research adds to the emerging literature supporting the critical role of a comprehensive strategy for the design of mHealth interventions and highlights the value of a scientifically based health literacy focus. This study aimed to stimulate discussion among target users about how to use mobile text messaging as a platform for delivering smoking cessation interventions for underserved postpartum women, as well as demonstrate a rigorous process of development to ensure that the messages are potent, easily understood, and delivered in an effective manner. Using an iterative developmental process, a multidisciplinary team, and user input, the text messaging intervention was progressively developed and refined based on formative participatory evaluations to achieve a culturally—and linguistically—appropriate psychosocial program that provides relevant content to underserved women who quit smoking during their pregnancies.

The needs assessment, message review, and cognitive response interviews were all essential to identify gaps in women's needs in postpartum and smoking relapse trigger stressors, which resulted in relevant and appropriate text messaging content and format. Furthermore, the health literacy review and painstaking editing significantly increased the readability and accessibility of the information. The final usability testing confirmed the preferred frequency of message delivery and the usefulness of the crave and lapse functions, prior to the final production and pilot study implementation. The intensity and functionalities of our final intervention program design is comparable to most of the studies in the text messaging smoking cessation literature, with an average of 1-5 text messages per day and the availabilities of crave and lapse functions [28,58,59].

As technology advances become more common as a delivery mechanism for health behavior interventions, it is important to recognize that the impact will depend on the interdigitation of well-designed content, technology, and end user input.Given advances in the field of behavior medicine, it has become increasingly clear that knowledge alone does not change behavior. Likewise, technology alone does not change behavior, but the combination of theory-based best practice approaches in content development, coupled with technology, increases access and reach and has great promise for improving outcomes through attention to evidence-based cessation barriers. The strengths of the study include the use of an established C-SHIP theoretical framework, application of health communication and health literacy best practices to guide text messaging content drafting and revision, extensive input from a community-based sample at various steps in development, and the use of a multidisciplinary expert advisory board. This approach extends our prior research, where the C-SHIP framework was successfully applied to smoking cessation and multimedia intervention behavior change studies [47,50,52,60,61]. To our knowledge, this is the first text messaging intervention guided by the C-SHIP framework. Because research has shown that messaging interventions designed by using behavioral theory are more likely to be successful [29], this paper contributes to the field by demonstrating how to apply a well-established framework in the context of new technology delivery. We also found that using a guiding theoretical framework, coupled with input from a diverse group of stakeholders, was helpful during the message revision process, particularly in terms of better addressing the target conceptual construct contained in each message as well as keeping the message within the limit of 160 characters.

This study provides insight into the systematic development of text messaging interventions for use in other behavior change contexts. The prevalence of mobile phone use and text messaging among the present underserved sample indicates the potential of text messaging as a delivery modality in a variety of health settings and behaviors. Therefore, the development concepts used in this intervention should be applicable to the development process for other health-related mHealth interventions, especially those targeted to diverse underserved populations. One important lesson learned was that although text messaging was an acceptable channel to communicate smoking relapse messages, postpartum women indicated their preference that these messages be written using formal language to highlight the credibility of the information.

As the vision of eHealth/mHealth is beginning to be actualized, development must also allow for the involvement of "consumers with diverse perspectives, circumstances, capacities, and experiences in the design of, evidence-based eHealth tools" [62]. This study supports the importance of a comprehensive developmental process as an essential foundational basis for rigorous research in this area [47-49,63]. The goal is to ensure that the intervention messages are appropriate, relevant, and understandable, with a view to developing meaningful interventions that can be evaluated for effectiveness, over the short and long term. With the increasing prevalence of mobile phone and text messaging use in underserved inner city populations in the United States and in low-income countries at the global level, harnessing this technological approach has great potential to address health disparities and improve health outcomes in a variety of challenging behavioral contexts.

Acknowledgments

This study was funded by National Institute of Health grants RC1CA145063 and R01 CA104979, the American Cancer Society TURSG 02-227, and the Fox Chase Cancer Center Behavioral Research Core Facility P30CA06927. The authors thank our study advisory board (Drs Ellen Gritz, Thomas Brandon, Michael Diefenbach, Dottie Schell, Damon Vidrine, and Joanne Buzaglo) for their consulting services in the development of this investigation; Mary Anne Ryan, Janiah Sanford, Tammy Stump, Allison Todd, and Ranwa Hammamy for their technical services; and Stephanie Raivitch and Rachel Slamon from Fox Chase's Office of Health Communications and Health Disparities for their assistance in the health literacy review. We especially are grateful to all the women who participated in the study.

Conflicts of Interest

None declared.

References

1. Schneider S, Huy C, Schütz J, Diehl K. Smoking cessation during pregnancy: a systematic literature review. Drug Alcohol Rev 2010 Jan;29(1):81-90. [doi: 10.1111/j.1465-3362.2009.00098.x] [Medline: 20078687]
2. Ananth CV, Savitz DA, Luther ER. Maternal cigarette smoking as a risk factor for placental abruption, placenta previa, and uterine bleeding in pregnancy. Am J Epidemiol 1996 Nov 1;144(9):881-889 [FREE Full text] [Medline: 8890666]
3. Andres RL, Day MC. Perinatal complications associated with maternal tobacco use. Semin Neonatol 2000 Aug;5(3):231-241. [doi: 10.1053/siny.2000.0025] [Medline: 10956448]
4. Quinn G, Ellison BB, Meade C, Roach CN, Lopez E, Albrecht T, et al. Adapting smoking relapse-prevention materials for pregnant and postpartum women: formative research. Matern Child Health J 2006 May;10(3):235-245. [doi: 10.1007/s10995-005-0046-y] [Medline: 16341911]
5. Levine MD, Marcus MD, Kalarchian MA, Houck PR, Cheng Y. Weight concerns, mood, and postpartum smoking relapse. Am J Prev Med 2010 Oct;39(4):345-351 [FREE Full text] [doi: 10.1016/j.amepre.2010.05.023] [Medline: 20837285]
6. McLeod D, Benn C, Pullon S, Viccars A, White S, Cookson T, et al. The midwife's role in facilitating smoking behaviour change during pregnancy. Midwifery 2003 Dec;19(4):285-297. [Medline: 14623508]
7. Stotts AL, DiClemente CC, Carbonari JP, Mullen PD. Pregnancy smoking cessation: a case of mistaken identity. Addict Behav 1996;21(4):459-471. [Medline: 8830904]
8. Edwards N, Sims-Jones N. Smoking and smoking relapse during pregnancy and postpartum: results of a qualitative study. Birth 1998 Jun;25(2):94-100. [Medline: 9668743]
9. Pletsch PK, Kratz AT. Why do women stop smoking during pregnancy? Cigarettes taste and smell bad. Health Care Women Int 2004 Aug;25(7):671-679. [doi: 10.1080/07399330490458051] [Medline: 15487485]
10. Merzel C, English K, Moon-Howard J. Identifying women at-risk for smoking resumption after pregnancy. Matern Child Health J 2010 Jul;14(4):600-611. [doi: 10.1007/s10995-009-0502-1] [Medline: 19653085]
11. Tong VT, Jones JR, Dietz PM, D'Angelo D, Bombard JM, Centers for Disease ControlPrevention (CDC). Trends in smoking before, during, and after pregnancy - Pregnancy Risk Assessment Monitoring System (PRAMS), United States, 31 sites, 2000-2005. MMWR Surveill Summ 2009 May 29;58(4):1-29 [FREE Full text] [Medline: 19478726]
12. Agboola S, McNeill A, Coleman T, Leonardi Bee J. A systematic review of the effectiveness of smoking relapse prevention interventions for abstinent smokers. Addiction 2010 Aug;105(8):1362-1380. [doi: 10.1111/j.1360-0443.2010.02996.x] [Medline: 20653619]
13. Keintz MK, Fleisher L, Rimer BK. Reaching mothers of preschool-aged children with a targeted quit smoking intervention. J Community Health 1994 Feb;19(1):25-40. [Medline: 8169249]
14. Snow WM, Connett JE, Sharma S, Murray RP. Predictors of attendance and dropout at the Lung Health Study 11-year follow-up. Contemp Clin Trials 2007 Jan;28(1):25-32 [FREE Full text] [doi: 10.1016/j.cct.2006.08.010] [Medline: 17015043]
15. Gariti P, Levin S, Whittingham T, Barou D, Kampman KM, Lynch K, et al. Why do those who request smoking treatment fail to attend the first appointment? J Subst Abuse Treat 2008 Jul;35(1):62-67 [FREE Full text] [doi: 10.1016/j.jsat.2007.08.009] [Medline: 17931823]
16. Wen KY, Miller SM, Lazev A, Fang Z, Hernandez E. Predictors of smoking cessation counseling adherence in a socioeconomically disadvantaged sample of pregnant women. J Health Care Poor Underserved 2012 Aug;23(3):1222-1238 [FREE Full text] [doi: 10.1353/hpu.2012.0096] [Medline: 24212170]
17. Ashford KB, Hahn E, Hall L, Rayens MK, Noland M. Postpartum smoking relapse and secondhand smoke. Public Health Rep 2009;124(4):515-526 [FREE Full text] [Medline: 19618788]
18. Bottorff JL, Johnson JL, Irwin LG, Ratner PA. Narratives of smoking relapse: the stories of postpartum women. Res Nurs Health 2000 Apr;23(2):126-134. [Medline: 10782871]
19. Carmichael SL, Ahluwalia IB. Correlates of postpartum smoking relapse. Results from the Pregnancy Risk Assessment Monitoring System (PRAMS). Am J Prev Med 2000 Oct;19(3):193-196. [Medline: 11020597]
20. Johnson JL, Ratner PA, Bottorff JL, Hall W, Dahinten S. Preventing smoking relapse in postpartum women. Nurs Res 2000;49(1):44-52. [Medline: 10667628]

21. McBride CM, Pirie PL, Curry SJ. Postpartum relapse to smoking: a prospective study. Health Educ Res 1992 Sep;7(3):381-390. [Medline: 10148743]
22. Fang WL, Goldstein AO, Butzen AY, Hartsock SA, Hartmann KE, Helton M, et al. Smoking cessation in pregnancy: a review of postpartum relapse prevention strategies. J Am Board Fam Pract 2004;17(4):264-275 [FREE Full text] [Medline: 15243014]
23. El-Mohandes AA, El-Khorazaty MN, Kiely M, Gantz MG. Smoking cessation and relapse among pregnant African-American smokers in Washington, DC. Matern Child Health J 2011 Dec;15 Suppl 1:S96-105 [FREE Full text] [doi: 10.1007/s10995-011-0825-6] [Medline: 21656058]
24. DiClemente CC, Dolan-Mullen P, Windsor RA. The process of pregnancy smoking cessation: implications for interventions. Tob Control 2000;9 Suppl 3:III16-III21 [FREE Full text] [Medline: 10982900]
25. Matsumoto S, Takita M, Shimoda M, Chujo D, Itoh T, Iwahashi S, et al. Insulin independence by supplemental islet transplantation 5 years after initial islet transplantation. J Diabetes 2011 Dec;3(4):353-355. [doi: 10.1111/j.1753-0407.2011.00146.x] [Medline: 21733129]
26. Chou WY, Prestin A, Lyons C, Wen KY. Web 2.0 for health promotion: reviewing the current evidence. Am J Public Health 2013 Jan;103(1):e9-18. [doi: 10.2105/AJPH.2012.301071] [Medline: 23153164]
27. Smith A. Pew Research Center,, 3, 4. 2010. Mobile Access 2010 URL: http://www.pewinternet.org/2010/07/07/mobile-access-2010/ [accessed 2014-03-25] [WebCite Cache ID 6OLVjXcBO]
28. Free C, Whittaker R, Knight R, Abramsky T, Rodgers A, Roberts IG. Txt2stop: a pilot randomised controlled trial of mobile phone-based smoking cessation support. Tob Control 2009 Apr;18(2):88-91. [doi: 10.1136/tc.2008.026146] [Medline: 19318534]
29. Cole-Lewis H, Kershaw T. Text messaging as a tool for behavior change in disease prevention and management. Epidemiol Rev 2010 Apr;32(1):56-69 [FREE Full text] [doi: 10.1093/epirev/mxq004] [Medline: 20354039]
30. Jordan ET, Ray EM, Johnson P, Evans WD. Text4Baby: using text messaging to improve maternal and newborn health. Nurs Womens Health 2011;15(3):206-212. [doi: 10.1111/j.1751-486X.2011.01635.x] [Medline: 21672170]
31. Rodgers A, Corbett T, Bramley D, Riddell T, Wills M, Lin RB, et al. Do u smoke after txt? Results of a randomised trial of smoking cessation using mobile phone text messaging. Tob Control 2005 Aug;14(4):255-261 [FREE Full text] [doi: 10.1136/tc.2005.011577] [Medline: 16046689]
32. Obermayer JL, Riley WT, Asif O, Jean-Mary J. College smoking-cessation using cell phone text messaging. J Am Coll Health 2004;53(2):71-78. [doi: 10.3200/JACH.53.2.71-78] [Medline: 15495883]
33. Bramley D, Riddell T, Whittaker R, Corbett T, Lin RB, Wills M, et al. Smoking cessation using mobile phone text messaging is as effective in Maori as non-Maori. N Z Med J 2005 Jun 3;118(1216):U1494. [Medline: 15937529]
34. Free C, Phillips G, Galli L, Watson L, Felix L, Edwards P, et al. The effectiveness of mobile-health technology-based health behaviour change or disease management interventions for health care consumers: a systematic review. PLoS Med 2013;10(1):e1001362 [FREE Full text] [doi: 10.1371/journal.pmed.1001362] [Medline: 23349621]
35. McBride CM, Curry SJ, Lando HA, Pirie PL, Grothaus LC, Nelson JC. Prevention of relapse in women who quit smoking during pregnancy. Am J Public Health 1999 May;89(5):706-711. [Medline: 10224982]
36. Pbert L, Ockene JK, Zapka J, Ma Y, Goins KV, Oncken C, et al. A community health center smoking-cessation intervention for pregnant and postpartum women. Am J Prev Med 2004 Jun;26(5):377-385. [doi: 10.1016/j.amepre.2004.02.010] [Medline: 15165653]
37. Bullock L, Everett KD, Mullen PD, Geden E, Longo DR, Madsen R. Baby BEEP: A randomized controlled trial of nurses' individualized social support for poor rural pregnant smokers. Matern Child Health J 2009 May;13(3):395-406. [doi: 10.1007/s10995-008-0363-z] [Medline: 18496746]
38. Lillington L, Royce J, Novak D, Ruvalcaba M, Chlebowski R. Evaluation of a smoking cessation program for pregnant minority women. Cancer Pract 1995;3(3):157-163. [Medline: 7599672]
39. Armstrong AW, Watson AJ, Makredes M, Frangos JE, Kimball AB, Kvedar JC. Text-message reminders to improve sunscreen use: a randomized, controlled trial using electronic monitoring. Arch Dermatol 2009 Nov;145(11):1230-1236. [doi: 10.1001/archdermatol.2009.269] [Medline: 19917951]
40. Franklin VL, Greene A, Waller A, Greene SA, Pagliari C. Patients' engagement with "Sweet Talk" - a text messaging support system for young people with diabetes. J Med Internet Res 2008;10(2):e20 [FREE Full text] [doi: 10.2196/jmir.962] [Medline: 18653444]
41. Patrick K, Raab F, Adams MA, Dillon L, Zabinski M, Rock CL, et al. A text message-based intervention for weight loss: randomized controlled trial. J Med Internet Res 2009;11(1):e1 [FREE Full text] [doi: 10.2196/jmir.1100] [Medline: 19141433]
42. Prestwich A, Perugini M, Hurling R. Can the effects of implementation intentions on exercise be enhanced using text messages? Psychol Health 2009 Jul;24(6):677-687. [doi: 10.1080/08870440802040715] [Medline: 20205020]
43. Whittaker R, Maddison R, McRobbie H, Bullen C, Denny S, Dorey E, et al. A multimedia mobile phone-based youth smoking cessation intervention: findings from content development and piloting studies. J Med Internet Res 2008;10(5):e49 [FREE Full text] [doi: 10.2196/jmir.1007] [Medline: 19033148]

44. Ybarra ML, Holtrop JS, Bağci Bosi AT, Emri S. Design considerations in developing a text messaging program aimed at smoking cessation. J Med Internet Res 2012;14(4):e103 [FREE Full text] [doi: 10.2196/jmir.2061] [Medline: 22832182]
45. Webb TL, Joseph J, Yardley L, Michie S. Using the internet to promote health behavior change: a systematic review and meta-analysis of the impact of theoretical basis, use of behavior change techniques, and mode of delivery on efficacy. J Med Internet Res 2010;12(1):e4 [FREE Full text] [doi: 10.2196/jmir.1376] [Medline: 20164043]
46. Fishbein MCappella JN. The role of theory in developing effective health communications. Journal of Communication 2006;56(s1):S1-S17.
47. Wen KY, Miller SM, Stanton AL, Fleisher L, Morra ME, Jorge A, et al. The development and preliminary testing of a multimedia patient-provider survivorship communication module for breast cancer survivors. Patient Educ Couns 2012 Aug;88(2):344-349 [FREE Full text] [doi: 10.1016/j.pec.2012.02.003] [Medline: 22770812]
48. Fleisher L, Buzaglo J, Collins M, Millard J, Miller SM, Egleston BL, et al. Using health communication best practices to develop a web-based provider-patient communication aid: the CONNECT study. Patient Educ Couns 2008 Jun;71(3):378-387 [FREE Full text] [doi: 10.1016/j.pec.2008.02.017] [Medline: 18417312]
49. Whittaker R, Merry S, Dorey E, Maddison R. A development and evaluation process for mHealth interventions: examples from New Zealand. J Health Commun 2012;17 Suppl 1:11-21. [doi: 10.1080/10810730.2011.649103] [Medline: 22548594]
50. Fang CY, Ma GX, Miller SM, Tan Y, Su X, Shive S. A brief smoking cessation intervention for Chinese and Korean American smokers. Prev Med 2006 Oct;43(4):321-324. [doi: 10.1016/j.ypmed.2006.06.009] [Medline: 16860858]
51. Schnoll RA, Rothman RL, Newman H, Lerman C, Miller SM, Movsas B, et al. Characteristics of cancer patients entering a smoking cessation program and correlates of quit motivation: implications for the development of tobacco control programs for cancer patients. Psychooncology 2004 May;13(5):346-358. [doi: 10.1002/pon.756] [Medline: 15133775]
52. Miller SM, Diefenbach MA. The cognitive-social health information-processing (C-SHIP) model: a theoretical framework for research in behavioral oncology. In: Krantz DS, Baum AS, editors. Technology and Methods in Behavioral Medicine. Mahwah, N.J: Erlbaum; 1998.
53. Gulliver SB, Hughes JR, Solomon LJ, Dey AN. An investigation of self-efficacy, partner support and daily stresses as predictors of relapse to smoking in self-quitters. Addiction 1995 Jun;90(6):767-772. [Medline: 7633293]
54. Cummings KM. Tobacco risk perceptions and behavior: implications for tobacco control. Nicotine Tob Res 2004 Dec;6 Suppl 3:S285-S288. [Medline: 15799591]
55. Lawhon D, Humfleet GL, Hall SM, Muñoz RF, Reus VI. Longitudinal analysis of abstinence-specific social support and smoking cessation. Health Psychol 2009 Jul;28(4):465-472. [doi: 10.1037/a0015206] [Medline: 19594271]
56. Cosci F, Pistelli F, Lazzarini N, Carrozzi L. Nicotine dependence and psychological distress: outcomes and clinical implications in smoking cessation. Psychol Res Behav Manag 2011;4:119-128 [FREE Full text] [doi: 10.2147/PRBM.S14243] [Medline: 22114542]
57. Sudman S, Bradburn NM, Schwarz N. Thinking About Answers: The Application of Cognitive Processes to Survey Methodology. San Francisco, CA: Jossey-Bass; 2010.
58. Riley W, Obermayer J, Jean-Mary J. Internet and mobile phone text messaging intervention for college smokers. J Am Coll Health 2008;57(2):245-248. [doi: 10.3200/JACH.57.2.245-248] [Medline: 18809542]
59. Abroms LC, Ahuja M, Kodl Y, Thaweethai L, Sims J, Winickoff JP, et al. Text2Quit: results from a pilot test of a personalized, interactive mobile health smoking cessation program. J Health Commun 2012;17 Suppl 1:44-53. [doi: 10.1080/10810730.2011.649159] [Medline: 22548598]
60. Miller SM, Shoda Y, Hurley K. Applying cognitive-social theory to health-protective behavior: breast self-examination in cancer screening. Psychol Bull 1996 Jan;119(1):70-94. [Medline: 8559860]
61. Miller SM, Siejak KK, Schroeder CM, Lerman C, Hernandez E, Helm CW. Enhancing adherence following abnormal Pap smears among low-income minority women: a preventive telephone counseling strategy. J Natl Cancer Inst 1997 May 21;89(10):703-708 [FREE Full text] [Medline: 9168185]
62. Baur C, Kanaan S. Rockville, MD: Office of Disease Prevention and Health Promotion, US Department of Health and Human Services. 2006. Expanding the reach and impact of consumer e-Health tools URL: http://www.health.gov/communication/ehealth/ehealthtools/pdf/ehealthreport.pdf [accessed 2014-03-25] [WebCite Cache ID 6OLWrhMhW]
63. Elwyn G, Kreuwel I, Durand MA, Sivell S, Joseph-Williams N, Evans R, et al. How to develop web-based decision support interventions for patients: a process map. Patient Educ Couns 2011 Feb;82(2):260-265. [doi: 10.1016/j.pec.2010.04.034] [Medline: 20627644]

Abbreviations

C-SHIP: cognitive-social health information processing
WIC: women, infants, and children

Edited by G Eysenbach; submitted 29.10.13; peer-reviewed by D Bowen, H Cole-Lewis, M Levine; comments to author 09.01.14; revised version received 27.01.14; accepted 20.02.14; published 03.04.14.

Please cite as:
Wen KY, Miller SM, Kilby L, Fleisher L, Belton TD, Roy G, Hernandez E
Preventing Postpartum Smoking Relapse Among Inner City Women: Development of a Theory-Based and Evidence-Guided Text Messaging Intervention
JMIR Res Protoc 2014;3(2):e20
URL: http://www.researchprotocols.org/2014/2/e20/
doi:10.2196/resprot.3059
PMID:24698804

Original Paper

A Web-Based Clinical Decision Support Tool for Primary Health Care Management of Back Pain: Development and Mixed Methods Evaluation

David Peiris[1], PhD; Christopher Williams[1,2], PhD; Rachel Holbrook[3], PhD; Robyn Lindner[3], PhD; James Reeve[3], PhD; Anurina Das[1], MMedSc; Christopher Maher[1], PhD

[1]The George Institute for Global Health, University of Sydney, Sydney, Australia

[2]Hunter Medical Research Institute, Newcastle, Australia

[3]NPS MedicineWise, Sydney, Australia

Corresponding Author:
David Peiris, PhD
The George Institute for Global Health
University of Sydney
PO Box M201
Missenden Rd
Sydney, 2050
Australia
Phone: 61 299934500
Fax: 61 299934502
Email: dpeiris@georgeinstitute.org

Abstract

Background: Many patients with back pain do not receive health care in accordance with best practice recommendations. Implementation trials to address this issue have had limited success. Despite the known effectiveness of clinical decision support systems (CDSS), none of these are available for back pain management.

Objective: The objective of our study was to develop a Web-based CDSS to support Australian general practitioners (GPs) to diagnose and manage back pain according to guidelines.

Methods: Asking a panel of international experts to review recommendations for sixteen clinical vignettes validated the tool. It was then launched nationally as part of National Pain Week and promoted to GPs via a media release and clinic based visits. Following this, a mixed methods evaluation was conducted to determine tool feasibility, acceptability, and utility. The 12 month usage data were analyzed, and in-depth, semistructured interviews with 20 GPs were conducted to identify barriers and enablers to uptake.

Results: The tool had acceptable face validity when reviewed by experts. Over a 12 month period there were 7125 website visits with 4503 (63.20%) unique users. Assuming most unique users are GPs, around one quarter of the country's GPs may have used the tool at least once. Although usage was high, GP interviews highlighted the sometimes complex nature of management where the tool may not influence care. Conversely, several "touch-points", whereby the tool may exert its influence, were identified, most notably patient engagement.

Conclusions: A novel CDSS tool has the potential to assist with evidence-based management of back pain. A clinical trial is required to determine its impact on practitioner and patient outcomes.

(JMIR Res Protoc 2014;3(2):e17) doi:10.2196/resprot.3071

KEYWORDS

clinical decision support systems; back pain; primary care

Introduction

Global Disease Burden From Back Pain

Back pain is the number one ranked disabling health condition worldwide [1]. Across 21 regions, the lowest ranking of burden was 4th of 291 diseases in both the Caribbean and Southern sub-Saharan Africa. This makes a compelling case for increased efforts to improve health care for this condition.

Back pain is best conceptualized as a chronic disease. Although symptoms usually improve quickly after onset, pain and disability frequently persist at low to moderate levels [2]. We found that nearly one third of the people with reported acute back pain still experienced pain one year later [3]. Around one quarter of those who recovered had a recurrence within one year [4], and the majority of those with a prolonged initial course of pain (> 3 months) reported persisting pain 12 months later [5]. Similar findings were noted in a UK study [6]. Thus, back pain is commonly a long term health condition with an unpredictable pattern of acute episodes, remission, and recurrence [7,8].

Evidence-Practice Gaps in Management of Back Pain

Despite high health care expenditure for back pain, clear improvements in outcomes do not necessarily follow. In the United States, back pain expenditure increased by 65% (inflation adjusted) in the period 1997-2005, yet the health status for people with back pain fell [9]. Further, 16.7% of visits for back pain include inappropriate imaging tests, resulting in over $175 million per year of unnecessary expenditure [10]; the principal driver for this is that people with back pain are not receiving the care endorsed in guidelines. Our large survey of Australian primary health care providers revealed that few patients received the care recommended in the nationally endorsed guideline [11]. Less than 10% of the patients received appropriate analgesia, and just 20% were provided with appropriate advice. Additionally, over one quarter of the patients were referred for diagnostic imaging. Crucially, this pattern of care was essentially the same in the periods before and after the guideline was released in 2004 [11]. Similar evidence-practice gaps have been reported in other countries [12-14].

Health Care Intervention Studies

Several health care intervention studies to improve back pain management have resulted in minimal or no improvements in mainly process outcome measures [15-20]. Clinical decision support systems (CDSS) are one of the most promising interventions to improve uptake of guideline recommendations. In two recent systematic reviews, around two thirds of CDSS trials demonstrated improvements [21,22]. In the broader eHealth arena, there is now growing evidence that interactive Internet and mobile interventions improve outcomes from chronic conditions. A Cochrane review of 124 studies concluded that computer based “Interactive Health Communication Applications” could improve cognitive and social support outcomes in patients with chronic conditions [23]. Despite this, we are not aware of any CDSS that have been trialed for back pain management.

In this paper, we outline the development of a Web-based CDSS for back pain management. We also discuss the development and validation of an algorithm, in addition to a feasibility study examining the acceptability and utility of the tool following national deployment for use by Australian general practitioners (GP). Our objective was to determine whether the tool had the potential to support GPs to diagnose and manage back pain in accordance with guideline recommendations, and to identify barriers and enablers to uptake. The study was designed to inform a future large scale trial evaluation.

Methods

Tool Development

First, our recent systematic search of relevant guidelines was drawn on to inform development of the decision support algorithm [24]. In this review, we searched for guidelines in MEDLINE, PEDro, the US Agency for Health Care Research and Quality National Guideline Clearinghouse, and the UK National Institute for Health and Clinical Excellence, and used backward and forward citation tracking, retrieving 15 eligible guidelines. A key finding from the review was that there was a high level of consistency in recommendations from all 15 guidelines. These recommendations were converted to plain language rules, hardcoded into an algorithm, and a prototype tool was developed. Figure 1 illustrates the key variables in the algorithm and treatment recommendations provided.

Second, the algorithm was validated as follows. There were 16 hypothetical cases representing all permutations of the algorithm that were entered into the tool to generate management recommendations. The output was compared to an expert's clinical decisions for each case based on their interpretation of the guidelines. Additionally, a panel of four experts who developed the UK, US, and Australian guidelines [25-27] reviewed the prototype and commented on the recommendations. Any misinterpretations were reviewed and inconsistencies resolved by a consensus process.

Third, a user interface was designed, resulting in a four step process of excluding serious pathology, clinical assessment, establishing treatment options, and building a personalized, patient information sheet (Figures 2-5 show this interface). Technical user acceptance testing was conducted to ensure the tool functioned as specified.

Figure 1. Decision support flowchart for management of low back pain (LBP). Nonspecific LBP (NSLBP).

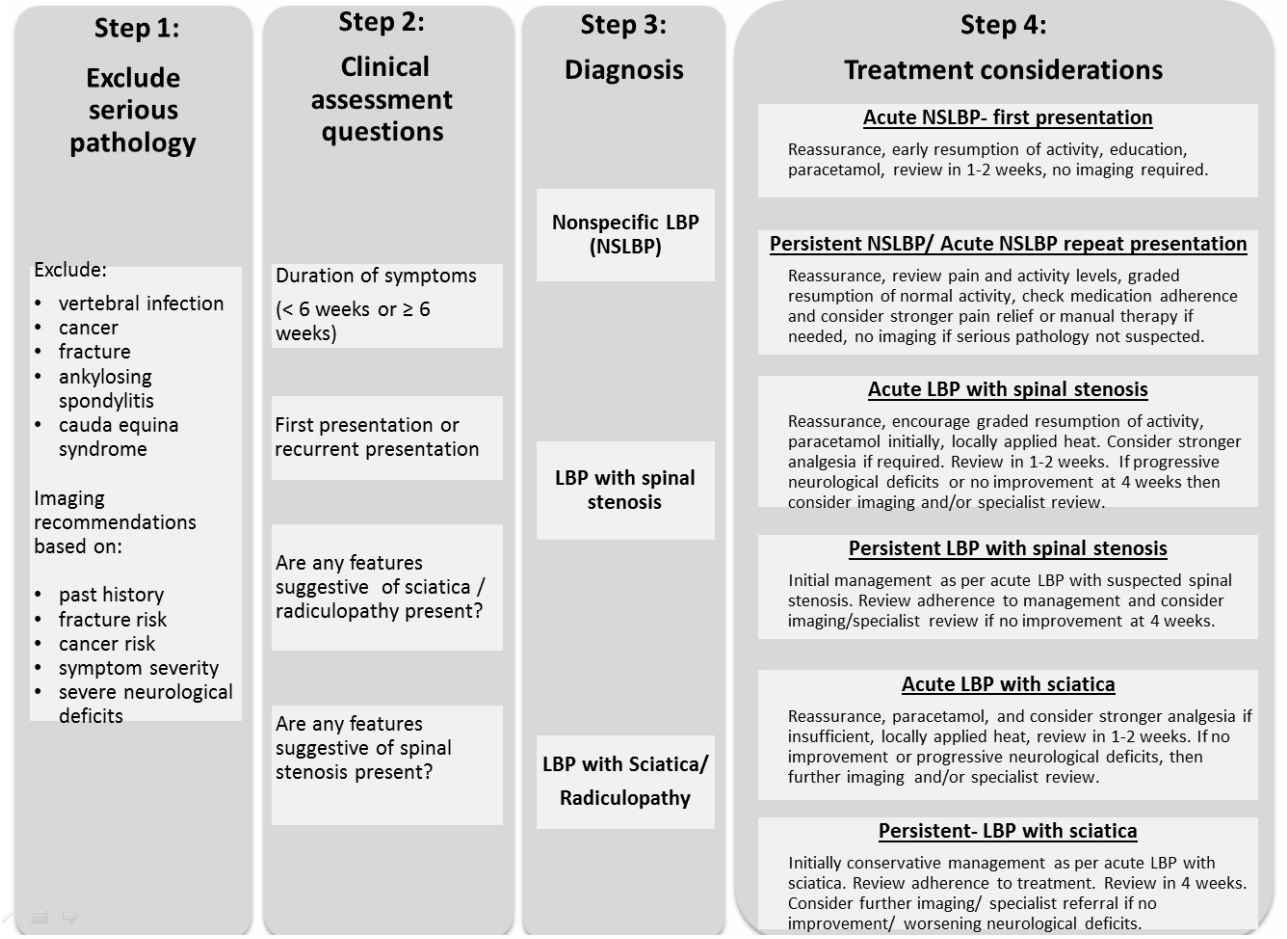
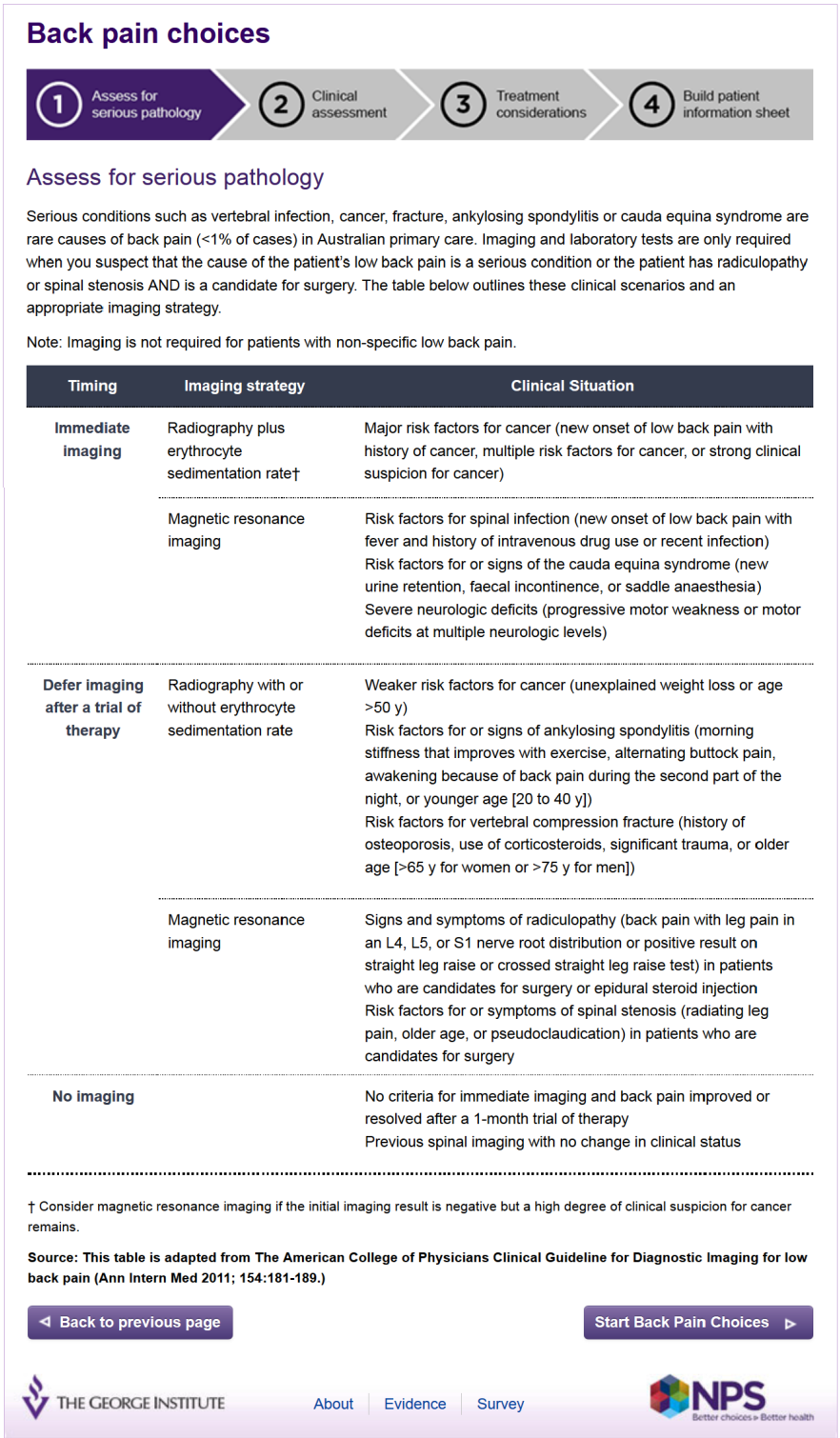


Figure 2. Screenshot Step 1 - Exclude serious pathology.



Back pain choices

1 Assess for serious pathology | 2 Clinical assessment | 3 Treatment considerations | 4 Build patient information sheet

Assess for serious pathology

Serious conditions such as vertebral infection, cancer, fracture, ankylosing spondylitis or cauda equina syndrome are rare causes of back pain (<1% of cases) in Australian primary care. Imaging and laboratory tests are only required when you suspect that the cause of the patient's low back pain is a serious condition or the patient has radiculopathy or spinal stenosis AND is a candidate for surgery. The table below outlines these clinical scenarios and an appropriate imaging strategy.

Note: Imaging is not required for patients with non-specific low back pain.

Timing	Imaging strategy	Clinical Situation
Immediate imaging	Radiography plus erythrocyte sedimentation rate†	Major risk factors for cancer (new onset of low back pain with history of cancer, multiple risk factors for cancer, or strong clinical suspicion for cancer)
	Magnetic resonance imaging	Risk factors for spinal infection (new onset of low back pain with fever and history of intravenous drug use or recent infection) Risk factors for or signs of the cauda equina syndrome (new urine retention, faecal incontinence, or saddle anaesthesia) Severe neurologic deficits (progressive motor weakness or motor deficits at multiple neurologic levels)
Defer imaging after a trial of therapy	Radiography with or without erythrocyte sedimentation rate	Weaker risk factors for cancer (unexplained weight loss or age >50 y) Risk factors for or signs of ankylosing spondylitis (morning stiffness that improves with exercise, alternating buttock pain, awakening because of back pain during the second part of the night, or younger age [20 to 40 y]) Risk factors for vertebral compression fracture (history of osteoporosis, use of corticosteroids, significant trauma, or older age [>65 y for women or >75 y for men])
	Magnetic resonance imaging	Signs and symptoms of radiculopathy (back pain with leg pain in an L4, L5, or S1 nerve root distribution or positive result on straight leg raise or crossed straight leg raise test) in patients who are candidates for surgery or epidural steroid injection Risk factors for or symptoms of spinal stenosis (radiating leg pain, older age, or pseudoclaudication) in patients who are candidates for surgery
No imaging		No criteria for immediate imaging and back pain improved or resolved after a 1-month trial of therapy Previous spinal imaging with no change in clinical status

† Consider magnetic resonance imaging if the initial imaging result is negative but a high degree of clinical suspicion for cancer remains.

Source: This table is adapted from The American College of Physicians Clinical Guideline for Diagnostic Imaging for low back pain (Ann Intern Med 2011; 154:181-189.)

◄ Back to previous page | Start Back Pain Choices ►

THE GEORGE INSTITUTE | About | Evidence | Survey | NPS Better choices > Better health

Figure 3. Screenshot Step 2 - Clinical assessment.

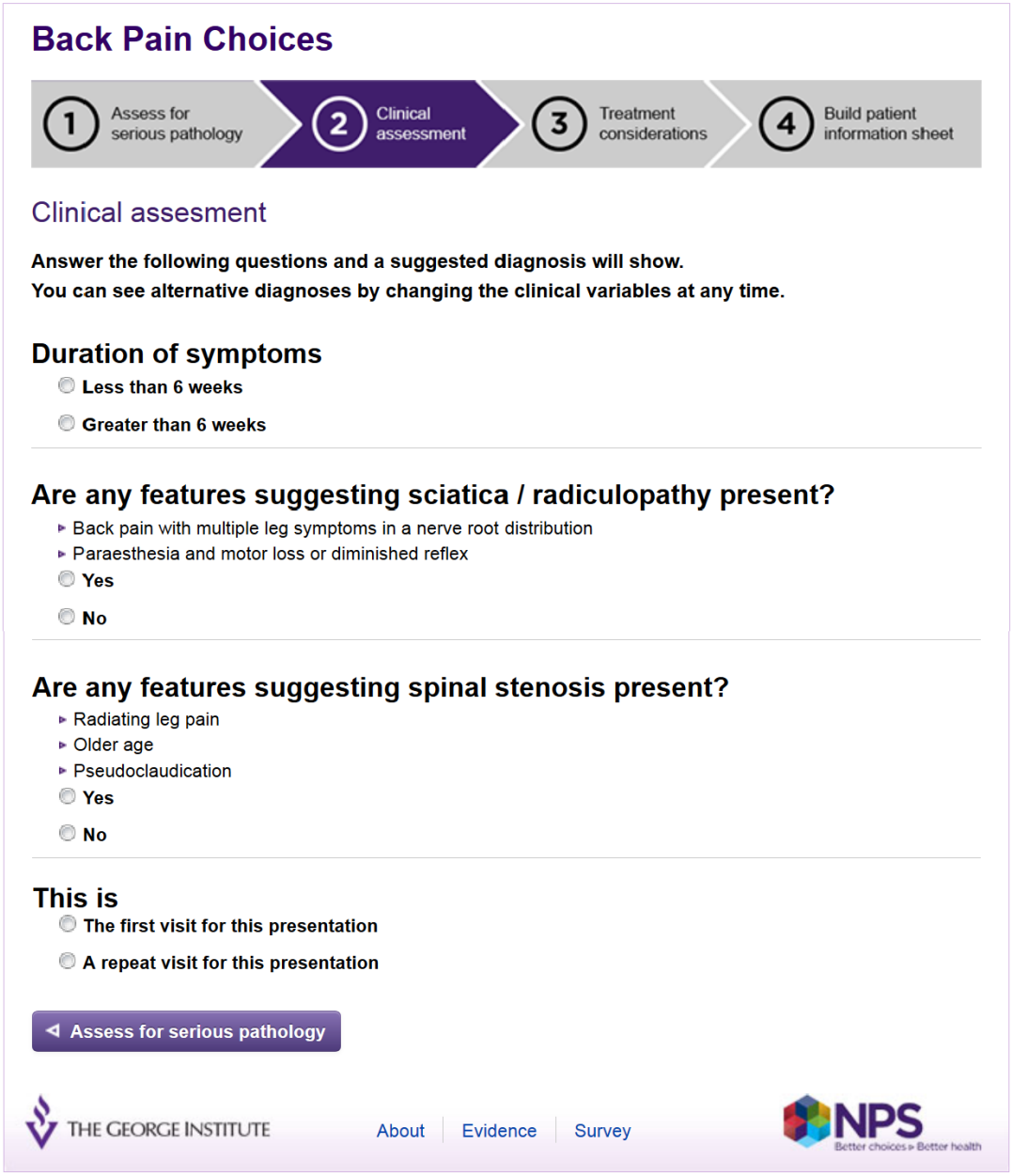


Figure 4. Screenshot Step 3 – Treatment considerations.

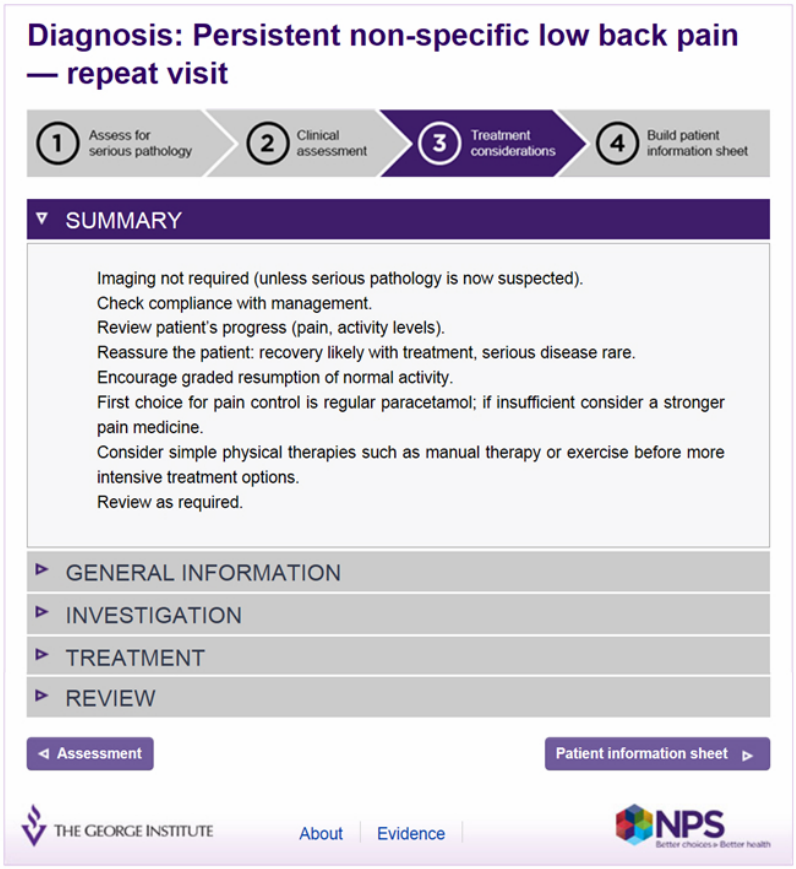
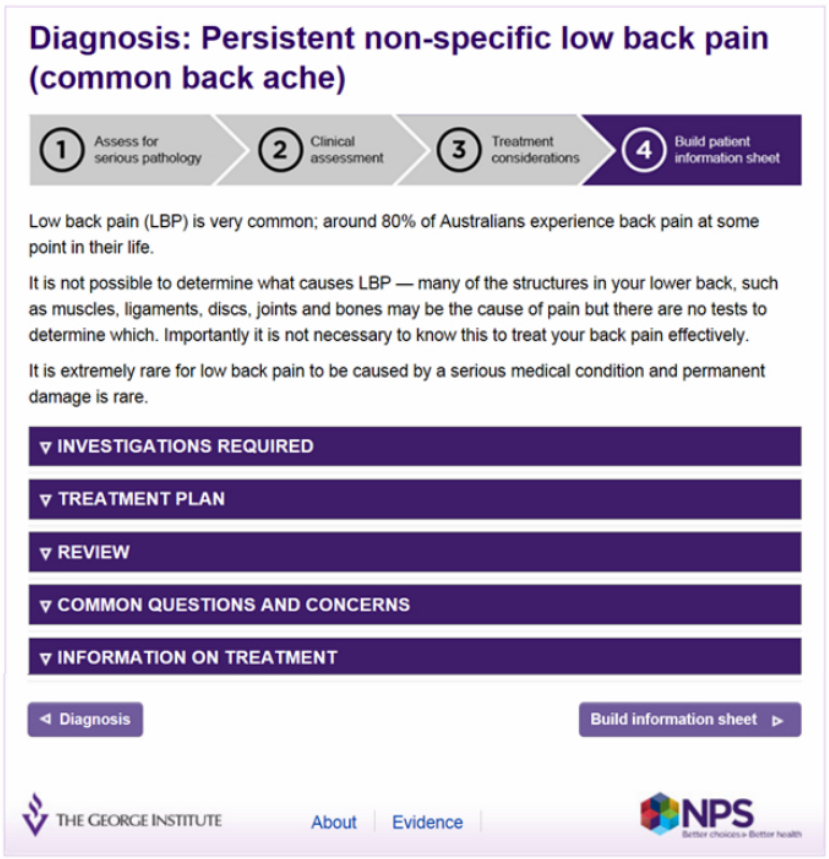


Figure 5. Screenshot Step 4 – Build information sheet.



Implementation

The tool was published on the Internet in June 2012, accompanied by a media release issued to coincide with Australian National Pain Week [28]. The tool was subsequently mentioned in several leading GP focused periodicals, the Royal Australian College of General Practitioners electronic newsletter, sent to over 20,000 GPs, the Australian Medicare Local Alliance newsletter, and circulated to all 61 Medicare Locals, which are government funded, middle tier primary health care organizations. The tool was also directly promoted via a NPS MedicineWise "visiting topic", in which physiotherapist educators conducted small clinic based workshops to support GPs in improved health care quality.

Following this, a convenience sample of twenty GPs in the Sydney area were invited to use the tool over a four week period in order to provide further insights into its utility, barriers, and enablers to uptake.

Evaluation

A mixed methods evaluation was conducted of the tool. Usage data were collected using Google Analytics over a 12 month period. Data included visit frequency, number of unique visitors, number of page views, and average visit duration. The qualitative component involved in-depth, semistructured interviews with all 20 GPs who had trialed the tool. A GP interviewer who was not involved in tool development conducted the semistructured interviews (see Multimedia Appendix 1 for the interview guide). The interviews covered four key domains: (1) opinions on back pain management, (2) a "live walk-through" of the website, (3) clinical and patient perspectives on utility, and (4) recommendations for improvements. The interviews were digitally recorded, transcribed, and imported for analysis into NVivo 10 (QSR International). An inductive approach was taken, with thematic content analysis conducted contemporaneously with data collection. A preliminary coding framework was collaboratively derived from the analysis of four interviews, discussed by the broader project team, and revised accordingly. There were two researchers that then independently coded the remaining interviews (eight each), and discussed new themes not previously identified. Saturation of themes occurred after around 15 interviews. At the end of the interview coding, final findings were again discussed by the project team and key themes were further refined.

The University of Sydney Human Research Ethics Committee approved the study.

Results

Website Usage Data

Figure 6 shows the usage data from June 2012 to May 2013 of the tool. The peak in early August 2012 coincides with the media release; subsequent to this usage, patterns remained relatively constant. The average time spent per visit was just over four minutes and the average number of pages viewed per visit was six pages. Almost all visitors clicked through to at least the second page of the back pain assessment.

Qualitative Evaluation

Table 1 outlines the characteristics of the GPs interviewed that had trialed use of the tool.

Figure 6. Usage patterns of the decision support tool for June 2012-May 2013.

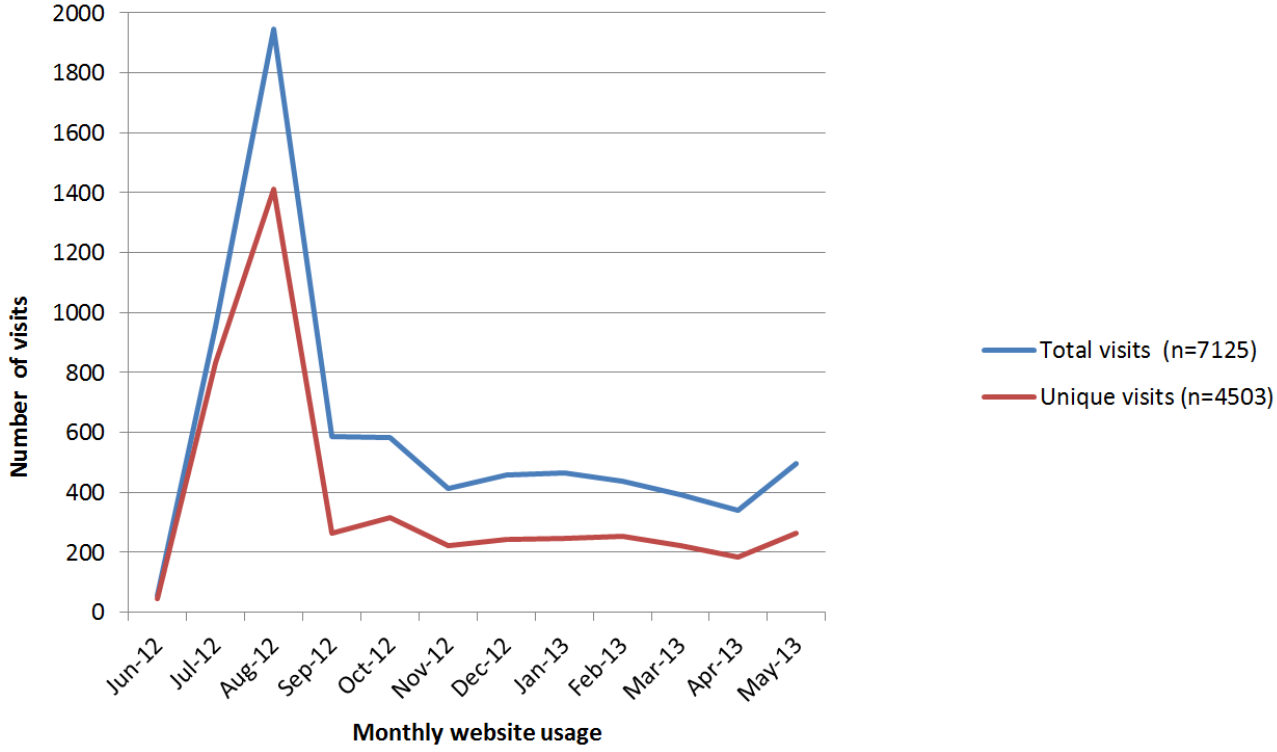


Table 1. GP and practice characteristics.

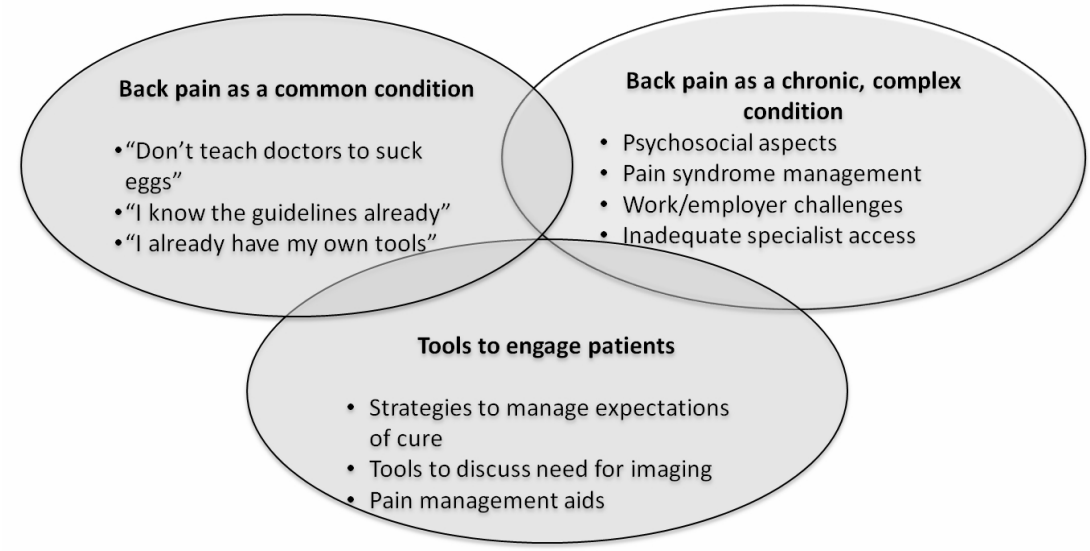
Characteristics	Total=20, n (%)
GP characteristics	
Age, years [a]	
<50	8 (40)
50-59	8 (40)
60+	3 (15)
Male	13 (65)
English primary language spoken at home	14 (70)
Australian university graduate	15 (75)
Vocationally registered	20 (100)
Number of sessions worked per week	
2-5	4 (20)
>5	16 (80)
Participates in research often or very often	6 (30)
Conducts own research	8 (40)
Daily use of Internet or email for work purposes	20 (100)
Practice characteristics	
Number of patients registered	
1001-3000	1 (5)
3001-5000	7 (35)
>5000	12 (60)
Number of doctors	
1-5	9 (45)
6-10	9 (45)
>10	2 (10)
Number of nurses	
0	2 (10)
1-3	15 (75)
>3	3 (15)
Practices with a practice manager	17 (85)
GP registrar placement	4 (20)

[a]One response missing

Identified Themes

There were three interrelated themes on the management of back pain and the role of tools that were identified. An additional theme, focused on the functional aspects of the tool, also yielded important information on recommendations for improvement. Figure 7 shows the key thematic domains and related subthemes.

Figure 7. Thematic domains from in-depth interviews with twenty GPs.



Theme 1: Low Back Pain Is a Common Condition

Our motivation for developing the CDSS tool was to improve adherence to guideline recommendations. Many of the GPs interviewed, however, considered back pain diagnosis and management to be common and relatively straightforward. It was viewed as integral to being a competent practitioner, and, therefore, the notion that GPs might need a tool to assist them seemed to indicate that "something was wrong" with their skills.

> *You can't have a tool for every presentation in general practice...this is something that should be up there (pointing to his head) rather than "Oh wait a second, let me use this tool...*" [GP 3]

Similarly, one GP was worried that the use of such a tool during a consultation would make him look "a bit strange" in the eyes of his patient, while another felt it was condescending and that he did not need "a step-by-step approach on how to suck an egg." These accounts highlight the tension between a perceived, sound knowledge of best practice and the published data demonstrating large evidence-practice gaps.

Theme 2: Low Back Pain Is a Complex, Chronic Condition

Juxtaposed with the notion that back pain is common, was a more nuanced appreciation that it may have a complex, chronic course. This course can be characterized by relapse and setbacks, psychosocial and work related repercussions, and fragmented health care experiences. Most GPs acknowledged that under these circumstances back pain management was challenging and required considerable effort to ensure satisfactory health care. These challenges are particularly pronounced with work related back pain, where health care costs are subsidized in Australia by the government worker's compensation schemes.

> *For one patient injured at work...he seems to be using it to get back at his employer...It also looks as though his relationship (with his partner) is going to break down...and he fosters a sense of entitlement through his back pain...* [GP 2]

In such circumstances, GPs may be more likely to conduct imaging tests or prescribe complex pain relief medications, while cognizant that these are not routinely indicated.

> *I tried to get (him) managing the pain, but he was also a very anxious man. He went to my colleague, had a CT scan, which then showed something he fixated on. It's been years to get him to a point where he's not obsessing about every twinge in his back.* [GP14]

Theme 3: Tools to Engage Patients

We came to appreciate that the tool was situated amid highly varied clinical contexts, ranging from where GPs required minimal additional support, through to complex situations where new resources were desirable. This helps to explain why at times the tool was seen as superfluous, and at other times it had the potential to assist with management dilemmas.

The tool was perceived to be the most useful in situations where patient reassurance and avoidance of complex tests or medicines were recommended. The GPs used the tool as a source of authoritative advice to support their recommendations. The patient information sheet was a particularly useful component, as it synthesized the key messages that would otherwise take some time to explain.

> *Well, I suppose we tended to make the patients feel happy if they want x-rays...Now at least we can say, "This is the evidence. You've got to wait for a while...*" [GP 3]

Similarly, in the context of a work related injury, one GP used the tool to communicate with the patient's employer.

> *I used the tool for the employer because the patient refused to go back to work...So I copied a few things from the tool and emailed it to the employer and they were quite happy.* [GP 5]

Theme 4: Recommendations to Improve Tool Content

While the tool had the potential to be of value, some GPs found that it was not sufficiently dynamic to be of use in the long term. Once the core components became clear, there was perceived to be little variation in the content. This was not necessarily an adverse finding, as many GPs felt that over time the recommendations would be "incorporated as part of their normal skills." Some GPs, however, wanted more detailed advice for complex pain management and indications for referral, whereas others wanted more autonomy in customizing the patient information.

The main influence to future tool uptake appeared to be integration into routine workflow. Integration with clinical software systems and the ability to rapidly navigate to the parts of immediate interest were frequently recommended by the GPs. They were also concerned with the growing number of tools that compete for their attention. Many described a process by which they establish their own "tool box" of resources, often compiled over many years. Tool developers therefore need to make new tools that complement rather than compete with existing tools.

Discussion

Principal Results

This study examined the development, uptake, and acceptability of an Australian GP Web-based CDSS for the management of back pain. There were three key findings that were observed. First, the algorithm underpinning the tool appeared to have acceptable face validity when reviewed by experts in the field and when implemented among GPs. This reflects consistency in guideline recommendations over several years. Second, we identified an effective implementation mechanism for rapid dissemination of the tool, drawing on a multi-pronged approach of media releases in target periodicals, alignment with National Pain Week, and promotion via an existing national network of facilitators who conduct face-to-face GP visits. Assuming that most unique visits were GPs, and that there are 20,360 GPs in Australia [29], then, over a 12 month period, around one quarter of the GPs in the country used the tool. Moreover, the ratio of new to returning users has remained constant, indicating the tool has not yet reached full market saturation. Third, and perhaps most importantly, the qualitative component revealed the complexities of managing low back pain and the "touch-points", whereby a CDSS tool may exert its influence.

Limitations

This study was exploratory in nature and did not assess the clinical effectiveness of the tool. The focus was to look at usability factors, identify enhancements needed, and further refine the tool. Further, although the usage data are useful, we were unable to analyze use by provider type, and to examine in more detail which parts of the tool were most/least popular. A final limitation was that we did not examine the perspectives of patients and other health care providers, such as physiotherapists and specialists.

Comparison With Prior Work

To our knowledge, this is the first CDSS for back pain to be evaluated. Although uptake and general satisfaction was encouraging, ongoing usage patterns are likely to be highly variable. Our findings resonate with our recent study of a cardiovascular CDSS tool and outline that GPs adopt guideline recommendations judiciously, depending on multiple social and environmental factors [30,31]. This may partly explain why interventions, including Internet interventions to improve back pain management, have thus far yielded small effects at best [32,33]. The notion that GPs establish their own "tool box" to conduct their work is useful in understanding how a new tool will be perceived. For common conditions like back pain, this compendium of existing tools tends to be well established, and, consequently, a tool that covers only the basics is likely to be less effective. Conversely, GPs clearly experience challenges in effectively managing back pain for their patients. If a CDSS tool can support GPs in these domains, especially complex pain management, psychosocial impact, and work related issues, then such a tool is likely to be concordant with their needs. Tool customization was of particular importance to the GPs. In a model akin to a mobile "app store", GPs could select and modify their preferred "apps" on the basis of personal interest, user feedback, or endorsement by trusted organizations.

Conclusions

Despite the existence of clear and consistent recommendations from national and international guidelines for the management of back pain, large evidence-practice gaps exist. Our findings suggest that decision support tools have the potential to serve as an effective dissemination mechanism for the implementation of guidelines. This study represents the initial stage of a research translation program to improve health care quality for back pain. Several tool features were identified to be useful, but, importantly, a number of contextual factors affecting how back pain is managed were also noted. These factors may require additional tools with a different focus. Further work with care providers and consumers is planned to develop and test these enhancements. The system will then be assessed for its effectiveness in improving health care for the world's most disabling health condition.

Acknowledgments

The George Institute for Global Health and NPS MedicineWise internally funded the study. We gratefully acknowledge the support of the GPs that participated in this study. We also thank the following NPS MedicineWise staff for their support with the project - Mallory Allsopp, Chris Hayward, Aine Heaney, Paul Heasley, Damon Judges, Ben Smyth, Andrew Sung-Hoon Jun, and Clare Weston. A National Health and Medical Research Council Fellowship (ID 1054754) supports DP. An Australian Research Council Fellowship supports CM.

Authors' Contributions

DP, CM, and CW designed the study. RH, RL, and JR led the implementation of the intervention and were responsible for the acquisition of quantitative data. AD was responsible for the acquisition of qualitative data. DP wrote the first draft of the study manuscript. All authors critically reviewed the manuscript and reviewed the final draft prior to submission.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Interview guide.

[PDF File (Adobe PDF File), 109KB - resprot_v3i1e17_app1.pdf]

References

1. Vos T, Flaxman AD, Naghavi M, Lozano R, Michaud C, Ezzati M, et al. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990-2010: A systematic analysis for the Global Burden of Disease Study 2010. Lancet 2012 Dec 15;380(9859):2163-2196. [doi: 10.1016/S0140-6736(12)61729-2] [Medline: 23245607]
2. da C Menezes Costa L, Maher CG, Hancock MJ, McAuley JH, Herbert RD, Costa LO. The prognosis of acute and persistent low-back pain: A meta-analysis. CMAJ 2012 Aug 7;184(11):E613-E624 [FREE Full text] [doi: 10.1503/cmaj.111271] [Medline: 22586331]
3. Henschke N, Maher CG, Refshauge KM, Herbert RD, Cumming RG, Bleasel J, et al. Prognosis in patients with recent onset low back pain in Australian primary care: Inception cohort study. BMJ 2008;337:a171 [FREE Full text] [Medline: 18614473]
4. Stanton TR, Henschke N, Maher CG, Refshauge KM, Latimer J, McAuley JH. After an episode of acute low back pain, recurrence is unpredictable and not as common as previously thought. Spine (Phila Pa 1976) 2008 Dec 15;33(26):2923-2928. [doi: 10.1097/BRS.0b013e31818a3167] [Medline: 19092626]
5. Costa Lda C, Maher CG, McAuley JH, Hancock MJ, Herbert RD, Refshauge KM, et al. Prognosis for patients with chronic low back pain: Inception cohort study. BMJ 2009;339:b3829 [FREE Full text] [Medline: 19808766]
6. Dunn KM, Jordan K, Croft PR. Characterizing the course of low back pain: A latent class analysis. Am J Epidemiol 2006 Apr 15;163(8):754-761 [FREE Full text] [doi: 10.1093/aje/kwj100] [Medline: 16495468]
7. Foster NE. Barriers and progress in the treatment of low back pain. BMC Med 2011;9:108 [FREE Full text] [doi: 10.1186/1741-7015-9-108] [Medline: 21943396]
8. Hay EM, Dunn KM. Prognosis of low back pain in primary care. BMJ 2009;339:b3694. [Medline: 19808764]
9. Martin BI, Deyo RA, Mirza SK, Turner JA, Comstock BA, Hollingworth W, et al. Expenditures and health status among adults with back and neck problems. JAMA 2008 Feb 13;299(6):656-664. [doi: 10.1001/jama.299.6.656] [Medline: 18270354]
10. Kale MS, Bishop TF, Federman AD, Keyhani S. "Top 5" lists top $5 billion. Arch Intern Med 2011 Nov 14;171(20):1856-1858. [doi: 10.1001/archinternmed.2011.501] [Medline: 21965814]
11. Williams CM, Maher CG, Hancock MJ, McAuley JH, McLachlan AJ, Britt H, et al. Low back pain and best practice care: A survey of general practice physicians. Arch Intern Med 2010 Feb 8;170(3):271-277. [doi: 10.1001/archinternmed.2009.507] [Medline: 20142573]
12. Jackson JL, Browning R. Impact of national low back pain guidelines on clinical practice. South Med J 2005 Feb;98(2):139-143. [Medline: 15759941]
13. Schers H, Braspenning J, Drijver R, Wensing M, Grol R. Low back pain in general practice: Reported management and reasons for not adhering to the guidelines in The Netherlands. Br J Gen Pract 2000 Aug;50(457):640-644 [FREE Full text] [Medline: 11042916]
14. Tacci JA, Webster BS, Hashemi L, Christiani DC. Clinical practices in the management of new-onset, uncomplicated, low back workers' compensation disability claims. J Occup Environ Med 1999 May;41(5):397-404. [Medline: 10337610]
15. Becker A, Leonhardt C, Kochen MM, Keller S, Wegscheider K, Baum E, et al. Effects of two guideline implementation strategies on patient outcomes in primary care: A cluster randomized controlled trial. Spine (Phila Pa 1976) 2008 Mar 1;33(5):473-480. [doi: 10.1097/BRS.0b013e3181657e0d] [Medline: 18317189]
16. Bishop PB, Wing PC. Knowledge transfer in family physicians managing patients with acute low back pain: A prospective randomized control trial. Spine J 2006;6(3):282-288. [doi: 10.1016/j.spinee.2005.10.008] [Medline: 16651222]
17. Dey P, Simpson CW, Collins SI, Hodgson G, Dowrick CF, Simison AJ, et al. Implementation of RCGP guidelines for acute low back pain: A cluster randomised controlled trial. Br J Gen Pract 2004 Jan;54(498):33-37 [FREE Full text] [Medline: 14965404]

18. Eccles M, Steen N, Grimshaw J, Thomas L, McNamee P, Soutter J, et al. Effect of audit and feedback, and reminder messages on primary-care radiology referrals: A randomised trial. Lancet 2001 May 5;357(9266):1406-1409. [doi: 10.1016/S0140-6736(00)04564-5] [Medline: 11356439]
19. Engers AJ, Wensing M, van Tulder MW, Timmermans A, Oostendorp RA, Koes BW, et al. Implementation of the Dutch low back pain guideline for general practitioners: A cluster randomized controlled trial. Spine (Phila Pa 1976) 2005 Mar 15;30(6):559-600. [Medline: 15770171]
20. Schectman JM, Schroth WS, Verme D, Voss JD. Randomized controlled trial of education and feedback for implementation of guidelines for acute low back pain. J Gen Intern Med 2003 Oct;18(10):773-780 [FREE Full text] [Medline: 14521638]
21. Kawamoto K, Houlihan CA, Balas EA, Lobach DF. Improving clinical practice using clinical decision support systems: A systematic review of trials to identify features critical to success. BMJ 2005 Apr 2;330(7494):765 [FREE Full text] [doi: 10.1136/bmj.38398.500764.8F] [Medline: 15767266]
22. Shojania KG, Jennings A, Mayhew A, Ramsay CR, Eccles MP, Grimshaw J. The effects of on-screen, point of care computer reminders on processes and outcomes of care. Cochrane Database Syst Rev 2009(3):CD001096. [doi: 10.1002/14651858.CD001096.pub2] [Medline: 19588323]
23. Murray E, Burns J, See TS, Lai R, Nazareth I. Interactive health communication applications for people with chronic disease. Cochrane Database Syst Rev 2005(4):CD004274. [doi: 10.1002/14651858.CD004274.pub4] [Medline: 16235356]
24. Koes BW, van Tulder M, Lin CW, Macedo LG, McAuley J, Maher C. An updated overview of clinical guidelines for the management of non-specific low back pain in primary care. Eur Spine J 2010 Dec;19(12):2075-2094 [FREE Full text] [doi: 10.1007/s00586-010-1502-y] [Medline: 20602122]
25. Chou R, Qaseem A, Snow V, Casey D, Cross JT, Shekelle P, Clinical Efficacy Assessment Subcommittee of the American College of Physicians, American College of Physicians, American Pain Society Low Back Pain Guidelines Panel. Diagnosis and treatment of low back pain: A joint clinical practice guideline from the American College of Physicians and the American Pain Society. Ann Intern Med 2007 Oct 2;147(7):478-491. [Medline: 17909209]
26. Australian Acute Musculoskeletal Pain Guidelines Group. Canberra: National Health and Medical Research Council. 2003 Evidence-based management of acute musculoskeletal pain URL: http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/cp94_evidence_based_management_acute_musculoskeletal_pain_131223.pdf [accessed 2014-02-11] [WebCite Cache ID 6NIicLP1P]
27. National Institute for Health and Care Excellence. Low back pain: Early management of persistent non-specific low back pain. 2009 URL: http://www.nice.org.uk/nicemedia/live/11887/44343/44343.pdf [accessed 2014-02-11] [WebCite Cache ID 6NIl58Lnu]
28. NPS MedicineWise. NPS MedicineWise. 2012. Back pain choices URL: http://www.nps.org.au/health-professionals/resources-and-tools/decision-and-management-tools/back-pain-choices [accessed 2013-10-30] [WebCite Cache ID 6KmUNJfKF]
29. Britt H, Miller GC, Henderson J, Charles J, Valenti L, Harrison C, et al. The University of Sydney. 2011. General practice activity in Australia 2011-2012 URL: http://ses.library.usyd.edu.au//bitstream/2123/8675/4/9781743320198_ONLINE.pdf [accessed 2013-10-31] [WebCite Cache ID 6KmUCBQUm]
30. Peiris D, Usherwood T, Weeramanthri T, Cass A, Patel A. New tools for an old trade: A socio-technical appraisal of how electronic decision support is used by primary care practitioners. Sociol Health Illn 2011 Nov;33(7):1002-1018. [doi: 10.1111/j.1467-9566.2011.01361.x] [Medline: 21671947]
31. Peiris DP, Joshi R, Webster RJ, Groenestein P, Usherwood TP, Heeley E, et al. An electronic clinical decision support tool to assist primary care providers in cardiovascular disease risk management: Development and mixed methods evaluation. J Med Internet Res 2009;11(4):e51 [FREE Full text] [doi: 10.2196/jmir.1258] [Medline: 20018588]
32. French SD, McKenzie JE, O'Connor DA, Grimshaw JM, Mortimer D, Francis JJ, et al. Evaluation of a theory-informed implementation intervention for the management of acute low back pain in general medical practice: The IMPLEMENT cluster randomised trial. PLoS One 2013;8(6):e65471 [FREE Full text] [doi: 10.1371/journal.pone.0065471] [Medline: 23785427]
33. Krein SL, Kadri R, Hughes M, Kerr EA, Piette JD, Holleman R, et al. Pedometer-based internet-mediated intervention for adults with chronic low back pain: Randomized controlled trial. J Med Internet Res 2013;15(8):e181 [FREE Full text] [doi: 10.2196/jmir.2605] [Medline: 23969029]

Abbreviations

CDSS: clinical decision support system
GP: general practitioner

Edited by G Eysenbach; submitted 04.11.13; peer-reviewed by J Lurie, A Bussieres; comments to author 19.01.14; revised version received 11.02.14; accepted 11.02.14; published 02.04.14.

Please cite as:
Peiris D, Williams C, Holbrook R, Lindner R, Reeve J, Das A, Maher C
A Web-Based Clinical Decision Support Tool for Primary Health Care Management of Back Pain: Development and Mixed Methods Evaluation
JMIR Res Protoc 2014;3(2):e17
URL: http://www.researchprotocols.org/2014/2/e17/
doi:10.2196/resprot.3071
PMID:24694921

Protocol

Cameras for Public Health Surveillance: A Methods Protocol for Crowdsourced Annotation of Point-of-Sale Photographs

Vinu Ilakkuvan[1], MSPH; Michael Tacelosky[2]; Keith C Ivey[2], Mphil; Jennifer L Pearson[3,4], MPH, PhD; Jennifer Cantrell[1,4], MPA, DrPH; Donna M Vallone[1,4], MPH, PhD; David B Abrams[3,4,5], PhD; Thomas R Kirchner[3,4,5], PhD

[1]Department of Research and Evaluation, Legacy, Washington, DC, United States

[2]Survos, Washington, DC, United States

[3]Steven A Schroeder Institute for Tobacco Research and Policy Studies, Legacy, Washington, DC, United States

[4]Department of Health, Behavior, and Society, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, United States

[5]Department of Oncology, Lombardi Comprehensive Cancer Center, Georgetown University Medical Center, Washington, DC, United States

Corresponding Author:
Vinu Ilakkuvan, MSPH
Department of Research and Evaluation
Legacy
1724 Massachusetts Avenue NW
Washington, DC, 20036
United States
Phone: 1 2024545791
Fax: 1 20224545599
Email: vilakkuvan@legacyforhealth.org

Abstract

Background: Photographs are an effective way to collect detailed and objective information about the environment, particularly for public health surveillance. However, accurately and reliably annotating (ie, extracting information from) photographs remains difficult, a critical bottleneck inhibiting the use of photographs for systematic surveillance. The advent of distributed human computation (ie, crowdsourcing) platforms represents a veritable breakthrough, making it possible for the first time to accurately, quickly, and repeatedly annotate photos at relatively low cost.

Objective: This paper describes a methods protocol, using photographs from point-of-sale surveillance studies in the field of tobacco control to demonstrate the development and testing of custom-built tools that can greatly enhance the quality of crowdsourced annotation.

Methods: Enhancing the quality of crowdsourced photo annotation requires a number of approaches and tools. The crowdsourced photo annotation process is greatly simplified by decomposing the overall process into smaller tasks, which improves accuracy and speed and enables adaptive processing, in which irrelevant data is filtered out and more difficult targets receive increased scrutiny. Additionally, zoom tools enable users to see details within photographs and crop tools highlight where within an image a specific object of interest is found, generating a set of photographs that answer specific questions. Beyond such tools, optimizing the number of raters (ie, crowd size) for accuracy and reliability is an important facet of crowdsourced photo annotation. This can be determined in a systematic manner based on the difficulty of the task and the desired level of accuracy, using receiver operating characteristic (ROC) analyses. Usability tests of the zoom and crop tool suggest that these tools significantly improve annotation accuracy. The tests asked raters to extract data from photographs, not for the purposes of assessing the quality of that data, but rather to assess the usefulness of the tool. The proportion of individuals accurately identifying the presence of a specific advertisement was higher when provided with pictures of the product's logo and an example of the ad, and even higher when also provided the zoom tool (χ^2_2=155.7, P<.001). Similarly, when provided cropped images, a significantly greater proportion of respondents accurately identified the presence of cigarette product ads (χ^2_1=75.14, P<.001), as well as reported being able to read prices (χ^2_2=227.6, P<.001). Comparing the results of crowdsourced photo-only assessments to traditional field survey data, an excellent level of correspondence was found, with area under the ROC curves produced by sensitivity analyses averaging over 0.95, requiring on average 10 to 15 crowdsourced raters to achieve values of over 0.90.

Results: Further testing and improvement of these tools and processes is currently underway. This includes conducting systematic evaluations that crowdsource photograph annotation and methodically assess the quality of raters' work.

Conclusions: Overall, the combination of crowdsourcing technologies with tiered data flow and tools that enhance annotation quality represents a breakthrough solution to the problem of photograph annotation, vastly expanding opportunities for the use of photographs rich in public health and other data on a scale previously unimaginable.

(JMIR Res Protoc 2014;3(2):e22) doi:10.2196/resprot.3277

KEYWORDS

image processing; crowdsourcing; annotation; public health; surveillance

Introduction

Near universal penetration of mobile phones with built-in cameras marks the advent of a highly valuable platform for collecting data on the distribution of health-related features in the built environment. Photographs can provide detailed and objective information that cannot be detected by other surveillance and sensing systems. In addition, the ubiquity of mobile phones and ease-of-use of built-in cameras empowers citizens to participate in data collection on a scale previously unimaginable. Further enhancing the usefulness of photographs is the rapid advancement of the quality of geolocation services on mobile phones, allowing the linkage of mobile photographs to the physical location at which they were taken [1,2].

Photographs have long been recognized as a useful tool for public health advocacy and research, such as in the context of photovoice, a process in which individuals take photographs to relay their experiences with the goal of informing dialogue and ultimately enhancing their community [3]. More recently, photographs have dramatically improved resource evaluation and natural disaster response efforts around the globe [4,5], and in another recent example, smartphone cameras have been worn on lanyards by study participants to track individual health behaviors using life logging software that takes pictures at regular intervals [6].

It is important to note that photographs are not merely a method of validating traditional data collection modes such as surveys; rather, photographs are a rich source of data in and of themselves. In the context of surveillance research, collecting data in the form of photographs provides an interesting advantage over traditional surveys in that a set of questions need not be developed ahead of time. Instead, photographs can be taken of generic targets such as storefronts or street corners and later annotated to identify features of interest. This has significant implications for the need to hire and train skilled field workers for surveillance work, lowering the bar such that any citizen interested in collecting data about features of their environment that might impact the health of their community can take concrete action.

A logistical bottleneck that has previously inhibited the use of photographs for systematic surveillance has been the need to accurately and reliably annotate (ie, identify features within) large numbers of images. Technological advances enable photographs to be captured in large quantities, but the annotation of these photos is often an expensive and time-consuming process. It is seldom feasible to hire and train enough independent "raters" to examine photos and annotate them based on content, particularly when the number of photographs reaches in the thousands or more (multiplied, of course, by the complexity of information in each photo and the targets under study). The challenge is magnified when new questions requiring additional rounds of annotation arise, along with the ever-present need to address interrater reliability and the validity of the entire endeavor. For the first time, distributed human processing or crowdsourcing platforms make it possible to accurately, quickly, and repeatedly annotate photos at relatively low cost.

This paper describes a methods protocol for the crowdsourced annotation of photographs. Specifically, the paper outlines the development and initial testing of a set of custom-built tools that may greatly enhance the quality of crowdsourced annotation of photographs. The usability tests described in this paper were designed to assess the functional utility of the tools described, not to systematically evaluate them as part of an applied or experimental research study. Photographs were obtained from a research study on point-of-sale product categories and availability that took place from September 2011 to May 2013. During this time, two point-of-sale surveillance studies were conducted to better understand tobacco advertising in the retail environment, one in Washington, DC and one in New York City. In addition to photographs, trained field surveyors collected data through a variety of electronic methods, including phone-based interactive voice response, text messaging, global positioning system technologies, and a mobile application [1,7].

Methods

Crowdsourced Annotation Framework and Tools

Crowdsourcing is a relatively recent term, introduced in a 2006 *WIRED* magazine article and defined as an "open call to a large network of potential laborers" [8,9]. The 4 common categories of crowdsourcing include: (1) knowledge discovery and management, such as information gathering and organizing, (2) large-scale data analysis, such as photo coding and language translation, (3) innovation or problem solving contests, games, or platforms, and (4) generation and selection of the best idea [10]. This paper focuses on category 2, large-scale data analysis, namely the annotation of photographs. Photographs of the retail environment provide a good test case for crowdsourced annotation because they consist of complex scenes full of fine detail. This complexity enables the testing of different approaches and tools that might enhance the quality of crowdsourced photo annotation.

A number of studies have examined the use of crowdsourcing for purposes of image and photo annotation. Raschtchian et al [11] describe their experience using crowdsourcing to annotate images with multiple, one-sentence descriptions, and Sorokin and Forsyth [12] describe their experience crowdsourcing the annotation of images to outline any persons appearing in the image. Two more recent biomedical studies have used crowdsourcing to process images of biomarkers related to malaria and retinopathy [13,14]. In the field of public health, crowdsourcing has been used to aid in the annotation of images collected from webcams in order to identify active transportation [15], and in a system entitled PlateMate, which crowdsources nutritional analysis of photographs to determine food intake and composition estimates [16]. However, examples such as these are rare, and there is limited information in the literature regarding specific methodologies that can facilitate crowdsourced photo annotation, particularly tasks that require further processing of images (eg, zooming or cropping) in order to complete annotation accurately.

Tiered Tasking Framework

Annotating photographs to the level of detail required for this project, which involves identifying the tobacco products, brands, and prices present in pictures of the point-of-sale environment, requires a tiered workflow. Decomposing the overall process into smaller tasks ensures that each separate task is simple, thereby improving the accuracy and speed with which the tasks can be completed and verified when needed. Tiered tasking also enables the simultaneous analysis of different photographs at different stages of the analytic process. Moreover, it enables the creation of an efficient workflow through adaptive processing, in which irrelevant or uninformative data are filtered out (eg, if there are no tobacco advertisements in a photograph, there is no need to ask for the identification of the type or brand of tobacco product advertised) and more difficult targets receive increased scrutiny (eg, if the crowd fails to reach consensus during the annotation of certain photographs, those photographs can be funneled to experts for further inspection).

Such a workflow greatly streamlines the crowdsourced photo annotation effort. For this project, an infrastructure was built to enable photographs to flow automatically from one stage of the process to the next. For example, in one workflow, photographs from a crowdsourced data-mining task (zooming into a storefront photograph and cropping out any tobacco advertisements) are automatically funneled into a subsequent annotation task involving identification of features, such as brand name or price.

Choosing a platform to operationalize this crowdsourced photo annotation workflow was the first consideration in building a customized annotation system. Amazon Mechanical Turk (MTurk) was the crowdsourcing platform used for this project. MTurk is a Web-based marketplace where “requestors” create open calls for “workers” (referred to as “raters” in the context of this project) to complete specified Human Intelligence Tasks (HITs) in return for a small payment. As such, raters completing crowdsourced tasks for the usability testing described in this paper are not selected or trained; they respond to an open call and the first raters to respond complete the task. MTurk is a marketplace for work that humans can achieve more effectively than computers, and image annotation is a prime example of such work [17]. While a simple interface for tasks is available within MTurk, for this project, MTurk application program interfaces were used to customize and configure workflow, task management, and reliability assessment processes external to the MTurk system. This enabled the automation of all processes, eliminating the need to export task results, manually filter data, and import back into the system, while still leveraging MTurk’s payment system and ability to attract workers.

Photographic Zoom Tool

In deploying a task to identify the lowest advertised price for a cigarette within a photograph of a storefront, it quickly became apparent that it was difficult to identify and read individual advertisements and see details without a zoom capability.

There are various ways that a zoom tool can be incorporated within an MTurk task. One option is to configure the zoom tool in such a way that moving the mouse over a section on a photograph displays a close-up version of that section instead of the entire photograph. This would serve the need to see details more clearly, but users lose the ability to orient themselves within the context of the larger photograph. For the purposes of annotating storefront photographs, seeing the larger context of the photograph and where within it certain advertisements are situated can be very important. Thus, the zoom tool developed for this project was configured so that moving the mouse over a section of the photograph displays a close-up version of that section on a separate area of the screen, leaving the full photograph visible (Figure 1). Although this separate window blocks out a portion of the survey questions on the right-hand side of the screen while the user is zooming, the close-up image disappears once an answer to a question is found, and this process provides the critical advantage of being able to orient oneself within the overall context of the photograph.

Figure 1. The Zoom Tool shows magnified detail while the mouse hovers over an image, temporarily obscuring the question.

Zoom Tool Usability Test

A test was conducted to examine the usefulness of the zoom tool in improving annotation and to determine what other information in conjunction with the zoom tool might help equip raters in annotating a storefront photograph to identify specific tobacco advertisements.

This test involved 3 phases using a prototypical photograph of a storefront from prior surveillance work, in this case a storefront in the Central Harlem area of New York City. In phase 1, raters were asked if advertisements for Eon, Logic, and Blu e-cigarettes were present in the photo. In phase 2, using the same photo and questions from phase 1, raters were given additional assistance in the form of pictures of the typical point-of-sale advertisements for these e-cigarettes along with a logo for each of the e-cigarette brands. In phase 3, using the same photo and questions from phase 2, raters were also given the zoom tool in addition to the e-cigarette logo and advertisements to better help them identify the presence or absence of e-cigarette ads at the point-of-sale. Each of the three tasks was completed 100 times by 100 raters.

Raters who were equipped with additional imagery (brand logo and example advertisement, phase 2) or additional imagery plus the zoom tool (phase 3) were significantly more adept at identifying ads for Eon e-cigarettes than raters who were only provided a photo of the storefront (phase 1). When provided with a single storefront image, only 7.0% (7/100) of respondents were able to accurately identify the presence of an Eon advertisement. This proportion was significantly higher among respondents who were provided with pictures of the product's logo and an example of the ad (73/100, 73.0%), and even higher among respondents given the zoom tool (88/100, 88.1%) (χ^2_2=155.7, P<.001). The Blu e-cigarette ad was more easily noticed in the original storefront image: 88.0% (88/100) were able to identify the ad looking at the storefront alone, with the proportion of respondents properly identifying ads being only slightly higher when provided with logo and ad images (92/100, 92.0%) and the zoom tool (92/100, 92.1%) (χ^2_2=3.70, P=.45).This task also contained a question about a Logic e-cigarette ad, which was not present on the storefront; adding additional information or the zoom tool did not improve accuracy (χ^2_2=6.89, P=.14).

Photographic Crop Tool

The crop tool evolved from the need to indicate the exact location of a specific tobacco advertisement within the image of the storefront. Initially, a different tool was set up that could mark a single point on the photograph where the specific advertisement was found. However, there is no way to determine how large this point is relative to the rest of the ad. Capturing the close-up image from the zoom tool was considered as a way to identify the specific ad. The problem with this approach is that a fixed zoom size might not capture the boundary of the ad given that ads are different shapes and sizes. Thus, a slight variation of the zoom tool was created where a user could draw a box around what he or she wanted to zoom into, and then could press a button to capture that image. This is the custom-built crop tool used in this project.

Initially, the crop tool–related task was designed as a repeatable, multipart task. In this iteration, raters were asked to use the crop tool to draw a box around a single advertisement from an overall storefront photograph, and then answer questions about that cropped picture. Three questions were asked, beginning with asking the crowdsourced rater to identify the brand of the tobacco product being advertised. This question was formatted as either a dropdown (for short lists of brands, such as for e-cigarettes) or an auto-fill question (for longer lists of brands; auto-fill questions are similar to dropdowns, but filter results based on the initial letters typed). The second question asked about the price of the product advertised, and the third question

asked about additional price-related information such as whether the advertisement includes information about a tax or special offer, if the price is per-pack or per-carton, and so on.

While this was a fast and efficient approach for experts attempting to complete the task, it was not well suited to crowdsourcing due to the difficulty of assessing reliability. In effect, a complex storefront photograph can be broken into dozens of pieces, each of which is associated with a different question, making it difficult to determine how similar responses are across raters.

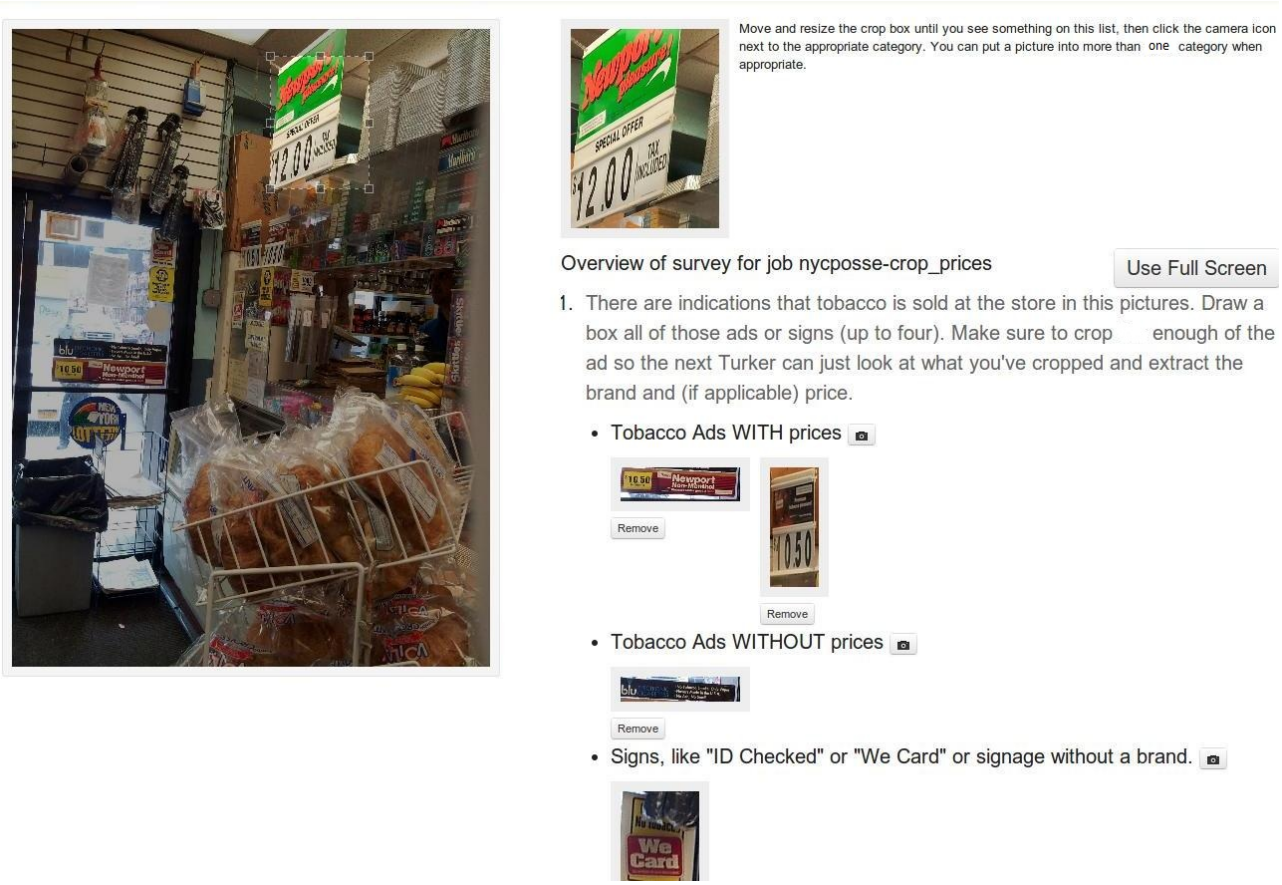
As a result, the first modification of this tool and task was simplified to ask a single question, for instance, “draw a box around the lowest price for a pack of cigarettes you see in the picture”. The result for this question would be a set of coordinates describing the box. However, this approach only allowed for one picture per question, leading to a long list of repetitive questions.

The next modification of this tool and task involved stringing together several smaller tasks, thus occupying a sweet spot between the expert-level, multipart crop task and the too-simple, basic crop that only answered a single question. In this version of the tool, called a “tagged crop” (Figure 2), multiple selections within an image can be associated with a tag. As illustrated in Figure 2, a single item can therefore produce a variable number of tags, each of which might be associated with multiple image selections.

This is a very efficient way to design a task and generate a set of images that answer specific questions. A simple task might ask raters to draw a picture around every tobacco ad in the storefront photograph, and categorize each as an advertisement with or without a price listed. A more complex task might have more options, asking raters to further separate ads and cigarette packs with shelf pricing, or asking them to separate out advertisements for different tobacco products (eg, combustible cigarettes, e-cigarettes, and little cigars).

Regardless of the way this crop tool is designed, one challenge that remains is that agreement on a cropped image is seldom exact; two raters may draw a very similar box and capture almost the same thing, yet their boxes are unlikely to be identical down to the level of pixels.

Figure 2. Example of a “tagged crop” task in which one or more selections within an image are associated with a tag, and multiple tags can be defined in a single question.



“Black-Out” Reverse Crop Tool

Another remaining challenge is that in the absence of additional controls over data flow and processing, efficiency in annotating images can be seriously undermined by redundancy and inaccuracy due to false negatives (ie, failures to identify and crop a feature). Some easy-to-spot items might be identified many times, leading to redundancy, and other difficult-to-spot items might not be found by anyone, leading to inaccuracy. In order to address this issue, a “reverse crop” tool was conceptualized to further enhance the annotation process. The reverse crop tool removed the cropped section from the photo, leaving a background image with one or more rectangular areas that are blank or blacked out. This tool enables sections cropped

by the first rater to be blacked out before the image is passed on to a second rater, so that the second rater is working from a less complex image, reducing redundancy and increasing the likelihood that no relevant advertisements are missed. An option to toggle on or off whether a rater can see the portion of the image that has been blacked out may be useful in cases where the initial crop is too wide and accidentally encroaches upon another portion of the image that could be a separate crop. This tool has the additional advantage of allowing a graded distribution of payment, with higher payments for crops of items that are more difficult to find.

Crop Tool Usability Test

A test was conducted to examine the usefulness of cropping for annotating photographs of storefront advertisements. The test involved 2 phases. In the first phase, raters were presented with an unaltered storefront photograph and asked questions related to the presence of cigarette advertising and the identification of cigarette and menthol cigarette prices on the storefront. In the second phase, raters were presented with cropped advertisements from the overall storefront image and asked the same questions. In the first phase, there was one task, completed 100 times by 100 different raters. In the second phase, there were two tasks (one for each cropped image), and each task was completed 100 times by 104 different raters.

When provided cropped images, nearly all respondents (103/104, 99.5%) were able to accurately identify the presence of cigarette product ads on the storefront, a significantly greater proportion than among respondents provided only with an overall storefront image (65/100, 65.0%) (χ^2_1=75.14, P<.001). Respondents receiving cropped images properly identified which ads promoted menthol and nonmenthol product types (104/104, 100.0% reported that Newport menthol was a menthol product, and 103/104, 99.0% correctly reported Newport nonmenthol as an unmentholated brand).

Respondents who received cropped images of ads were significantly more successful at recognizing that prices appeared on the storefront (80/104, 76.5%), compared with respondents who were provided an image of the storefront alone (24/100, 23.5%) (χ^2_2=85.5, P<.001). Similarly, nearly all respondents who were provided with cropped images reported being able to read the prices (100/104, 96.6%), while none said they could read the prices when given the storefront image alone (χ^2_2=227.6, P<.001). When provided with a cropped image of Newport nonmenthol brand cigarettes, all respondents were able to accurately identify the lowest price in the image (mean $6.34, SD 0.00). For the Newport menthol image (accurate price, $7.29), the average identified lowest price was $7.24 (SD 0.45), which was not significantly different from the accurate price (P=.31). For respondents receiving only the storefront image, the lowest identified price was significantly less than the accurate price ($6.34), (mean $2.24, SD 0.72; P<.001). The storefront image contained an advertisement of a nontobacco product at a low price ($2.59), which respondents reported instead of the lowest-priced tobacco product. It is the only condition in which the average of lowest reported prices was significantly different from the accurate prices.

Optimizing Crowd Size for Accuracy and Reliability

Data quality and reliability are of paramount importance when testing new data collection methods. Beyond improvements in feasibility and cost, a key advancement enabled by crowdsourcing is the potential to drastically improve methods for assessing interrater reliability. Reliability is improved not only because individual tasks can be simpler, but also because it is possible to collect large numbers of independent ratings. To capitalize on this methodology, a new "crowd-size resampling" approach to reliability assessment was developed.

Each MTurk task requires one to specify the desired number of raters, essentially defining the size of a simple random sample of raters drawn from the entire population of over 500,000 registered workers [18]. Because photos vary so much in quality and quantity of detail and, thus, coding difficulty, a very important challenge is that of determining the optimal number of raters needed to reach the best achievable level of accuracy regarding the contents of the photo. As is the case for any sample drawn from a population with unknown parameters, larger samples of raters will more closely approximate the actual population parameters as variance estimates decrease, while smaller samples will be more volatile. A researcher who selects a crowdsourced rater sample size that is too small risks unreliable results even when the interrater agreement is otherwise high, as smaller samples of raters will reach consensus about what is actually an incorrect answer more often than larger samples.

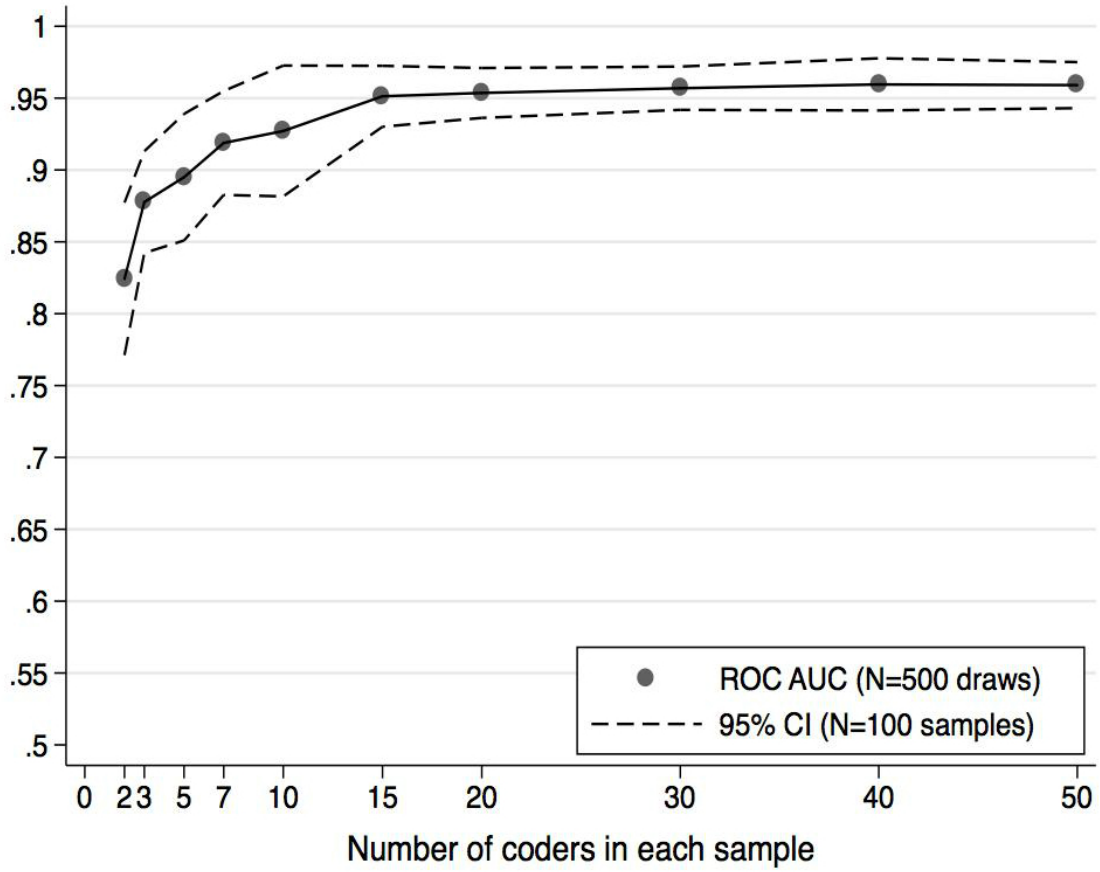
We sought to optimize crowd size by characterizing the degree of variation in accuracy among various sample sizes of raters in order to identify the point at which between-sample variation is stabilized, such that it approximated the true population level variance for a given task.

A population of 500 raters was established who all rated the same set of eight retail photographs along a number of dimensions. Jackknife resampling methods were then used to draw random subsamples of raters, beginning with 50 random samples of 2 raters, then 50 random samples of 3 raters, and so forth [19]. The ratings of each random sample of raters were evaluated relative to the ratings provided by trained field surveyors, making it possible to estimate the variance in accuracy derived from each randomly drawn sample of raters at each crowd size.

Receiver operating characteristic (ROC) regression was used to quantify the quality of this binary classification process, estimating the balance between true- and false-positive results from each photo rating task, relative to the results produced by our field surveyors [20,21]. A summary statistic called the area under the curve (AUC) was used to characterize the results from each ROC analysis. The AUC reflects the mean sensitivity, or true-positive fraction, averaged uniformly over the whole range of false positive fractions in 0,1 [20,21]. The resampling process produced pointwise CIs for the AUC at each crowd size, ultimately identifying the number of independent raters required to reliably approximate the maximum achievable AUC, given the characteristics of each given photograph and the difficulty of the question under study.

Results reveal the optimal number of raters needed to compare the quality of crowd-sourced photo-only assessments with traditional field survey data collected at all DC tobacco outlets. Beginning with exterior store-front images, raters coded each for the presence versus absence of any tobacco product advertising, the presence versus absence of tobacco advertising that also included a price, and the presence versus absence of menthol tobacco product advertising. An excellent level of correspondence between crowdsourced-rater and field-worker ratings was found, with AUC produced by sensitivity analyses averaging over 0.95 (Figure 3). Crowd size needed to reach maximum correspondence ranged, however, with the more difficult menthol item requiring a considerable number of raters, 10 to 15 total, to get the variation of consensus above an AUC of 0.90.

Figure 3. Area under the receiver-operating characteristic (ROC) curves produced by sensitivity analyses indicate an excellent level of correspondence between crowdsourced-rater and field-worker ratings.



Results

Further testing and improvement of these tools and processes is currently underway. This includes conducting systematic evaluations that crowdsource photograph annotation and methodically assess the quality of raters' work.

Discussion

Principal Findings

In the past, photos such as those described in this paper have remained uncollected or underused due to the extremely high burden of annotating images. Crowdsourcing makes it possible to access information contained within these rich data sources in a time-efficient and low-cost manner. This article describes an interface and associated methodologies used to crowdsource the annotation of photographs, including new approaches to improve the quality and reliability of this annotation.

Results from the zoom tool test suggest that the tool helps raters identify specific tobacco ads within a larger storefront photograph, particularly when paired with pictures of the product's logo to aid in identification. Similarly, the test of the crop tool indicates that the tool improves raters' ability to accurately identify the presence of cigarette product ads, as well as details about the ads, such as determining which ads are for menthol products and what tobacco product prices appear on a storefront. Finally, the ROC analysis confirms that in the context of photograph annotation, for more difficult coding targets, larger crowd sizes are likely needed to maximize the likelihood that results reflect the "emergent" accuracy available from the crowd. Methods such as the ROC analysis presented in this paper can be used in a preliminary step to estimate a reasonable crowd size to use for target types with different levels of difficulty.

Overall, results from testing the methods described here suggest that in the future, the traditional model of operationalizing manually collected field survey data as the gold standard for

comparison should be flipped, instead collecting photographs to achieve coverage of an area and then surveying some proportion of the targets for the purpose of reliability. Interestingly, this photo archive can be integrated into a longitudinal record and mined for new information in perpetuity. This formative work demonstrates the scalable, sustainable nature of this solution, transforming an otherwise unfeasible task into one that is quite attainable and sustainable.

Next Steps

Key next steps in this work include further testing and improvement of the tools and process described here, developing other tools and processes that will further enhance the quality of crowdsourced annotation, and conducting systematic studies that crowdsource photograph annotation and assess the quality of raters' work in a methodical fashion. While the work described in this paper suggests that crowdsourced photograph annotation has promise, these next steps are necessary to systematically determine the quality of data produced through this process and how it compares with other traditional methods of analyzing surveillance photographs.

Further applications of crowdsourcing to public health research present a range of exciting opportunities. Advancements are needed to move beyond simple image tagging, in which images are tagged with certain identifying words, to extract more complex information, such as calculating the size of an object relative to others in the picture, examining change across a series of pictures, detecting anomalies in an image, and so on. This is an important area for development because questions such as these are challenging in the absence of computational assistance. For instance, questions about the size of objects or areas, and especially their relative size (eg, proportion of a store-front or lunch-tray left empty), are of great interest, but also of great difficulty to raters, to the point that reliable ratings have not yet been attained.

Leveraging crowd-sized scaling to optimize reliable and valid processing of data could prove more useful than anything else crowdsourcing has to offer public health researchers and advocates. In the past, manual processing of photographic data has often proven a cost-prohibitive or otherwise insurmountable challenge. Even when an effort is made to code images, there is pressure to burden raters with as many simultaneous coding tasks as possible to maximize the amount of data that can be obtained. In contrast, crowdsourcing enables the deconstruction of research questions into many smaller tasks, thus lowering the burden of any one task and minimizing difficulty and disagreement, subsequently increasing overall reliability. Crowdsourcing also offers the scale needed to conduct repeated independent ratings of images under study. As these methodologies iteratively improve, researchers will be able to adaptively optimize task design to maximize reliability.

Lastly, there are significant opportunities to go beyond annotation and expand the use of crowd-based systems for the collection of health relevant data itself. Researchers have already coined the term "participatory sensing" to describe the collection of data using mobile phones by individuals and communities; examples include exploration of transportation and consumption habits and reporting of problems and assets in the context of civic engagement and advocacy [22]. Combined with gaming dynamics like leader boards and scavenger hunts, the crowdsourced data collection approach will likely prove highly valuable as the need for information that can guide rapid response from regulatory and relief agencies continues to grow.

Crowdsourcing Considerations

There are a number of important issues that must be considered when implementing a crowdsourced data processing project [10,23-25]. Most of these are beyond the scope of this paper, but we highlight a few that are directly relevant to the systems we have developed.

First are payment alternatives. MTurk's built-in payment mechanism enables both flat-rate and bonus payments to raters, reducing the complexity and hassle of either building or using a separate third party payment mechanism. Researchers considering other crowdsourcing platforms should ensure a user-friendly payment system is either in place or can be created. Regardless, we recommend accounting for the hourly wage that can be reasonably obtained by any rater engaging with the task at hand, rather than simply focusing on minimizing costs. Providing the opportunity for raters to obtain reasonable compensation for their time and effort attracts and retains more highly skilled raters, and thus superior results.

Secondly, it is important to consider the reputation systems within a crowdsourcing community. The provision of accurate and detailed information about the quality of raters' work has important implications for task design, especially in terms of how difficult a task can be. MTurk operationalizes reputation with a Worker HIT approval rate, which requestors can incorporate into task qualification requirements (eg, requiring that over 95% of prior HITs completed by the worker must have been accepted). The creation of more nuanced reputation systems across MTurk and other crowdsourcing platforms would likely enhance the quality of crowdsourced annotation. Reputations cut both ways, however, and research or advocacy groups must be aware of their own reputation within the crowd community when designing tasks and attempting to understand rates of completion, as well as quality and quantity of effort exerted by individual workers.

Conclusions

Ultimately, there is great potential for the use of crowdsourcing for data collection and analysis in public health research, particularly data in the form of photographs. Iterative, in-depth experimentation with platforms, approaches, and tools is necessary to optimize the crowdsourced photo annotation process and explore further use of crowdsourcing for photo collection. As these tools are optimized, they will vastly increase capacity for large-scale, fast, high-quality photograph annotation, which in turn will expand opportunities for collection and analysis of photographs rich in public health data, and thus significantly advance our understanding of environmental influences on public health.

Acknowledgments

This work was supported by the Legacy Foundation.

Conflicts of Interest

None declared.

References

1. Kirchner TR, Cantrell J, Anesetti-Rothermel A, Ganz O, Vallone DM, Abrams DB. Geospatial exposure to point-of-sale tobacco: real-time craving and smoking-cessation outcomes. Am J Prev Med 2013;45(4):379-385. [doi: 10.1016/j.amepre.2013.05.016] [Medline: 24050412]
2. Kerr J, Duncan S, Schipperijn J, Schipperjin J. Using global positioning systems in health research: a practical approach to data collection and processing. Am J Prev Med 2011;41(5):532-540. [doi: 10.1016/j.amepre.2011.07.017] [Medline: 22011426]
3. Wang C, Burris MA. Photovoice: concept, methodology, and use for participatory needs assessment. Health Educ Behav 1997;24(3):369-387. [Medline: 9158980]
4. Gao H, Barbier G, Goolsby R. Harnessing the Crowdsourcing Power of Social Media for Disaster Relief. IEEE Intell. Syst 2011;26(3):10-14. [doi: 10.1109/MIS.2011.52]
5. FEDweekIT. FEMA app aims to crowd-source emergency response. URL: http://m.fedweek.com/item-view.php?tbl=15&ID=7 [accessed 2014-01-21] [WebCite Cache ID 6MnEtDIvq]
6. Gurrin C, Qiu Z, Hughes M, Caprani N, Doherty AR, Hodges SE, et al. The smartphone as a platform for wearable cameras in health research. Am J Prev Med 2013;44(3):308-313. [doi: 10.1016/j.amepre.2012.11.010] [Medline: 23415130]
7. Cantrell J, Kreslake JM, Ganz O, Pearson JL, Vallone D, Anesetti-Rothermel A, et al. Marketing little cigars and cigarillos: advertising, price, and associations with neighborhood demographics. Am J Public Health 2013;103(10):1902-1909. [doi: 10.2105/AJPH.2013.301362] [Medline: 23948008]
8. Howe J. Wired. 2006. The rise of crowdsourcing. URL: http://www.wired.com/wired/archive/14.06/crowds.html [accessed 2014-03-28] [WebCite Cache ID 6OQ0maXNW]
9. Howe J. Crowdsourcing Blog. 2006 Jun 02. Crowdsourcing: A definition. URL: http://crowdsourcing.typepad.com/cs/2006/06/crowdsourcing_a.html [accessed 2014-01-21] [WebCite Cache ID 6MnI8V8OE]
10. Brabham DC, Ribisl KM, Kirchner TR, Bernhardt JM. Crowdsourcing applications for public health. Am J Prev Med 2014;46(2):179-187. [doi: 10.1016/j.amepre.2013.10.016] [Medline: 24439353]
11. Rashtchian C, Young P, Hodosh M, Hockenmaier J. Collecting image annotations using Amazon's Mechanical Turk. 2010 Presented at: Proceedings of the NAACL HLT 2010 Workshop on Creating Speech and Language Data with Amazon's Mechanical Turk; June 6, 2010; Los Angeles, California p. 139-147.
12. Sorokin A, Forsyth D. Utility Data Annotation with Amazon Mechanical Turk. 2008 Presented at: IEEE Computer Society Conference on Computer Vision and Pattern Recognition Workshops; June 24-26, 2008; Anchorage, Alaska p. 1-8. [doi: 10.1109/CVPRW.2008.4562953]
13. Luengo-Oroz MA, Arranz A, Frean J. Crowdsourcing malaria parasite quantification: an online game for analyzing images of infected thick blood smears. J Med Internet Res 2012;14(6):e167 [FREE Full text] [doi: 10.2196/jmir.2338] [Medline: 23196001]
14. Brady CJ, Pearson JL, Villanti AC, Kirchner T, Gupta OP, Shah CP. Rapid grading of fundus photos for diabetic retinopathy using crowdsourcing. 2014 Presented at: Association for Research in Vision and Ophthalmology Annual Meeting; 2014; Orlando, FL.
15. Hipp JA, Adlakha D, Eyler AA, Chang B, Pless R. Emerging technologies: webcams and crowdsourcing to identify active transportation. Am J Prev Med 2013;44(1):96-97. [doi: 10.1016/j.amepre.2012.09.051] [Medline: 23253658]
16. Noronha J, Hysen E, Zhang H, Gajos KZ. Platemate: Crowdsourcing Nutritional Analysis from Food Photographs. 2011 Presented at: Proceedings of the 24th Annual ACM Symposium on User Interface Software Technology; Oct 16-19, 2011; Santa Barbara, CA p. 1-12. [doi: 10.1145/2047196.2047198]
17. Amazon Mechanical Turk. 2013. FAQ – Amazon Mechanical Turk. URL: https://www.mturk.com/mturk/help?helpPage=main [accessed 2014-01-21] [WebCite Cache ID 6MnGtLYsx]
18. Amazon Mechanical Turk. 2014. Overivew of Mechanical Turk. URL: http://docs.aws.amazon.com/AWSMechTurk/latest/RequesterUI/Overviewof Mturk.html [accessed 2014-03-26] [WebCite Cache ID 6OMeH3ERE]
19. QUENOUILLE MH. Notes on bias in estimation. Biometrika 1956;43(3-4):353-360. [doi: 10.1093/biomet/43.3-4.353]
20. Pepe MS. The Statistical Evaluation of Medical Tests for Classification and Prediction. Oxford, UK: Oxford University Press, 2004; 2004.
21. Selvin E, Steffes MW, Gregg E, Brancati FL, Coresh J. Performance of A1C for the classification and prediction of diabetes. Diabetes Care 2011;34(1):84-89 [FREE Full text] [doi: 10.2337/dc10-1235] [Medline: 20855549]
22. Estrin D. Participatory sensing: applications and architecture [Internet Predictions]. IEEE Internet Comput 2010;14(1):12-42. [doi: 10.1109/MIC.2010.12]

23. Doan A, Ramakrishnan R, Halevy AY. Crowdsourcing systems on the World-Wide Web. Commun ACM 2011;54(4):86-96. [doi: 10.1145/1924421.1924442]
24. Horton JJ, Chilton LB. The Labor Economics of Paid Crowdsourcing. 2010 Presented at: The 11th ACM conference on Electronic Commerce; June 7-11, 2010; Harvard University, Massachusetts p. 209-218.
25. Zhang Y, van der Schaar M. Reputation-Based Incentive Protocols in Crowdsourcing Applications. 2012 Presented at: IEEE International Conference on Computer Communications; March 25-30, 2012; Orlando, Florida p. 2140-2148.

Abbreviations

AUC: area under the curve
HIT: Human Intelligence Task
MTurk: Mechanical Turk
ROC: receiver operating characteristic

Edited by G Eysenbach; submitted 28.01.14; peer-reviewed by A Hipp, J Bernhardt; comments to author 21.02.14; revised version received 05.03.14; accepted 13.03.14; published 09.04.14.

Please cite as:
Ilakkuvan V, Tacelosky M, Ivey KC, Pearson JL, Cantrell J, Vallone DM, Abrams DB, Kirchner TR
Cameras for Public Health Surveillance: A Methods Protocol for Crowdsourced Annotation of Point-of-Sale Photographs
JMIR Res Protoc 2014;3(2):e22
URL: http://www.researchprotocols.org/2014/2/e22/
doi:10.2196/resprot.3277
PMID:24717168

Original Paper

A Computer-Based Screening Method for Distress in Patients With Multiple Sclerosis: A Feasibility Study

Rosa E Boeschoten[1,2], MSc; Bernard MJ Uitdehaag[3,4], MD, PhD; Patricia van Oppen[1,2], PhD; Vincent de Groot[2,5], MD, PhD; Emma H Collette[6], PhD; Kim AA Bakker[3], RN; Chris H Polman[3], MD, PhD; Joost Dekker[1,2,5], PhD

[1]Department of Psychiatry, VU University Medical Center and GGZinGeest, Amsterdam, Netherlands

[2]EMGO Institute for Health and Care Research, VU University and VU University Medical Center, Amsterdam, Netherlands

[3]Department of Neurology, VU University Medical Center, Amsterdam, Netherlands

[4]Department of Epidemiology and Biostatistics, VU University Medical Center, Amsterdam, Netherlands

[5]Department of Rehabilitation Medicine, VU University Medical Center, Amsterdam, Netherlands

[6]Department of Medical Psychology, VU University Medical Center, Amsterdam, Netherlands

Corresponding Author:
Rosa E Boeschoten, MSc
Department of Psychiatry
VU University Medical Center and GGZinGeest
M1.12, 1st Fl.
AJ Ernststraat 1187
Amsterdam, 1081 HL
Netherlands
Phone: 31 20 788 4659
Fax: 31 20 788 5664
Email: r.boeschoten@ggzingeest.nl

Abstract

Background: In multiple sclerosis (MS) patients, symptoms of anxiety, depression, pain, and cognitive impairment are highly prevalent and contribute to lower wellbeing. As these physical and psychological symptoms of distress often stay unnoticed, regular screening could offer possibilities to identify and refer impaired patients to appropriate care.

Objective: The aim of our study was to pilot a new computer-based method in 43 MS patients to efficiently screen for a variety of psychological and physical symptoms of distress.

Methods: Data on feasibility and psychological and physical distress (anxiety, depression, fatigue, physical disability, cognitive functioning) were collected via a touch screen computer. Referral to psychosocial care and rehabilitation was retrospectively checked.

Results: The results demonstrated that most patients (35/40, 88%) considered the screening meaningful and the system easily usable (37/40, 93%). Average completion time of the screening was below 8 minutes. Many patients (35/40, 88%) had elevated distress levels, of whom the majority was referred.

Conclusions: These findings imply that computer-based screening for MS-related distress incorporated in clinical care is feasible and aids to identify psychological or physical needs. A randomized controlled trial with follow-up should address whether this screening method could be more effective than routine care, and whether it can improve costs and efficiency of care.

(JMIR Res Protoc 2014;3(2):e29) doi:10.2196/resprot.3098

KEYWORDS

multiple sclerosis; distress; computer-based; screening; feasibility; depression; anxiety; cognitive functioning

Introduction

Multiple sclerosis (MS) is a chronic inflammatory disease of the central nervous system that can have a great impact on a patient's life. In multiple sclerosis patients, symptoms such as depression, anxiety, fatigue, pain, and cognitive dysfunction, are highly prevalent both in early and more advanced disease stages and related to lower quality of life [1-3]. In the present study, we focus on this wide variety of physical and psychological symptoms impairing MS patients in their daily

activities, and refer to them with the umbrella term “distress”. Although treatments are available that can help to minimize some of these symptoms, still much distress remains unrecognized and untreated [2,4]. Consequently, it has been recommended that, with each visit to the neurologist or clinic, neurological nurses should screen and evaluate the level of distress in MS patients [5].

In clinical care, routine screening techniques can help to enable adequate recognition of distress and referral to appropriate care. Lately, successful initiatives of computer-assisted data collection in health care have increased. Advantages are high compliance rates, rapid completion and processing, and immediately available results [6-11]. The aim of the present study was to pilot a computer-based screening method, which can be easily incorporated into clinical care to support MS nurses in identifying psychological or physical needs of MS patients.

Methods

Patients and Procedure

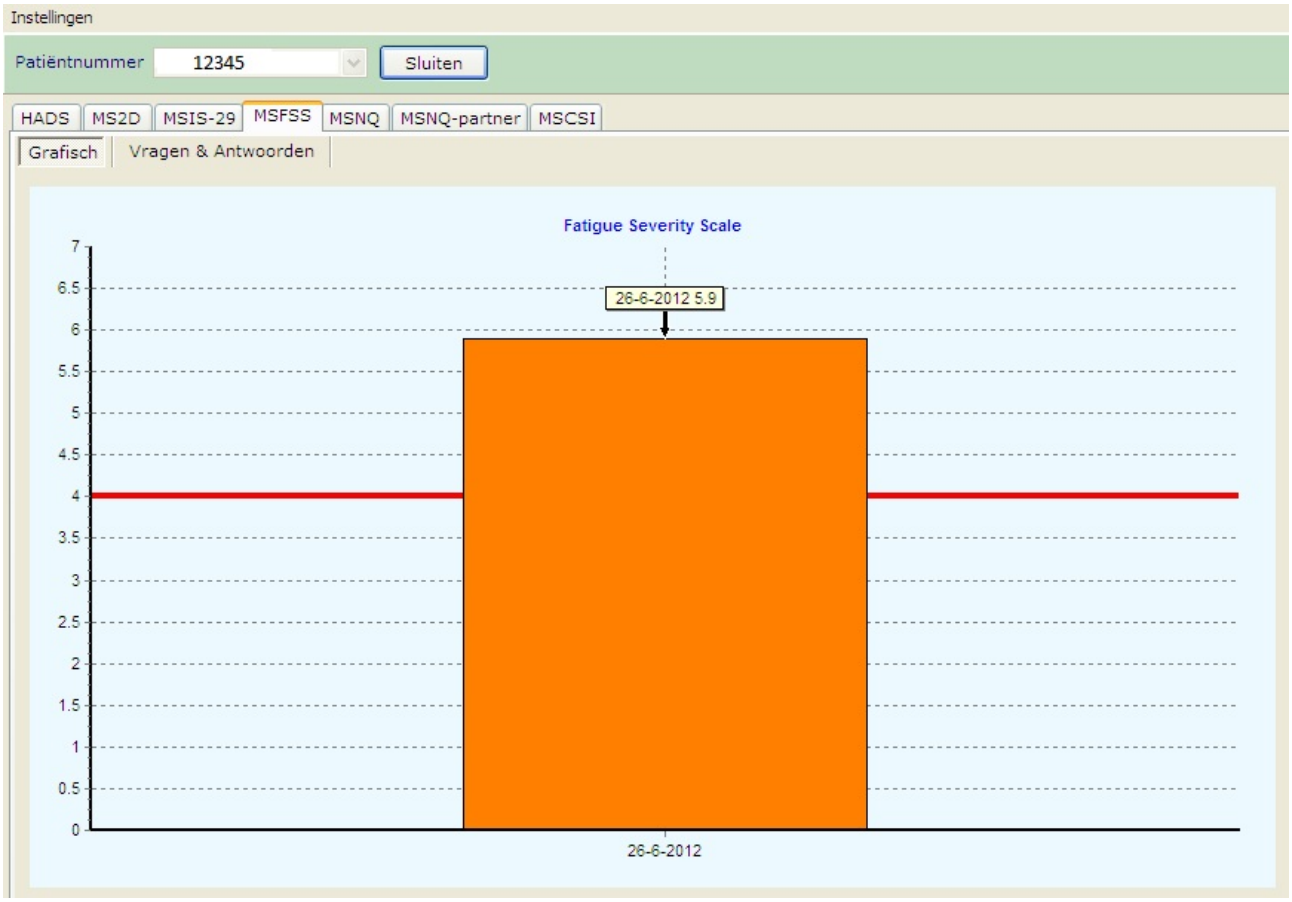
From February to August 2012, consecutive MS patients who visited the MS nurse of the Department of Neurology of the VU University Medical Center in Amsterdam, the Netherlands, were asked to complete a computer-based screening with six self-report questionnaires. Patients were mainly referred to the MS nurse by their neurologist after their first visit, a standard procedure for patients who remain under our care, or could make a request for consultation themselves. Consultation with the MS nurse was aimed at getting acquainted, providing information on MS and treatment, and discussing further assistance if required.

One week before the visit, patients were invited by telephone and letter to participate in the pilot. Fifteen minutes before the consultation, nursing staff assisted the patient to the touch screen computer in a private room to fill out the questionnaires. The patient identification number was filled in, which was linked with the hospital database that contains general data on the patient’s age, gender, and disease history. Then, questions on psychological and physical distress followed by questions on satisfaction about the screening procedure were presented to the patient on the computer screen one by one (Figure 1). The patient answered by touching the appropriate response on the screen and then moved on to the next question. More details of the software and computer system have been described elsewhere [9].

When patients finished the screening, they were assisted to visit the MS nurse in another room. By using the patient identification number, the nurse had direct access to the results that were displayed in graphs on her computer screen (Figure 2). At the end of the pilot project, the MS nurse was asked to evaluate the screening.

Figure 1. Screenshot of one of the questions of the Hospital Anxiety and Depression Scale as presented to the patient on the touchscreen (translated from Dutch to English).

Figure 2. Screenshot of the patient score on one of the questionnaires (Fatigue Severity Scale) as presented to the nurse. The red line indicates the cut-off value.



Measures

Feasibility

Compliance rate and time needed to complete the questions were recorded. Patient satisfaction regarding the system and procedure was evaluated by seven self-designed questions and a 10-point visual analogue scale (VAS). Also the MS nurse was presented with comparable questions of satisfaction on paper.

Distress

We used questionnaires that have been shown to be reliable, valid, and frequently used in clinical practice and/or research in MS. Clinical relevant cut-offs based on literature or clinical practice were used for all questionnaires. Anxiety and depression were measured with the Hospital Anxiety and Depression Scale (HADS, each subscale cut-off>7) [12], fatigue with the Fatigue Severity Scale (FSS, cut-off≥4) [13], and cognitive functioning with the Multiple Sclerosis Neurological Questionnaire (MSNQ, cut-off>27) [14]. The Multiple Sclerosis Impact Scale-29 (MSIS-29) was used to explore the impact of MS on physical (cut-off>60) and psychological wellbeing (cut-off>24) [15]. Finally, patients were asked to fill in the VAS health thermometer from the EuroQol-5D (EQ-5D). The EQ VAS self-rating records the respondent's own assessment of their health status on a vertical VAS where the endpoints are labeled "best imaginable health state" (100) and "worst imaginable health state (0)" [16].

Referral

Several weeks after the consultation, we explored patients' medical files. Referrals were retrospectively coded to social workers, psychologists, physiatrists, physiotherapists, and occupational therapists.

Results

Feasibility

Of the 43 referred patients, 2 patients did not give consent for scientific documentation and 1 was excluded because he was physically unable to complete the screening questionnaires. It took the 40 remaining patients on average 7.4 minutes (median=6.8; interquartile range=3.1) to complete the 66 questions on distress. This was evaluated as "little time" by 36 of 40 patients (90%) and the majority (37/40, 93%) reported that the equipment was easy to use and experienced the screening as meaningful (35/40, 88%). On average, the screening was graded 7.5 (range 3-10, N=38).

The MS nurse evaluated the screening positive on the VAS (7.5). She was satisfied with the quality and content, the system was easy to use and it took her little time to consult the screening data. The screening facilitated her work and helped her to more specifically focus on actual problems to be addressed, including unmentioned problems that could be overlooked easily.

Outcome Measures

For the total group (N=40), the mean HADS-score for anxiety was 8.3 (SD 3.6) and depression 5.4 (SD 3.8). Mean FSS and total MSIS-29 scores were 5.0 (SD 1.6) and 67.7 (SD 25.3), respectively. Mean MSNQ-score was 23.4 (SD 12.2). On average, patients gave their general health 66 (SD 17.7) points out of 100. A large part of patients (35/40, 88%) had scores above cut-off, indicating high levels of distress. More specifically, Figure 3 shows that 21 of 40 patients (53%) met criteria for anxiety. A remarkably lower percentage of patients met the criteria for depression (10/40, 25%). Fourteen of 40 patients (35%) had significant cognitive complaints, 10 of 40 patients (25%) experienced a high physical impact of MS, and 28 of 40 patients (70%) met criteria for significant fatigue.

Referral

Some patients reported already suitable treatment for their distress. However, Table 1 shows that the majority was referred by the MS nurse to psychosocial care or rehabilitation.

Figure 3. Percentage of MS patients (N=40) with high level of psychological or physical distress.

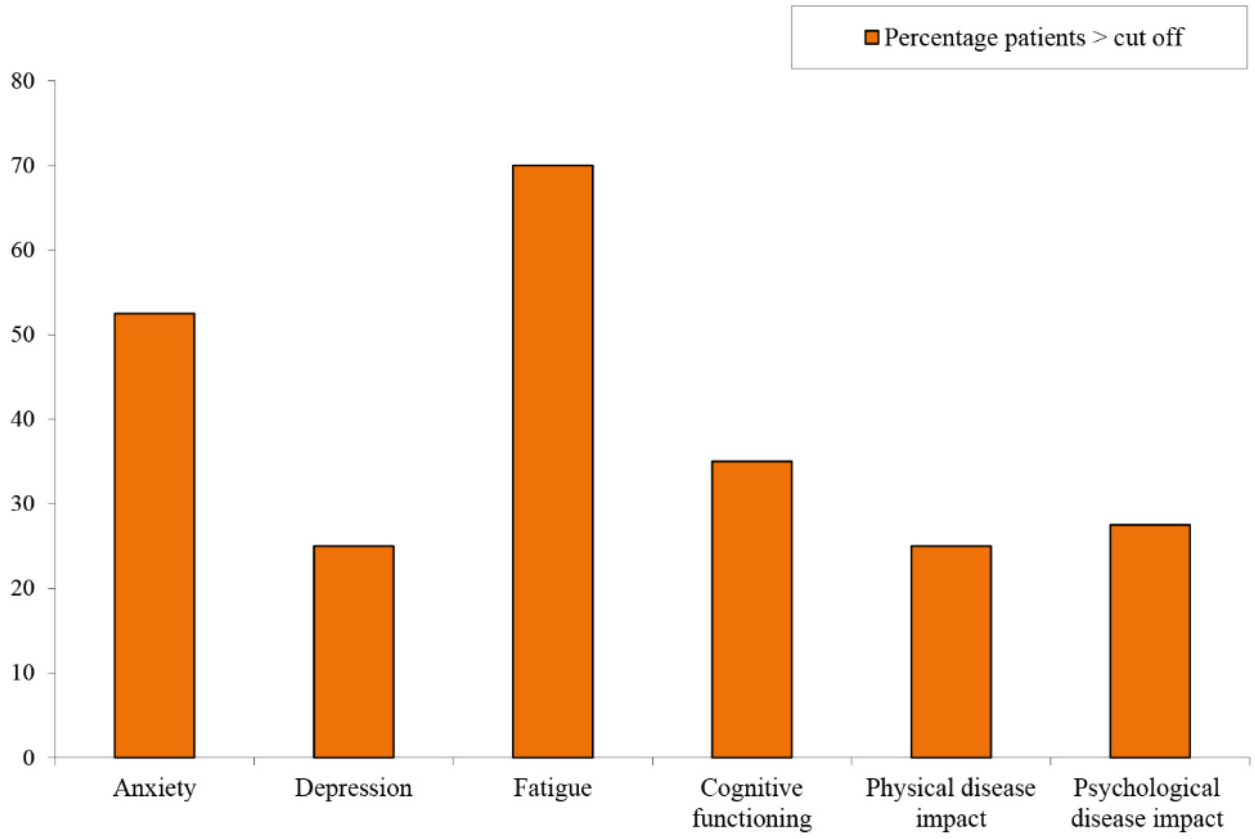


Table 1. Percentage referred and treated MS patients with low and high levels of distress (N=40).

	HADS[a]		MSIS-29[b]		FSS[c]		MSNQ[d]	
	<cut off (n=18), %	>cut off (n=22), %	<cut off (n=25), %	>cut off (n=15), %	<cut off (n=12), %	>cut off (n=28), %	<cut off (n=26), %	>cut off (n=14), %
No referral	28	18	32	7	34	18	31	7
Suitable care	17	14	12	20	8	14	19	0
Referral	55	68	56	73	58	68	50	93
Referral only	17	18	16	20	8	25	15	29
Treatment after referral	38	50	40	53	50	43	35	64

[a]Hospital Anxiety and Depression Scale, measures anxiety and depression

[b]Multiple Sclerosis Impact Scale-29, measures Physical and Psychological disease impact

[c]Fatigue Severity Scale, measures fatigue

[d]Multiple Sclerosis Neurological Questionnaire; measures cognitive functioning

Discussion

Principal Findings

This pilot study shows that computer-based screening is a feasible way to detect psychological and physical distress in MS patients in clinical care, and could support MS nurses in their work. It constitutes an easy way to administer questionnaires and processing data that can be directly available to patients and nurses. The computer-based method we demonstrated here can be easily adapted for routine screening. It would be suitable for application on personal mobile devices or via an Internet website, offering patients the possibility to complete it in their own time and pace, improving costs and efficiency of care.

Regular screening offers possibilities to identify and refer impaired patients to appropriate care as early as possible and monitor distress. Also, screening could increase patient awareness that their experienced distress can be related to MS, which might decrease barriers to request appropriate treatment. Next to clinical use, data collection could be suitable for scientific documentation.

Conclusions

MS patients appear to be willing to complete a computer-based screening. Average completion time of our assessment was comparable with similar initiatives (5-8.7 minutes) [6-8]. Many patients showed elevated levels of distress, and were referred to further care. However, the number of referred patients with minimal distress was disproportionally high. Moreover, the results do not provide us with a complete overview of prescribed medication and referrals other than psychosocial and revalidation care. In addition, whether relevant needs of MS patients are covered by this procedure is still unclear because our study concerns a pilot design using an uncontrolled unselected sample. Therefore, the findings of this study should be used with caution. A randomized controlled trial with longer follow-up should reveal whether routine screening, in comparison to routine care, is effective in detecting distress that would otherwise remain unnoticed, and results in appropriate referrals, adequate treatments, and improved distress outcomes.

Acknowledgments

This work was funded by “Fonds NutsOhra” (Grant number 0904-58). The authors thank IM Verdonck-de Leeuw and A Houffelaar for their contribution to the project.

Conflicts of Interest

None declared.

References

1. Janssens AC, van Doorn PA, de Boer JB, van der Meché FG, Passchier J, Hintzen RQ. Impact of recently diagnosed multiple sclerosis on quality of life, anxiety, depression and distress of patients and partners. Acta Neurol Scand 2003;108(6):389-395. [Medline: 14616290]
2. Goldman Consensus Group. The Goldman Consensus statement on depression in multiple sclerosis. Mult Scler 2005;11(3):328-337. [Medline: 15957516]
3. de Groot V, Beckerman H, Lankhorst GJ, Polman CH, Bouter LM. The initial course of daily functioning in multiple sclerosis: a three-year follow-up study. Mult Scler 2005;11(6):713-718. [Medline: 16320733]
4. Marrie RA, Horwitz R, Cutter G, Tyry T, Campagnolo D, Vollmer T. Comorbidity delays diagnosis and increases disability at diagnosis in MS. Neurology 2009;72(2):117-124 [FREE Full text] [doi: 10.1212/01.wnl.0000333252.78173.5f] [Medline: 18971448]
5. White CP, White MB, Russell CS. Invisible and visible symptoms of multiple sclerosis: which are more predictive of health distress? J Neurosci Nurs 2008;40(2):85-95, 102. [Medline: 18481738]
6. Millsopp L, Frackleton S, Lowe D, Rogers SN. A feasibility study of computer-assisted health-related quality of life data collection in patients with oral and oropharyngeal cancer. Int J Oral Maxillofac Surg 2006;35(8):761-764. [doi: 10.1016/j.ijom.2006.03.011] [Medline: 16697148]
7. Snoek FJ, Kersch NY, Eldrup E, Harman-Boehm I, Hermanns N, Kokoszka A, et al. Monitoring of Individual Needs in Diabetes (MIND): baseline data from the Cross-National Diabetes Attitudes, Wishes, and Needs (DAWN) MIND study. Diabetes Care 2011;34(3):601-603 [FREE Full text] [doi: 10.2337/dc10-1552] [Medline: 21266654]
8. Verdonck-de Leeuw IM, de Bree R, Keizer AL, Houffelaar T, Cuijpers P, van der Linden MH, et al. Computerized prospective screening for high levels of emotional distress in head and neck cancer patients and referral rate to psychosocial care. Oral Oncol 2009;45(10):e129-e133. [doi: 10.1016/j.oraloncology.2009.01.012] [Medline: 19362038]
9. de Bree R, Verdonck-de Leeuw IM, Keizer AL, Houffelaar A, Leemans CR. Touch screen computer-assisted health-related quality of life and distress data collection in head and neck cancer patients. Clin Otolaryngol 2008;33(2):138-142. [doi: 10.1111/j.1749-4486.2008.01676.x] [Medline: 18429869]
10. Lapshin H, Lanctôt KL, O'Connor P, Feinstein A. Assessing the validity of a computer-generated cognitive screening instrument for patients with multiple sclerosis. Mult Scler 2013;19(14):1905-1912. [doi: 10.1177/1352458513488841] [Medline: 23652217]

11. Ziemssen T, Kempcke R, Eulitz M, Großmann L, Suhrbier A, Thomas K, et al. Multiple sclerosis documentation system (MSDS): moving from documentation to management of MS patients. J Neural Transm 2013;120(suppl 1):S61-S66. [doi: 10.1007/s00702-013-1041-x] [Medline: 23728704]
12. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand 1983;67(6):361-370. [Medline: 6880820]
13. Krupp LB, LaRocca NG, Muir-Nash J, Steinberg AD. The fatigue severity scale. Application to patients with multiple sclerosis and systemic lupus erythematosus. Arch Neurol 1989;46(10):1121-1123. [Medline: 2803071]
14. Benedict RH, Munschauer F, Linn R, Miller C, Murphy E, Foley F, et al. Screening for multiple sclerosis cognitive impairment using a self-administered 15-item questionnaire. Mult Scler 2003;9(1):95-101. [Medline: 12617275]
15. Hobart J, Lamping D, Fitzpatrick R, Riazi A, Thompson A. The Multiple Sclerosis Impact Scale (MSIS-29): a new patient-based outcome measure. Brain 2001;124(Pt 5):962-973 [FREE Full text] [Medline: 11335698]
16. EuroQol Group. EuroQol--a new facility for the measurement of health-related quality of life. Health Policy 1990;16(3):199-208. [Medline: 10109801]

Abbreviations

EQ: EuroQol
FSS: fatigue severity scale
HADS: hospital anxiety and depression scale
MS: multiple sclerosis
MSIS-29: multiple sclerosis impact scale-29
MSNQ: multiple sclerosis neurological questionnaire
VAS: visual analogue scale

Edited by G Eysenbach; submitted 11.11.13; peer-reviewed by R Benedict, A Chiovetti, L Strober; comments to author 11.02.14; revised version received 07.04.14; accepted 10.05.14; published 04.06.14.

Please cite as:
Boeschoten RE, Uitdehaag BMJ, van Oppen P, de Groot V, Collette EH, Bakker KAA, Polman CH, Dekker J
A Computer-Based Screening Method for Distress in Patients With Multiple Sclerosis: A Feasibility Study
JMIR Res Protoc 2014;3(2):e29
URL: http://www.researchprotocols.org/2014/2/e29/
doi:10.2196/resprot.3098
PMID:24902042

Original Paper

An Interactive-Technology Health Behavior Promotion Program for Heart Failure Patients: A Pilot Study of Experiences and Needs of Patients and Nurses in the Hospital Setting

Rony Oosterom-Calo[1,2], MSc; Tineke A Abma[3], RN, MSc, PhD; Merel A Visse[4], MA, PhD; Wim Stut[5], MSc, PhD; Saskia J te Velde[2], MSc, PhD; Johannes Brug[2], MSc, PhD

[1]Philips Research, Briarcliff Manor, NY, United States

[2]EMGO Institute for Health and Care Research and the Department of Epidemiology and Biostatistics, VU University Medical Center, Amsterdam, Netherlands

[3]EMGO Institute for Health and Care Research and the Department of Medical Humanities, VU University Medical Center, Amsterdam, Netherlands

[4]University of Humanistic Studies, Ethics of Care, Utrecht, Netherlands

[5]Philips Research, Eindhoven, Netherlands

Corresponding Author:
Rony Oosterom-Calo, MSc
Philips Research
345 Scarborough Rd
Briarcliff Manor, NY, 10510
United States
Phone: 1 4804040717
Fax: 1 20 4448181
Email: rony.calo@philips.com

Abstract

Background: Heart failure (HF) is a chronic condition, prevalent especially among older people, characterized by acute episodes leading to hospitalization. To promote HF patients' engagement in physical activity (PA) and adherence to medication, we developed Motivate4Change: a new interactive, information and communication technology (ICT)-based health promotion program for delivery in the hospital. The development of this program was guided by the Intervention Mapping protocol for the planning of health promotion programs. The users of Motivate4Change were defined as hospitalized HF patients and hospital nurses involved in HF patient education.

Objective: Two aims were addressed. First, to explore the use of interactive technology in the hospital setting and second, to evaluate user needs in order to incorporate them in Motivate4Change.

Methods: Participant observations at a hospital in the United Kingdom and semistructured interviews were conducted with hospitalized HF patients and HF nurses following their completion of Motivate4Change. Interviews were recorded, transcribed, and analyzed according to a thematic coding approach.

Results: Seven patients and 3 nurses completed Motivate4Change and were interviewed. Results demonstrated that patient needs included empathic and contextual content, interactive learning, and support from others, including nurses and family members. The nurse needs included integration in current educational practices and finding opportunities for provision of the program.

Conclusions: The current work provides insight into user needs regarding an interactive-technology health promotion program for implementation in the hospital setting, such as Motivate4Change.

(JMIR Res Protoc 2014;3(2):e32) doi:10.2196/resprot.3188

KEYWORDS

heart failure; health promotion; interactive-technology; hospital; user needs; patients; nurses; physical activity; medication adherence

Introduction

Heart failure (HF) is a chronic cardiac condition prevalent especially among older people, characterized by acute episodes leading to hospitalization [1]. HF is usually irreversible but can be managed with medication and with nonpharmacological treatment, which includes a range of behaviors, such as dietary, physical activity (PA), self-management, and monitoring behaviors [2]. However, adherence rates to the behavioral treatment plans are suboptimal [3], which has been linked to adverse clinical outcomes [4]. There is a need for effective programs that promote the adherence of HF patients to behavioral treatment.

To promote engagement in PA and adherence to medication among patients with HF, we developed Motivate4Change: a new interactive health promotion program for delivery in the hospital (Figure 1). Patients with HF are often educated regarding self-management by HF nurses during hospitalization, and Motivate4Change was developed to assist nurses in the delivery of the education, as well as to optimize the promotion of self-management health behaviors among patients. The development of this program was guided by the Intervention Mapping protocol [5,6] for the planning of health promotion programs. Using this protocol, health promotion program planners can integrate evidence and theory in a structured manner in the planning of health promotion programs.

Figure 1. Screenshot of the main menu from Motivate4Change.

A user-centered design approach was followed in the development of the program, to incorporate user perspectives, needs, and preferences. When users are not involved, they often refrain from using a system [7]. If a program is poorly or incompletely implemented in the intended setting, or fails to reach a sufficient proportion of the target group, it may lack success [8]. The users of Motivate4Change were defined as hospitalized HF patients and hospital nurses involved in HF patient education and health promotion.

Motivate4Change was designed to educate hospitalized HF patients about PA and medication adherence, and motivate them to become more adherent to these behaviors after hospital discharge. The aim of the research is to formatively evaluate the use and experiences of patients and nurses with the program and its implementation in the hospital setting, in order to incorporate the results in a next version of Motivate4Change.

Motivate4Change consists of an introduction module, a medication adherence module, and a PA module. Within each module there are four components: (1) an introduction, (2) a list of take away messages (the key messages patients should remember from the module), (3) a video with information on medication adherence and PA that shows a “typical” HF patient, John, living his daily life and dealing with difficulties related to medication adherence and PA, and (4) assessments and feedback. Specifically, in the medication adherence module, an assessment of the patient’s knowledge on how to take medications appears first. Patients can answer the multiple choice questions by clicking a button on the tablet’s touch screen. Next, an assessment of barriers to medication adherence is presented. This assessment includes barriers of HF patients to taking medications. Finally, an assessment of beliefs about medications is presented. Next, in the PA module, an assessment of the patient’s knowledge on how to perform PA is firstly presented, followed by an assessment of barriers to PA performance. Based on their answer to each question in the assessments, patients receive tailored feedback messages.

Previous qualitative studies have been published about perspectives and experiences of older people with health technology [9,10]. One study, for example, explored reactions and perceptions to home monitoring systems of cognitive and

physical health [9], and found that older people can accept home monitoring technology, if they perceive it as valuable. In addition, qualitative studies have been published about perspectives and experiences of health technology and Web-based health applications of patients with various health conditions [11-14] including HF [15]. For example, one study showed that stroke patients found an Internet portal with information on stroke easy to use and valuable [13]. These studies show that older patients can accept technology for health promotion and management.

However, few studies have explored patient experiences with information and communication technology (ICT) in the hospital setting. There are aspects of the hospital setting that may have an impact on the experiences of patients. For instance, the patient's physical and emotional state when in the hospital [16] may influence their experiences with the program, which may influence its efficacy level. Therefore, the current work is an important addition to our understanding of the experiences with new technology-based health promotion programs for older patients in a setting that has not yet been explored, but may be used more in the future. Qualitative research is an effective approach for gaining in-depth information about topics on which there has been limited prior research [9].

When there is a lack of knowledge on a particular topic, grounded theory is a particularly useful framework to adopt as the research framework [17,18]. According to grounded theory, behavior is influenced by the context in which it takes place. In the current research, the context of the hospital setting will be studied, and the meaning of experiences and behaviors of patients and nurses in this context will be interpreted.

In sum, two aims were addressed in the current work. First, to explore the use of, and experiences with, interactive technology used in health promotion delivered in the hospital setting, and second, to evaluate user needs in order to incorporate them in Motivate4Change.

Methods

Sampling

A convenience sample of 7 patients and 3 nurses was selected from an academic hospital in the United Kingdom, which has a total of 610 beds including 42 on the cardiology ward. To select participant patients, the following inclusion criteria were applied: (1) they were hospitalized for HF, (2) they were able, cognitively and physically, to use a tablet and read the information provided in the Motivate4Change program, and (3) they did not have a medical condition (eg, an infection) that could infect the researcher. Patients awaiting valve surgery were excluded, because the behavioral recommendations for these patients may be different than for the rest of patients, depending on the outcome of the surgery. An attempt was made at achieving maximum variation, in terms of age, sex, and experience with ICT. However, the sample was restricted to patients that were hospitalized for HF at recruitment period of the study. Participant nurses were recruited based on their involvement in HF patient education and behavior change promotion during hospitalization. Only nurses who have HF patient education tasks in their role were included.

Recruitment

Recruitment to the study took place during two phases in 2012. Each phase was 1 work-week long. In each phase, to select patients meeting the inclusion criteria, a nurse reviewed the list of patients on a daily basis, and selected patients she believed met the criteria. She then approached the patients at their hospital bed, described the study, provided a patient information sheet that described the study in detail, and asked for their participation. If a patient agreed to participate, a suitable time was discussed. All nurses who met the inclusion criteria were contacted by email and asked to participate by the researcher. If they agreed, a suitable time was discussed.

Procedure

The researcher (first author) approached participant patients at the agreed time by their hospital bed, or at a separate room on the ward, depending on the preference of the participant. The researcher asked each participant to sign an informed consent form, and then provided them with Motivate4Change on a tablet and a brief explanation on how to use the program. Each participant then started the program, while the researcher sat on the ward, in the vicinity of the participant, and waited for each patient to go through the whole program. If participants had questions, these were answered by the researcher. After they had completed Motivate4Change, the researcher turned on an audio recording device and interviewed the patients according to the predefined, semistructured interview guide. Interviews lasted between 10 and 40 minutes (Table 1). The interview guide explored participants' expectations of Motivate4Change, personal assessments of the program, experiences receiving Motivate4Change on interactive technology, and possible behavior change as a result of using the program.

Observations were made by the researcher during the periods of time that participants were completing Motivate4Change, while sitting in the ward. These periods were approximately 45 minutes per patient. An observation protocol was used. Items included possibilities and obstacles for providing a health promotion tablet on the cardiology ward and potential user needs expressed nonverbally. Extensive field notes were taken during the observations periods, and if any questions arose, or if any issues required clarification, these were discussed by the researcher with the participating nurses.

The interviews with nurses were conducted at office rooms at the hospital. First, the researcher gave a brief explanation about the program and the study, then nurses were provided with the tablet and completed the Motivate4Change program, and finally structured interviews took place using a semistructured interview guide, and were recorded with an audio recording device. The interview guide explored nurses' expectations and opinions regarding use of interactive technology as a tool for health behavior promotion in the hospital, possible fit of Motivate4Change in their patient education-related workflow, and possible impact on patients.

Table 1. Participant characteristics.

Participant number/ interview length, in minutes[a]	Age	Experience with ICT[b]: PCs[c], smartphones, and tablets
Patient 1/20	58	None
Patient 2/25	75	None
Patient 3/20	76	None
Patient 4/30	71	None
Patient 5/40	75	Experience with laptop, needs help with internet
Patient 6/10	37	Experience with PC's[c], tablets and smartphones
Patient 7/40	64	Experience with tablets and smartphones but needs help using them
Nurse 1/15	48	Experience with PC's[c], smartphones and tablets
Nurse 2/20	36	Limited experiences with PC's[c], smartphones and tablets
Nurse 3/30	45+	Experience with PC's[c] and smartphones, limited experience with tablets

[a]Rounded to the nearest whole minute.

[b]Information and communication technology.

[c]Personal computers.

Analysis

Data was analyzed according to the grounded theory approach, which postulates that data collection and analysis are interrelated. The analysis of the first interviews directs the analysis of the next interviews. Therefore, the results of a study that uses this approach are achieved through an iterative process of collecting and analyzing data [18]. In order not to miss anything important, it is crucial to analyze all information and see if any new information appears that was not prospectively considered. An inductive approach to the analysis will be adopted, whereby explanations and patterns will be sought with a bottom-up approach [18].

The audio recordings of the patient and nurse interviews were transcribed. The patient interviews were analyzed separately from the nurse interviews in order to assess both perspectives. The text of the first 3 patient interviews was coded separately by 2 researchers, in order to maximize the quality of the analysis [18]. Coding the text was achieved by assigning codes to chunks of data in order to label and organize the data. First, codes were identified and created. Then, data was assigned to codes. The emerging themes were captured. Finally, codes were sorted into categories. In this stage a coding framework was developed. Codes were grouped into categories in an iterative process. This coding process was first completed for the interview transcript separately (open coding), then a process of axial coding was initiated, were material from the various transcripts was related and compared. Also, the texts from the field notes were analyzed by assigning codes to chunks of data and grouping the codes into categories, and finally capturing the emerging themes. Topics from patient interviews and from the observations were informally checked with the nurses.

Results

Patient and Nurse Participation

Seven patients completed Motivate4Change and were interviewed. The age range of patients was 37-76 (Table 1). All patients were male and had been diagnosed with HF before the current hospitalization. Patients had varying levels of experience with ICT. Twelve patients met the inclusion criteria and 4 refused to participate. One of the 8 patients who agreed to participate was sleeping when the researcher arrived at the scheduled time, and was discharged soon thereafter. Reasons for nonparticipation included participating in other studies and not wanting to participate in more studies during hospitalization and feeling upset following the recent HF diagnosis.

The analysis of all data revealed two general themes, patients' and nurses' needs. The theme "patients' needs" was divided into three subthemes, including contextual and empathic content, interactive learning, and support from others. The theme "nurses' needs" was divided into two subthemes, including integration in current educational practices and finding opportunities for provision of the program.

Patients' Needs

Contextual and Empathic Content

Participating patients have been living with HF before using the Motivate4Change program, and they viewed the information in Motivate4Change in light of their own experiences with HF management. They viewed the content as empathic as it acknowledged their emotions and own personal experiences, and contextual, since it addressed the context of their life as HF patients. Patients felt their personal situations were acknowledged in the videos and with the assessment questions and feedback, and this seemed to encourage them that PA is relevant and possible for them. For example, one patient remarked that "he [John from the video] wasn't an athlete. He was just an ordinary chap. He was doing all sorts of things"

[Patient 04], and concluded that he can start being more active after his discharge from the hospital. In addition, various pieces of information from Motivate4Change were recognized by patients based on their own physical abilities, and this acknowledgement of their abilities made them feel encouraged to perform PA in the future. A patient that has not been doing enough PA, and has been experiencing limitations that make it difficult to be physically active, recalled from the Motivate4Change content that he can build up his aerobic capacity by performing a little more activity on a daily basis. Another patient, that has been very active, recalled that he should pace himself and spread the activities throughout the day. Nurses also appreciated the contextuality of the videos and the fact that the video provides a concrete example of a HF patient engaging in the behaviors in daily life situations "to see potentially what a patient can do" [Nurse 2].

The importance of contextuality was demonstrated also in discussions about the medication adherence content. Most patients did not view this content as acknowledging their personal situation, since they indicated they are adherent to their medications and viewed Motivate4Change as more relevant for patients who are not: "Well, I think it would benefit some people, because I know some people think that they are alright and they can stick the day with one tablet" [Patient 03]. Regardless, some patients did recognize that some difficulties to taking their medications were acknowledged. For example, one patient remarked, "That bloke going out and not taking his diuretic. I know what it is like", referring to fluid retention that results from skipping a diuretic dose. Although most appreciated having a repetition of information regarding medication adherence, patients appreciated the information on medication adherence to a lesser extent than that on PA, due to the fact that it was not perceived as personally relevant.

The empathic tone of the program, which included acknowledgement of possible difficulties and emotions, evoked feelings of safety and reduced insecurity and fear. Patients indicated that HF patients can be panicked, and that Motivate4Change can help with this and help people understand they can still do things:

> *You know, people tend to […] panic! They do! I've seen them, seen lots of them! […] you say it in a nice way, you see what I mean [...] because people are so… they panic you see. Heart failure!? Oh! Panic, panic, panic! […]People are frightened. But that [Motivate4Change] is sensible. It's telling to keep going [...]. So that's right, that's a good idea then. […] you can still do this, you can still do that, you can still do more things […] and learn how to go back to the way you were. That's what you're doing with that [Motivate4Change], isn't it?* [Patient 07]

Notably, not all patients felt acknowledged by the program. One patient, who was younger than a typical HF patient (37-years old) did not perceiveMotivate4Change as relevant for him because he thought it addresses only older people. He mentioned that John, the character from the video, is an older man. Another patient, who receives home care including medication support and a physiotherapist to help with PA, did not perceive that Motivate4Change was relevant for him since his situation was not acknowledged. Likewise, participating patients commented that Motivate4Change would not be relevant for patients with cognitive and physical limitations, or depression.

> *Well, you may find an old lady that does not understand anything very much. And that gentleman there, it would be a waste of time to show him this, they can't even get him to read, he would not be into that.* [Patient 05]

Interactive Learning With ICT

The patients expressed their preferences for learning in an interactive manner. This was in comparison to being "told" what to do with traditional written materials.

> *I think that [Motivate4Change] is probably more useful to people than, you know, some of the books […] because it interacts with people, and the book doesn't ask you a question. It's just telling the things. When it's asking a question, you can think about it. If you get the answer wrong it puts you right. And if you look at the pamphlets, all they do is tell this, that, and the other, it's like reading a novel, in a sense* [Patient 05]

They perceived that interactive learning better addresses their learning needs. It provided information that is relevant for them and included less information.

> *The trouble [with the booklets] is that they try to give people complete information. It's information overload to some. […]. And some of the other pamphlets overlap quite a lot. […] So this [Motivate4Change] provides a better picture of what you need to do* [Patient 05]

Nurses appreciated the interactivity because of its potential to facilitate learning "they [patients] can get both answers, in case it is not clear in their mind what the right answer is" [Nurse 02]. Nurses also related the program to digital video discs (DVDs) provided at hospitals in the United Kingdom to post myocardial infarction (MI) patients. They remarked that Motivate4Change could work in a similar way, but they appreciated the interactive aspect in Motivate4Change, which is not available in DVDs.

> *MI patients have a lot of different DVDs, which they can watch and use […] I think for the heart failure patients they need more things. And different tools to help them […]. So, yeah, I think things like this [Motivate4Change] are great. I do really like the format.* [Nurse 02]

Nurses also made clear that a prerequisite to the provision of an interactive technology program is simplicity. They also indicated that Motivate4Change is simple:

> *you only have to switch it on and it loads on- I think it's really easy. […] You have only got one button to press* [Nurse 02]

Terms such as "straightforward", "not too complicated", "quite easy to show to people", "not too difficult for the patients" [Nurse 03], "easy to use, really easy to use", "user-friendly"

[Nurse 02] were brought up. Nurses considered simplicity to be an advantage of the program.

It was interesting that although most of the interviewed patients had a positive or neutral attitude toward the use of ICT as a means to receive health promotion information, some patients expressed a general negative attitude toward ICT. One patient, for example, commented that he has "seen some people become slaves to them [computers]" and associated computers with "not doing things" [Patient 04]. Notably, some patients viewed nurse education sessions as more interactive than ICT-based education:

> *she gives feedback when you ask a question. She answers everything and she is there for a lot longer* [Patient 06]

One patient commented that he already received information from nurses and doctors. He felt that there was no need to also get this from a computer: "you don't need a computer to tell you to walk" [Patient 02].

The nurses, however, thought Motivate4Change can facilitate the interaction that patients have with them in the educational sessions, and thereby make the sessions with them more interactive. They indicated that patients may not think of all of their questions during the face-to-face education sessions, and by using Motivate4Change patients can become triggered to ask additional questions in the sessions. The nurses indicated this is especially relevant for newly-diagnosed patients, who have little knowledge about HF and therefore no pre-existing questions to ask.

It was observed by the researcher that all patients read all of the information. When asked why he read everything in the program, one patient remarked,

> *It looked interesting. When you go further into that, it was more interesting* [Patient 01]

Which indicates that something compelled him to continue to completion. Interestingly, patients read the information regardless of whether the attitude to learning that they expressed was positive or indifferent. Specifically, some patients expressed a positive attitude toward learning:

> *Oh I am the one that ought to read everything. Not everybody does! It's just me […] Yes, I do try to learn.* [Patient 07]

Other patients were indifferent to learning about HF management. They even preferred to refrain from learning-related activities:

> *I think things like this anyways, you just look at them if you want to look at them. You know what I mean? I've always tried to avoid this business* [Patient 06]

When the researcher asked if he read the booklet that was provided to him in the past by the nurse, the patient remarked: "not all of it, but the bits that I was interested in, well, not interested in, that seemed relevant" [Patient 06], indicating that booklets were not completely read in the way the content in Motivate4Change was. This patient further indicated although he did not appreciate the content of Motivate4Change (as discussed above) he did appreciate the interactivity, and even made suggestions for additional features. The reason for completion seemed to be, therefore, the interactive aspect, which was appreciated even when the content was not.

Support From Others

Patients would need some support from nurses to engage in the program. First, they would require an explanation regarding the meaning of the program and to how to use it. All patients indicated that Motivate4Change was easy for them to use, including the patients who expressed negative attitudes toward ICT. Indeed, it was observed that all patients could use the program, although they sometimes leaned on the tablet with their hands, which caused usability issues. Some patients demonstrated insecurity by asking the researcher questions regarding how to navigate, while, in fact, clicking on the correct buttons. This might indicate that some support would be needed to reduce the insecurity.

Also, some patients remarked that it is difficult to complete the program when lying in bed, since it can cause them to lose their attention. Indeed, it was observed that patients could better interact with, and seemed more attentive, when performing the program while sitting in the chair, which was available at every bedside. Therefore, patients may need some support getting out of bed and sitting on the bedside chair, or walking to the common room on the ward.

The nurses indicated that family members could also use the program, and thereby support patients, both during the program use, as well as after discharge from the hospital. "I think families could get quite a lot of benefit from it, because they come to visit somebody […] and want to know what's happening, how easy is it for them to flip through something like this?" [Nurse 01]. They specified that some family members visit only during the late visiting hours and do not get to meet with the nurse, and Motivate4Change can be used to inform them about HF self-management.

Finally, patients would have to know that they have been diagnosed with HF and what HF is, and be ready to receive information regarding HF self-management, before receiving Motivate4Change, because, according to nurses, it could be psychologically difficult to deal with the diagnosis. Therefore, before providing the program, nurses would need to assess if patients are aware that they have HF and are ready for receiving information about HF self-management.

Nurses' Needs

Integration in Current Educational Practices

Motivate4Change was placed by patients and nurses in the context of past and future educational encounters. They discussed booklets, pamphlets, and nurse education sessions as learning materials they have previously received (patients) or used in their education sessions (nurses). Motivate4Change was viewed as a welcome addition to these materials, since it can reinforce their existing knowledge:

> *I felt that (Motivate4Change) reinforced what I've read, which is a good idea, because if somebody talks to you for a while you're not going to remember all of it. If you see it again in a book, you think "oh yes I remember that" – if you see it in a different format*

> *altogether it's another cue to your memory so it's a good idea.* [Patient 05]

Since nurses are those that provide patients with education, including the various educational materials, they discussed the need for Motivate4Change to be integrated with current educational practices. They expressed their opinion that the program could be most efficacious in conjunction with other learning materials (leaflets, booklets, face-to-face sessions), which are typically already provided to patients in current care practices.

In addition, they discussed the efficacy of home-based education provided by the community nurse. This education is provided in the context of the setting where patients actually perform PA and take their medications. Nurses recommended that this type of education would be provided in conjunction with Motivate4Change to reinforce it in a real-life setting. Patients who have already been receiving education at home viewed Motivate4Change also in relation to this type of education, and expressed their desire to keep their contact with the community nurse:

> *if I'm poorly she knows whom to phone […] yeah I still need her to come […] she checks me out, feet, breathing, everything. She makes sure my lungs are clear. She's a good nurse.* [Patient 03]

Finding Opportunities for the Provision of the Program

Finding a suitable opportunity for nurses to provide, and thereafter for patients to complete, Motivate4Change is an issue of importance to nurses. One of the nurses described how she would introduce the program:

> *You would discuss the heart failure, the condition, what's it about. Then, a little bit down the line, you would introduce that [Motivate4Change] and leave it with the patient and while you're doing that you could go off and start with another patient the basic introduction to HF and so on.* [Nurse 02]

Most patients took approximately 1 hour to complete the whole program, including both modules, but 1 patient took about 30 minutes, and another requested a break between the two modules. A few patients discussed that they would "need their time with it". According to the nurses it would be necessary for patients to be able to go through Motivate4Change on their own, as the nurse would not be able to do this with all patients individually due to time constraints. It was observed, and corroborated with information from nurses, that due to medical procedures, physician rounds, visiting hours and meal times, and the fluctuating symptoms patients may experience in the hospital, it may be challenging to find an uninterrupted period of time to complete the program during hospitalization. The researcher observed that, during the recruitment process, it was often difficult to find a time slot to administer Motivate4Change. Some patients gave their informed consent, but felt too unwell at the time the researcher arrived to administer the program, or were engaged with one of the aforementioned activities. The HF nurses suggested letting the ward nurses provide the program outside of their own working hours. This may maximize the time being spent on education, since patients would be able to become educated also when the nurses are away. If tablets were to be left on the ward, however, their placement would need to be considered. Although leaving it on the bedside table may be possible, it can fall or be stolen. In addition, it was observed that bedside tables are filled with items, and there is limited space available on them.

The nurses indicated that no added work would result if they would be using Motivate4Change as an educational tool. One of the nurses indicated that the time nurses would need to spend on training patients before using Motivate4Change would be minimal.

In sum, it was found that, regarding Motivate4Change, a health promotion program delivered on ICT in the hospital setting, patients appreciate empathic content, which acknowledges their personal situation. Patients appreciate receiving an interactive program and they are able to use such a program, even when they have limited experience with ICT. Finally, when completing a health promotion program delivered on ICT in the hospital setting, patients require some support from others, including nurses and possibly family members. Nurses require an integration of a new program in current educational practices and tools. Finding an opportunity to deliver the program to patients is a challenge for nurses, but possible ways to overcome this exist, including making the program available to patients also when HF nurses are not present on the ward.

Discussion

Aims of the Study

Two aims were addressed in the current work. First, the possible use of interactive technology-based health promotion programs in the hospital setting was explored. This investigation is especially interesting because education and health promotion via interactive technology has not been previously explored in the hospital setting, and therefore information on users' experiences is scarce. Second, we aimed to evaluate user needs in order to incorporate them in Motivate4Change. In order to obtain the most accurate information regarding user needs in relation to the environment intended for the program's use, we conducted the study in a hospital setting. Assessing user needs is a vital step in the development of innovative technologies, and if this step is not taken, the new technology may not be accepted, and therefore not taken up by the intended user population [7]. As such, researchers have called for exploration of user needs and their integration in the development of applications [19,20].

Discussion of the Findings

Acknowledgement of patients' own situation, via contextual content, was a central need for patients. By acknowledging their experiences with HF self-management, as well as the difficulties they experience, and by demonstrating how, regardless of these difficulties, health behaviors can be performed, patients felt empowered to perform the behaviors, and this empowerment motivated patients to perform them. Self-efficacy, or the perception that one is able to perform a behavior, is one of the central constructs of Social Cognitive Theory (SCT) [21]. Based on previous research, behavior change interventions for patients

with chronic diseases that focus on enhancing self-efficacy are promising [22].

When patients did not perceive that their personal situation was acknowledged, as was the case with a younger patient, they were less engaged in the program and expressed a lack of appreciation of it. It is therefore important that all individuals feel acknowledged, even those that are less "typical," although it may be difficult to achieve this. It remains to be seen if Motivate4Change is perceived as personally relevant for female and newly diagnosed patients, since all participants were male and have been living with HF previously.

Common difficulties experienced by HF patients were acknowledged in Motivate4Change by including a video with a typical HF patient as a role model. According to SCT role modeling is a strategy to increase self-efficacy, whereby seeing similar others perform certain behaviors leads to expectations about one's own efficacy in performing these behaviors [21]. Therefore, acknowledgement through a role model, as is done in Motivate4Change, is also expected to lead to an increased level of self-efficacy, and thereby behavior change. In addition, patients' personal situations were acknowledged by providing tailored feedback messages. Tailoring of health communications is a behavior change strategy in which information is provided to individuals based on the unique characteristics of those individuals [23,24]. To achieve this, people are assessed regarding characteristics of interest [23] and need to actively provide input. This approach has been found to be effective in changing health behaviors [24-26]. In addition, it requires the patients to actively interact with the program, an aspect of Motivate4Change that patients and nurses particularly appreciated.

Interactive learning was a second need for patients. Both patients and nurses thought that the interactivity aspect of Motivate4Change can facilitate learning. It should be pointed out that the interactivity in Motivate4Change was very simple and included either pressing only one button (eg, "next" to navigate to the next page) or choosing one out of two buttons to press (eg, selecting "true" or "false" to answer a question). Importantly, one of the strengths of Motivate4Change, according to nurses, was its simplicity. It was stressed that a program delivered via ICT to HF patients should be easy for patients to use.

It remains to be seen, however, if simplicity is sufficient for patients' use of the program. In the current pilot study, all patients used the program; however, it is unclear if they would have used it if the researcher was not present. Although most patients expressed positive attitudes toward using ICT during their hospital stay, and very few usability problems were observed, some insecurity regarding their ability to use Motivate4Change was expressed by patients and also observed by the researcher. Previous research on the use of telerehabilitation by chronic pain patients demonstrated that although patients may perceive benefits to using technology, insecurity in their abilities to use it may be a barrier [27]. Further research is necessary on patients' feelings of insecurity with the use of technology, the sources of this insecurity, and its potential effects on their actual use of the technologies, in order to address this issue in future programs.

A third need for patients was support in the use of the program, especially regarding the initiation of use. This support would be provided by HF nurses, since they are in charge of patient education, and it is therefore important that they appreciate Motivate4Change. The nurses interviewed in the current study welcomed Motivate4Change as a possible addition to their current educational tools. Their needs included integrating Motivate4Change in their current educational practices. Nurses discussed that they would potentially use Motivate4Change in their current educational routine and how they would integrate it in current educational practices.

It was discussed by nurses that a good option would be to also involve family members in the program, which could be an additional source of support to patients. The role of family members is central in patient self-management [28], and as such they could also potentially be involved in the process of patient motivation and activation.

Nurses viewed challenges regarding opportunities to deliver the program to patients. Possible ways to overcome this were brought up, including making the program available to patients also when nurses are not present at the hospital, so they can use it on their own. Family members may be instrumental if this option were to be pursued and their needs should therefore be explored in future research. It was observed that leaving a tablet with patients on the ward presents challenges, including location to place the tablet and safety issues. It is therefore advisable to create a solution that takes into account also the physical environment in the hospital.

Some patients discussed the importance of their connection with the nurses. They expressed a desire to keep the human contact and the ongoing support provided by the nurses. This is in line with previous research [29], which showed that some patients refused participation in a telehealth and telecare trial in part due to fear of losing their relationships with their care providers. Patients also regarded the education provided by nurses to be more interactive than the education provided by Motivate4Change. Interpersonal health communication, such as face-to-face educational sessions provided by nurses, is the most individualized form of health communication [23]. However, it also requires the highest level of assessment of individuals [23], which could mean it is more labor-intensive, and therefore more costly, than tailored health communication. It remains to be seen how to combine education and health promotion strategies, which are ICT-based with those provided by health care providers in a manner that is appreciated by most patients.

Strengths and Limitations

The current work provides insight into possible acceptance and use of Motivate4Change. Scant information about the acceptance and use by patients and nurses of ICT-based health promotion programs in the hospital setting is available to date. Qualitative research methods are well suited to address this topic, since they allow exploring issues on which there is little information [18] because in the context of a qualitative study it is possible

to ask patients to describe their experiences and provide feedback, rather than to use a predefined questionnaire, requiring a priori assumptions on behalf of the researcher [18]. In addition, the current study was conducted in the natural environment where usage of the program would occur. This can lead to rich information and reveal aspects that would not be uncovered if the researcher does not take part in the environment to truly understand it [18]. Moreover, three sources of information were used to reach conclusions, including interviews with patients and nurses, and observations. In this manner, a higher level of confidence in the results is reached.

However, the sample size was relatively small and the research was conducted in one specific setting, making it difficult to generalize the results. Since the recruitment of potential participants was limited to patients hospitalized during the recruitment period, the sample included only male patients that were experienced with HF. In addition, it is difficult to make concrete conclusions regarding the effects of Motivate4Change. An additional investigation, in the form of a clinical trial with quantitative results, is necessary to investigate the effects of the program on patients' behavior and on clinical outcomes.

Acknowledgments

The authors would like to thank the patients and nurses who participated in this study for their time and valuable contributions. The authors would also like to thank Frederike Fransen for her contributions to the data collection and analysis process. We would also like to thank Paul ten Brink for his dedicated contributions to Motivate4Change. Finally, the authors would like to thank Aleksandra Tesanovic for her consulting and support during the study set up and design process. Motivate4Change is a research prototype.

Conflicts of Interest

None declared.

References

1. Kannel WB. Incidence and epidemiology of heart failure. Heart Fail Rev 2000;5(2):167-173. [doi: 10.1023/A:1009884820941] [Medline: 16228142]
2. McMurray J, Adamopoulos S, Anker S, Auricchio A, Böhm M, Dickstein K, ESC Committee for Practice Guidelines. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012: the Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC. Eur Heart J 2012;33(14):1787-1847 [FREE Full text] [doi: 10.1093/eurheartj/ehs104] [Medline: 22611136]
3. van der Wal MH, Jaarsma T. Adherence in heart failure in the elderly: problem and possible solutions. Int J Cardiol 2008;125(2):203-208. [doi: 10.1016/j.ijcard.2007.10.011] [Medline: 18031843]
4. van der Wal MH, van Veldhuisen DJ, Veeger N, Rutten F, Jaarsma T. Compliance with non-pharmacological recommendations and outcome in heart failure patients. Eur Heart J 2010;31(12):1486-1493 [FREE Full text] [doi: 10.1093/eurheartj/ehq091] [Medline: 20436049]
5. Parcel GS, Kok G, Gottlieb NH. Planning health promotion programs: an intervention mapping approach. San Francisco, CA: Jossey-Bass; 2006.
6. Kok G, Schaalma H, Ruiter RA, van Empelen P, Brug J. Intervention mapping: protocol for applying health psychology theory to prevention programmes. J Health Psychol 2004;9(1):85-98. [doi: 10.1177/1359105304038379] [Medline: 14683571]
7. Johnson CM, Johnson TR, Zhang J. A user-centered framework for redesigning health care interfaces. J Biomed Inform 2005;38(1):75-87. [doi: 10.1016/j.jbi.2004.11.005] [Medline: 15694887]
8. Saunders RP, Evans MH, Joshi P. Developing a process-evaluation plan for assessing health promotion program implementation: a how-to guide. Health Promot Pract 2005;6(2):134-147. [doi: 10.1177/1524839904273387] [Medline: 15855283]
9. Wild K, Boise L, Lundell J, Foucek A. Unobtrusive in-home monitoring of cognitive and physical health: reactions and perceptions of older adults. J Appl Gerontol 2008;27(2):181-200 [FREE Full text] [doi: 10.1177/0733464807311435] [Medline: 19165352]
10. Demiris G, Rantz M, Aud M, Marek K, Tyrer H, Skubic M, et al. Older adults' attitudes towards and perceptions of "smart home" technologies: a pilot study. Med Inform Internet Med 2004;29(2):87-94. [doi: 10.1080/14639230410001684387] [Medline: 15370989]
11. Gerhards SA, Abma TA, Arntz A, de Graaf LE, Evers SM, Huibers MJ, et al. Improving adherence and effectiveness of computerised cognitive behavioural therapy without support for depression: a qualitative study on patient experiences. J Affect Disord 2011;129(1-3):117-125. [doi: 10.1016/j.jad.2010.09.012] [Medline: 20889214]
12. ten Napel-Schutz MC, Abma TA, Bamelis L, Arntz A. Personality disorder patients' perspectives on the introduction of imagery within schema therapy: a qualitative study of patients' experiences. Cognitive and Behavioral Practice 2011;18(4):482-490. [doi: 10.1016/j.cbpra.2011.04.005]

13. Rochette A, Korner-Bitensky N, Tremblay V, Kloda L. Stroke rehabilitation information for clients and families: assessing the quality of the StrokEngine-Family website. Disabil Rehabil 2008;30(19):1506-1512. [Medline: 19230119]
14. Nijland N, van Gemert-Pijnen J, Boer H, Steehouder M, Seydel ER. Evaluation of internet-based technology for supporting self-care: problems encountered by patients and caregivers when using self-care applications. J Med Internet Res 2008;10(2):e13 [FREE Full text] [doi: 10.2196/jmir.957] [Medline: 18487137]
15. Seto E, Leonard KJ, Cafazzo JA, Barnsley J, Masino C, Ross HJ. Perceptions and experiences of heart failure patients and clinicians on the use of mobile phone-based telemonitoring. J Med Internet Res 2012;14(1):e25 [FREE Full text] [doi: 10.2196/jmir.1912] [Medline: 22328237]
16. Giuli C, Spazzafumo L, Sirolla C, Abbatecola AM, Lattanzio F, Postacchini D. Social isolation risk factors in older hospitalized individuals. Arch Gerontol Geriatr 2012;55(3):580-585. [doi: 10.1016/j.archger.2012.01.011] [Medline: 22349007]
17. Corbin J, Strauss A. Grounded theory research: procedures, canons, and evaluative criteria. Qual Sociol 1990;13(1):3-21. [doi: 10.1007/BF00988593]
18. Holloway I. Qualitative research in health care: edited by Immy Holloway. Maidenhead, England: Open University Press; 2005.
19. Arnhold M, Quade M, Kirch W. Mobile applications for diabetics: a systematic review and expert-based usability evaluation considering the special requirements of diabetes patients age 50 years or older. J Med Internet Res 2014;16(4):e104 [FREE Full text] [doi: 10.2196/jmir.2968] [Medline: 24718852]
20. Grindrod KA, Li M, Gates A. Evaluating user perceptions of mobile medication management applications with older adults: a usability study. JMIR Mhealth Uhealth 2014;2(1):e11. [doi: 10.2196/mhealth.3048]
21. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. Psychol Rev 1977;84(2):191-215. [Medline: 847061]
22. Marks R, Allegrante JP, Lorig K. A review and synthesis of research evidence for self-efficacy-enhancing interventions for reducing chronic disability: implications for health education practice (part II). Health Promot Pract 2005;6(2):148-156. [doi: 10.1177/1524839904266792] [Medline: 15855284]
23. Kreuter M, Farrel D, Olevitch L, Brennen L. Tailoring health messages: customizing communication with computer technology. Mahwah, NJ: Routledge; 2000.
24. Brug J, Oenema A. Campbell M: past, present, and future of computer-tailored nutrition education. Am J Clin Nutr 2003;77(4 Suppl). [Medline: 12663313]
25. Noar SM, Benac CN, Harris MS. Does tailoring matter? Meta-analytic review of tailored print health behavior change interventions. Psychol Bull 2007;133(4):673-693. [doi: 10.1037/0033-2909.133.4.673] [Medline: 17592961]
26. Broekhuizen K, Kroeze W, van Poppel MN, Oenema A, Brug J. A systematic review of randomized controlled trials on the effectiveness of computer-tailored physical activity and dietary behavior promotion programs: an update. Ann Behav Med 2012;44(2):259-286 [FREE Full text] [doi: 10.1007/s12160-012-9384-3] [Medline: 22767052]
27. Cranen K, Drossaert CH, Brinkman ES, Braakman-Jansen AL, Ijzerman MJ, Vollenbroek-Hutten MM. An exploration of chronic pain patients' perceptions of home telerehabilitation services. Health Expect 2012;15(4):339-350. [doi: 10.1111/j.1369-7625.2011.00668.x] [Medline: 21348905]
28. Fisher L, Weihs KL. Can addressing family relationships improve outcomes in chronic disease? Report of the National Working Group on Family-Based Interventions in Chronic Disease. J Fam Pract 2000;49(6):561-566. [Medline: 10923558]
29. Sanders C, Rogers A, Bowen R, Bower P, Hirani S, Cartwright M, et al. Exploring barriers to participation and adoption of telehealth and telecare within the Whole System Demonstrator trial: a qualitative study. BMC Health Serv Res 2012;12:220 [FREE Full text] [doi: 10.1186/1472-6963-12-220] [Medline: 22834978]

Abbreviations

DVD: digital video disc
HF: heart failure
ICT: information and communication technology
MI: myocardial infarction
PA: physical activity
PC: personal computer
SCT: social cognitive theory

Edited by G Eysenbach; submitted 23.01.14; peer-reviewed by D Patterson, J Hanley; comments to author 28.04.14; revised version received 27.05.14; accepted 02.06.14; published 19.06.14.

Please cite as:
Oosterom-Calo R, Abma TA, Visse MA, Stut W, te Velde SJ, Brug J
An Interactive-Technology Health Behavior Promotion Program for Heart Failure Patients: A Pilot Study of Experiences and Needs of Patients and Nurses in the Hospital Setting
JMIR Res Protoc 2014;3(2):e32
URL: http://www.researchprotocols.org/2014/2/e32/
doi:10.2196/resprot.3188
PMID:24945160

Original Paper

Use of a Google Map Tool Embedded in an Internet Survey Instrument: Is it a Valid and Reliable Alternative to Geocoded Address Data?

Sharoda Dasgupta[1], MPH; Adam S Vaughan[1], MPH, MS; Michael R Kramer[1], PhD; Travis H Sanchez[1], DVM, MPH; Patrick S Sullivan[1], DVM, PhD

Department of Epidemiology, Rollins School of Public Health, Emory University, Atlanta, GA, United States

Corresponding Author:
Sharoda Dasgupta, MPH
Department of Epidemiology
Rollins School of Public Health
Emory University
1518 Clifton Rd NE
Mailstop: 1518-002-4AA
Atlanta, GA, 30322
United States
Phone: 1 404 727 2773
Fax: 1 404 712 8392
Email: sdasgu4@emory.edu

Abstract

Background: Men who have sex with men (MSM) in the United States are at high risk for human immunodeficiency virus (HIV) and poor HIV related outcomes. Maps can be used to identify, quantify, and address gaps in access to HIV care among HIV-positive MSM, and tailor intervention programs based on the needs of patients being served.

Objective: The objective of our study was to assess the usability of a Google map question embedded in a Web-based survey among Atlanta-based, HIV-positive MSM, and determine whether it is a valid and reliable alternative to collection of address-based data on residence and last HIV care provider.

Methods: Atlanta-based HIV-positive MSM were recruited through Facebook and from two ongoing studies recruiting primarily through venue-based sampling or peer referral (VBPR). Participants were asked to identify the locations of their residence and last attended HIV care provider using two methods: (1) by entering the street address (gold standard), and (2) "clicking" on the locations using an embedded Google map. Home and provider addresses were geocoded, mapped, and compared with home and provider locations from clicked map points to assess validity. Provider location error values were plotted against home location error values, and a kappa statistic was computed to assess agreement in degree of error in identifying residential location versus provider location.

Results: The median home location error across all participants was 0.65 miles (interquartile range, IQR, 0.10, 2.5 miles), and was lower among Facebook participants (P<.001), whites (P<.001), and those reporting higher annual household income (P=.04). Median home location error was lower, although not statistically significantly, among older men (P=.08) and those with higher educational attainment (P=.05). The median provider location error was 0.32 miles (IQR, 0.12, 1.2 miles), and did not vary significantly by age, recruitment method, race, income, or level of educational attainment. Overall, the kappa was 0.20, indicating poor agreement between the two error measures. However, those recruited through Facebook had a greater level of agreement (κ=0.30) than those recruited through VBPR methods (κ=0.16), demonstrating a greater level of consistency in using the map question to identify home and provider locations for Facebook-recruited individuals.

Conclusions: Most participants were able to click within 1 mile of their home address and their provider's office, and were not always able to identify the locations on a map consistently, although some differences were observed across recruitment methods. This map tool may serve as the basis of a valid and reliable tool to identify residence and HIV provider location in the absence of geocoded address data. Further work is needed to improve and compare map tool usability with the results from this study.

(JMIR Res Protoc 2014;3(2):e24) doi:10.2196/resprot.2946

KEYWORDS

HIV; geographic mapping; survey; validity; reliability

Introduction

Internet-Based Questionnaires

Internet-based questionnaires have become more popular as a mode of data collection because of the expansive connectivity of individuals in the United States to the Internet overall, and across different social strata, such as education and income [1-3]. Internet-based sampling and data collection have become more practical over the years, as they have the potential to increase responses rates through improved convenience of participation, improved quality of data through programmed validated checks, and decreased costs associated with printing and postage in sending paper-based questionnaires [4,5].

In the context of human immunodeficiency virus (HIV) research, Web-based surveys may provide a sense of anonymity for men who have sex with men (MSM) in the United States, potentially reducing misclassification bias for sensitive questions pertaining to risky sexual behavior and history of HIV testing, diagnosis, and care engagement patterns [4]. Internet recruitment is also an attractive option in studies of MSM who are at high risk for HIV or poor HIV related outcomes. In a longitudinal study conducted by author PSS, 432/483 (89.4%) Atlanta-based MSM, recruited primarily through venue-based sampling, reported using Facebook, Twitter, or another social media site in the previous six months; 328/483 (67.9%) accessed such sites at least once a day (oral personal communication with Nicole Luisi, MPH, and Eli Rosenberg, PhD, July 2013). Further, a meta-analysis showed that an estimated 40% of MSM in the United States reported finding sex partners on the Internet [6]. Finding partners on the Internet may be associated with an increased risk of unprotected anal intercourse [6-8], and potentially sexually transmitted infections such as HIV [9].

Geographic Information Systems

Recently, there has been a growing emphasis on how certain contextual factors can affect disease; specifically, trends in disease incidence or prevalence, or potential predictors of poor outcomes, may vary based on an individual's environment or setting. Quantifying such differences across neighborhoods and community level factors using a geographic information systems (GIS)-based approach can impact public health programs and policy [10,11]. In the context of HIV, maps may be important in discerning hot spots of disease, high risk behaviors, such as illicit drug use and unprotected sex, and the level of health care access and utilization once diagnosed. GIS analyses can also examine how certain neighborhood level characteristics affect the dynamics of HIV transmission and patterns in HIV care engagement, which may lead to tailored interventions based on individual characteristics and needs [12,13]. For instance, using maps to quantify accessibility (in relation to proximity to different health services) may be helpful in identifying and addressing gaps in access to care, and tailoring intervention programs based on the needs of the patients being served [14].

However, map tools embedded in Internet surveys used to identify key locations for study participants are not widely used currently, and to our knowledge, have never been evaluated for usability in the context of validity and reliability. In the absence of address data, the development of a valid and reliable map tool to identify key locations, such as patient's residence and location of the patient's HIV care provider office, may be important in quantifying place-based barriers to care attendance, including travel distance and proximity to public transportation. Alternatively, such a map tool can be used to identify where people test for HIV or might be finding high risk sex partners (it may not be easy to obtain a valid address for the latter location). Even given a known address, however, automated geocoding systems vary in the degree of accuracy, result in nonnormally distributed errors, and may be less accurate outside of urban areas [15,16].

We conducted a cross-sectional study of Atlanta-based, HIV-positive MSM, called "The Engage Study", to explore potential place-based barriers to care, including proximity to HIV care provider and neighborhood level characteristics, such as socioeconomic status (SES). In this analysis, we assess the level of usability of a Google map question embedded in a Web-based survey, and determine whether it is a valid and reliable alternative to a geocoded address in identifying residence and last attended HIV care provider.

Methods

Study Population

The Engage Study is a cross-sectional study of self-identifying HIV-positive MSM living in the Atlanta area. The study was designed to examine potential structural and psychosocial barriers to accessing HIV care and treatment. Men were recruited from October 2012 to June 2013 through two sources: (1) based on participation in prior studies of MSM conducted by Emory University, and (2) from Facebook.

Men documented to be HIV-positive through HIV testing in two other Emory-based studies of MSM were recontacted by phone and email for participation in The Engage Study. These two prior studies aimed to examine racial/ethnic differences in black and white HIV epidemics in Atlanta, so only black and white MSM were eligible to participate in these two studies. Participants from the two studies were originally recruited in Atlanta, primarily through venue-based sampling or peer referral (VBPR). Men who agreed to participate in the present study were sent an email with a link that directed them to the eligibility screener and informed consent form.

Facebook advertisements for the study were targeted toward men who were interested in other men and lived within 50 miles of Atlanta. Those who clicked on the advertisement were directed to the survey and presented with a Web-based eligibility screener (including assessment of self-reported HIV status) and informed consent form. Men recruited from Facebook were not restricted by race. However, since very few Facebook-recruited

participants reported another race, those who did not identify as black or white were excluded from all analyses to avoid sparsely populated data by race and maintain comparable groups across recruitment method.

Men from both methods of recruitment were deemed eligible to participate in the present study if they reported being at least 18 years of age, ever having sex with another man, being told they are HIV-positive by a health care provider, and currently living in the Atlanta area. All consenting participants were directed to the one-time, Web-based survey instrument, administered using the Internet survey software platform, SurveyGizmo [17]. Participants were asked to take the survey on a personal computer or tablet to minimize issues with the display and layout of the questionnaire that might have occurred on a smartphone or simple mobile device. The Emory University Institutional Review Board approved the protocol (approval number, IRB00060430).

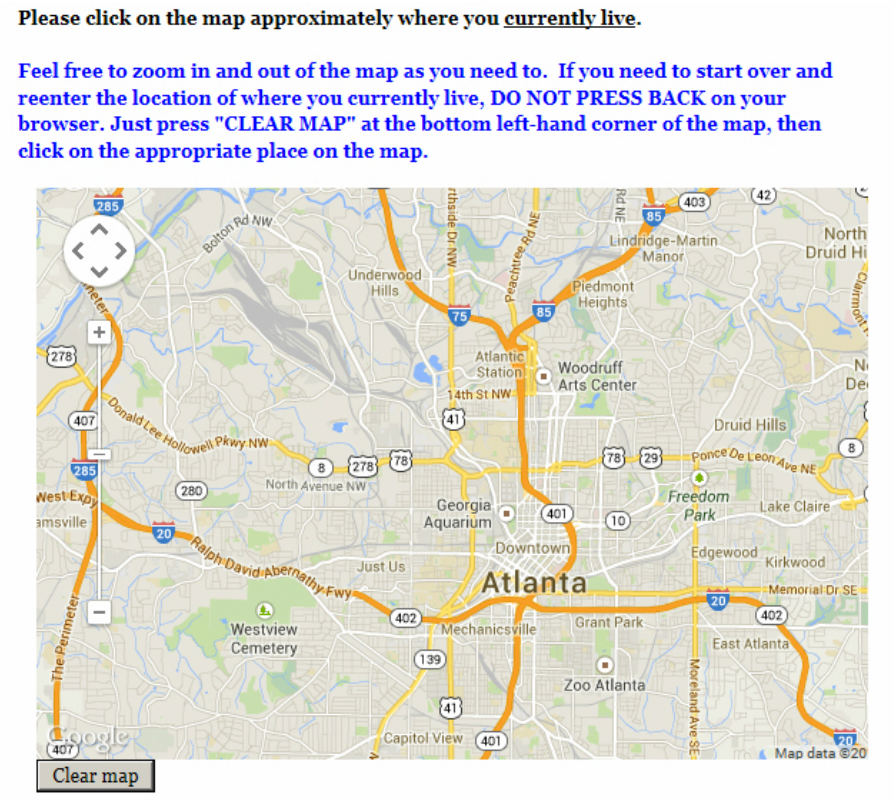
Measures

The questionnaire collected detailed information on demographic characteristics, where participants lived and sought HIV care and potential structural and psychosocial barriers to HIV care engagement, such as transportation, travel distance, and HIV related stigma. For two key locations, their home and the provider or clinic where they last received HIV care, respondents were asked to provide location information in two ways: (1) using a text address field (or name of the provider or clinic, to allow research staff to find the street address), and (2) by clicking on the location in the Google map embedded in the survey.

For their residential location, participants first entered address data using text fields for street address, city, state, and zip code. Next, they were asked to click on their residential location on a Google map embedded in the survey. For the HIV care provider location, respondents first selected from a checkbox menu of providers located in, or close to, Atlanta, based on information from the Southeast AIDS Training and Education Center (SEATEC) Key Contacts booklet [18]. Addresses for each of these HIV care providers were also available in the SEATEC booklet. If participants reported receiving care from a provider outside of the SEATEC network (eg, a private infectious diseases provider practice), they were asked to report the name of their doctor and the address or area of town where his or her office was located. The research staff then determined the exact address of the provider's office. Next, participants clicked on the approximate location of their provider's office using the Google map.

Detailed instructions on how to specify a location on the map were provided in each map question. Address and map derived locations were collected independently (ie, the physical address provided in one section did not change the initial map focus for the map derived location). The map allowed the user to zoom in as much as needed to click on the appropriate location, but the initial zoom level allowed users to view major streets in Atlanta (approximately 1:127,000, or an inch representing approximately 2 miles). Participants had the option to clear the map and click on another point on the map, if they incorrectly identified the location. Figure 1 shows a screen shot of this survey question.

Figure 1. A screenshot of a survey question used to identify, using the Google map, the location of residence among a convenience sample of HIV-positive men who have sex with men, Atlanta, Georgia, 2012-2013. A similar survey question was used to identify the location of each participant's HIV health provider's office.



Analytic Methods

Using the residential address and the address of the attended HIV care provider or clinic as gold standards, we assessed the validity of using map derived information by examining how the locations specified using map-based technology differed from the gold standard locations. Further, to assess reliability, we examined the consistency in the level of error in identifying residential location versus the location of the most recent HIV care provider. All analyses were restricted to participants who were of black or white race, did not report being homeless at the time of the survey, and lived more than 50 miles away from the center of Atlanta, and were conducted using ArcGIS 10.1 and SAS 9.3.

Descriptive Statistics

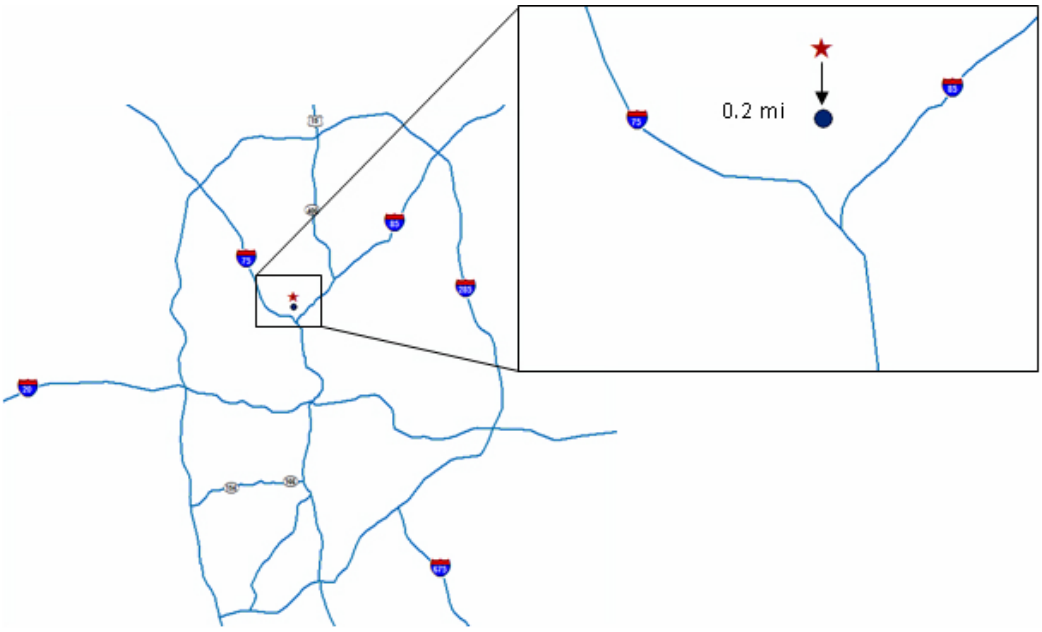
Descriptive statistics for demographic characteristics of respondents were computed using counts and frequencies. Differences in demographic characteristics were evaluated across recruitment method using the Mantel-Haenszel chi-square test.

Analysis of Validity

Respondents' text-based residential and HIV care provider addresses were geocoded (defined by geographic coordinates corresponding to address data) [19] using ArcGIS 10.1. Geocoded addresses and the latitude and longitude coordinates corresponding to the clicked map points for both the residence and HIV care provider were then mapped (using the North American Albers Equal Area Conic projection) [19], and geodesic distances (the shortest distance between two points on a sphere or curved surface) between the address data ("the gold standard") and the clicked map coordinates were calculated. These geodesic distances represent the "error" between the gold standard location and where participants identified them to be on a Google map. Figure 2 shows a visual example of this calculation. To distinguish between the residential and HIV care provider validation analyses in this paper, we will refer to the comparison of map-based versus gold standard locations for patient's residence as home location error, and the comparison of map-based versus gold standard locations for last attended HIV care provider as provider location error.

We computed descriptive statistics for the two primary outcomes (home and provider location errors) using medians and interquartile ranges (IQR), because both were continuous, but nonnormally distributed. Because we hypothesized, a priori, that participants have a greater Internet literacy and might be better able to navigate through the map questions, we assessed differences in the home and provider location errors across both recruitment method and demographic characteristics using the Wilcoxon-Mann-Whitney test. An alpha cutoff of 0.05 determined statistical significance.

Figure 2. A visual example of how home and provider location errors were calculated among The Engage Study participants in Atlanta, Georgia. The starred point represents the gold standard, geocoded address, and the dot is where the participant perceived the location to be on the map. Geodesic distance (the shortest distance between two points, or "as the crow flies") was then computed between these two points.



Analysis of Reliability

To examine whether home and provider location errors were consistent within participants, the provider location error values were plotted against home location error values; results were stratified by recruitment method. Further, geodesic distances were dichotomized as either less than one mile or at least one mile, and a kappa statistic was computed to assess "agreement" or "reliability" of degree of error in identifying the patient's residential location versus the HIV care provider location. A kappa statistic less than or equal to 0.20 indicated poor agreement, 0.21-0.40 indicated fair agreement, 0.41-0.60 indicated moderate agreement, and greater than 0.60 indicated substantial agreement [20] of degree of error in identifying the residential location versus the provider location. In this portion of the analysis, we hypothesized, a priori, that the residential and provider location errors are consistent within each participant and expect at least fair to moderate agreement between the two measures.

Results

Descriptive Statistics

Out of the 293 HIV-positive, VBPR-recruited MSM who agreed to be recontacted for other research studies, 131 (44.7%) participated. Approximately 40,000 Facebook users were targeted for recruitment based on the criteria described above, out of which 82 (0.21%) met the eligibility criteria and participated in the study. Thus, a total of 213 self-identifying HIV-positive MSM participated in The Engage Study. There were 3 (1.4%) participants that were excluded from all analyses because they lived more than 50 miles outside Atlanta. For the home location error analysis, 35/210 (16.7%) participants were further excluded because they did not respond to the map-click question to identify their residential location, 27/210 (12.9%) participants were excluded because they did not report a valid text version of the home address, and 6/210 (2.9%) participants were excluded because both of these were missing. Thus, out of 210 participants living in the Atlanta area, 142 (67.6%) were included in the patient's home error analysis. For the HIV care provider location error analysis, 8/210 (3.8%) participants were excluded because they reported never receiving HIV care, 33/210 (15.7%) participants were excluded because they did not complete the map click question to identify their provider location, 12/210 (5.7%) participants were excluded because they listed a provider whose office location could not be geocoded, and 3/210 (1.4%) participants were excluded because neither provider address nor clicked points were available. As such, 154/210 (73.3%) respondents were included in the HIV care provider error analysis. A total of 112 (53.3%) out of the 210 participants living within 50 miles of Atlanta completed all four questions related to their home and HIV care provider locations and were used in the analysis of reliability.

The distribution of demographic characteristics of study participants is described in Table 1. Median age of participants was 34 years old. Almost half of the participants reported an annual household income of less than US $20,000, a majority of participants reported being of black/African American race, and about a third of the sample reported having a college degree. Demographic characteristics varied across method of recruitment.

Table 1. Demographic characteristics and error distances among a convenience sample of HIV-positive MSM, overall and by recruitment method, Atlanta, Georgia, 2012-2013.

		All participants (N=210) number (%)[a]	Internet recruitment (n=81) number (%)[a]	VBPR recruitment (n=129) number (%)[a]	*P* [b]
Age					<.001
	18-35 years	117 (55.7)	24 (29.6)	93 (72.1)	
	> 35 years	93 (44.3)	57 (70.4)	36 (27.9)	
Race					<.001
	White/Caucasian	73 (36.9)	45 (63.4)	28 (22.0)	
	Black/African American	125 (63.1)	26 (36.6)	99 (78.0)	
Household income					<.001
	< US $20,000 / year	111 (54.4)	31 (38.8)	80 (64.5)	
	> US $20,000 / year	93 (45.6)	49 (61.2)	44 (35.5)	
Education					.06
	High school education or less	41 (19.7)	14 (17.5)	27 (21.1)	
	Some college, associate's degree, and/or technical school	99 (47.6)	33 (41.3)	66 (51.6)	
	College, post graduate, or professional school	68 (32.7)	33 (41.3)	35 (27.3)	
Location type [c]					
	Home location error	142 (67.6)	63 (77.8)	79 (61.2)	.01
	Provider location error	154 (73.3)	57 (70.4)	97 (75.2)	.44

[a]Whole percentages may not sum to 100 due to rounding. Numbers may not sum up to total because of missing values.

[b]Mantel-Haenszel chi-square test was used to determine statistical significance.

[c]These rows indicate counts of data available to calculate the patient's home and the HIV care provider location errors.

Analysis of Validity

Out of 142 participants included in the home location error analysis, 80 (56.3%) clicked within a mile of their home address; however, a greater proportion of Facebook-recruited individuals clicked within a mile of their reported residential address, compared to VBPR-recruited participants (47/63, 74% vs 33/79, 41%; *P*<.001). Figure 3 shows a detailed plot of the distribution of home location error by recruitment method. The median home location error across all participants was 0.65 miles (IQR, 0.10, 2.5 miles), but was also significantly higher among VBPR participants (*P*<.001), as well as among blacks (*P*<.001), and those reporting lower annual household income (*P*=.04). Younger age (*P*=.08) and lower educational attainment (*P*=.05) were also associated with greater median home location error, but not statistically significantly (Table 2).

Out of 154 participants included in the provider location error analysis, 109 (70.8%) clicked within a mile of their HIV care provider. Figure 4 shows a detailed plot of the distribution of provider location error by recruitment method. The median provider location error was 0.32 miles (IQR, 0.12, 1.2 miles), and did not vary significantly by recruitment method, race, income, or level of educational attainment. Although not statistically significant (*P*=.06), the median provider location error was notably lower among older participants compared to younger participants (0.46 miles compared to 0.23 miles) (Table 2).

Table 2. The level of the patient's home and HIV care provider location error among a convenience sample of HIV-positive MSM by demographic characteristics and recruitment mode, Atlanta, Georgia, 2012-2013.

		Home location error (miles)			Provider location error (miles)		
		Median	IQR	*P* [a]	Median	IQR	*P* [a]
Overall		0.65	(0.10, 2.47)		0.32	(0.12, 1.15)	
Age				.08			.06
	18-35 years	0.79	(0.11, 5.56)		0.46	(0.12, 1.74)	
	> 35 years	0.56	(0.08, 1.95)		0.23	(0.11, 1.02)	
Race							.58
	White/Caucasian	0.20	(0.05, 0.68)	<.001	0.26	(0.11, 1.00)	
	Black/African American	1.53	(0.30, 5.02)		0.32	(0.11, 1.15)	
Household income				.04			.92
	< US $20,000	1.22	(0.15, 5.34)		0.39	(0.11, 1.15)	
	> US $20,000	0.44	(0.08, 1.55)		0.30	(0.12, 1.34)	
Education				.05			.55
	High school or less	1.28	(0.17, 4.43)		0.36	(0.12, 2.12)	
	Some college, associate's degree, or technical school	0.85	(0.16, 4.77)		0.34	(0.11, 1.05)	
	College, post graduate, or professional school	0.35	(0.08, 1.33)		0.19	(0.11, 1.07)	
Recruitment mode				<.001			.31
	VBPR	1.71	(0.24, 5.34)		0.38	(0.12, 1.51)	
	Internet	0.30	(0.06, 1.17)		0.29	(0.11, 1.12)	

[a]Wilcoxon-Mann-Whitney test was used to determine statistical significance.

Figure 3. The probability density function and cumulative distribution function of home location error among a convenience sample of HIV-positive men who have sex with men who reported their home address and identified the location on a map (n=142) by recruitment mode, Atlanta, Georgia, 2012-2013. Δmi=geodesic distance between geocoded location of home address and where participants identified their home on the map. VBPR=venue-based sampling or peer referral.

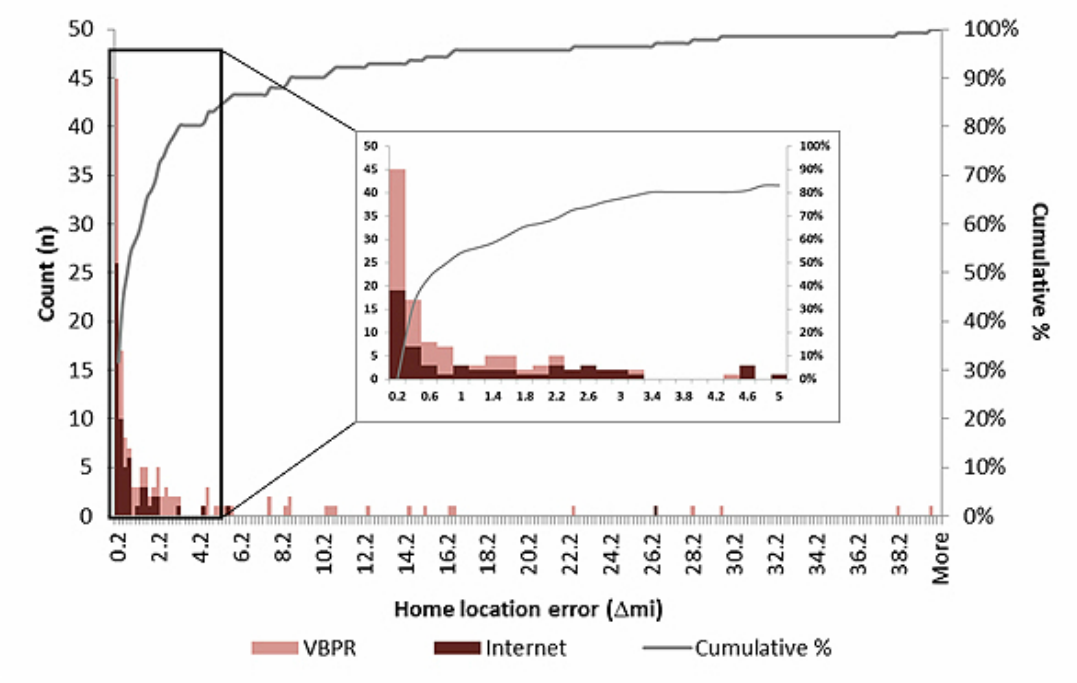
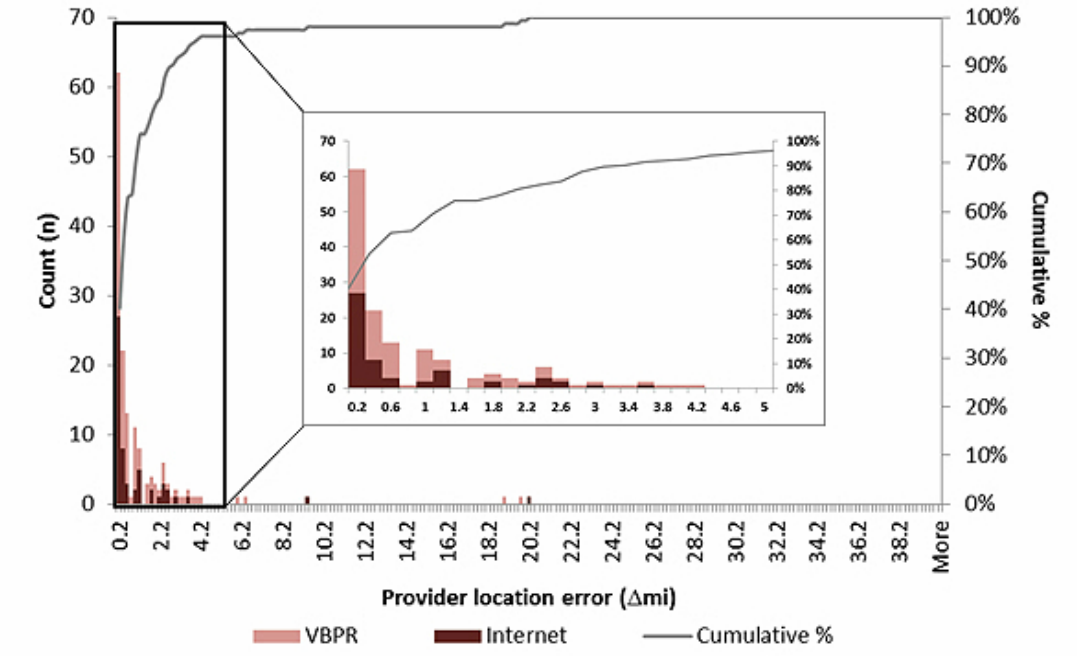


Figure 4. The probability density function and cumulative distribution function of provider location error among a convenience sample of HIV-positive men who have sex with men who reported where they last received HIV care and identified the location on a map (n=154) by recruitment mode, Atlanta, Georgia, 2012-2013. Δmi=geodesic distance between geocoded location of the HIV care provider address and where participants identified their provider on the map. VBPR=venue-based sampling or peer referral.



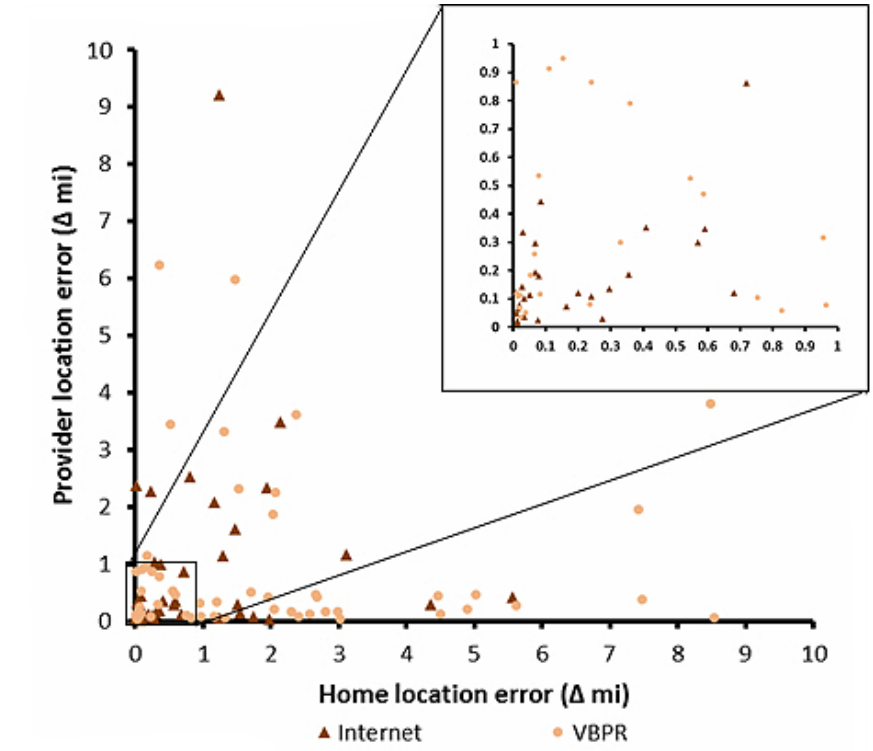
Analysis of Reliability

The plot of the provider location error against home location error in Figure 5 illustrates that, among VBPR-recruited individuals, the spread of the home location error (range, 39.8 miles) is much greater than that of the provider location error (range, 19.7 miles). Further, the range of errors overall were smaller and more consistent among Facebook participants (home location error range, 26.2 miles; provider location error range, 20.1 miles), compared to VBPR participants. Only 23/64 (35%) VBPR participants clicked within a mile of the gold standard locations for their residence and HIV care provider, while 27/48 (56%) Facebook-recruited participants clicked within the same distance of the gold standard locations. R-squared values were

calculated to measure the correlation between home location error and provider location error, but were not significant, and therefore are not reported. Because the plot of the two error measures was restricted to observations for which all four location-based questions were answered, we examined, in a post-hoc analysis, the demographic characteristics of those who answered all four questions versus those who did not, to address any potential concerns related to selection bias. There were no statistically significant differences in age, race, income, or educational attainment across these two groups.

A simple kappa coefficient was also computed to assess the level of reliability between home location error and provider location error. Overall, the kappa statistic was 0.20, bordering on poor to fair agreement between the two error measures. However, those recruited through Facebook had a greater agreement (κ=0.30) than those recruited through VBPR methods (κ=0.16), demonstrating a greater level of consistency in using the map question to identify the patient's home and the HIV care provider locations for Facebook-recruited individuals.

Figure 5. Plot of the home location error versus the provider location error among a convenience sample of HIV-positive men who have sex with men who answered all four location questions (n=112), coded by recruitment method; Atlanta, Georgia, 2012-2013. Δmi=geodesic distance between geocoded location of the HIV care provider address and where participants identified their provider on the map. VBPR=venue-based sampling or peer referral.



Discussion

Principal Results

In this study, we aimed to assess, among a convenience sample of Internet-using, Atlanta-based, HIV-positive MSM, the validity (ie, the degree of error between map derived location information and the gold standard) and reliability (ie, the consistency in the degree of error in locating the patient's home vs the HIV care provider location) of using a Google map question embedded in an Internet survey instrument to identify the patient's residential and the HIV care provider location, as compared to the geocoded address information. The results demonstrate the map tool's validity, as a majority of the study participants were able to click within a mile of their home and most recently attended HIV care provider. However, the reliability and usability varied by recruitment method.

Although most participants were able to click within a mile of their residence, there were observed differences in home location error by recruitment method and markers of SES, such as race and household income, which may be attributed to differences in the intensity of Internet use among participants. Though a majority of US residents have access to the Internet [2,21], population-based estimates in the United States show that Internet use varies by race, education, and income [2,22]. Specifically, blacks, those with lower educational attainment and those reporting a lower household income, are less likely to report using the Internet either at home or elsewhere [22,23]. Further, by 2012, nearly half of all Americans reported owning a smartphone, a potential indicator of the level of connectivity to the Internet through multiple devices. This proportion is lower among those reporting a lower household income and lower educational attainment, suggesting possible differences in the level of connectivity and intensity of Internet use across markers of SES [24]. Participants recruited through Facebook in the present study were more likely to be older, be of white race, report a higher annual household income, and report a higher level of educational attainment, and thus, may have had greater connectivity to the Internet than VBPR participants.

Higher intensity of Internet use, especially through multiple devices, may also be associated with a greater ability to navigate through the mapping questions successfully. In addition, eligible

Facebook users who check their accounts more frequently may have been more likely to view the recruitment advertisement, and thus, may have been more likely to click through the advertisement and participate. Therefore, Facebook-recruited participants, who were more likely to accurately and consistently identify their residence and provider's office, may also have been more frequent Internet users and, therefore, more likely to be able to navigate through an interactive, Internet-based mapping tool.

Observed differences in consistency by recruitment method may also be explained by the order in which the mapping questions were presented in the survey. The map asking participants to identify their residence was shown first in the questionnaire, whereas the HIV care provider map was presented later on in the survey. If participants were more likely to have trouble initially orienting themselves to the mapping questions, but became accustomed to the format of the question for the HIV care provider map, there may have been a "learning effect", resulting in a higher patient's home location error and a lower HIV care provider location error. Conversely, those individuals already accustomed to using Google maps may have been more consistently and accurately able to identify both residence and place of care in the survey. This may be why a greater level of consistency was observed among Facebook-recruited participants, if they are more frequent Internet users than VBPR-recruited individuals. It may also be important to note that the zoom level on each map question was not fixed. The participant could zoom in and out as needed to identify each location; therefore, those who utilized the zoom level may have been more likely to click closer to the gold standard location than those who did not. Again, perhaps frequency of Internet use may be associated with the level of comfort and usability of the mapping question format and zoom feature, which may explain why this "learning effect" trend may have been observed to a lesser extent among Facebook-recruited participants.

Limitations

There are several limitations to this analysis. First, we recruited a convenience sample that may not be representative of the target population of Internet-using, HIV-positive MSM in Atlanta. Homeless individuals were excluded from the analysis, further limiting generalizability of the results. Even among those recruited, a large proportion of participants did not provide both map-based location and address data for their home and HIV care provider, respectively, and thus, had to be excluded from the validation analysis. The reliability analysis was underpowered, as almost half of the participants did not complete all four questions related to residential and care provider locations. There is also a potential for selection bias in excluding participants in the reliability analysis, but no statistically significant differences in age distribution, race, annual household income, and level of educational attainment were observed between those who answered both location-based questions for the patient's residence and the HIV care provider's office and those who did not. The reasons for not answering these survey questions should be further explored by convening a small post test focus group.

In addition, the zoom level at which participants clicked on the map questions was not recorded during data collection, which may be associated with the level of accuracy of clicked map points in relation to the gold standard location. Either implementing a fixed zoom level or capturing information on the zoom level used for each participant would be helpful in controlling for any potential variability caused by this factor. The usability of the map tool could vary by the type of device used to take the questionnaire, but information on the exact device type used was not collected, and participants were encouraged to take the survey on a personal computer or tablet instead of a phone. Future studies should highlight device type as a potential source of variation in usability, validity, and reliability of a map-based tool.

Last, one minor limitation of using geodesic distances as a metric for assessing home and provider location error is that they may actually underrepresent the difference in actual distance between the map-based locations and the address data. Further, for subsequent neighborhood level analyses using these data, even small values for home or provider location errors may point to a different neighborhood with different community level characteristics from those of the gold standard location.

Despite these limitations, future studies incorporating improvements to the zoom level, information on the device type used, feedback from pre and post test focus groups, and training sessions to assess feasibility and usability could add to the results from this study and existing knowledge on the usability of a map tool to evaluate location-based information.

Conclusions

Despite the observed differences in the patient's home and the HIV care provider location errors across certain markers of SES and recruitment method, the map tool proved to be a valid alternative to geocoded addresses, as most participants were able to click within a mile of their home address and their HIV care provider's office. However, the tool bordered on poor to fair reliability between home location error and the HIV care provider location error, although those recruited on the Internet generally had better agreement, or consistency, between their home and HIV care provider location errors.

Although there are improvements to be made in this map tool, it may serve as the basis for a valid and reliable tool to identify important locations in the absence of geocoded address data. The limitations in the usability of the tool should be addressed by offering a short training session for participants prior to taking the survey. Other problems related to the layout, functionality, or usability of the tool can also be identified and addressed in a small focus group. An improved version of this Google map-based survey question can be used to capture important data on health care utilization and neighborhood level risk factors for poor health outcomes, which can have important implications in intervention planning.

Acknowledgments

We acknowledge the work of Pete Grigg, who developed the Google map question for the SurveyGizmo platform. We are also grateful for the work of Eli Rosenberg and Nicole Luisi, who provided additional technical support when needed. The Engage Study was financially supported by the National Institute of Mental Health (grant number R01MH085600), Eunice Kennedy Shriver National Institute for Child Health and Human Development (grant number R01HD067111), Emory University Center for AIDS Research (grant numbers P30AI050409, P30AI050409), and Professional Development Support Funds provided by Laney Graduate School, Emory University.

Conflicts of Interest

None declared.

References

1. Morton LM, Cahill J, Hartge P. Reporting participation in epidemiologic studies: A survey of practice. Am J Epidemiol 2006 Feb 1;163(3):197-203 [FREE Full text] [doi: 10.1093/aje/kwj036] [Medline: 16339049]
2. Anonymous. Pew internet research project. Washington, DC: Pew Internet and American Life Project Three technology revolutions URL: http://pewinternet.org/Trend-Data-(Adults)/Whos-Online.aspx [accessed 2013-09-02] [WebCite Cache ID 6JKn3dUpd]
3. Anonymous. Nielsen.com. An overview of home internet access in the U.S URL: http://www.nielsen.com/content/dam/corporate/us/en/newswire/uploads/2009/03/overview-of-home-internet-access-in-the-us-jan-6.pdf [accessed 2013-09-02] [WebCite Cache ID 6JKn5MJVG]
4. van Gelder MM, Bretveld RW, Roeleveld N. Web-based questionnaires: The future in epidemiology? Am J Epidemiol 2010 Dec 1;172(11):1292-1298 [FREE Full text] [doi: 10.1093/aje/kwq291] [Medline: 20880962]
5. Smith B, Smith TC, Gray GC, Ryan MA, Millennium Cohort Study Team. When epidemiology meets the Internet: Web-based surveys in the Millennium Cohort Study. Am J Epidemiol 2007 Dec 1;166(11):1345-1354 [FREE Full text] [doi: 10.1093/aje/kwm212] [Medline: 17728269]
6. Liau A, Millett G, Marks G. Meta-analytic examination of online sex-seeking and sexual risk behavior among men who have sex with men. Sex Transm Dis 2006 Sep;33(9):576-584. [doi: 10.1097/01.olq.0000204710.35332.c5] [Medline: 16540884]
7. Jenness S, Neaigus A, Hagan H, Wendel T, Acosta CG, Murrill CS. Reconsidering the Internet as an HIV/STD risk for men who have sex with men. AIDS and Behavior 2010 Dec;14(6):1353-1361. [doi: 10.1007/s10461-010-9769-x]
8. Rosser BR, Oakes JM, Horvath KJ, Konstan JA, Danilenko GP, Peterson JL. HIV sexual risk behavior by men who use the Internet to seek sex with men: Results of the Men's INTernet Sex Study-II (MINTS-II). AIDS Behav 2009 Jun;13(3):488-498 [FREE Full text] [doi: 10.1007/s10461-009-9524-3] [Medline: 19205866]
9. Jin F, Prestage GP, Mao L, Kippax SC, Pell CM, Donovan B, et al. Incidence and risk factors for urethral and anal gonorrhoea and chlamydia in a cohort of HIV-negative homosexual men: The Health in Men Study. Sex Transm Infect 2007 Apr;83(2):113-119 [FREE Full text] [doi: 10.1136/sti.2006.021915] [Medline: 17005541]
10. Brown SA, Richards ME, Elwell EC, Rayburn WF. Geographical information systems for mapping maternal ground transport to level III care neonatal centers. Am J Perinatol 2014 Apr;31(4):287-292. [doi: 10.1055/s-0033-1348029] [Medline: 23765706]
11. Rodriguez RA, Hotchkiss JR, O'Hare AM. Geographic information systems and chronic kidney disease: Racial disparities, rural residence and forecasting. J Nephrol 2013;26(1):3-15 [FREE Full text] [doi: 10.5301/jn.5000225] [Medline: 23065915]
12. Law DC, Serre ML, Christakos G, Leone PA, Miller WC. Spatial analysis and mapping of sexually transmitted diseases to optimise intervention and prevention strategies. Sex Transm Infect 2004 Aug;80(4):294-299 [FREE Full text] [doi: 10.1136/sti.2003.006700] [Medline: 15295129]
13. Goswami ND, Hecker EJ, Vickery C, Ahearn MA, Cox GM, Holland DP, et al. Geographic information system-based screening for TB, HIV, and syphilis (GIS-THIS): A cross-sectional study. PLoS One 2012;7(10):e46029 [FREE Full text] [doi: 10.1371/journal.pone.0046029] [Medline: 23056227]
14. Nykiforuk CI, Flaman LM. Geographic information systems (GIS) for health promotion and public health: A review. Health Promot Pract 2011 Jan;12(1):63-73. [doi: 10.1177/1524839909334624] [Medline: 19546198]
15. Kumar S, Liu M, Hwang SA. A multifaceted comparison of ArcGIS and MapMarker for automated geocoding. Geospat Health 2012 Nov;7(1):145-151 [FREE Full text] [Medline: 23242688]
16. Zandbergen PA, Hart TC, Lenzer KE, Camponovo ME. Error propagation models to examine the effects of geocoding quality on spatial analysis of individual-level datasets. Spat Spatiotemporal Epidemiol 2012 Apr;3(1):69-82 [FREE Full text] [doi: 10.1016/j.sste.2012.02.007] [Medline: 22469492]
17. Anonymous. surveygizmo. Build surveys and forms in minutes URL: http://www.surveygizmo.com/ [accessed 2013-09-02] [WebCite Cache ID 6JKn7X7Kw]
18. Anonymous. SEATEC 15th edition July 2013. Atlanta, GA: Southeast AIDS training and education center; 2013. SEATEC-Southeast AIDS training and education center URL: http://content.yudu.com/A1zr5o/SEATECNov2012Editi17/

resources/index.htm?referrerUrl=http%3A%2F%2Fwww.seatec.emory.edu%2Fresources%2Fkeycontacts.html [accessed 2013-09-02] [WebCite Cache ID 6JKn9Q2Bj]
19. Waller LA, Gotway CA. Applied spatial statistics for public health data. Hoboken, N.J: John Wiley & Sons; 2004.
20. Viera AJ, Garrett JM. Understanding interobserver agreement: The kappa statistic. Fam Med 2005 May;37(5):360-363 [FREE Full text] [Medline: 15883903]
21. Anonymous. Nielsen/netratings. New York City, NY: Nielson; 2004. Three out of four Americans have access to the internet, according to Nielsen/netratings URL: http://www.nielsen-online.com/pr/pr_040318.pdf [accessed 2013-09-02] [WebCite Cache ID 6JKnDOGJc]
22. US Government. U.S. Census Bureau. Washington, DC: US Census Bureau; 2010. Information and communications, table 1154 public library use of the internet: 2009 and 2010 URL: http://www.census.gov/compendia/statab/2012/tables/12s1155.pdf [accessed 2013-09-02] [WebCite Cache ID 6JKnEyo2L]
23. US Government. US census. Computer and internet use in the United States: Population characteristics URL: http://www.census.gov/prod/2013pubs/p20-569.pdf [accessed 2013-09-02] [WebCite Cache ID 6JKnGpurD]
24. Smith A. Pew internet and American life project. Washington, DC: Pew internet and American life project 46% of American adults are smartphone users URL: http://pewinternet.org/~/media//Files/Reports/2012/Smartphone%20ownership%202012.pdf [accessed 2013-09-02] [WebCite Cache ID 6JKnIDAX7]

Abbreviations

GIS: geographic information systems
HIV: human immunodeficiency virus
IQR: interquartile range
MSM: men who have sex with men
SEATEC: Southeast AIDS Training and Education Center
SES: socioeconomic status
VBPR: venue-based sampling or peer referral

Edited by G Eysenbach; submitted 07.09.13; peer-reviewed by T Stopka, I Jakopanec; comments to author 15.11.13; revised version received 02.12.13; accepted 18.01.14; published 10.04.14.

Please cite as:
Dasgupta S, Vaughan AS, Kramer MR, Sanchez TH, Sullivan PS
Use of a Google Map Tool Embedded in an Internet Survey Instrument: Is it a Valid and Reliable Alternative to Geocoded Address Data?
JMIR Res Protoc 2014;3(2):e24
URL: http://www.researchprotocols.org/2014/2/e24/
doi:10.2196/resprot.2946
PMID:24726954

Original Paper

The Origin and Impact of Ideals in eHealth Research: Experiences From the U-CARE Research Environment

Jonas Sjöström[1,2], PhD; Louise von Essen[1], PhD; Helena Grönqvist[1], PhD

[1]U-CARE, Department of Public Health and Caring Sciences, Uppsala University, Uppsala, Sweden

[2]Information Systems, Department of Informatics and Media, Uppsala University, Uppsala, Sweden

Corresponding Author:
Jonas Sjöström, PhD
U-CARE
Department of Public Health and Caring Sciences
Uppsala University
Box 564
Uppsala, 75122
Sweden
Phone: 46 738171359
Fax: 46 184716675
Email: jonas.sjostrom@im.uu.se

Abstract

Background: The prevalence of information technology (IT) in society is a foundation for new modes of interaction between patients and health specialists. IT plays an important role in the renewal of care. Several countries have incorporated eHealth plans into their national health strategies. Part of the eHealth evolution concerns Internet psychological treatment and psychosocial care. These interventions are complex to design and evaluate due to legal, ethical, organizational, technical, and methodological challenges.

Objective: The objective of our study was to seek to make explicit contributions to the understanding of ideals in eHealth research, and illuminate their implications for establishing an effective research environment. Our analysis draws from three years of experience in establishing an eHealth research environment, and the literature.

Methods: We worked inductively to characterize challenging research ideals, and their origins, in our environment. Thereafter, we made a selective search of the literature to scrutinize and illuminate each ideal and it's implications.

Results: In this work, we propose a structured approach to address ideals in eHealth research. The scrutinized ideals are accountability, innovation, rigor, relevance, and sustainability. The approach supports researchers to systematically understand the ideals, their origin, and to manage their implications within an eHealth research environment.

Conclusions: The complexity of eHealth research causes a need for sustainable, multi-disciplinary research environments. There is a need for a structured approach to organize eHealth research. The proposed approach helps to systematically scrutinize ideals, thus promoting high quality research.

(JMIR Res Protoc 2014;3(2):e28) doi:10.2196/resprot.3202

KEYWORDS

research management; stakeholders; innovation; accountability; rigor; relevance; sustainability

Introduction

The Prevalence of Information Technology

The prevalence of information technology (IT) in society is a foundation for new modes of interaction between patients and health specialists. While the field of eHealth is still in its infancy, it is clearly conceived of as an important strategy for the future of health care. This is signified by the status of eHealth as a key area in the Digital Agenda for Europe and the Innovation Union, both major parts of the Europe 2020 strategy presented by the European Commission in 2010.

Part of the eHealth evolution is the growth of Web-based psychological treatment and psychosocial care. Web-based self help is effective for psychiatric disorders and promotion of health behaviors [1,2]. The approach is also promising with

regard to costs, by using less therapist time per effectively treated patient compared to face-to-face therapy [3,4].

eHealth Research Challenges

Web-based interventions are complex to develop and evaluate, and substantial investments are required [5]. Several authors have addressed the challenges related to eHealth research [1,6-8]. Barak et al [1] highlight the challenges related to: (1) transition from face-to-face to Web-based communication, (2) ethical issues related to patient confidentiality and handling of emergency situations, (3) laws and regulations, and (4) practical and technical concerns that follow from appropriating technology for critical activities in organizations. Whitehouse et al [7] discussed legal, ethical, and governance challenges, and Ahern [6] pointed out both conceptual and methodological challenges, as well as and design issues, concluding that there is a need for more research in order to "leverage the opportunities for public health impact afforded by eHealth programs".

The challenges with eHealth research at least partly originate from the environment in which the research takes place. Researchers need to relate to ideals put forward by numerous stakeholders including, but not limited to, the research community, legislative bodies, and the media. Ideals are in flux, continually reinforced and challenged by stakeholder groups [9]. In this work, we propose an approach to systematically address ideals in eHealth research. The approach supports researchers to understand the ideals and their origins, and to adapt their work to comply with the ideals. We seek to contribute to the understanding of stakeholder ideals, and their implications for establishing an effective research environment. Our analysis draws from three years of experience of establishing an eHealth research environment and the literature.

Methods

The Research Setting

The research setting at hand is a multi-disciplinary research environment at Uppsala University, Uppsala, Sweden, between 2010 and 2014, and the development of the Uppsala University Psychosocial Care (U-CARE) program. The program was established to support three randomized controlled trials on Internet-based treatment of depression and anxiety for patients with somatic disease. The development may be characterized as an entangled design of the research environment, trials, interventions, and software. The U-CARE program involves academics from psychology, medicine, information systems, caring sciences, and economics, as well as health practitioners. A set of organizational decisions was made at the inception of the program. A scientific advisory board was established, including a set of scholars with expertise in their respective academic fields. The scientific advisory board meets with U-CARE staff annually to provide feedback on the U-CARE research activities. In addition, coordination groups, including researchers from different disciplines, were established to coordinate the work between and within various studies. Information systems researchers were contributing practically with software development, as well as doing research on information systems issues.

eHealth Services for Patients

U-CARE is oriented toward eHealth services for patients. The overall aim of the U-CARE program is to prevent and reduce emotional distress in persons struck by a somatic disease. Being struck by a potentially life threatening disease such as cancer can cause, for example, depression and anxiety [10]. This distress may not only cause human suffering, but can also negatively impact the treatment of the somatic disease and bring about other issues for the individual and society. For example, a depressive state may cause a patient to engage in less physical activity [11], contribute to sleeping problems, and nonadherence to prescribed medications [12]. The interventions evaluated within the trials are based on cognitive behavioral therapy [13,14]. Some of the interventions include psychosocial care consisting of information and interactive support. In the interactive parts, patients become part of an online community, allowing them to interact with peers in discussion forums, online chats, and through internal messages. Patients are recruited to trials at various hospitals in Sweden through collaboration with hospital staff.

The eHealth Software

The eHealth software at hand was designed to be configurable in a number of ways to facilitate the diverging needs within the three initial trials. An example of this flexibility is the option to either compose new interventions that are to be evaluated in additional trials, these possibly based on the intervention content in the original trials, or to reuse the original content. In the same manner, it is possible to use the questionnaires in the original trials, or to use new ones as well as to use the original inclusion and randomization logic, or to develop a new logic for inclusion and randomization. The software and the interventions have already attracted a number of research groups who will perform observational or intervention studies via the software. At this point, nine research groups are in different stages of planning and starting studies. These studies are both benefitting from and contributing to knowledge and technology within the U-CARE environment. In addition, the ethical approval required for each trial increased the experience of ethical considerations in online trials among U-CARE staff.

The Research Approach

Our research approach follows the pragmatist assumption that design and intervention in a real world setting are effective ways to understand social mechanisms [15,16]. The underlying idea is that social phenomena are more likely to be disclosed in action rather than via observations or interviews. Thus, the development of the U-CARE program and the subsequent interpretation of experiences are based on the notion that design and change in a specific domain is a viable approach to understand the domain [17].

The domain at hand is the evolution of a research environment. Given the complexity of the environment, aiming at researching psychosocial support for people with somatic disease, through collaboration across disciplines and including multiple hospitals, we conceive of the establishment of the research environment as a rich source for reflections on performing eHealth research. During the evolution of the U-CARE environment, a number

of situations occurred that were not easily remedied. The situations typically included design complexities that were not anticipated, for example, the uncertainty on how to manage details of IT-reliant communication between patients and staff. Over time, the awareness emerged that these challenges needed to be more systematically addressed to avoid "bottlenecks" in the design process. The experiences connected to these situations were interpreted in the light of relevant literature and abstracted into the results presented in this paper, consisting of five identified ideals that affect eHealth research, and an approach to scrutinizing such ideals. The process was initially inductive, for example, it was based on the prevalent challenges that were encountered during the design of research protocols, patient treatment, and software. Through literature studies, the approach was iteratively refined in an interpretive and hermeneutic process. The resulting approach is thus an abstraction from a single case study [18], for example, the evolution of the U-CARE research environment. The literature, however, indicates that the results are valid in a broader context.

An Approach to Scrutinize Ideals in eHealth Research

In this section, we provide a structure to scrutinize ideals based on: (1) a practice perspective on organizations, and (2) a stakeholder centric approach. Since the objective of this paper is to discuss the challenges in building an eHealth research environment, there is a need for reflection about the definition of a "research environment". Numerous theories can be used to explain and analyze organizations. A contemporary view is that organizations may be studied using a "practice lens". Social science researchers have elaborated on the concept of practice for a long time, and there is no unified view of what it means. We here subscribe to Schatzki's view on practice [19], recognizing the materiality of the social world, for example, that artifacts affect human action and vice versa. The practice stance, drawing on Giddens' structuration theory [20], highlights the reciprocal shaping of action and structure. The reciprocity means that social structures govern human behaviors, while at the same time; individuals' actions reinforce and challenge social structure. The practice view resonates well with the phenomena under scrutiny in this paper; the way that social structures (in this case ideals imposed on research by various external stakeholders) enable and constrain action, for example, they cause challenges in organizing a research environment.

A research environment operates in a context continually influenced by and adapting to external parties, such as academic journals, ethical approval boards, funding agencies, and legislative bodies. An implication of adopting the practice view on the research environment is that a successful research environment needs to adapt to their stakeholders, who define the preconditions for research practice, and evaluate its outcome.

Table 1. A structure to scrutinize ideals in eHealth research.

Aspect	Explanatory question
Theoretical discussion and definition	What is the meaning of the ideal and why is it important?
Stakeholders	Who reinforces the ideal?
Impact on the U-CARE environment	How, when, and where did the ideal affect the environment?
Managerial implications	What are the managerial implications for the research environment?

What, Who, Why, How, When, and Where

An approach to make sense of qualitative data is to appropriate the six interrogatives: (1) what, (2) who, (3) why, (4) how, (5) when, and (6) where [21]. We adapt the interrogatives to the current context to scrutinize each identified ideal, as outlined in Table . In addition, each ideal is discussed from the point-of-view of managerial implications. These include: (1) accountability, (2) innovation, (3) relevance, (4) rigor, and (5) sustainability.

In the remainder of this section, we adopt the approach to scrutinizing ideals to provide an account of each ideal and its impact on the research environment.

Accountability

Theoretical Discussion and Definition

Accountability is a core concern in health care. The meaning of information accountability is that "[...] use of information should be transparent so it is possible to determine whether a particular use is appropriate under a given set of rules, and that the system enables individuals and institutions to be held accountable for misuse" [22]. Accountability in an eHealth context, for example, concerns about privacy issues and avoiding misuse of patient information. As stated in the Universal Declaration of Human Rights [23] (Article 12), "...no one shall be subjected to arbitrary interference with his privacy, family, home, or correspondence, nor to attacks upon his honor and reputation". A main concern in eHealth is that privacy should be protected at all times. Information access should always be motivated by caregiving needs, and research should be based on informed consent [24]. Accountability is reached when it can be reconstructed how an undesired situation occurred. Accountability is not only a matter of securing safe access to information, but also about making people aware about policies and facilitating transparency in information use [22]. Managing accountability is a challenge both from a knowledge point of view and from a technological point of view. Researchers need to be aware of and comply with detailed legislation and ethics concerning how patient information should be retrieved and handled. Technology needs to be aligned with state-of-the-art practices for security, authentication, and procedures to scrutinize information use and misuse.

Stakeholders

Accountability builds on human rights and legislation, and differs between nations. Researchers need to account for the way they manage patient information to research funders, ethical

approval boards, journals, and government agencies, and not least the citizens.

Managerial Implications

Accountability needs to be addressed using multiple competencies, including law, health, and information technology expertise. While substantial resources are required to find solutions to accountability issues, it is imperative to systematically reuse knowledge and technology to efficiently set up and execute new projects within the eHealth area.

Innovation

Theoretical Discussion and Definition

We adhere to the view of innovation as "...the multi-stage process whereby organizations transform ideas into new/improved products, services or processes, in order to advance, compete, and differentiate themselves successfully in their marketplace" [25]. In health care research, innovation concerns the translation of evidence-based knowledge into everyday care. Only 14% of findings from medical research translates into practice in 17 years [26]. Innovative health care research needs to take into account how research results should be implemented in practice. Such planning impacts the design of research. If the gap between the research setting and the practice is too wide, the results are unlikely to be adopted by practice. Carrying out a randomized controlled trial (RCT) requires extensive resources and rigorous research. There is a need for innovative alternative methods to evaluate complex interventions, such as those developed and evaluated within the U-CARE. The slow implementation rate has resulted in a call for more pragmatic and client-centered research [27,28]. Intellectual property (IP) rights issues and business models affect the implementation of results, and policymaking is a critical factor. A challenge for policymakers is to establish regulations that promote innovation, while still maintaining the public's trust [29].

Innovation capability may affect research funding, thus this capability is crucial for the survival of the research environment. If research results do not affect health care practice, their value is questionable. Following the innovation ideal, new treatments that prove effective should be implemented into practice.

Stakeholders

Innovation is desired by research funders, no matter if funding is commercial, governmental, or comes from nonprofit organizations. Innovation is important both for public health and industrial growth. In addition, in many cases researchers desire that their results be implemented due to commercial or "altruistic" reasons.

Managerial Implications

A research environment aiming at innovation needs a strategy to handle IP rights, preferably from the inception of a project. Innovation requires collaboration with, for example, software companies, legal experts, and health care providers. The research environment needs to collaborate with experts in related areas such as implementation science, service management, and business administration to develop business models supporting the translation of results into practice.

Relevance

Theoretical Discussion and Definition

Researchers should be able to explain the societal relevance of their work. Applied research is expected to contribute to society, and research legitimacy is demonstrated in terms of practical relevance [5,30]. As stated, "[...] Researchers should describe the context in which the intervention was developed, applied, and evaluated, so that readers can determine the relevance of the results to their own situation" [5]. Relevance is related to innovation and concerns the kind of knowledge we seek to develop, while innovation emphasizes the translation of knowledge from research into practice. The development of psychological interventions is a complex process. The design literature suggests that the understanding of a certain problem unfolds in the design process [30,31]. Understanding the problem and its relevance is a challenging task. It has been proposed that qualitative [5] and interpretive [32] research is well suited to build a solid understanding of a problem domain, and to formulate hypotheses [33,34]. Relevance in research is a highly discussed ideal, for example, it is used to assess applications for funding and in the peer-review process. Relevance is thus a critical success factor for a research environment.

Stakeholders

Stakeholders related to the relevance ideal are similar to those related to innovation. To promote relevance, there is a need to center the design process on health care practice, and include those who will receive the interventions, for example, the patients, the significant others, and those who will provide them, for example, the health care specialists. Relevance builds on an understanding of societal needs. Such needs are periodically investigated and reported by government agencies and the European Union, important stakeholders with regard to relevance.

Managerial Implications

Research should proactively adopt a stakeholder-centric design process, including a broad range of stakeholders. The experiences from U-CARE support an iterative approach to development research, interventions, and software. In addition, relevance highlights the need for a continuous monitoring of knowledge gaps and improvement opportunities in the health sector. The research environment needs to engage in intelligence work to understand societal needs in order to maintain and improve the relevance of research.

Rigor

Theoretical Discussion and Definition

Rigor concerns the effective use of knowledge, including both the theoretical foundations and the research methodology throughout the research process [30]. Rigor thus encompasses both the manner in which the researcher selects the appropriate techniques for design and evaluation, and the manner in which the proposed theoretical contributions are justified.

In research on online interventions, it has been argued that trials should lead to an increased understanding of the processes and

mechanisms that make treatment effective [5]. Rigor concerns: (1) the way that research methods are enacted, (2) the way that interventions build on existing theory, and (3) that research makes a theoretical contribution. A meta-analysis has shown that the more extensive use of theory in intervention design has a positive impact on effect sizes [35]. Theoretical contributions may include knowledge about processes and mechanisms that make interventions successful, and research methodology, such as novel data collection methods. Researchers in eHealth face new challenges as well as opportunities to collect and analyze data, for example, through the logging of patient behaviors, for example, in forum, chat conversations, and when completing questionnaires [36].

Stakeholders

Rigor is important for researchers who aim for high impact publications. It is equally important for journals to maintain and improve their credibility in the academic community. Arguably, publication in high impact outlets strengthens the research environment, and its capability to have an impact on health care practice. Thus, rigor plays an important role as a foundation for research and its meaning for health care practice.

Managerial Implications

Senior researchers play an important role in promoting rigor in the research environment. Knowledge management strategies, including formal routines and informal discussions, need to be applied to support all coworkers to continually reflect on the three aspects of rigor outlined above. The elaborate reuse of software and interventions enhances rigor by providing new projects with well tested practices.

Sustainability

Theoretical Discussion and Definition

Something is sustainable if it ‘‘...meets the needs of the present without compromising the ability of future generations to meet their own needs” [37]. Sustainability has been more precisely defined as social, economic, and environmental sustainability [38]. While environmental sustainability has been in focus in IT research (eg, server energy consumption), there is less research on economic and social sustainability [38]. Economic sustainability pertains to how actions contribute to long-term societal development. The contemporary discourse on openness, for example, open source, open content, open data, open standards, and open access publications, relates to economic sustainability. Openness may be beneficial, but it requires new skills and competencies, for example, with respect to legislation and IP rights issues. Social sustainability relates to ethical implications of research, for example, health care should be equally offered to all humans. Social sustainability thus includes the digital divide and access to health care everywhere. As explained by Eysenbach [39], “The digital divide currently runs between rural versus urban populations, rich versus poor, young versus old, male versus female people, and between neglected/rare versus common diseases”. Social sustainability leads to the normative implication that research should take into account the equity implications of new findings.

Stakeholders

The European Union Horizon 2020 program, along with some other funding agencies, reinforces sustainability ideals. Social sustainability—promoting equal health care for all—concerns all citizens. However, commercial and public organizations are affected by the trend toward openness, and it’s meaning for organizing and making profits on a market.

Managerial Implications

Sustainability adds complexity to organizing research, since it enhances the need for competences in social and ethical issues, IP rights, and the design of technology that benefits society outside the scope of the ongoing trials.

Results

The Five Ideals

During 2010-2014, the following five ideals repeatedly occurred while planning and executing research. These ideals constitute a comprehensive rather than complete list: (1) accountability, (2) innovation, (3) relevance, (4) rigor, and (5) sustainability. The challenges regarding each issue of research have been reviewed for their impact on the U-CARE environment.

Impact on the Uppsala University Psychosocial Care Environment

Accountability was a challenging aspect in the setup of the U-CARE environment and had an impact on how work was organized, and how interventions and software were designed. As psychological treatment is provided within the original trials, Uppsala University (hosting the U-CARE program) registered as a caregiver. A health care organization was set up within the research environment. These organizational implications of accountability were not anticipated initially. The legal and ethical aspects of the management of participant data were continuous concerns radically affecting the software design. Some examples include the way participant data is logged and accessed, the use of double authentication for participants, role-based privileges to access information, and organizational and technical solutions to protect the information. Electronic health record legislation adds further complexity, and health records are at this point managed manually. While accountability issues need to be addressed in the design process, they also need to be aligned with research goals, development, and evaluation of interventions etc.

In order to promote innovation, the U-CARE environment strives toward open sourcing of the software and the interventions. Other research groups may utilize software and interventions developed within U-CARE. Interventions are released under a Creative Commons license, allowing anyone to use them for noncommercial purposes. Research groups associated with U-CARE contribute with new interventions for future reuse. The licensing of software is not yet determined, but the intention is to make it open source. Swedish legislation provides researchers with the IP rights of their innovations and results. Licensing thus becomes subject to a negotiation between contributing researchers. The challenge is to agree about licensing in a way that supports an effective implementation of

the software and the interventions, while at the same time resonating with the interests of researchers who are legible IP rights holders. The issue of "effective implementation" cannot be solved without an understanding of stakeholders', such as IT companies and caregiving organizations having incentives to use and further develop research deliverables. At this point, the U-CARE research environment operates as a service provider. The software is hosted at Uppsala University, providing associated researchers with the opportunity to conduct their studies via the eHealth software. It is a temporary solution, since the university should focus on research, rather than service provisions like IT hosting, software development, and IT support. The university hosts a unit to support innovation, which is periodically consulted by the researchers.

The relevance of the research to the patients is important. Initially, the work was centered on developing interventions and flexible software. In the first feasibility study, directed to adolescents with cancer, the software and the intervention, for example, a self-help program consisting of cognitive behavioral therapy, information, and interactive support, was not received well. Recruitment was difficult and retention was low. In order to improve recruitment, participation, and retention, a group of adolescents with lived experience of cancer was involved in research activities. Patient representatives were also involved in the development of self-help programs for adults with cancer, and adults having had a myocardial infarct. The group of adolescents with lived experience of cancer provided important feedback on various issues, for example, the content of the self-help program, the software user interface, the inclusion criteria, and inclusion procedures. Ideally patient representatives should have been involved in all U-CARE activities from the very start. In the multi-disciplinary setting, there is also exploratory research. As an example, information systems researchers identified relevant research questions during the design process, such as management and design issues concerning privacy and accountability in eHealth.

The U-CARE environment emphasized methodological rigor from the very start. Theoretical foundations have been discussed extensively, but an emphasis has been placed on methodological rigor. However, in response to internal discussions and input from the scientific advisory board, the environment has increasingly paid attention to theoretical foundations and potential theoretical contributions. There are several arenas within U-CARE where methodology and theory is discussed; for example, it is discussed at research seminars, and study coordination group meetings, with the purpose of improving rigor. Rigor is also tightly connected to software design. Well recognized and extensively used instruments are available for reuse in the software, as well as features to improve adherence, for example, rule-based email reminders to participants. In addition, the software has been equipped with extensive, theory-based, logging functionality to improve post hoc scrutiny of patient behaviors. It is believed that such logging is important for rigorous development of theory and for accountability purposes. In essence, rigor is implemented in the organizational routines and in the software to support research.

The aspect of "openness" in U-CARE has been illustrated in the presentation of the innovation ideal. Open sourcing, however, is also a matter of sustainability. In relation to the digital divide, it is clear that eHealth interventions target only part of the population. In the Swedish context, interventions such as those developed and evaluated within U-CARE would make psychological treatment and psychosocial care available for larger groups than they are available for today. First, the online mode of treatment expands the geographical reach of support. Second, at least in the Swedish context, the U-CARE online treatment protocols facilitate support to a group of patients not regularly offered any support today. However, while overall access to psychosocial support and psychological interventions in society is improved, the new form of support may add to the digital divide, due to the dependency on technical equipment and proficiency in using IT. Even though sustainability has affected the work so far, we believe that the research environment would benefit from a more systematic approach to address economic and social sustainability.

Discussion

Our Research

Some research has emphasized the operational aspects of online intervention research, for example, the guidelines for conducting online trials [8], and the methods to develop and evaluate complex interventions [5]. Our work contributes to the literature through the focus on research practice at a managerial level. The results, originating from a context of online psychosocial treatment and support, should be seen as relevant for the management of a research environment that conducts research where patients are given care via the Internet. Our approach is thus likely to be useful in other research environments that conduct online trials where patients interact with caregivers.

A Tentative Set of Ideals for eHealth Research

We suggest that a research environment benefits from systematically scrutinizing ideals that govern research, and their origin in terms of stakeholders. We have identified five ideals and addressed them in a novel way by discussing their implications for managing a research environment. A specific ideal, accountability, originates from the ethics of privacy, and the need to hold people accountable of their actions in case of information misuse or maltreatment. Another two of the discussed ideals, relevance and rigor, are established scientific ideals. Health research is concerned with ethics and the long-term effects of new policies and practices. These concerns are manifested in the ideals sustainability and innovation. Depending on the research context, the ideals may be more or less important to factor into the research design. Given our approach to identify ideals based on a single research environment, it should also be emphasized that a different research context might be influenced by other ideals than those included here. Research management needs to incorporate mechanisms into the environment to continually address ideals, for example, integrating discussions about the proposed ideals into research planning, execution, and reporting.

The result emphasizes the need for different skills, which fuels the argument that an eHealth research environment benefits from a multi-disciplinary collaboration. We have pointed out skills that are of importance to meet each ideal noted in the

paper, and the challenges associated with each of these ideals. The need for multiple skills—as well as reuse of knowledge and technology—underscores the complexity of eHealth research. We argue that strong, sustainable, multi-disciplinary research environments are required in order to conduct eHealth research that appropriately addresses the complexity that follows from the five ideals. We have given practical examples of the implications of these ideals by giving examples of the impact of the five identified ideals in the U-CARE research environment.

Finally, ideals are sometimes conflicting. Within the U-CARE program, there is an ongoing discussion about whether open sourcing is an effective way to disseminate results into practice. A commercialization of software and interventions developed within U-CARE might be considered less sustainable, even though commercialization may promote innovation. In addition, research tends to require a trade-off between relevance and rigor. Our goal here is not to provide prescriptions for such decisions; we merely suggest an approach to systematically scrutinize ideals. Such scrutiny informs decisions, and contributes to well reflected multi-disciplinary eHealth research.

Conflicts of Interest

None declared.

References

1. Barak A, Hen L, Boniel-Nissim M, Shapira N. A comprehensive review and a meta-analysis of the effectiveness of internet-mased psychotherapeutic interventions. Journal of Technology in Human Services 2008 Jul 03;26(2-4):109-160. [doi: 10.1080/15228830802094429]
2. Cuijpers P, Donker T, van Straten A, Li J, Andersson G. Is guided self-help as effective as face-to-face psychotherapy for depression and anxiety disorders? A systematic review and meta-analysis of comparative outcome studies. Psychol Med 2010 Dec;40(12):1943-1957. [doi: 10.1017/S0033291710000772] [Medline: 20406528]
3. Tate D, Finkelstein EA, Khavjou O, Gustafson A. Cost effectiveness of internet interventions: Review and recommendations. Ann Behav Med 2009 Aug;38(1):40-45 [FREE Full text] [doi: 10.1007/s12160-009-9131-6] [Medline: 19834778]
4. Warmerdam L, Smit F, van Straten A, Riper H, Cuijpers P. Cost-utility and cost-effectiveness of internet-based treatment for adults with depressive symptoms: Randomized trial. J Med Internet Res 2010;12(5):e53 [FREE Full text] [doi: 10.2196/jmir.1436] [Medline: 21169166]
5. Campbell N, Murray E, Darbyshire J, Emery J, Farmer A, Griffiths F, et al. Designing and evaluating complex interventions to improve health care. BMJ 2007 Mar 3;334(7591):455-459 [FREE Full text] [doi: 10.1136/bmj.39108.379965.BE] [Medline: 17332585]
6. Ahern D. Challenges and opportunities of eHealth research. Am J Prev Med 2007 May;32(5 Suppl):S75-S82. [doi: 10.1016/j.amepre.2007.01.016] [Medline: 17466822]
7. Whitehouse D, George C, Duquenoy P. Assessing legal, ethical and governance challenges in eHealth. In: eHealth: Legal, ethical and governance challenges. Berlin: Springer-Link; 2013:3-22.
8. Proudfoot J, Klein B, Barak A, Carlbring P, Cuijpers P, Lange A, et al. Establishing guidelines for executing and reporting internet intervention research. Cognitive Behaviour Therapy 2011 Jun;40(2):82-97. [doi: 10.1080/16506073.2011.573807]
9. Sjöström JO, Donnellan B, Helfert M. Product semantics in design research practice. In: Battacherjee A, Fitzgerald B, editors. Shaping the future of ICT research, methods, and approaches. Heidelberg: Springer; 2012:35-48.
10. Mitchell A, Ferguson DW, Gill J, Paul J, Symonds P. Depression and anxiety in long-term cancer survivors compared with spouses and healthy controls: A systematic review and meta-analysis. Lancet Oncol 2013 Jul;14(8):721-732. [doi: 10.1016/S1470-2045(13)70244-4] [Medline: 23759376]
11. Roshanaei-Moghaddam B, Katon WJ, Russo J. The longitudinal effects of depression on physical activity. Gen Hosp Psychiatry 2009;31(4):306-315. [doi: 10.1016/j.genhosppsych.2009.04.002] [Medline: 19555789]
12. Grenard J, Munjas BA, Adams JL, Suttorp M, Maglione M, McGlynn EA, et al. Depression and medication adherence in the treatment of chronic diseases in the United States: A meta-analysis. J Gen Intern Med 2011 Oct;26(10):1175-1182 [FREE Full text] [doi: 10.1007/s11606-011-1704-y] [Medline: 21533823]
13. Bower P, Gilbody S. Stepped care in psychological therapies: Access, effectiveness and efficiency. Narrative literature review. Br J Psychiatry 2005 Jan;186:11-17 [FREE Full text] [doi: 10.1192/bjp.186.1.11] [Medline: 15630118]
14. Riley S, Veale D. Behav. Cogn. Psychother. 1999. The internet and its relevance to cognitive behavioral psychotherapists URL: http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=48687 [WebCite Cache ID 6Pc7OwbBa]
15. Dewey J. Logic - The theory of inquiry. New York: Saerchinger Press; 2007.
16. Susman GI, Evered RD. Administrative Science Quarterly. 1978. An assessment of the scientific merits of action research URL: http://www.jstor.org/discover/10.2307/2392581?uid=3739920&uid=2129&uid=2&uid=70&uid=4&uid=3739256&sid=21104172715243 [WebCite Cache ID 6Pc8h2k6g]
17. Baskerville R, Kaul M, Storey V. ICIS 2011 Proceedings. 2011. Unpacking the duality of design science URL: http://aisel.aisnet.org/icis2011/proceedings/generaltopics/10/ [accessed 2014-05-16] [WebCite Cache ID 6Pc8pwbGG]

18. Lee AS, Baskerville R. Information systems research. 2003. Generalizing generalizability in information systems research URL: http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.95.7154&rep=rep1&type=pdf [WebCite Cache ID 6Pc8wJaI2]
19. Schatzki T, Knorr-Cetina K, Savigny EV. Introduction: Practice theory. In: The practice turn in contemporary theory. London: Routledge; 2001.
20. Giddens A. The constitution of society: Outline of the theory of structuration. Berkeley: University of California Press; 1986.
21. Miles M, Huberman AM. B. In: Qualitative data analysis: An expanded sourcebook. Thousand Oaks: Sage Publications; 1994.
22. Weitzner D, Abelson H, Berners-Lee T, Feigenbaum J, Hendler J, Sussman GJ. Information accountability. Commun. ACM 2008 Jun 01;51(6):82-87. [doi: 10.1145/1349026.1349043]
23. United Nations: The universal declaration of human rights. URL: http://www.un.org/en/documents/udhr/ [accessed 2013-11-21] [WebCite Cache ID 6LIK5GgYI]
24. Kluge E. Secure e-Health: Managing risks to patient health data. Int J Med Inform 2007;76(5-6):402-406. [doi: 10.1016/j.ijmedinf.2006.09.003] [Medline: 17084665]
25. Baregheh A, Rowley J, Sambrook S. Towards a multidisciplinary definition of innovation. Management Decision 2009;47(8):1323-1339. [doi: 10.1108/00251740910984578]
26. Balas EA, Boren SA. Yearbook of medical informatics 2000: Patient-centered systems. Stuttgart, Germany: Schattauer Verlagsgesellschaft; 2000. Managing clinical knowledge for health care improvement URL: http://www.ihi.org/resources/Pages/Publications/Managingclinicalknowledgeforhealthcareimprovement.aspx [accessed 2014-05-16] [WebCite Cache ID 6Pc9MqLrm]
27. Thorpe K, Zwarenstein M, Oxman AD, Treweek S, Furberg CD, Altman DG, et al. A pragmatic-explanatory continuum indicator summary (PRECIS): A tool to help trial designers. CMAJ 2009 May 12;180(10):E47-E57 [FREE Full text] [doi: 10.1503/cmaj.090523] [Medline: 19372436]
28. Glasgow R, Green LW, Taylor MV, Stange KC. An evidence integration triangle for aligning science with policy and practice. Am J Prev Med 2012 Jun;42(6):646-654. [doi: 10.1016/j.amepre.2012.02.016] [Medline: 22608384]
29. Fried B, Weinreich G, Cavalier GM, Lester KJ. e-Health: Technologic revolution meets regulatory constraint. Health Aff (Millwood) 2000;19(6):124-131 [FREE Full text] [Medline: 11192395]
30. Hevner AR, March ST, Park J, Ram S. MIS Quarterly. 2004. Design science in information systems research URL: http://em.wtu.edu.cn/mis/jxkz/sjkx.pdf [accessed 2014-05-16] [WebCite Cache ID 6PcAQFXVh]
31. Simon H. The sciences of the artificial. Cambridge, Mass: MIT Press; 1996.
32. Sein M, Henfridsson O, Purao S, Rossi M, Lindgren R. MIS Quarterly. 2011. Action design research URL: http://misq.org/cat-articles/action-design-research.html [accessed 2014-05-16] [WebCite Cache ID 6PcAmDoIl]
33. Venkatesh V, Brown SA, Bala H. MIS Quarterly. 2013. Bridging the qualitative-quantitative divide: Guidelines for conducting mixed methods research in information systems URL: http://aisel.aisnet.org/misq/vol37/iss1/3/ [accessed 2014-05-16] [WebCite Cache ID 6PcAxOlzz]
34. Eysenbach G, Wyatt J. Using the Internet for surveys and health research. J. Med. Internet Res 2002;4. [doi: 10.2196/jmir.4.2.e13]
35. Webb T, Joseph J, Yardley L, Michie S. Using the internet to promote health behavior change: A systematic review and meta-analysis of the impact of theoretical basis, use of behavior change techniques, and mode of delivery on efficacy. J Med Internet Res 2010;12(1):e4 [FREE Full text] [doi: 10.2196/jmir.1376] [Medline: 20164043]
36. Sjöström JO, Rahman MH, Rafiq A, Lochan R, Ågerfalk PJ. Design science at the intersection of physical and virtual design. Heidelberg: Springer; 2013. Respondent behavior logging: An opportunity for online survey design URL: http://link.springer.com/chapter/10.1007%2F978-3-642-38827-9_44 [accessed 2014-05-16] [WebCite Cache ID 6PcBGd5JO]
37. United Nations. Report of the World Commission on environment and development. General Assembly Resolution 42. United Nations: United Nations; 1987. URL: http://www.un.org/documents/ga/res/42/ares42-187.htm [accessed 2014-05-16] [WebCite Cache ID 6PcZxZkDD]
38. Bengtsson F, Ågerfalk PJ. Information technology as a change actant in sustainability innovation: Insights from Uppsala. The Journal of Strategic Information Systems 2011 Mar;20(1):96-112. [doi: 10.1016/j.jsis.2010.09.007]
39. Eysenbach G. What is e-health? J Med Internet Res 2001;3(2):E20 [FREE Full text] [doi: 10.2196/jmir.3.2.e20] [Medline: 11720962]

Abbreviations

IP: intellectual property
IT: information technology
RCT: randomized controlled trial
U-CARE: Uppsala University Psychosocial Care Programme

Edited by G Eysenbach; submitted 20.12.13; peer-reviewed by V Vimarlund, V Wilson; comments to author 09.01.14; revised version received 14.03.14; accepted 13.04.14; published 23.05.14.

Please cite as:
Sjöström J, von Essen L, Grönqvist H
The Origin and Impact of Ideals in eHealth Research: Experiences From the U-CARE Research Environment
JMIR Res Protoc 2014;3(2):e28
URL: http://www.researchprotocols.org/2014/2/e28/
doi:10.2196/resprot.3202
PMID:24860071

Corrigenda and Addenda

Metadata Correction: Diagnosis and Prediction of Neuroendocrine Liver Metastases: A Protocol of Six Systematic Reviews

Stephan Arigoni[1*]; Stefan Ignjatovic[1*]; Patrizia Sager[1]; Jonas Betschart[1]; Tobias Buerge[1]; Elena Scherrer[1]; Josephine Wachtl[1]; Christoph Tschuor[1], MD; Perparim Limani[1], MD; Milo A Puhan[2], MD, PhD; Mickael Lesurtel[1], MD, PhD; Dimitri A Raptis[1], MD, PhD; Stefan Breitenstein[3], MD, PD

[1]Clinic for Visceral and Transplantation Surgery, Department of Surgery, University Hospital Zurich, Zurich, Switzerland

[2]Institute for Social and, Preventive Medicine, University of Zurich, Zurich, Switzerland

[3]Cantonal Hospital Winterthur, Department of Surgery, Clinic for Visceral and Thoracic Surgery, Winterthur, Switzerland

[*]these authors contributed equally

Corresponding Author:
Stefan Breitenstein, MD, PD
Cantonal Hospital Winterthur
Department of Surgery
Clinic for Visceral and Thoracic Surgery
Brauerstrasse 15
Winterthur, 8401
Switzerland
Phone: 41 0522662402
Fax: 41 0522662454
Email: stefan.breitenstein@usz.ch

Related Article:

Correction of: http://www.researchprotocols.org/2013/2/e60/

(JMIR Res Protoc 2014;3(2):e25) doi:10.2196/resprot.3488

The author Elena Scherrer was inadvertently omitted from the list of authors during the submission process of the paper "Diagnosis and Prediction of Neuroendocrine Liver Metastases: A Protocol of Six Systematic Reviews" (JMIR Res Protoc 2013;2(2):e60). The author Elena Scherrer (Clinic for Visceral and Transplantation Surgery, Department of Surgery, University Hospital Zurich, Zurich, Switzerland) should have been added after Tobias Buerge in the original published manuscript. This error was corrected in the online version of the paper on the JMIR Research Protocols website on April 28, 2014 along with the publication of this correction notice. This correction notice has been sent to PubMed and the correct full-text has been resubmitted to Pubmed Central and other full-text repositories.

Edited by G Eysenbach; submitted 23.04.14; this is a non–peer-reviewed article;accepted 24.04.14; published 28.04.14.

Please cite as:
Arigoni S, Ignjatovic S, Sager P, Betschart J, Buerge T, Scherrer E, Wachtl J, Tschuor C, Limani P, Puhan MA, Lesurtel M, Raptis DA, Breitenstein S
Metadata Correction: Diagnosis and Prediction of Neuroendocrine Liver Metastases: A Protocol of Six Systematic Reviews
JMIR Res Protoc 2014;3(2):e25
URL: http://www.researchprotocols.org/2014/2/e25/
doi:10.2196/resprot.3488
PMID:

Original Paper

An eHealth Intervention for Patients in Rural Areas: Preliminary Findings From a Pilot Feasibility Study

Geoffrey Schrader[1], MBBS, FRANZCP, PhD; Niranjan Bidargaddi[1,2], B Eng (Hons), PhD; Melanie Harris[3], BTech, MEd, DipInfMan/Lib, PhD; Lareen Newman[4], BA(Hons), PhD; Sarah Lynn[5], DipMentalHealth; Leigh Peterson[6], MMentalHealthNursing; Malcolm Battersby[3], MBBS, FAChAM, FRANZCP, PhD

[1]Mental Health Observatory Research Unit, Country Health SA Local Health Network, Adelaide, Australia

[2]e-Health Research, School of Medicine, Flinders University, Bedford Park, Australia

[3]Flinders Human Behaviour Health Research Unit, School of Medicine, Flinders University, Adelaide, Australia

[4]Southgate Institute for Health Society & Equity, School of Medicine, Flinders University, Adelaide, Australia

[5]Uniting Care Wesley Port Adelaide Inc, Mt Gambier, Australia

[6]Mount Gambier District Health Service, Country Health SA Local Health Network, Mt Gambier, Australia

Corresponding Author:
Niranjan Bidargaddi, B Eng (Hons), PhD
e-Health Research
School of Medicine
Flinders University
Room 4T103 | Margaret Tobin Centre | Sturt Road,
Bedford Park, 5042
Australia
Phone: 61 423416543
Fax: 61 8404 2101
Email: niranjan.bidargaddi@flinders.edu.au

Abstract

Background: eHealth facilitation of chronic disease management has potential to increase engagement and effectiveness and extend access to care in rural areas.

Objective: The objective of this study was to demonstrate the feasibility and acceptability of an eHealth system for the management of chronic conditions in a rural setting.

Methods: We developed an online management program which incorporated content from the Flinders Chronic Condition Management Program (Flinders Program) and used an existing software platform (goACT), which is accessible by patients and health care workers using either Web-enabled mobile phone or Internet, enabling communication between patients and clinicians. We analyzed the impact of this eHealth system using qualitative and simple quantitative methods.

Results: The eHealth system was piloted with 8 recently hospitalized patients from rural areas, average age 63 (SD 9) years, each with an average of 5 chronic conditions and high level of psychological distress with an average K10 score of 32.20 (SD 5.81). Study participants interacted with the eHealth system. The average number of logins to the eHealth system by the study participants was 26.4 (SD 23.5) over 29 weeks. The login activity was higher early in the week.

Conclusions: The pilot demonstrated the feasibility of implementing and delivering a chronic disease management program using a Web-based patient-clinician application. A qualitative analysis revealed burden of illness and low levels of information technology literacy as barriers to patient engagement.

(JMIR Res Protoc 2014;3(2):e27) doi:10.2196/resprot.2861

KEYWORDS

eHealth; chronic disease; rural health

Introduction

eHealth facilitation of chronic disease management has potential to add to program components, increase engagement and effectiveness, and extend access for underserved groups [1-5]. Systems have been developed for specific chronic conditions, particularly diabetes [6], but generic chronic disease management systems are also needed to structure overall care, especially for the majority of patients who have multi-morbidities [7,8]. However, there appear to be no well-evaluated eHealth systems to support delivery of generic chronic disease management and self-management support for individual patients [9]. Comorbidity is the norm in chronic illness, and mental health problems are often present [8,10]. We therefore piloted an eHealth disease management program in people with comorbid mental health and physical health conditions or risk factors who live in rural areas. eHealth technologies should be developed and evaluated from the start as complex individual, social, organizational, and technical interventions [11]. We therefore report quantitative and qualitative data from this pilot, providing preliminary assessment of initial patient acceptance, patient engagement, feasibility of delivery, and outcome measurement to inform further system development.

Our objective was to inform development of an eHealth system of chronic disease management by observing its use by patients with comorbid chronic diseases who live in rural areas and health care workers delivering the program to the patients.

Methods

The Intervention

An online management program was specifically developed for the study. This incorporated content from the Flinders Chronic Condition Management Program (Flinders Program) and used an existing software platform (goACT), which is accessible by patients and health care workers using either Web-enabled mobile phone or Internet [12].

The Flinders Program is an overarching program for chronic condition management applicable to medical and psychiatric conditions and to multi-morbidities [7]. It provides a structured collaborative disease management process addressing behaviors of both patient and clinician. The program is based on cognitive behavior therapy, motivational interviewing, and behavioral psychotherapy. It uses a set of tools: the Partners in Health scale (PIH), Cue and Response interview (C&R), and Problem and Goals assessment (P&G). The patient completes the PIH to assess self-management knowledge, attitudes, behaviors, and impacts of chronic conditions. The health care worker uses the C&R to further explore the same concepts and shares his or her perspective with the patient. Strengths, barriers, priorities, and goals identified through shared use of these tools are incorporated into a negotiated care plan that integrates self-management and medical issues, management aims, agreed interventions, responsibilities, and review dates. The Flinders Program care plan tailors a range of possible self-management interventions to the individual, including disease-specific programs, skill-building programs, or community activities. The Flinders care plan is provided to the patient and, with permission, their health professionals and can be incorporated into an overall medical care plan.

Research studies have shown improved outcomes with use of the Flinders Program across a variety of conditions and patient groups [13-16], including patients with mental health disorders [17].

goACT is an online platform accessible by patients and health workers using either Web-enabled mobile phone or computer. Tools for some psychological therapies were already available on the platform but additional forms and communications could readily be added. Investigators wished to assess the feasibility of eHealth delivery of as many components of the Flinders Program as possible. All Flinders Program components (PIH, C&R, and P&G and the Flinders care plan) were therefore added to the goACT platform. Features of electronic systems were used where possible to improve on paper-based methods, for example in transfer of information between components of the program, and continual updating and sharing of information. eHealth features, such as reminders about goals, appointments, and activities, were integrated and negotiated so patients could view them as short message service (SMS) text or email messages or by logging into their goACT webpage. The patient was able to engage with goACT software to record progress and notes against their goals and activities on the Flinders Program and to send messages to the coach. Clients could also access additional goACT tools such as mood diaries.

eHealth-supported delivery of the Flinders Program included completion of PIH, C&R, and P&G tools and care plan into the goACT system where results could be accessed and updated by patients and health care workers, automated delivery of patient supports (such as action and appointment reminders), and email and SMS communication options to supplement any meetings or telephone contact agreed upon between patient and health care worker. The Flinders care plan was shared with health care providers and support network as identified by the patient, using appropriate electronic or physical formats.

Setting

The study was conducted in 2011 and 2012 and based in Mount Gambier, a regional center in South Australia with a population of about 25,000. The intervention was delivered by staff of a local community care organization, UnitingCare Wesley.

Participants

Inclusion criteria for the study were the presence of chronic physical and psychological comorbidities as recorded in case records of the recruiting organization, being a patient of the Mount Gambier Hospital (in rural South Australia) either as an inpatient or an outpatient, or a client of the local community care organization that delivered the program. Patients were not invited if currently physically or mentally distressed (eg by acute illness) where participation in the study would be burdensome. Participants were also required to use a simple mobile phone or Internet-based program. Mobile phones and dongles were provided for those participants who were experienced in the use of mobile phones and the Internet but who did not currently have access. Patients would be approached

for recruitment after case note review, in medical or surgical wards of the hospital, in outpatient clinics, in the emergency department, and in community care settings. Potential participants were approached by nursing staff in the hospital and by community care workers in the community. The study was approved by the government of South Australia, Department of Health, Department of Health Human Research Ethics Committee.

Training in the Program

Health care workers had existing credentials and experience in delivery of the Flinders Program but had no knowledge of goACT prior to the study. The health care workers were provided with initial training in goACT and follow-up support. Ongoing modifications were made to the health care worker interface and functions in response to in-use experiences.

The health care worker introduced each participant to the goAct software on an Internet-enabled computer at the care organization or on a mobile phone that had an Internet connection. Ongoing technology-related education was provided by the health care worker at face-to-face visits and/or over the phone to match the learning needs of the participant.

Quantitative: Measures of Online Activity

The goACT program had the capacity to record a range of on line activity of subjects, including the number and date of subject logins.

Quantitative: Outcome Measures

At baseline, a range of sociodemographic and diagnostic data were recorded. Subjects also completed the SF36 [18], the K10 [19], and the Partners in Health scale [20]. These scales were repeated at 6 months.

Qualitative Assessment

Qualitative findings were drawn from documentary records. These were notes recorded by the health care worker conducting recruitment at Mount Gambier Hospital and a study report written by the health care worker responsible for delivery of the intervention program. This narrative report was based on the experiences and observations of the two health care workers delivering the program, along with findings from exit interviews performed by the workers as participants left the program. The content of the notes and report were analyzed using established thematic analysis methods to derive the two themes of feasibility of use and acceptability of use, and the subcategories such as "infrastructure/hardware problems" and "IT skills and confidence" [21,22].

We report quantitative and qualitative findings for recruitment (as an indicator of patient acceptance), use of the system by patients and clinicians (as indicators of engagement and feasibility of delivery), and outcome measures (as an indicator of potential effectiveness).

Results

Recruitment: Quantitative Findings

We recruited 8 participants to the program during the study: 5 from medical and surgical wards of the Mt Gambier Hospital and 3 from community services. The profiles of subjects recruited into the study are shown in Table 1 and their online interactions are shown in Table 2.

Table 1. Participant demographic data and diagnosis.

Case	Gender	Age (y)	Marital status	Source of referral	Diagnosis/conditions
1	M	54	Not known	A&E[a]/hospital	Diabetes, multiple sclerosis
2	F	63	Married	A&E/hospital	Diabetes, post-traumatic stress disorder, hypertension, tachyarrhythmia
3	M	78	Married	Mental health team	Depression, back pain, eyesight, low mobility
4	F	65	Not known	A&E/hospital	Diabetes type 2, fibromyalgia, hypercholesterolemia, hypertension, diabetic neuropathy, restless legs, low mobility
5	F	51	Not known	A&E/hospital	Chronic pain, social agoraphobia
6	M	62	Not known	General practitioner	Depression, Crohn disease, osteoarthritis, anemia, bipolar disorder
7	F	70	Not known	Psychosocial rehabilitation service	Bipolar disorder
8	F	49	Single	Employment access (disability employment) service	Fibromyalgia, depression, scoliosis

[a]A&E/hospital: Accident and emergency department in a hospital.

Table 2. Participants' online interactions.

Interaction (No. of patients)	Mean (SD; SEM)
Number of logins (8)	26.4 (23.5; 8.3)
Communications	
emails to patients (4)	1.8 (0.5; 0.3)
SMS to patients (3)	1.7 (0.6; 0.3)
Internal emails sent to patients (7)	3.9 (3.4; 1.3)
Internal emails sent by patients (2)	4.5 (2.1; 1.5)
Diary entries	
Exercise (3)	17.3 (19.6; 11.3)
Mood (5)	11.2 (14.3; 6.4)
Notes (3)	9.7 (13.3; 7.7)
Activities tracked	
Not done (8)	16.5 (18.9; 6.7)
Completed (8)	16.5 (15.2; 5.4)
Completion rate (6) (%)	45.2 (26.3; 10.7)

During the recruitment period, 16 inpatients were identified from notes as meeting inclusion criteria, and 12 (75%) of these were available when study staff were available to conduct recruitment (eg, not transferred to another hospital or died). Of the 12, 5 (42%) consented and participated, 3 (25%) declined, and 3 (25%) initially consented but withdrew before participating. A further 3 patients were approached from community services, all of them consented and participated. The recruitment and intervention processes are outlined in Figures 1 and 2.

Figure 1. Participant recruitment process.

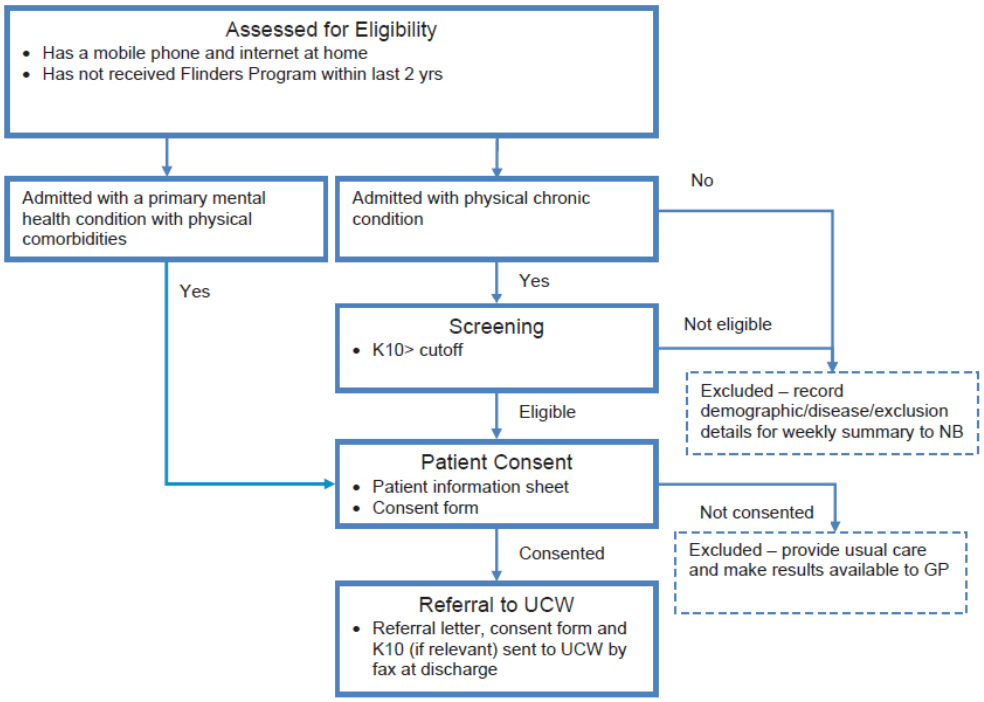
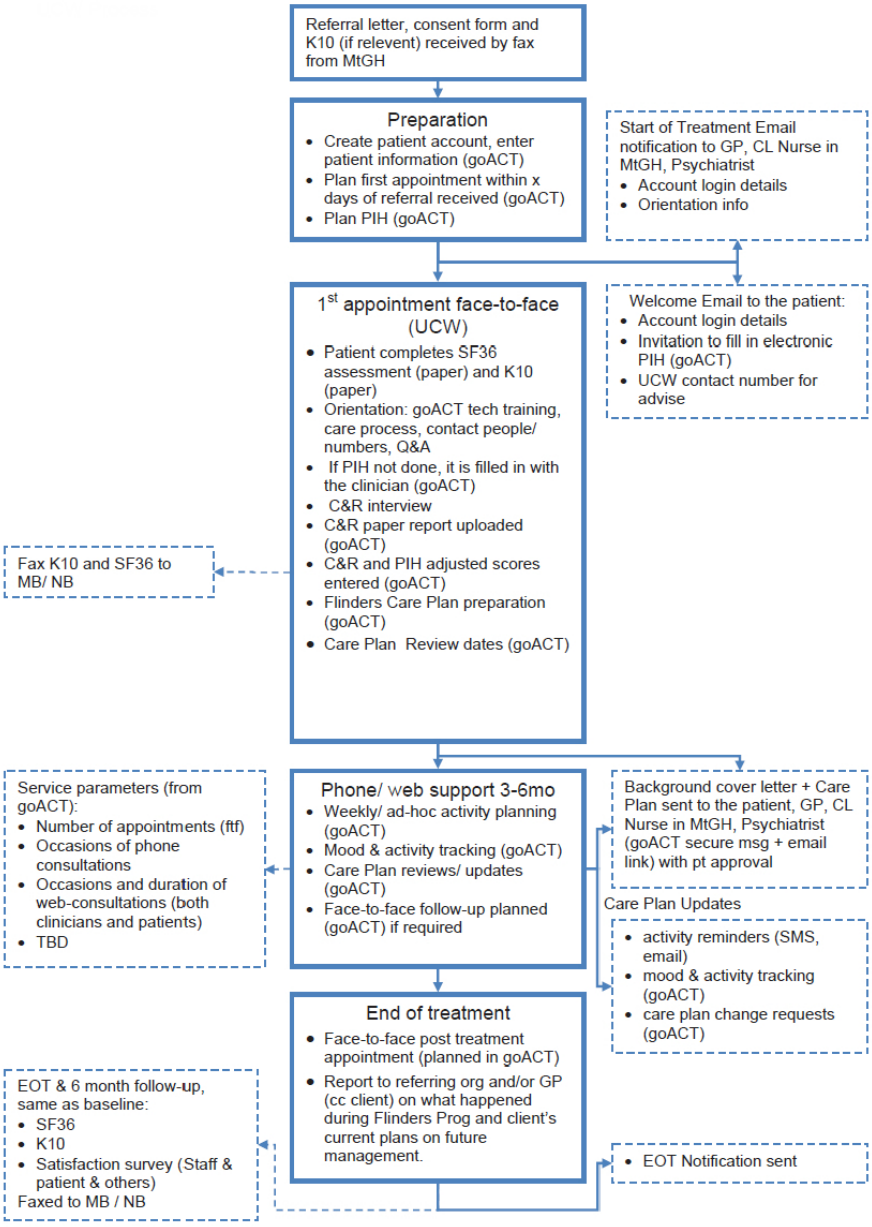


Figure 2. Intervention process.



Recruitment: Qualitative Findings

The health care workers' narrative report of the project commented on unexpected difficulties with recruitment. Severity of illness was the main reason that approaches were not made. The report noted that there were unexpectedly high numbers of younger, more acutely ill patients admitted to the hospital during the period of the study, thereby reducing the number of patients who fit the inclusion criteria due to the severity of illness. The study report also noted that recruitment from the emergency department was not feasible due to high levels of acuity, lack of privacy to discuss the study project, and pressure for patients to be quickly triaged. Those who were approached but declined gave a range of reasons, including stigma associated with participating in a project associated with psychological health.

System Use: Quantitative Findings

All participants owned a mobile phone or had Internet access except for 2 participants, who were provided with a mobile phone and dongle to enable participation.

Overall, the goACT online management program was accessed 383 times during the study period. The 2 health care workers logged in 172 times (169 by the main health worker for the study). There were 211 logins by 6 of the 8 participants and no logins by 2 participants (see breakdown in Figure 4 below). The median number of logins for each week after recruitment and total number of participants logging in per week are also shown in Figure 5. The number of logins varies between 4 and 8 per week during the first 8 weeks and decreases rapidly after this period. Table 2 contains descriptive statistics for different types of interactions with patients.

The average number of logins by day of the week is shown in Figure 4.

Figure 3. goACT platform.

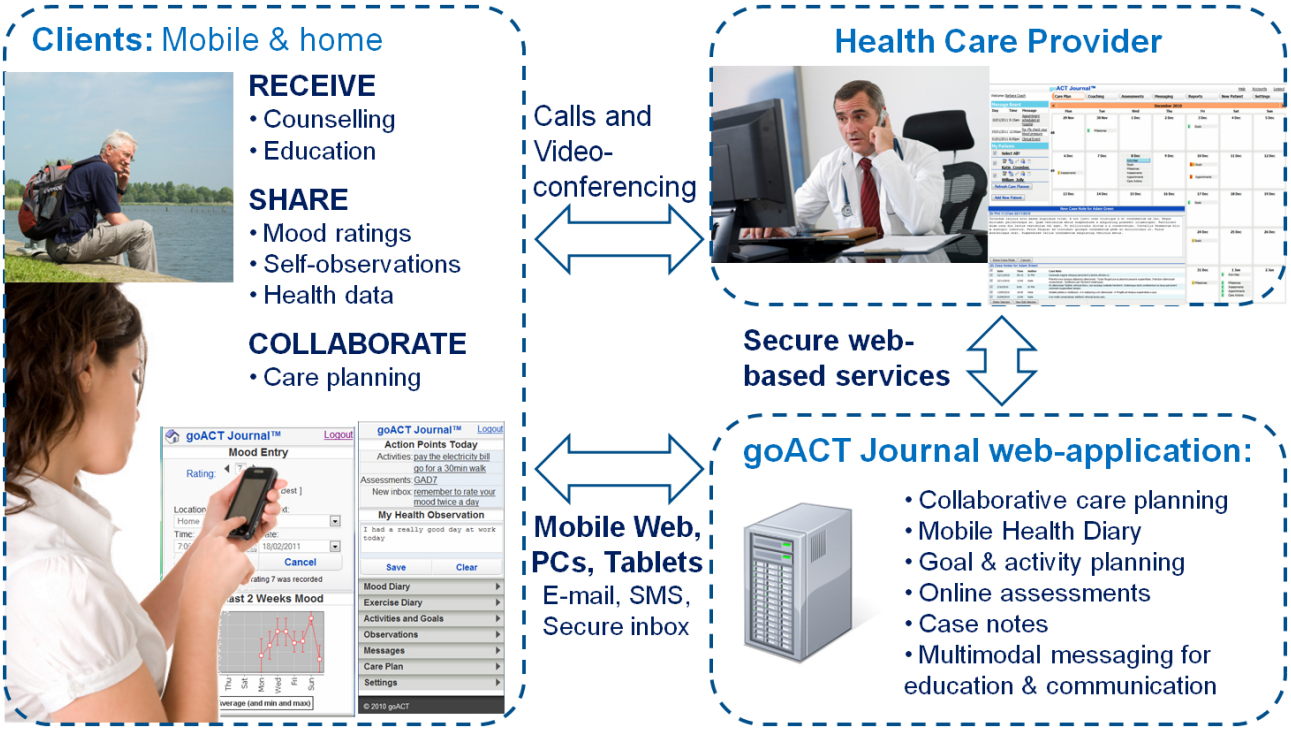


Figure 4. Average number of logins using goACT.

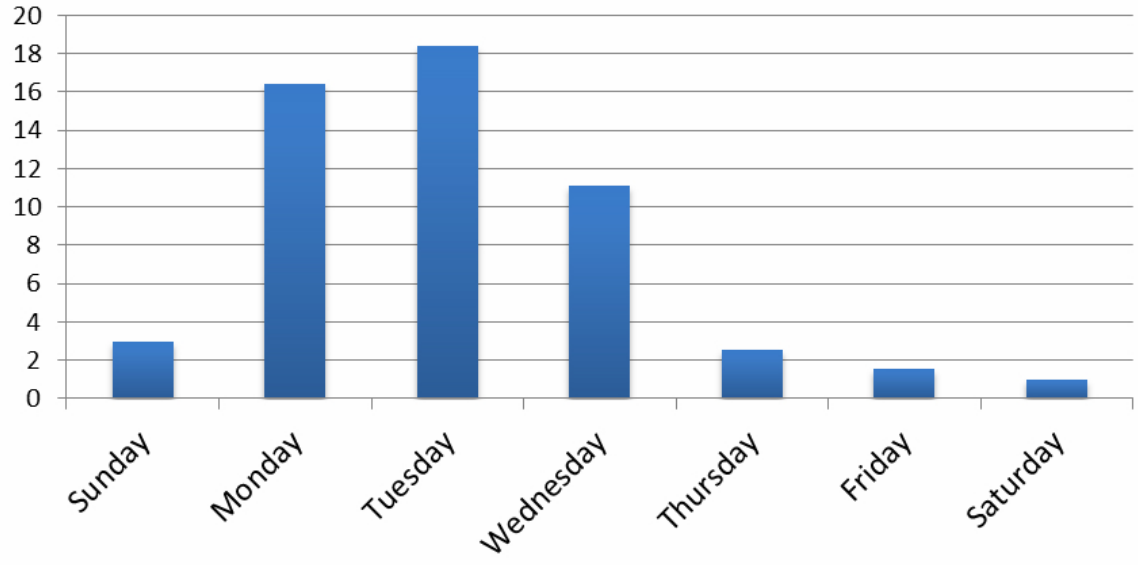
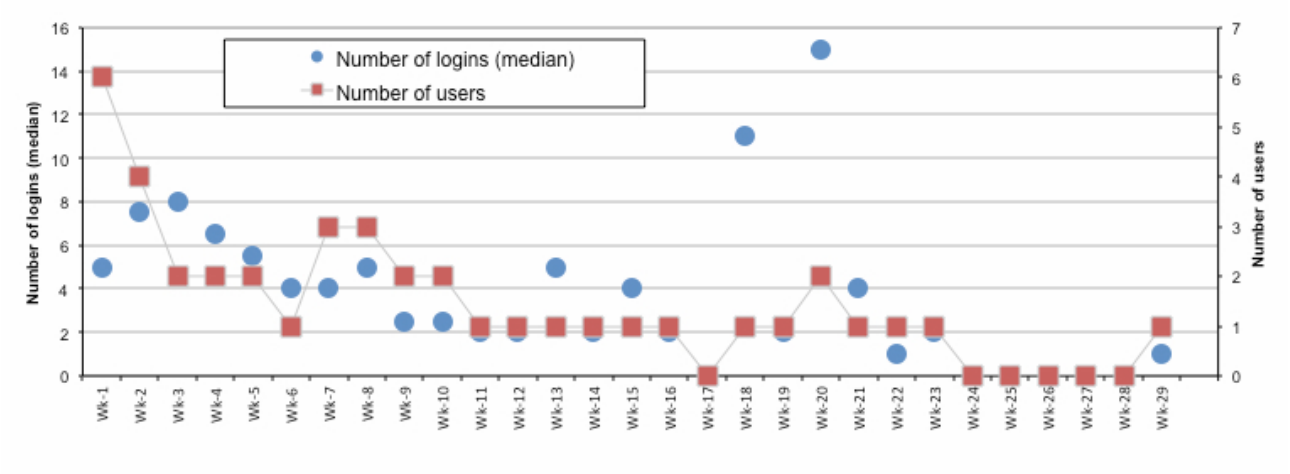


Figure 5. Daily login pattern.



System Use by Health Care Workers: Qualitative Findings

The narrative study report provided the views and experiences of the health care workers in relation to the feasibility, acceptability, and development issues of delivering the Flinders Program via the goACT platform.

The health care worker was able to use goACT online management program to manage delivery, record-keeping, and communication with patients and other health professionals for the Flinders Program. However, Flinders Program aspects requiring in-depth conversations between health care worker and patient were entered into the software after the consultation. This was deemed necessary by the health care worker to achieve effective and conversational face-to-face interaction. This is important because the Flinders Program is based on patient-centered communication and shared decision-making.

Staff reported that the software was beneficial in that it supported electronic scoring of problems, goals, and activities. This was more useful than the traditional scoring on paper copies because it removed any need for transcribing. For example, goACT increased the ease of sharing information with other staff, including general practitioners who were not in the same area.

Despite the difficulties that the pilot group of participants experienced with the e-version of the program (as explained in the next section), the health care workers thought that the ability to deliver the Flinders Program via goACT added extra layers to the communication between staff and patient. They thought that there could be more attractive or convenient ways for some patients to interact with their health care workers, or for the patients to be more involved in their self-management. The goACT program clearly offers new communication options via email, as well as tools such as an exercise diary and the capacity to provide links to high-quality disease information and online therapy websites.

System Use by Patients: Qualitative Findings

In the narrative report, health care workers observed that most participants encountered difficulties with technology use and none used the software extensively. Information technology issues fell into three different categories. First, infrastructure/hardware problems, including drop-out of rural Internet connections (which are still not highly reliable in all areas of rural Australia) and 1 participant's mobile phone being stolen. It was difficult for staff to complete the C&R and P&G with 1 participant as they were repeatedly logged off the Internet. This problem was later resolved by obtaining a more efficient Internet dongle. Physical barriers to use included small-sized phone screens and poor eyesight. The second problem was related to general information technology (IT) skills and confidence. Client difficulties with using the FP+goACT software reflected their general lack of basic knowledge and confidence for use of IT. Participants may have had general lack of familiarity with mobile phones and the Internet or limited experience (eg, familiarity with voice calls on a mobile phone but not SMS or Internet access). Third, the degree of illness severity affected performance. For 2 participants, their health conditions affected their ability to use the software. For example, due to multiple sclerosis, 1 participant reported having difficulty comprehending and remembering information. This reduced his ability to use the goACT software because he was unable to recall how to use the software after training from both the health care worker and his wife.

Outcome Measures: Quantitative Findings

Differences between scores at admission and exit were analyzed using paired t-test, in SPSS version 19. There was little change in functional outcome during the period of the study, as indicated in Table 3.

Table 3. Functional outcome changes in health.

Scale	Admission to Program Mean, SEM, SD	Exit from Program Mean, SEM, SD	Change Mean, SEM, SD	Student's *t* test	*P* value
PIH[a]	71.4, 3.7, 8.2	66.8, 3.5, 7.8	4.6, 5.0, 11.1	0.92	0.4
K10[b]	32.2, 2.6, 5.8	30.8, 2.4, 5.3	1.4, 1.1, 2.5	1.25	0.3
SF36 (Bodily pain score)[c]	37.8, 12.5, 28.0	43.6, 5.1, 11.5	−5.8, 11.6, 25.9	−0.50	0.6
SF36 (Emotional score)[c]	13.3, 8.2, 18.3	26.7, 12.5, 27.9	−13.3, 17.0, 38.0	−0.78	0.5
SF36 (Physical functioning score)[c]	29.0, 12.4, 27.7	22.0, 9.3, 20.8	7.0, 3.7, 8.4	1.87	0.1
SF36 (Social functioning score)[c]	40.0, 10.8, 24.0	62.5, 11.9, 26.5	−22.5, 14.5, 32.4	−1.55	0.2
SF36 (Mental health score)[c]	50.4, 6.0, 13.4	46.4, 5.9, 13.1	4.0, 5.5, 12.3	0.73	0.5
SF36 (Physical health summary)[c] using Australian norms	31.8, 7.8, 17.5	29.2, 3.0, 6.6	2.6, 5.3, 11.8	0.49	0.7

[a]Range, 0-96.

[b]Range, 0-100.

[c]Range, 10-50.

Discussion

This pilot study has demonstrated that an existing chronic disease management program can be successfully transferred to an existing eHealth platform for combined face-to-face and eHealth delivery. It also provides pointers for further development and targeting of eHealth-facilitated chronic disease management.

After training, the 2 health care workers used the goACT platform to successfully manage and deliver the Flinders Program, although a significant amount of additional time and effort was required for the health care worker to become familiar and skilled with goACT. They reported advantages to the eHealth version over the traditional paper-based program, such as greater ease of sharing patient information with other health care professionals. The health care workers proposed however that the eHealth version piloted was useful as an additional layer in service delivery, but not as a complete replacement.

The rapid decrease in number of weekly logins after the first 8 weeks (Figure 3) might be explained by the decrease in intensity of coaching that occurs during the later parts of the Flinders care plan. It is encouraging to note that the automated weekly care summary email sent each Sunday night was associated with a higher number of logins in the earlier part of the week. The email summarized care plan activities, appointments, and data provision scheduled for the upcoming week and reminded participants that they could go into the system to see more detail and check off completed activities. The emails could be switched off by participants but none chose to do so. Future research in eHealth interventions should focus on strategies to maintain engagement beyond the early period, such as optimizing automated and personalized online support.

The intervention achieved only limited participant use. One reason may be that most participants had complex and severe illnesses and their daily lives were concerned with managing their health conditions. As well as health status, other factors limiting successful eHealth use among study participants may be the age profile (49-78 years old, with the average in their 50s or 60s), and the rural location of residents. These factors are consistently associated with lower levels of IT use in Australia [23,24]. These factors would limit their ability to be interested in, or successfully deal with, the addition of an unfamiliar eHealth program. We suggest that future studies of this kind might include initial screening using an e-literacy tool [25]. This would allow assessment of participants' needs for support to use the hardware and software, thereby increasing the likelihood of success with the eHealth program, and identification of those patients requiring continuation with the offline version of the program. It would also be useful to identify the extent to which basic IT use and/or IT use for health self-management are barriers to engagement. In a study N=2,928, adults living with chronic disease (n=538) were less likely to go online (51%) than those without such disease (n=2,367) (74%), but once online, they were avid consumers of health information [26].

Study limitations included the small sample size. While outcome measurement was demonstrated to be feasible, the inclusion of 8 participants was too small to demonstrate any changes in health-related measures.

In summary, the pilot study demonstrated the feasibility of implementing and delivering a chronic disease management program using a Web-based patient-clinician application in a rural setting. If initial barriers to IT use can be addressed, then people with chronic conditions can be successful users of eHealth systems such as FP+goACT.

Acknowledgments

We acknowledge financial input and contribution of staff time and expertise from goACT, Country Health South Australia, and UnitingCare Wesley Port Adelaide, and thank the patients who volunteered as participants. The study was partially funded by a Faculty of Health seeding grant from Flinders University. Special thanks to Gina Kasprzyk for assisting with manuscript formatting and submission process.

Conflicts of Interest

Geoffrey Schrader and Niranjan Bidargaddi have commercial interest in goACT.

References

1. Arnrich B, Mayora O, Bardram J, Tröster G. Pervasive healthcare: paving the way for a pervasive, user-centered and preventive healthcare model. Methods Inf Med 2010;49(1):67-73. [doi: 10.3414/ME09-02-0044] [Medline: 20011810]
2. Ludwig W, Wolf KH, Duwenkamp C, Gusew N, Hellrung N, Marschollek M, et al. Health-enabling technologies for the elderly--an overview of services based on a literature review. Comput Methods Programs Biomed 2012 May;106(2):70-78 [FREE Full text] [doi: 10.1016/j.cmpb.2011.11.001] [Medline: 22115611]
3. Luxton DD, McCann RA, Bush NE, Mishkind MC, Reger GM. mHealth for mental health: Integrating smartphone technology in behavioral healthcare. Professional Psychology-Research and Practice 2011;42(6):505-512 [FREE Full text] [doi: 10.1037/a0024485]
4. Chumbler NR, Haggstrom D, Saleem JJ. Implementation of health information technology in Veterans Health Administration to support transformational change: telehealth and personal health records. Med Care 2011 Dec;49 Suppl:S36-S42. [doi: 10.1097/MLR.0b013e3181d558f9] [Medline: 20421829]
5. Hall AK, Stellefson M, Bernhardt JM. Healthy Aging 2.0: the potential of new media and technology. Prev Chronic Dis 2012;9:E67 [FREE Full text] [Medline: 22405474]
6. Ramadas A, Quek KF, Chan CK, Oldenburg B. Web-based interventions for the management of type 2 diabetes mellitus: a systematic review of recent evidence. Int J Med Inform 2011 Jun;80(6):389-405. [doi: 10.1016/j.ijmedinf.2011.02.002] [Medline: 21481632]
7. Lawn S, Schoo A. Supporting self-management of chronic health conditions: common approaches. Patient Educ Couns 2010 Aug;80(2):205-211. [doi: 10.1016/j.pec.2009.10.006] [Medline: 19931372]
8. Boyd CM M, Fortin M. Future of multimorbidity research: How should understanding of multimorbidity inform health system design. Public Health Reviews 2010;32(2):451-474 [FREE Full text]
9. Beatty L, Lambert S. A systematic review of internet-based self-help therapeutic interventions to improve distress and disease-control among adults with chronic health conditions. Clin Psychol Rev 2013 Jun;33(4):609-622. [doi: 10.1016/j.cpr.2013.03.004] [Medline: 23603521]
10. Barnett K, Mercer SW, Norbury M, Watt G, Wyke S, Guthrie B. Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study. Lancet 2012 Jul 7;380(9836):37-43. [doi: 10.1016/S0140-6736(12)60240-2] [Medline: 22579043]
11. Sarela A, Bidargaddi N, Giansiracusa M. Patient Management System and Method. WO Patent 2,013,033 2013:788.
12. Harvey PW, Petkov JN, Misan G, Fuller J, Battersby MW, Cayetano TN, et al. Self-management support and training for patients with chronic and complex conditions improves health-related behaviour and health outcomes. Aust Health Rev 2008 May;32(2):330-338. [Medline: 18447824]
13. W. Battersby M, Ah Kit J, Prideaux C, Harvey PW, Collins JP, Mills PD. Research Implementing the Flinders Model of Self-management Support with Aboriginal People who have Diabetes: Findings from a Pilot Study. Aust. J. Prim. Health 2008;14(1):66. [doi: 10.1071/PY08009]
14. Crotty M, Prendergast J, Battersby MW, Rowett D, Graves SE, Leach G, et al. Self-management and peer support among people with arthritis on a hospital joint replacement waiting list: a randomised controlled trial. Osteoarthritis Cartilage 2009 Nov;17(11):1428-1433. [doi: 10.1016/j.joca.2009.05.010] [Medline: 19486959]
15. Battersby MW, Beattie J, Pols RG, Smith DP, Condon J, Blunden S. A randomised controlled trial of the Flinders Program™ of chronic condition management in Vietnam veterans with co-morbid alcohol misuse, and psychiatric and medical conditions. Aust N Z J Psychiatry 2013 May;47(5):451-462. [doi: 10.1177/0004867412471977] [Medline: 23307806]
16. Lawn S, Battersby MW, Pols RG, Lawrence J, Parry T, Urukalo M. The mental health expert patient: findings from a pilot study of a generic chronic condition self-management programme for people with mental illness. Int J Soc Psychiatry 2007 Jan;53(1):63-74. [Medline: 17333952]
17. Ware JE, Kosinski M, Dewey JE. SF-36? health survey manual & interpretation guide. Lincoln, R.I: QualityMetric Inc; 2000.
18. Andrews G, Slade T. Interpreting scores on the Kessler Psychological Distress Scale (K10). Aust N Z J Public Health 2001 Dec;25(6):494-497. [Medline: 11824981]

19. Petkov J, Harvey P, Battersby M. The internal consistency and construct validity of the partners in health scale: validation of a patient rated chronic condition self-management measure. Qual Life Res 2010 Sep;19(7):1079-1085. [doi: 10.1007/s11136-010-9661-1] [Medline: 20437206]
20. Rozenblum R, Donzé J, Hockey PM, Guzdar E, Labuzetta MA, Zimlichman E, et al. The impact of medical informatics on patient satisfaction: a USA-based literature review. Int J Med Inform 2013 Mar;82(3):141-158. [doi: 10.1016/j.ijmedinf.2012.12.008] [Medline: 23332922]
21. Pearce C, Arnold M, Phillips CB, Trumble S, Dwan K. The many faces of the computer: an analysis of clinical software in the primary care consultation. Int J Med Inform 2012 Jul;81(7):475-484. [doi: 10.1016/j.ijmedinf.2012.01.004] [Medline: 22325592]
22. Australian Government A. o. Australian: ..55.001 - Patterns of internet access in , , Bureau of Statistics: B URL: http://www.ausstats.abs.gov.au/ausstats/free.nsf/0/1B7DD59C9E8F52ECCA2573A1007EE8DA/$File/8146055001_2006.pdf [accessed 2013-11-27] [WebCite Cache ID 6LR8Nw8OM]
23. Newman LA, Biedrzycki K, Baum F. Digital technology access and use among socially and economically disadvantaged groups in South Australia. URL: http://ci-journal.net/index.php/ciej/article/view/639 [accessed 2014-04-28] [WebCite Cache ID 6PAHakK3F]
24. Collins SA, Currie LM, Bakken S, Vawdrey DK, Stone PW. Health literacy screening instruments for eHealth applications: A systematic review. Journal of Biomedical Informatics 2012 Jun;45(3):598-607 [FREE Full text] [doi: 10.1016/j.jbi.2012.04.001]
25. Fox S. American: . Pew Internet & Life Project; 2007. E-patients with a disability or chronic disease URL: http://www.pewinternet.org/~/media//Files/Reports/2007/EPatients_Chronic_Conditions_2007.pdf.pdf [accessed 2013-11-27] [WebCite Cache ID 6LSCZYjMj]
26. Montague E, Perchonok J. Health and wellness technology use by historically underserved health consumers: systematic review. J Med Internet Res 2012;14(3):e78 [FREE Full text] [doi: 10.2196/jmir.2095] [Medline: 22652979]

Abbreviations

C&R: cue and response interview
IT: information technology
PIH: partners in health scale
P&G: problem and goals assessment
SMS: short message service

Edited by G Eysenbach; submitted 06.08.13; peer-reviewed by F Grajales III; comments to author 31.10.13; revised version received 03.12.13; accepted 18.01.14; published 12.06.14.

Please cite as:
Schrader G, Bidargaddi N, Harris M, Newman L, Lynn S, Peterson L, Battersby M
An eHealth Intervention for Patients in Rural Areas: Preliminary Findings From a Pilot Feasibility Study
JMIR Res Protoc 2014;3(2):e27
URL: http://www.researchprotocols.org/2014/2/e27/
doi:10.2196/resprot.2861
PMID:24927511

Publisher:
JMIR Publications
130 Queens Quay East.
Toronto, ON, M5A 3Y5
Phone: (+1) 416-583-2040
Email: support@jmir.org