

Proposal

Use of Relational Agents to Improve Family Communication in Type 1 Diabetes: Methods

Debbe Thompson¹, PhD; Karen W Cullen¹, PhD; Maria J Redondo², PhD; Barbara Anderson³, PhD

¹USDA/ARS Children's Nutrition Research Center, Department of Pediatrics, Baylor College of Medicine, Houston, TX, United States

²Texas Children's Hospital, Pediatric Endocrinology and Metabolism, Baylor College of Medicine, Houston, TX, United States

³Psychology, Department of Pediatrics, Baylor College of Medicine, Houston, TX, United States

Corresponding Author:

Debbe Thompson, PhD

USDA/ARS Children's Nutrition Research Center

Department of Pediatrics

Baylor College of Medicine

1100 Bates St

Houston, TX, 77030

United States

Phone: 1 713 798 7076

Fax: 1 713 798 7098

Email: dit@bcm.edu

Abstract

Background: Physiological and environmental risk factors interact to undermine blood glucose control during early adolescence. This has been documented to be associated with family conflict and poor adherence to diabetes management tasks. Family Teamwork is an efficacious program demonstrated to enhance family communication and reduce conflict during this vulnerable period. It was designed to be delivered to families in-person, which limited reach and potential impact.

Objective: The purpose of this paper is to present the protocol for adapting Family Teamwork for Web-based delivery.

Methods: Formative research with health care providers, parents, and adolescents will help modify Family Teamwork for Web-based delivery by a relational agent (ie, a computerized character with human-like features and actions). Sessions will be interactive, requiring both parent and adolescent participation, with the relational agent serving as a health coach. After programming, usability testing will be conducted to help ensure the program is easy to use. Video and instructional materials will be developed to facilitate use, and a small pilot study will be conducted to assess feasibility. Families will provide written informed consent prior to participation in any phase of the study. The Institutional Review Board at Baylor College of Medicine reviewed and approved the protocol (H-37245).

Results: Formative research is underway. No results are available at this time.

Conclusions: This research has the potential to make an important contribution to diabetes management by using technology to enhance the reach of an efficacious program.

(*JMIR Res Protoc* 2016;5(3):e151) doi: [10.2196/resprot.5817](https://doi.org/10.2196/resprot.5817)

KEYWORDS

adolescents; family communication; pre-adolescents; relational agent; type 1 diabetes

Introduction

The incidence of type 1 diabetes (T1D) is increasing worldwide [1], and T1D is the second most prevalent chronic illness among US children, after asthma [2]. Despite the recent introduction of new types of insulin, insulin delivery systems, and innovative blood glucose (BG) monitoring technologies to improve T1D self-management and BG control, non-adherence to a diabetes

management regimen remains common, especially in young adolescents with T1D [3]. Unfortunately, physiological and environmental risk factors interact to undermine BG control during pre- and early adolescence. While the physiologic insulin resistance that occurs normally during pubertal development and resulting deterioration of BG control have been well-established [4], only recently have investigators documented the significant role of the family in diabetes

adherence and BG control during this period [5]. Recent longitudinal studies [6-8] have demonstrated that poor adherence and BG control during adolescence, as well as family problems, often persist into early adulthood, amplifying the risk of long-term microvascular, macrovascular, and psychological complications. Therefore, it is increasingly clear that the pre- and early-adolescence periods are particularly critical. Intervening during this period is essential for improving both adherence and diabetes-specific family interactions, which will establish a trajectory of strong, stable self-management behavior and more optimal BG during adolescence, thus lowering the risk for long-term complications [9,10].

Family Teamwork (FT) is a clinic-based face-to-face intervention for pre- and early-adolescent youth with T1D and their parents. It targets potentially modifiable factors documented to impact glycemic control and adherence to BG monitoring, such as parent-youth conflict and communications around BG monitoring. FT was designed to increase positive parent involvement in, and reduce family conflict around, T1D management in young adolescents with T1D. Its goal was to improve adherence and BG control as reflected by hemoglobin A1c (HbA1c) [11]. The 8-session program was delivered to 10-14 year-olds and a parent during routine clinic visits by a trained research assistant. Two randomized controlled trials demonstrated its efficacy (ie, significant improvement in BG monitoring adherence and HbA1c in the FT group compared with the standard care group [11,12], as well as increases in self-reported quality of life [13]). Parents in the FT group maintained or increased involvement in diabetes management tasks, especially BG monitoring, with no increase in diabetes-specific family conflict [14]. Youth in the intervention arm improved BG monitoring adherence [11] and self-reported quality of life [13]. Furthermore, participants who received the intervention had a decrease in HbA1c from 8.4% \pm 1.3% to 8.2% \pm 1.1% compared with the deterioration from 8.3% \pm 1.0% to 8.7% \pm 1.5% ($P < .05$) observed in the control group, as expected during early adolescence [12].

Even though FT was proven to be efficacious, its reach was severely limited by the need for families to travel to a particular location to participate in the intervention and the costs associated with delivery by a trained research assistant. Since there is an urgent need to broadly disseminate effective interventions for the high-risk group of early adolescent youth with T1D [11], a method to deliver FT in a more convenient, lower-cost format is needed. Internet use is prevalent in today's world [15]. Therefore, adapting FT for delivery via a Web-based format, led by a relational agent (an animated computer character with human-like features and behaviors) may offer a solution.

Research has demonstrated the feasibility and acceptability of relational agents. For example, relational agents have been utilized in a variety of adult populations and with a wide array of health behaviors (eg, a virtual nurse providing discharge instructions to low health literate patients [16] and patients with depressive symptoms [17]; an exercise advisor for college students [18,19], adults [20], and low health literate older adults [16,18,21]; a health advisor promoting medication adherence to adults with schizophrenia [18,22]; a virtual coach promoting adherence to physical activity in overweight adults [23]; and a

virtual agent promoting fruit and vegetable consumption to healthy adults [20]). They are also being developed for use in group settings and for multiple behaviors. Because research shows promising evidence that relational agents can establish a therapeutic relationship with patients and that they are well accepted by a variety of patient populations [18,19], this approach has potential as a method for overcoming limitations commonly associated with face-to-face behavioral interventions, such as limited reach, scheduling constraints, and variable fidelity [24,25]). Thus, incorporating relational agents into programs traditionally delivered in-person could overcome these limitations and provide a low-cost, easy-to-disseminate method for reaching families in need.

This research will convert FT to a Web-based delivery format guided by a relational agent (ie, Family Teamwork Online [FTO]) and assess the feasibility of this approach. This research addresses an important gap in the field and has the potential to enhance the reach and potential impact of a proven, efficacious intervention developed for an at-risk group. The purpose of this paper is to describe the protocol for adapting FT to a Web-based format guided by a relational agent.

Methods

Overview

This research will be conducted in two phases: development and pilot. The purpose of the development phase is to conduct formative research with parents and adolescents with T1D and their providers in order to adapt the program to a Web-based format. The pilot phase will assess feasibility of this approach. Each phase is described below. Ethical approval was provided by the Institutional Review Board at Baylor College of Medicine (H-37245). Because the purpose of this trial is to establish the feasibility of this approach versus a randomized control trial to determine efficacy or effectiveness, the trial has not been registered with a trial registry accredited by the World Health Organization.

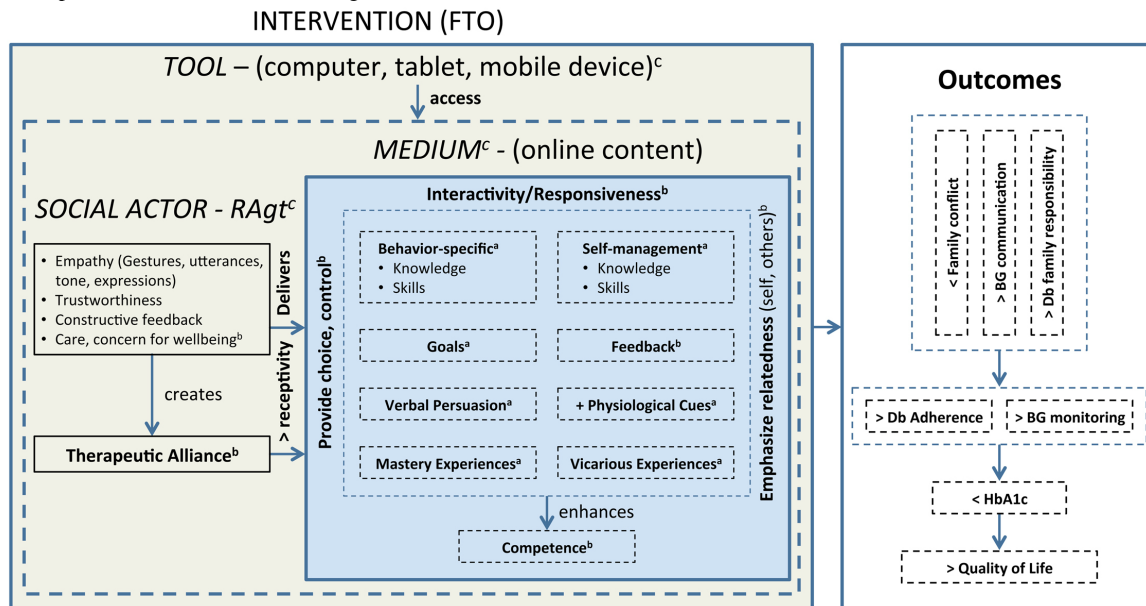
Theoretical Framework

The content and structure of the original FT was grounded in social cognitive theory (SCT) [26]. The adaptation of FT to FTO will be guided by Computers As Persuasive Technologies (CAPTOLOGY) [27] and self-determination theory (SDT) [28]. CAPTOLOGY provides a framework for understanding how computers can be used as a persuasive mechanism to intentionally change attitudes and behaviors. For example, computers can personalize the encounter (eg, greeting family members by name), provide an interactive versus didactic session, simulate experiences (eg, provide opportunities for the parent/adolescent dyad to practice skills taught in the session), and receive tailored feedback based on responses, problems, or issues brought up in the session [27]. The framework posits that this is achieved through the "functional triad," which is a unique combination of the tool (eg, access device, such as a computer or tablet), medium (eg, delivery mode, such as the Internet), and social actor (eg, relationship builder, such as the relational agent) [27]. SDT [28] contends that three basic needs drive behavior: competence (ie, knowledge, skills, ability to successfully perform a behavior), autonomy (ie, choice, control),

and relatedness (ie, connection to important others). A high level of need satisfaction promotes internalization and integration of the behavior into one’s sense of self (ie, “I am a person who routinely monitors my BG,” “I am a person who tries to understand my parent’s perspective when we disagree over my diabetes”). Internalization and integration of a behavior with one’s sense of self increases internally driven motivation to perform the behavior. This, in turn, increases the likelihood that the behavior will be performed and maintained over time [28]. The relational agent will be constructed to emphasize need

fulfillment. For example, it will enhance effective communication among parents and adolescents around T1D self-management behaviors by presenting skills, encouraging practice (ie, competence), and emphasizing personal choice regarding how they interpret comments and respond to each other (ie, autonomy). Improved communication will provide insight into what the other person’s motivations may be when they react in a certain way, and it will help establish a bond of trust and rapport with the relational agent (ie, relatedness). **Figure 1** shows the conceptual model guiding the adaptation.

Figure 1. Conceptual Model of how FTO is designed to influence outcomes.



The conceptual model provides an overview of how FTO-RAgt integrates Social Cognitive Theory^a, Self Determination Theory^b, and Captology^c to promote intentional behavior change. Note: RAgt=relational agent; Db=diabetes; BG=blood glucose; SDT=Self Determination Theory; +=positive.

Study Sample

Health care providers at a diabetes care center in a large tertiary care children’s hospital in the southwestern United States are eligible if they are employed full or part time by the facility. They will be invited by email to participate in the first phase of the study.

Current patients and their primary diabetes caregivers attending a large diabetes care center in Texas are eligible to participate in this study: 10-14 year olds with T1D as defined by the American Diabetes Association criteria [29], disease duration at least 1 but not over 5 years, fluent in English with access to high-speed Internet, and a parent willing to participate in the study are eligible to participate. Adolescents are ineligible if the average HbA1c over the past year is ≥12% (due to a greater likelihood of having psychiatric conditions [30]) or 7% (excellent glycemic control), unable to attend regular clinic visits, or have a physical/mental disease or condition that may conflict with study protocol and limit ability to complete data collection activities or participate in the intervention.

Eligible parents must be the primary caregiver of a child with T1D enrolled in the study, be willing to participate in study activities, be fluent in English, have access to high-speed Internet, and not be planning to leave the geographic area.

Recruitment

To identify families, a research coordinator experienced in working with families with diabetes will screen the clinic appointment schedule to identify families who meet the eligibility criteria. Eligible families will be invited by letter to participate. Within a week of sending the letter, study staff will contact the families to answer questions, ascertain interest, and screen for eligibility. If families are interested and eligible, written informed consent and child assent will be obtained.

Development Phase

The purpose of this phase is to conduct formative research to adapt FT for Web-based delivery by a relational agent. It consists of in-person interviews with health care providers, Web-based surveys and telephone interviews with parents and adolescents, in-person usability testing with parents and adolescents, and development of a brief instructional video and supporting materials to facilitate intervention completion.

Sample Sizes

A purposive sampling approach will be used to identify sample sizes for the formative research [31]. We selected this approach expecting that it would provide key insights from stakeholders (health care providers, families who have a child with T1D) that could be used to update the content and develop a program sensitive to the needs of families enrolled in the study. In this

sampling approach, sample size is driven by the number of participants needed to address key research questions. Therefore, formative research will involve 10 health care providers and up to 24 parent/adolescent dyads. Usability testing will be conducted with a different sample of up to 12 parent/adolescent dyads. If analysis does not yield adequate information with which to address the research questions, additional data will be collected until this point is attained.

Health Care Providers

Health care providers will participate in a scripted, semistructured interview to identify their general thoughts about FTO, diabetes management concerns, and issues often seen in clinic related to family conflict. Interviews will be digitally recorded and transcribed verbatim. Data will be coded and analyzed using thematic analysis [32]. A priori codes will provide the initial coding framework; they will be augmented with additional codes that emerge during analyses. Codes will be examined to identify themes and patterns. Discrepancies will be discussed and resolved.

Parent/Adolescent Dyads

Formative research with families will include up to two Web-based surveys, each followed by a telephone interview to clarify, expand, and understand survey responses. Parents and adolescents will participate in this phase separately. They will be asked to provide feedback on the relational agent (eg, looks, clothing, skin tone, hair style, name, facial expressions), issues their family commonly faces surrounding diabetes management, usual reactions, and suggested session topics. This information will be used to adapt FT for Web-based delivery (FTO) and to develop the relational agent. Sample questions will include, regarding relational agent mock-ups, "Which virtual health educator appeals to you the most?" (response options will include Male, Female with curly hair, Female with straight hair); relating to structure, "The sessions will be delivered online through your computer. Parents and children will view the program together. In your opinion, about how long should each session last?" (response options will range from 15 minutes-1 hour); and regarding content, "What is your [parent's/teen's] usual reaction to high blood glucose readings?" (response options will include Calmly talks about it, Refuses to talk about it, Gets upset or angry, Gets frustrated, Gets defensive, None apply).

Creating Family Teamwork Online

The information presented in each content segment, including content, questions, response options, and feedback will be adapted from the original FT for Web-based delivery by a relational agent based on feedback from health care providers and families. Each session will focus on a specific topic informed by the original FT and the formative research. Sessions will be scripted and will include (1) didactic components where the relational agent conveys content, components where "typical" family scenarios are demonstrated, and (2) interactive components where the relational agent poses a question for the families, parent, and/or adolescent, they select a response, and the relational agent responds. Parents and adolescents will view the sessions together. Session delivery will mimic the original

FT delivery by a trained research coordinator as closely as possible. For example, during each session, the relational agent will convey the session content in segments, rather than all at once. Similar to in-person delivery, after presenting content, the relational agent will ask the family a question. The family will have several response options from which to select. Then feedback will be provided. Responses will be made via mouse click. This pattern will continue until the end of the session, which ends in a joint goal-setting task specific to family communication around T1D management. The relational agent's verbal and nonverbal behaviors will be generated using pre-rendered three-dimensional animated video clips. The video clips will be based on scripts generated for each session. Responses will trigger the next video clip in the sequence. The list of questions is set and will not branch.

FTO will be programmed to be viewed over a high-speed Internet connection, from a desktop, laptop, tablet, or mobile device. It will include high-resolution graphics and vocal tracks, animation, and interactivity. Because it is being programmed to be viewed online, the program will not be device dependent.

Usability Testing

After development, FTO usability (ie, ease of use) will be assessed with up to 12 new families to identify technical issues and ease of navigation (ie, do parents/adolescents understand what to do and can they do it without assistance). Following standard usability procedures [33], research staff will observe and keep a log of difficulties as participants (parent/adolescent dyads) work through sessions. On completion, the retrospective think-aloud technique will be used to guide the family through a description of what they did, why, problems they encountered, and how they addressed them as they navigated the program. The research coordinator will take notes of their comments. When the parent/child dyad has finished, using the retrospective probing technique, the research coordinator will ask questions about their thoughts and actions based on the notes taken during the observation and think aloud sessions. Each parent and adolescent will also complete the System Usability Scale [34]; a score of >80.3 will be interpreted to mean that the system has a high level of usability [35].

Instruction

A brief video and colorful print information guide will be developed demonstrating how to navigate FTO. These materials will be written at a 5th grade reading level to facilitate comprehension by both parents and adolescents.

Pilot Phase

Sample Size

Feasibility studies are designed to contribute to a well-informed main trial [36-38] and are the first step in intervention development [37-39]. Although the literature does not offer consistent guidance, an appropriate sample size should represent the minimum number of participants needed to adequately assess the feasibility criteria [40]. A sample size of 24 dyads would provide a reasonable evaluation of feasibility; it would also be large enough to examine trends in HbA1c over time.

Design

The feasibility study will use a one-group design with three data collection periods: baseline, post 1 (immediately after completion of the online program, ie, approximately 3 months after baseline), and post 2 (approximately 3 months after post 1, ie, approximately 6 months after baseline). Because the primary outcome in a future efficacy study will include HbA1c, the pilot study will encompass 6 months. This will enable an examination of trends in intervention effects on HbA1c over time.

Procedure

FTO will be completed online using procedures from other online studies [41,42]. Parents/adolescents will complete the sessions together; they will each be given unique passwords to log on to the program. Both parent and adolescent will need to log on to view a new session. Families will receive email reminders when eligible to log on to the next session. Clinical data collection will occur during the usual clinic visits, online, and as parents/adolescents navigate FTO. Each session will be led by the relational agent who will work with the parent/adolescent dyad during the program. At the end of each session, families will have the option to print their goal and a tip sheet offering suggestions for ways to enhance goal attainment. Families can replay previously viewed sessions unlimited times.

Data Collection Procedure and Measures

Several types of data will be collected during this study. Self-report questionnaires will be completed by parents/adolescents separately over a secure, password-protected website at baseline, post 1, and post 2. Trained research staff will extract clinic data needed for the study from the medical record following approved clinic procedures. Program use data will be automatically collected as families navigate FTO. Staff

logs will be maintained to assess key process evaluation variables (see Table 1; [17,43-49]).

Feasibility Outcomes

FTO will be considered feasible if (1) recruitment goals are met, (2) families complete $\geq 75\%$ of the sessions (ie, login rate), (3) attrition rate is $\leq 10\%$, (4) program satisfaction with FTO is high (average score of $\geq 16/20$), (5) therapeutic alliance with the relational agent is high (average score of $5/7$), (6) families express positive attitudes toward the relational agent (average score of $5/7$), (7) $\geq 80\%$ of data are collected at post 1 and post 2, and (8) few technical issues ($< 10\%$) with intervention delivery occur.

Analysis Plan

Feasibility

Analysis for the feasibility study will be mainly descriptive. To enrich understanding of the FTO process, descriptive statistics will be calculated and compared to the target goals. FTO will be considered feasible if target goals are met.

Exploratory

Using a within-subject design, linear effect mixed models will examine change in HbA1c and self-report psychosocial measures over time (ie, baseline to post 1, post 2), controlling for potential confounders (eg, gender, race/ethnicity). Separate models will be conducted for psychological and behavioral outcomes. Self-report outcomes will be analyzed separately for parents and adolescents. Although statistical significance is not expected due to the small sample size, changes will be examined to determine if they are in the expected directions. Analyses will be calculated with SAS 9.4 [50].

Anticipated Results

We anticipate that feasibility criteria will be met and that families in the FTO group will have favorable changes in the expected directions.

Table 1. Pilot study measures.

Who	What	Method	Prior	Baseline	Intervention	Post 1	Post 2	
Adolescent	Diabetes Self-Management Questionnaire [43]	Self-report		x		x	x	
	Peds QL Diabetes Module 3.2 [44]	Self-report		x		x	x	
	Revised Diabetes Family Conflict Scale [45]	Self-report		x		x	x	
	BG Monitoring Communication Survey [46]	Self-report		x		x	x	
	Diabetes Family Responsibility Questionnaire [47]	Self-report		x		x	x	
	Program satisfaction [41,48]	Self-report				x		
	Therapeutic Alliance [49]	Self-report				x		
	Attitudes toward Relational Agent [17]	Self-report				x		
	Program reactions	Interview				x	x	
	BG meter/insulin pump readings	EHR ^a			x		x	x
	HbA1c	EHR			x		x	x
	Height	EHR			x		x	x
	Weight	EHR			x		x	x
	Treatment regimen	EHR			x		x	x
	Severe hypoglycemia/ketoacidosis	EHR			x		x	x
Emergency room visits/hospitalizations	EHR			x		x	x	
Parent	Revised Diabetes Family Conflict Scale [45]	Self-report		x		x	x	
	BG Monitoring Communication Survey [46]	Self-report		x		x	x	
	Diabetes Family Responsibility Questionnaire [47]	Self-report		x		x	x	
	Demographics	Self-report		x				
	Program satisfaction	Self-report				x		
	Therapeutic Alliance [49]	Self-report				x		
	Attitudes toward Relational Agent [17]	Self-report				x		
Program reactions	Interview					x	x	
Program	Logins	Program			x			
	Responses	Program			x			
	Technical issues	Program			x			
	Recruitment	Staff logs	x					
	Attrition	Staff logs		x	x	x	x	
Health care providers	Opinions to help develop FTO	Interview	x					

^aEHR: electronic health record.

Discussion

Principal Considerations

The Diabetes Control and Complications Trial and its findings heightened awareness of the critical importance of maintaining near-normal BG levels to delay and/or prevent T1D complications [51]. Adolescents are particularly affected by poor adherence to the demanding T1D regimen. Family conflict and negative communication around diabetes management, especially around BG monitoring, are barriers to adolescent adherence to their treatment plan [14]. A meta-analysis of

pediatric T1D interventions with adherence-promoting components concluded that behavioral interventions focusing “on direct, behavioral processes and neglected emotional, social and family processes are unlikely to have an impact on BG control” (p. 1658) [52]. The most efficacious interventions addressed both [52]. The FT intervention meets these criteria: it targets interactions of the parent and adolescent with T1D and addresses T1D management behaviors (eg, BG monitoring, administering insulin, carbohydrate counting).

Although face-to-face interactions with health care providers have historically been thought of as the most effective method

for achieving health behavior change and are considered the “gold standard” [18,53], limited reach [53], time [18], and consistency in intervention delivery can reduce effectiveness [18]. Relational agents may help overcome these limitations. They simulate characteristics of face-to-face interactions with a health care provider, including verbal and nonverbal behaviors that contribute to trust, rapport, and relationship-building. Programs delivered by relational agents are also convenient, accessible, and likely cost effective, particularly when delivered online [18].

Relational agents have been utilized in a variety of populations and health behaviors [16-23]. However, to our knowledge, they have not been used to enhance family communication around T1D in adolescence. Because research shows promising evidence that relational agents can establish a therapeutic relationship with patients and that they are accepted by a wide variety of patient populations [18,19], relational agents have the potential to enhance reach and public health impact of efficacious interventions by overcoming limitations associated with face-to-face delivery. Thus, if proven feasible, this research has the potential to ultimately impact how health education programs are delivered to families of adolescents with T1D and other chronic diseases in which effective family communication is essential.

Limitations

Limitations of this research include conducting the research in one geographic region of the United States, which may limit generalizability. However, this is a pilot study, seeking to establish feasibility and proof of concept, which somewhat overcomes this concern at this stage of intervention development. The sample size is also small; however, once feasibility is established, fully powered efficacy and effectiveness trials can be conducted with larger, more diverse samples. Self-report questionnaires are also used to report psychological information. However, objective measures of adherence will be captured by retrieving BG meter readings and other health outcomes, such as lab values of glycemic control (HbA1c), from the electronic health record. However, whenever possible, gold standard measures will be used in order to obtain the best information possible.

Conclusions

In conclusion, this research is novel and has the potential to make an important contribution to the scientific literature by expanding the reach and thus the public health impact of programs typically delivered in-person to families that have a child or adolescent with T1D.

Acknowledgments

This work is a publication of the United States Department of Agriculture/Agricultural Research Center (USDA/ARS), Children’s Nutrition Research Center, Department of Pediatrics, Baylor College of Medicine (Houston, Texas). This project was supported by National Institute of Diabetes and Digestive and Kidney Diseases, grant #DK106505 (to DT and BA). This work is also a publication of the USDA/ARS and Children’s Nutrition Research Center at Baylor, funded in part with federal funds from the USDA/ARS under Cooperative Agreement No. 58-3092-5-001.

The contents of this publication do not necessarily reflect the views or policies of the USDA, nor does mention of trade names, commercial products, or organizations imply endorsement from the US Government. We would also like to thank Jerald Reichstein and Jackson Lau of Bouncing Pixel for their creative services.

Conflicts of Interest

None declared.

References

1. International Diabetes Federation (IDF). IDF Diabetes Atlas - 7th Edition. 2015. URL:<http://www.diabetesatlas.org/> [accessed 2016-07-11] [WebCite Cache ID 6iv5uGNMK]
2. Lipton RB. Incidence of diabetes in children and youth--tracking a moving target. JAMA 2007 Jun 27;297(24):2760-2762. [doi: [10.1001/jama.297.24.2760](https://doi.org/10.1001/jama.297.24.2760)] [Medline: [17595278](https://pubmed.ncbi.nlm.nih.gov/17595278/)]
3. Anderson B, Ho J, Brackett J, Finkelstein D, Laffel L. Parental involvement in diabetes management tasks: relationships to blood glucose monitoring adherence and metabolic control in young adolescents with insulin-dependent diabetes mellitus. J Pediatr 1997 Feb;130(2):257-265. [Medline: [9042129](https://pubmed.ncbi.nlm.nih.gov/9042129/)]
4. Amiel SA, Sherwin RS, Simonson DC, Lauritano AA, Tamborlane WV. Impaired insulin action in puberty. A contributing factor to poor glycemic control in adolescents with diabetes. N Engl J Med 1986 Jul 24;315(4):215-219. [doi: [10.1056/NEJM198607243150402](https://doi.org/10.1056/NEJM198607243150402)] [Medline: [3523245](https://pubmed.ncbi.nlm.nih.gov/3523245/)]
5. Lewin AB, Heidgerken AD, Geffken GR, Williams LB, Storch EA, Gelfand KM, et al. The relation between family factors and metabolic control: the role of diabetes adherence. J Pediatr Psychol 2006 Mar;31(2):174-183 [FREE Full text] [doi: [10.1093/jpepsy/jsj004](https://doi.org/10.1093/jpepsy/jsj004)] [Medline: [16467317](https://pubmed.ncbi.nlm.nih.gov/16467317/)]
6. Bryden KS, Neil A, Mayou RA, Peveler RC, Fairburn CG, Dunger DB. Eating habits, body weight, and insulin misuse. A longitudinal study of teenagers and young adults with type 1 diabetes. Diabetes Care 1999 Dec;22(12):1956-1960 [FREE Full text] [Medline: [10587825](https://pubmed.ncbi.nlm.nih.gov/10587825/)]
7. Insabella G, Grey M, Knafel G, Tamborlane W. The transition to young adulthood in youth with type 1 diabetes on intensive treatment. Pediatr Diabetes 2007 Aug;8(4):228-234. [doi: [10.1111/j.1399-5448.2007.00266.x](https://doi.org/10.1111/j.1399-5448.2007.00266.x)] [Medline: [17659065](https://pubmed.ncbi.nlm.nih.gov/17659065/)]

8. Northam EA, Lin A, Finch S, Werther GA, Cameron FJ. Psychosocial well-being and functional outcomes in youth with type 1 diabetes 12 years after disease onset. *Diabetes Care* 2010 Jul;33(7):1430-1437 [[FREE Full text](#)] [doi: [10.2337/dc09-2232](https://doi.org/10.2337/dc09-2232)] [Medline: [20357379](#)]
9. Wysocki T, Taylor A, Hough BS, Linscheid TR, Yeates KO, Naglieri JA. Deviation from developmentally appropriate self-care autonomy. Association with diabetes outcomes. *Diabetes Care* 1996 Feb;19(2):119-125. [Medline: [8718430](#)]
10. Weissberg-Benchell J, Glasgow AM, Tynan WD, Wirtz P, Turek J, Ward J. Adolescent diabetes management and mismanagement. *Diabetes Care* 1995 Jan;18(1):77-82. [Medline: [7698052](#)]
11. Anderson BJ, Brackett J, Ho J, Laffel LM. An office-based intervention to maintain parent-adolescent teamwork in diabetes management. Impact on parent involvement, family conflict, and subsequent glycemic control. *Diabetes Care* 1999 May;22(5):713-721 [[FREE Full text](#)] [Medline: [10332671](#)]
12. Laffel LM, Vangsness L, Connell A, Goebel-Fabbri A, Butler D, Anderson BJ. Impact of ambulatory, family-focused teamwork intervention on glycemic control in youth with type 1 diabetes. *J Pediatr* 2003 Apr;142(4):409-416. [doi: [10.1067/mpd.2003.138](https://doi.org/10.1067/mpd.2003.138)] [Medline: [12712059](#)]
13. Laffel LM, Connell A, Vangsness L, Goebel-Fabbri A, Mansfield A, Anderson BJ. General quality of life in youth with type 1 diabetes: relationship to patient management and diabetes-specific family conflict. *Diabetes Care* 2003 Nov;26(11):3067-3073. [Medline: [14578241](#)]
14. Anderson BJ, Vangsness L, Connell A, Butler D, Goebel-Fabbri A, Laffel LM. Family conflict, adherence, and glycaemic control in youth with short duration Type 1 diabetes. *Diabet Med* 2002 Aug;19(8):635-642. [Medline: [12147143](#)]
15. File T, Ryan C. Computer and Internet Use in the United States: 2013. Washington, DC: US Census Bureau; 2014. URL:<http://www.census.gov/hhes/computer/> [accessed 2016-07-11] [[WebCite Cache ID 6iv6SX5yI](#)]
16. Bickmore TW, Pfeifer LM, Byron D, Forsythe S, Henault LE, Jack BW, et al. Usability of conversational agents by patients with inadequate health literacy: evidence from two clinical trials. *J Health Commun* 2010;15 Suppl 2:197-210. [doi: [10.1080/10810730.2010.499991](https://doi.org/10.1080/10810730.2010.499991)] [Medline: [20845204](#)]
17. Bickmore TW, Mitchell SE, Jack BW, Paasche-Orlow MK, Pfeifer LM, Odonnell J. Response to a Relational Agent by Hospital Patients with Depressive Symptoms. *Interact Comput* 2010 Jul 1;22(4):289-298 [[FREE Full text](#)] [doi: [10.1016/j.intcom.2009.12.001](https://doi.org/10.1016/j.intcom.2009.12.001)] [Medline: [20628581](#)]
18. Bickmore T. Relational agents for chronic disease self management. In: Hayes BM, Apray W, editors. *Health Informatics: A Patient-Centered Approach to Diabetes*. Cambridge, MA: MIT Press; 2010:181-204.
19. Bickmore T, Gruber A. Relational agents in clinical psychiatry. *Harv Rev Psychiatry* 2010;18(2):119-130. [doi: [10.3109/10673221003707538](https://doi.org/10.3109/10673221003707538)] [Medline: [20235777](#)]
20. Bickmore TW, Schulman D, Sidner CL. A reusable framework for health counseling dialogue systems based on a behavioral medicine ontology. *J Biomed Inform* 2011 Apr;44(2):183-197 [[FREE Full text](#)] [doi: [10.1016/j.jbi.2010.12.006](https://doi.org/10.1016/j.jbi.2010.12.006)] [Medline: [21220044](#)]
21. King AC, Bickmore TW, Campero MI, Pruitt LA, Yin JL. Employing virtual advisors in preventive care for underserved communities: results from the COMPASS study. *J Health Commun* 2013;18(12):1449-1464. [doi: [10.1080/10810730.2013.798374](https://doi.org/10.1080/10810730.2013.798374)] [Medline: [23941610](#)]
22. Puskar K, Schlenk EA, Callan J, Bickmore T, Sereika S. Relational agents as an adjunct in schizophrenia treatment. *J Psychosoc Nurs Ment Health Serv* 2011 Aug;49(8):22-29. [doi: [10.3928/02793695-20110705-01](https://doi.org/10.3928/02793695-20110705-01)] [Medline: [21766736](#)]
23. Watson A, Bickmore T, Cange A, Kulshreshtha A, Kvedar J. An internet-based virtual coach to promote physical activity adherence in overweight adults: randomized controlled trial. *J Med Internet Res* 2012;14(1):e1 [[FREE Full text](#)] [doi: [10.2196/jmir.1629](https://doi.org/10.2196/jmir.1629)] [Medline: [22281837](#)]
24. Kaufman N. Internet and information technology use in treatment of diabetes. *Int J Clin Pract Suppl* 2010 Feb(166):41-46. [doi: [10.1111/j.1742-1241.2009.02277.x](https://doi.org/10.1111/j.1742-1241.2009.02277.x)] [Medline: [20377663](#)]
25. Harris MJ, Rosenthal R. Mediation of interpersonal expectancy effects: 31 meta-analyses. *Psychol Bull* 1985;97(3):363-386. [doi: [10.1037/0033-2909.97.3.363](https://doi.org/10.1037/0033-2909.97.3.363)]
26. Bandura A. *Social foundations of thought and action: a social cognitive theory*. Englewood Cliffs, NJ: Prentice-Hall; 1986.
27. Fogg BJ. *Persuasive Technology: Using Computers to Change What We Think and Do*. San Francisco, CA: Morgan Kaufmann Publishers; 2002.
28. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *Am Psychol* 2000 Jan;55(1):68-78. [Medline: [11392867](#)]
29. American Diabetes Association. Diagnosis and classification of diabetes mellitus. *Diabetes Care* 2010 Jan;33 Suppl 1:S62-S69 [[FREE Full text](#)] [doi: [10.2337/dc10-S062](https://doi.org/10.2337/dc10-S062)] [Medline: [20042775](#)]
30. Rewers A, Chase HP, Mackenzie T, Walravens P, Roback M, Rewers M, et al. Predictors of acute complications in children with type 1 diabetes. *JAMA* 2002 May 15;287(19):2511-2518. [Medline: [12020331](#)]
31. Teddlie C, Yu F. Mixed methods sampling: a typology with examples. *J Mix Methods Res* 2007 Jan 01;1(1):77-100. [doi: [10.1177/2345678906292430](https://doi.org/10.1177/2345678906292430)]
32. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006 Jan;3(2):77-101. [doi: [10.1191/1478088706qp063oa](https://doi.org/10.1191/1478088706qp063oa)]

33. US Department of Health and Human Services. Improving the User Experience. URL:<https://www.usability.gov/> [accessed 2016-07-11] [[WebCite Cache ID 6iv7s7s9k](#)]
34. Brooke J. A “quick and dirty” usability scale. In: Jordan PW, Thomas B, Weerdmeester BA, McClelland IL, editors. Usability Evaluation in Industry. London: Taylor and Francis; 1996:189-194.
35. Sauro J. Measuring Usability with the System Usability Scale (SUS). 2011. URL:<http://www.measuringu.com/sus.php> [accessed 2016-07-11] [[WebCite Cache ID 6iv8D3Fg8](#)]
36. Stevens J, Taber DR, Murray DM, Ward DS. Advances and controversies in the design of obesity prevention trials. *Obesity* (Silver Spring) 2007 Sep;15(9):2163-2170 [[FREE Full text](#)] [doi: [10.1038/oby.2007.257](https://doi.org/10.1038/oby.2007.257)] [Medline: [17890483](#)]
37. Kraemer HC, Mintz J, Noda A, Tinklenberg J, Yesavage JA. Caution regarding the use of pilot studies to guide power calculations for study proposals. *Arch Gen Psychiatry* 2006 May;63(5):484-489. [doi: [10.1001/archpsyc.63.5.484](https://doi.org/10.1001/archpsyc.63.5.484)] [Medline: [16651505](#)]
38. Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. *J Psychiatr Res* 2011 May;45(5):626-629 [[FREE Full text](#)] [doi: [10.1016/j.jpsychires.2010.10.008](https://doi.org/10.1016/j.jpsychires.2010.10.008)] [Medline: [21035130](#)]
39. Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D, et al. How we design feasibility studies. *Am J Prev Med* 2009 May;36(5):452-457 [[FREE Full text](#)] [doi: [10.1016/j.amepre.2009.02.002](https://doi.org/10.1016/j.amepre.2009.02.002)] [Medline: [19362699](#)]
40. Billingham SA, Whitehead AL, Julious SA. An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network database. *BMC Med Res Methodol* 2013;13:104 [[FREE Full text](#)] [doi: [10.1186/1471-2288-13-104](https://doi.org/10.1186/1471-2288-13-104)] [Medline: [23961782](#)]
41. Thompson D, Bhatt R, Lazarus M, Cullen K, Baranowski J, Baranowski T. A serious video game to increase fruit and vegetable consumption among elementary aged youth (Squire's Quest! II): Rationale, design, and methods. *JMIR Res Protoc* 2012;1(2):e19 [[FREE Full text](#)] [doi: [10.2196/resprot.2348](https://doi.org/10.2196/resprot.2348)] [Medline: [23612366](#)]
42. Thompson D, Mahabir R, Bhatt R, Boutte C, Cantu D, Vazquez I, et al. Butterfly Girls; promoting healthy diet and physical activity to young African American girls online: rationale and design. *BMC Public Health* 2013;13:709 [[FREE Full text](#)] [doi: [10.1186/1471-2458-13-709](https://doi.org/10.1186/1471-2458-13-709)] [Medline: [23915235](#)]
43. Markowitz JT, Laffel LM, Volkening LK, Anderson BJ, Nansel TR, Weissberg-Benchell J, et al. Validation of an abbreviated adherence measure for young people with Type 1 diabetes. *Diabet Med* 2011 Sep;28(9):1113-1117 [[FREE Full text](#)] [doi: [10.1111/j.1464-5491.2011.03321.x](https://doi.org/10.1111/j.1464-5491.2011.03321.x)] [Medline: [21843307](#)]
44. Varni JW, Curtis BH, Abetz LN, Lasch KE, Pault EC, Zeytoonjian AA. Content validity of the PedsQL™ 3.2 Diabetes Module in newly diagnosed patients with Type 1 diabetes mellitus ages 8-45. *Qual Life Res* 2013 Oct;22(8):2169-2181. [doi: [10.1007/s11136-012-0339-8](https://doi.org/10.1007/s11136-012-0339-8)] [Medline: [23269541](#)]
45. Hood KK, Butler DA, Anderson BJ, Laffel LM. Updated and revised Diabetes Family Conflict Scale. *Diabetes Care* 2007 Jul;30(7):1764-1769. [doi: [10.2337/dc06-2358](https://doi.org/10.2337/dc06-2358)] [Medline: [17372149](#)]
46. Hood KK, Butler DA, Volkening LK, Anderson BJ, Laffel LM. The Blood Glucose Monitoring Communication questionnaire: an instrument to measure affect specific to blood glucose monitoring. *Diabetes Care* 2004 Nov;27(11):2610-2615. [Medline: [15504994](#)]
47. Anderson BJ, Auslander WF, Jung KC, Miller JP, Santiago JV. Assessing family sharing of diabetes responsibilities. *J Pediatr Psychol* 1990 Aug;15(4):477-492. [Medline: [2258796](#)]
48. Cullen KW, Thompson D, Boushey C, Konzelmann K, Chen T. Evaluation of a web-based program promoting healthy eating and physical activity for adolescents: teen choice: food and fitness. *Health Educ Res* 2013 Aug;28(4):704-714 [[FREE Full text](#)] [doi: [10.1093/her/cyt059](https://doi.org/10.1093/her/cyt059)] [Medline: [23748162](#)]
49. Horvath AO, Greenberg LS. Development and validation of the Working Alliance Inventory. *J Couns Psychol* 1989;36(2):223-233. [doi: [10.1037/0022-0167.36.2.223](https://doi.org/10.1037/0022-0167.36.2.223)]
50. SAS Institute Inc. SAS version 9. 2014. URL:http://www.sas.com/en_us/software/sas9.html [accessed 2016-07-19] [[WebCite Cache ID 6j7SdZ3VR](#)]
51. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med* 1993 Sep 30;329(14):977-986. [doi: [10.1056/NEJM199309303291401](https://doi.org/10.1056/NEJM199309303291401)] [Medline: [8366922](#)]
52. Hood KK, Rohan JM, Peterson CM, Drotar D. Interventions with adherence-promoting components in pediatric type 1 diabetes: meta-analysis of their impact on glycemic control. *Diabetes Care* 2010 Jul;33(7):1658-1664 [[FREE Full text](#)] [doi: [10.2337/dc09-2268](https://doi.org/10.2337/dc09-2268)] [Medline: [20587726](#)]
53. Bickmore T, Giorgino T. Some novel aspects of health communication from a dialogue systems perspective. In: Proceedings of the American Association for Artificial Intelligence (AAAI). 2004 Presented at: AAAI Fall Symposium on Dialogue Systems for Health Communication; October 22-24, 2004; Arlington, VA.

Abbreviations

BG: blood glucose

CAPTOLGY: Computers as Persuasive Technology

EHR: electronic health record

FT: Family Teamwork
FTO: Family Teamwork Online
HbA1c: hemoglobin A1c
SAS: Statistical Analysis Software
SCT: social cognitive theory
SDT: self-determination theory
T1D: type 1 diabetes

Edited by G Eysenbach; submitted 30.03.16; peer-reviewed by T Bickmore, J Callan; comments to author 18.04.16; accepted 06.05.16; published 28.07.16

Please cite as:

*Thompson D, Cullen KW, Redondo MJ, Anderson B
Use of Relational Agents to Improve Family Communication in Type 1 Diabetes: Methods
JMIR Res Protoc 2016;5(3):e151
URL: <http://www.researchprotocols.org/2016/3/e151/>
doi: [10.2196/resprot.5817](https://doi.org/10.2196/resprot.5817)
PMID: [27468762](https://pubmed.ncbi.nlm.nih.gov/27468762/)*

©Debbe Thompson, Karen W Cullen, Maria J Redondo, Barbara Anderson. Originally published in JMIR Research Protocols (<http://www.researchprotocols.org>), 28.07.2016. This is an open-access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/2.0/>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Research Protocols, is properly cited. The complete bibliographic information, a link to the original publication on <http://www.researchprotocols.org>, as well as this copyright and license information must be included.