Using an mHealth App to Transition Care of Type-1 Diabetes from Parents to Teens:
Protocol for a Pilot Study

Bree E. Holtz
Katharine M. Murray
Denise D. Hershey
Shelia R. Cotten
Amanda Holmstrom
Joshua Richman
Julie K. Dunneback
Michael A. Wood

1. Department of Advertising & Public Relations, Michigan State University, USA
2. College of Nursing, Michigan State University, USA
3. Department of Media & Information, Michigan State University, USA
4. Department of Communication, Michigan State University, USA
5. Department of Surgery, University of Alabama-Birmingham, USA
6. Department of Pediatric Endocrinology, Sparrow Health Systems, USA
7. Department of Pediatrics, University of Michigan, USA

Corresponding Author: Bree E. Holtz, Department of Advertising & Public Relations, Michigan State University, 404 Wilson Road, Rm 309, East Lansing, MI 48824-1212, USA. Email: bholtz@msu.edu

Keywords: Type 1 diabetes, mhealth, telemedicine, adolescents
Abstract

**Background:** Type 1 diabetes (T1D) afflicts approximately 154,000 people under the age of 20. Most people with T1D are diagnosed at a young age and parents have to take on the responsibility of T1D management. Eventually, the child must begin to transition to self-management. Adolescents often struggle to take on responsibility for all the necessary tasks to successfully self-manage their T1D. In fact, approximately three-quarters of adolescents are not achieving ADA HbA1c targets. This lack of adherence can lead to negative health outcomes, such as the development of diabetic ketoacidosis, increased infections, and hospitalizations.

**Objective:** The goals of this interdisciplinary proposal are: (1) to develop a unique and theory-driven technology using a mobile phone application (app) to promote self-management behaviors for adolescents aged 10 to 15 years with T1D and their parents; and (2) to explore the feasibility and impact of the self-management mobile app.

**Methods:** This study has two phases: app development and pilot testing. In the app development phase, the app will be conceptualized and a prototype will be tested. In phase two, the mobile app will undergo pilot testing to determine its feasibility and impact on diabetes self-management.

**Results:** The pilot test was launched in September 2017. Data collection is underway and results are forthcoming.
Using an mHealth App to Transition Care of Type-1 Diabetes from Parents to Teens:

Protocol for a Pilot Study

Type 1 diabetes (T1D) afflicts approximately 154,000 people under the age of 20 in the United States.[1-3] Most people with T1D are diagnosed at a young age and parents take on most of the responsibility for T1D management. Optimal treatment requires the entire family to quickly learn about the disease and to oversee its management.[4] Starting in the early teen years, the child must begin to transition to self-management. During this transition, adolescents often struggle to take on responsibility for all the necessary tasks in order to successfully manage their T1D.[2, 5] Approximately three-quarters of adolescents are not achieving ADA HbA1c targets.[6] This lack of adherence to the prescribed treatment regimen can lead to negative health outcomes, such as the development of diabetic ketoacidosis, increased infections, and hospitalizations.

There are data to suggest that improving communication between the adolescents and their parents facilitates a smoother transition to self-care, and is one way to improve HbA1c.[7] Mobile health (mHealth) technologies can also ease this transition by facilitating trust building, improving family communication, relationships, and health outcomes. Nearly three-quarters of American teens (13-17 years old) have access to a smartphone.[8] Our hypothesis is that a mobile phone based intervention will be effective in providing both the adolescents and their parents with real-time, tailored information about their diabetes. The objective of this study is to develop a T1D self-management mobile phone app intervention for adolescents and their parents and conduct pilot testing of the app to determine its feasibility and impact on diabetes
self-management. Below we discuss the methodology for developing the app, as well as the theoretical foundations guiding this development.

**Methods**

**Study Design**

This study has two phases that correspond with the study aims (see Figure 1): app development and pilot testing. In the app development phase, the app will be conceptualized and a prototype will be tested. In phase two, the mobile app will undergo pilot testing to determine its feasibility and impact on diabetes self-management.

**Theoretical Foundation**

Social cognitive theory (SCT) will inform the development of the intervention. The use of this theory to guide interventions has demonstrated success in changing behaviors around disease management.[9-12] SCT posits that a change in an individual’s environmental, personal, or behavioral factors will impact the other two factors [13-16]; thus, the relationship among these factors is reciprocal. The self-management mobile app is being developed to lead to changes in each of the three factors. For example, to change the adolescents’ environmental factors we will provide social support through a forum feature.[17-19] We believe that receiving messages from their parents via the self-management mobile app will also be a part of the environmental change.[20-23] Personal factors will be modified by prompts sent to the adolescents to set small and achievable daily goals, blood sugar reminders and educational tips about living with T1D to improve the adolescents’ self-efficacy.[24-29] Behavioral change will result from reinforcement through reminders and awarding points for achieving goals and
entering data. The points encourage use (behavior), which we predict will improve adolescent adherence.[30] As a result of all of these factors, children will have an improved HbA1c, a higher quality of life, and reduced conflict with their parents, which we believe will reinforce the use of the self-management mobile app, strengthening the links. Figure 2 shows the theoretical model for the intervention.

**Figure 2 About Here**

**Phase 1**

The technical app development (phase 1) will take place over a nine-month period. This process will be monitored through set goals, and progress will be measured by achieving two objectives. The two objectives include developing the self-management mobile app and finalizing content. To complete this objective, content development will be completed based on several sources, including Understanding Diabetes,[31] and other literature from the ADA, in conjunction with an expert panel who will also advise on the project during implementation. This panel includes a pediatric endocrinologist, a pediatric diabetes nurse practitioner, a college student with T1D, and a parent of an adolescent with T1D (not part of the study).

Based upon best practices in app design principles,[32] we will also conduct focus groups with participants recruited from our target population. We will invite six adolescents and their parents for concept-testing focus groups. We will present the app concept and mock screenshots to the participants and solicit feedback with regard to the app's look and feel, message wording, and what would help the adolescents to log their values. The data from the focus groups will inform message content refinement, the timing of the messages, their appropriateness, and the ease of logging information. This information will inform the app's
technical development. The technology development (app interfaces, web portal, and servers) will be informed by the focus groups, concept testing, and best practices literature. We have 10 benchmarks with deadlines for app development (Figure 3).

Once the prototype is developed, objective two will be met by prototype testing the app. We will recruit 10 family dyads (each dyad includes a teen and his/her parent, n=20) to use the self-management mobile app prototype over a four-week period. We will conduct usability interviews, measuring perceptions and satisfaction with the app. Additionally, server information will be used to quantify learning time, efficiency of use, engagement, and user errors. All of the problems and issues identified in the usability interviews will inform app development and refinement.

The Mobile App

App Functionalities

The self-management mobile app will be an intervention mechanism to encourage adolescents aged 10 to 15 years to self-manage their diabetes by recording their values while allowing their parents seamless and unobtrusive access to the same blood glucose (BG) values, carbohydrate intake, and physical activity, which will be time-stamped, encrypted, and sent to a remote server for storage. The parent users will have a separate login and will be able to review their child’s history of BG values, carbohydrate intake, and physical activity from their own phone. Parents may also send messages via the application to their child. However, the parent can still communicate outside of the app, and we will ask about this communication in the post-study interviews. Along with customizable test reminders and BG ranges, the app will also have
an educational component and a moderated forum for the adolescents and the parents (separate forums) to post and discuss questions and comments to peers. The adolescents will be incentivized through the use of points, accumulated based on usage. As this is a feasibility study, we will have the adolescents manually input their BG readings into the app. While this may seem cumbersome, most meters and pumps do not have the ability to automatically send data through Bluetooth. Once we can determine the feasibility and other design requirements through this pilot, we will develop the app to be Bluetooth enabled. The participants and their parents are responsible for notifying their medical providers regarding any issues with their diabetes. Our app will not cause an actual health concern, as it is just a monitoring and communication device.

Technical Details of the App

The mobile application will be initially developed for the Android platform. Future iterations will include an iOS platform. Focusing on one operating system will allow us to develop a self-management mobile app using the highest-quality control standards. We have selected Android because it is the world’s most popular platform.[33] Mobile phones will be provided to any participant who does not have a phone or one compatible with the app. The application will feature separate and secure login mechanisms for the adolescent user and parent user. All data will be stored on a remote encrypted server rather than the phone itself. If the phone is lost or stolen, we will have the ability to remotely erase the phone’s contents and turn off the data plan associated with it.

Phase 2
This portion of the intervention involves having the adolescents and their parents use the app over the course of three months.

**Study Setting**

Recruitment will take place in Sparrow Hospital's Pediatric Subspecialty Clinic in Lansing, Michigan. The Sparrow Endocrinology Clinic team consists of one registered pediatric dietitian, a full-time nurse practitioner, two certified diabetes educators, and two endocrinologists, all of whom provide diabetes care four days per week within the larger subspecialty clinic. All patients are scheduled to come to clinic every three months for care.

**Sample and Recruitment of Participants**

The clinic nurse diabetes educator acts as the site coordinator. Participants for the pilot testing will be recruited from the hospital's Pediatric Endocrinology Clinic. Invitations will be mailed three times over two months to all of the potential participant dyads, as identified by hospital providers. Additionally, the health care providers in the clinics will be given a presentation on the study by the researchers so they can offer it to the families who meet the inclusion criteria during any typical interactions they have with the adolescent and parent. If interested, the parent will contact the researchers to learn more about the study. A researcher will be in the waiting room of the pediatric endocrinologists, providing study information to possible participants. The researcher will explain the study and determine if the adolescent and parent are eligible through a brief screening questionnaire. We will recruit a total of 70 adolescent/parent dyads, which would correspond with similar past research studying T1D and mobile phone interventions.[34] See Figure 4 for Inclusion and Exclusion Criteria.

**Figure 4 about here**
**Study Procedures**

During the study, there will be four contact points with the participants: the enrollment/baseline data collection visit (Visit 1); a midpoint review (Visit 2, three months after Visit 1); an end-of-study visit (Visit 3, six months after Visit 1) and a follow-up visit, three months after app usage has stopped (Visit 4) (See Figure 3). Visit 1 (month 0) will be scheduled during the screening process. At Visit 1, a member of the research team will review and obtain informed consent (parent) and assent (adolescent) from the participants. The participants will then complete the baseline surveys to measure self-efficacy, quality of life, social support and conflict, and we will collect the teen’s HbA1c and download data from their glucometer/pump. If a participant does not have a mobile device that can download and operate this app, the research team will provide the participant with a device and data plan for the duration of the study. The researcher will demonstrate how to use the technology and have the participants use each of the functions. At Visit 2 (month 3), a research team member will obtain the adolescents’ HbA1c and download data from their glucometer/pump. The participants will also complete the survey at the midpoint. The midpoint data will be used to demonstrate whether any change at 6 months is part of an increasing trend, a plateau, or a waning trend. At Visit 3 (month 6), the participants will complete the survey and participate in interviews. Additionally, the adolescents’ A1c and meter/pump readings will be collected. Finally, any participant that has borrowed any equipment will need to return it at this time. Qualitative methods will also be used to better examine perceptions and intentions, or if participants were light users or why participants dropped out of the study.[35] After Visit 3, the participants will not use the app for three months. At Visit 4 (month 9), all the participants will complete the survey. The
researchers will obtain the adolescents’ HbA1c and download data from their glucometer/pump.

Outcome Measures

Specific aim 2 seeks to determine the feasibility and impact on diabetes of the self-management mobile app among the adolescents and their parents. Demographic information will also be collected, including current age, age of diagnosis, race, gender, parental status (i.e., mom, dad, stepdad, etc.), and method of diabetes treatment (e.g., pump).

Hypothesis 1 seeks to demonstrate that adherence to self-management correlates with mobile app usage and a decrease in HbA1c.

HbA1c will be collected through the Hospital Lab system. The patient will be provided with a lab slip to obtain the baseline HbA1c. The patient will be instructed to obtain the labs within one week. Once the results are obtained they will be faxed to the PI via a secure fax line.

Adherence will be measured in two ways: first, the participants will complete the Diabetes Behavior Rating Scale (DBRS). We will use data from the server to determine if they are monitoring blood sugars on schedule and what mechanisms of the app helped the adolescents follow the medical recommendations. For example, we will use time stamped logins, number of sections the user visited, number of individual logs, communication through the app, educational information accessed, and duration of use per logon.

Hypothesis 2 states that through use of the app, the participants’ self-efficacy, quality of life, and perception of social support will improve and conflict between the child and parent will be
reduced from baseline to three-months. These secondary outcomes are key in helping the adolescents maintain adherence and a normal HbA1c [36-38] and will be measured through surveys. The survey instruments, the participants who will complete them, and reliability for each measure can be found in Figure 5.

**Figure 5 about here**

**Analysis and Statistical Power**

This is a pilot project, so all analyses will be exploratory, focusing on identifying temporal trends in the self-management mobile app usage and changes in study outcomes, and identifying associations between outcomes. Preceding analyses we will calculate summary statistics for all measures, as well as exploratory plots (histograms and box-plots) for all measures at each time point to identify outliers and potentially spurious values.

Trends over the four visits will be examined graphically as a function of time using non-parametrically smoothed plots to help identify when potential effects reach their maximum, plateau, and begin to decrease, which may indicate a time to target for additional interventions. At each time point we will calculate pairwise correlations between the self-management mobile app usage measures and all study outcomes, and examine bivariate scatter-plots with estimated trends for each pair. Distribution appropriate correlations (Person or Spearman) will be calculated as appropriate for each measure and formally tested for statistical significance. These analyses will also be repeated using change from baseline as the outcome rather than the score itself, both as a simple bivariate analysis and using linear regression to model the change as a function of the app usage measures while controlling for baseline values. Analyses will also be
repeated using paired t-tests for differences from baseline in HbA1c and self-management adherence.

Statistical power will be established based on a small pilot study. A 2010 report on a small RCT of an Internet-based intervention in teenagers showed a significant change in self-management adherence from a mean of 3.7 (sd=0.4) at baseline to 3.9 (sd=0.4) at the 12-week follow-up, at an effect size of \( d = 0.64 \).[39] Given our longer follow-up, we expect to observe a larger effect size in our feasibility study. While using a small pilot study to calculate power may not be ideal, it provides a foundation for us to estimate this study's sample size in order to estimate the critical parameters necessary for this study.[40] That study also reported no change in HbA1c for the intervention group but an increase in the control group, with standard deviations ranging from 1.2 to 1.9. Considering that their groups were imbalanced with respect to HbA1c at baseline, it is difficult to project a difference for our study except to note that observing no change in HbA1c may be an improvement over a possible increase in adolescents with usual care. Despite our limited sample size, assuming the use of two-sided tests with a type-one error rate of 0.05, with 70 participants we will have 80% power to detect relatively modest correlations of 0.29. In the event of unanticipated difficulties with recruitment or of attrition of up to 20%, leaving a final sample of \( n=56 \), the correlation detectable with 80% power increases only slightly to 0.32. For t-tests, \( n=70 \) provides 80% power to detect an effect size of 0.30, which is smaller than that reported in the RCT, while the effect size detectable with \( n=56 \) increases slightly to 0.34.[39]

Additionally, the primary foci of this study include assessment of: 1) the effect size of the intervention to power a larger study; 2) feasibility; 3) practicality of data collection procedures;
and 4) the ability to implement. We will also perform a post-hoc analysis on personal characteristics and satisfaction related to use of the system. Additionally, at the completion of the study (Month 9), we will ask both those who completed the whole intervention and those who withdrew early about their experience with the intervention.

The interview data will be analyzed by developing broad code categories based off perception themes and will serve as a preliminary sorting tool. The researchers will then use thematic analysis and create a list of common perceptions. Once a coding scheme is developed, two coders will perform a pretest by coding randomly selected interview transcripts in order to measure reliability. Coders will work together to reconcile any disagreements; this will allow us to achieve a high level of reliability.

Results

The study has been approved by the Institutional Review Board of the university. Formative research for app development was conducted in April 2016.[41] Prototype testing of the app was conducted in February 2017.[42] The final pilot test was launched in September 2017. Data collection is underway and results are forthcoming.

Discussion

Adolescents with type 1 diabetes and their parents often struggle during the transition from parent care to adolescent self-management.[43] This transition to young adulthood is challenging for all families, but families facing the added complexity of diabetes management often find this time especially challenging. The proposed intervention aims to shift diabetes management responsibility to the adolescent and increase their independence, while
encouraging parents to remain engaged and supportive of their adolescent in an effort to ease some difficulties of this challenging time.

To do this, a mobile app for adolescents and their parents is proposed. Previous mHealth research indicates that mobile apps provide an innovative approach to impact health[34, 44] using technology that is frequently part of adolescents' and parents' daily life.[45, 46] Additionally, communication through an app may allow for adolescents to ask for help and communicate more honestly with their parent than they would in face-to-face communication.[47] This improved communication between adolescents and their parents has been shown to facilitate a smoother transition to self-care by improving communication between parents and adolescents, providing adolescents with tangible self-management skills, and providing families with social support, and has been shown to improve HbA1c.[7, 48, 49]

One difficulty of using mobile app technology is keeping adolescents engaged with app use over long periods of time. This is also an issue when designing an intervention with outcomes that take three or more months to realize significant changes. Data suggests that the majority of user engagement begins to drop after 21 days of use.[50, 51] To combat this difficulty, the app includes a points-based customizable avatar, however it is important to note that researchers anticipate seeing a similar trend in engagement.

Easing transition difficulties in an effort to increase positive health outcomes is imperative to the well-being of adolescents with T1D and their families, and studies have shown that participants using mobile phone interventions had higher adherence rates and more participation.[34] Therefore, this study will develop a mobile app that addresses the difficulties
of the adolescent transition to self-management and pilot test the app to determine its feasibility and impact on diabetes self-management.

Future Directions

After we have successfully completed this study, the data gathered will be integrated with machine learning in order to modify the app for a wider audience and better tailor the application to the individual user’s behavior and usage preferences. Once completed, we will design and conduct a full-scale randomized controlled trial. We will also expand the project to iOS (Apple phones). Additionally, we will seek to integrate the data into the patient’s electronic health record.

Acknowledgements

We would like to recognize Bion Bilateral who helped us develop the app.

Conflicts of Interest

The authors have no conflicts of interest to disclose.

Funding

This research is supported by the American Diabetes Association (ADA).
References


