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Original Paper

Glucose Control, Disease Burden, and Educational Gaps in People With Type 1 Diabetes: Exploratory Study of an Integrated Mobile Diabetes App

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Abstract

Background: Self-monitoring and self-management, crucial for optimal glucose control in type 1 diabetes, requires many disease-related decisions per day and imposes a substantial disease burden on people with diabetes. Innovative technologies that integrate relevant measurements may offer solutions that support self-management, decrease disease burden, and benefit diabetes control.

Objective: The objective of our study was to evaluate a prototype integrated mobile phone diabetes app in people with type 1 diabetes.

Methods: In this exploratory study, we developed an app that contained cloud-stored log functions for glucose, carbohydrates (including a library), insulin, planned exercise, and mood, combined with a bolus calculator and communication functions. Adults with diabetes tested the app for 6 weeks. We assessed the feasibility of app use, user experiences, perceived disease burden (through questionnaires), insulin dose and basal to bolus ratio, mean glucose level, hemoglobin A_{1c}, and number of hypoglycemic events.

Results: A total of 19 participants completed the study, resulting in 5782 data entries. The most frequently used feature was logging blood glucose, insulin, and carbohydrates. Mean diabetes-related emotional problems (measured with the Problem Areas in Diabetes scale) scores decreased from 14.4 (SD 10.0) to 12.2 (SD 10.3; $P=.04$), and glucose control improved, with hemoglobin A_{1c} decreasing from 7.9% (mean 62.3, SD 8 mmol/mol) to 7.6% (mean 59.8, SD 7 mmol/mol; $P=.047$). The incidence of hypoglycemic events did not change. Participants were generally positive about the app, rating it as “refreshing,” and as providing structure by reinforcing insulin-dosing principles. The app revealed substantial knowledge gaps. Logged data enabled additional detailed analyses.

Conclusions: An integrated mobile diabetes app has the potential to improve diabetes self-management and provide tailored educational support, which may decrease disease burden and benefit diabetes control.

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KEYWORDS

diabetes; app; self-care; medication suggestion; disease management; diabetes mellitus, type 1; mobile applications

Introduction

Optimizing Self-Management of Type 1 Diabetes

Type 1 diabetes is an autoimmune disease that occurs in genetically susceptible individuals and leads to the complete absence of insulin production by pancreatic beta cells [1]. It often debuts in childhood or early adolescence and requires insulin replacement therapy. To reduce the risk of long-term complications, people with diabetes aim for optimal blood glucose control, which requires self-monitoring of blood glucose levels at least four times daily, injection of rapid-acting insulin before every meal and of long-acting insulin before night (or by continuous subcutaneous insulin infusion by insulin pump), and adjustment of insulin dose based on food (carbohydrate) intake, actual glucose levels, intended physical activity, and experience (self-management) [2]. Optimal self-monitoring and self-management requires not only extensive education but also substantial efforts from people with diabetes. Still, and frustratingly, episodes of high and low glucose levels are often a fact of everyday life [3]. It has been estimated that life with type 1 diabetes requires an astonishing number of health-related decisions, even estimated at about 180 per day [4]. Altogether, the self-management of type 1 diabetes presents a significant burden [5].

Technological tools and mobile apps could support people with diabetes in everyday diabetes self-management. These include systems that facilitate data logging to integrate the various relevant measurements, provide educational information, and provide decision support software. An example of decision support software is the Bolus Wizard or bolus calculator, which advises people with diabetes on meal insulin dose [6]. Although technology and innovation have the potential of making a meaningful impact on diabetes care and could offer important solutions, clinical effects of digital health care solutions are often poorly investigated [7,8], particularly regarding diabetes type 1 [9-11]. Moreover, past studies focused on a limited number of outcomes [12].

Objectives

In close collaboration with people with diabetes, the Radboud University Medical Center (Radboudumc; Nijmegen, the Netherlands), Royal Philips (Eindhoven, the Netherlands), and Salesforce (San Francisco, CA, USA) developed a prototype of an integrated mobile diabetes app to be used on a mobile phone, including a bolus calculation function, data logging, a forum, and direct messaging with health care providers. We studied its potential effect on disease burden and assessed its feasibility and participants' experiences with this prototype app.

Methods

Design and Setting

In this exploratory study, conducted at the Radboudumc in Nijmegen, the Netherlands, among adults with type 1 diabetes, we compared baseline measurements with measurements taken

during and after the intervention. We also applied qualitative methods to assess users' experiences, barriers and facilitators for using the app, and perceived effects. Finally, we analyzed objective and subjective data.

The Mobile App

The integrated mobile phone diabetes app is a prototype diabetes mobile support software app for iOS (Apple) and Android (Google). This app was developed for use by people with type 1 diabetes and contains the functionalities presented below. These functionalities were chosen based on technical possibilities, clinical expert input, and opinions expressed by people with diabetes (n=10) who were interviewed and reviewed layout and features on two occasions during the development process. These persons were not included in this study.

- Logbook capabilities to capture key measurements: users can manually enter blood glucose levels, as well as hypoglycemic events, carbohydrate intake, injected insulin dose, expected physical activity, stress, and mood. These data can be displayed in the app as last-entered values and trend graphics (history values) of blood glucose (day, week, and month views).
- Carbohydrate intake data entry support: the "meal picker" provides a means to define personal standard meals and to look up carbohydrate contents of frequently used ingredients.
- Custom settings: users (or their health care providers) can set a target blood glucose level, alarms as reminders, and settings for the bolus calculator (eg, ratios), as well as an on-off switch for a warning if blood glucose value entries exceed individual limits. In the case of the entry of blood glucose levels above 25 mmol/L, a text message appears and direct contact with a nurse (by telephone) is offered.
- Insulin bolus advice: based on data entered and personal settings, such as the personal carbohydrate to insulin ratio, the app calculates bolus advice using a modified version of an equation by Schmidt et al [6]. We removed the insulin on board variable for safety reasons, with no dose advice given within 3 hours.
- Secure communication: people with diabetes can communicate with health care providers through a secure connection.
- Online community: people with diabetes can connect with their peers.
- Privacy and security measures: the app was developed respecting international privacy and security standards, including a secured connection. All data were coded, and all users used a fake username and credentials for the app to make sure no data were in the system that could be traced back to an individual or his or her medical data. Data were stored on a cloud server based in Europe and according to the privacy and security policy of Salesforce. Moreover, the privacy and security procedures were reviewed and approved by Radboudumc's and Royal Philips' privacy and security officers.

Multimedia Appendix 1 provides screenshots of the app.

Participants

As this was an initial feasibility study, we recruited a representative sample of people with type 1 diabetes from the outpatient clinic of the Radboudumc, aged between 18 and 65 years, with a diabetes duration of at least 2 years and stable glycemic control (hemoglobin A_{1c} [HbA_{1c}] between 7% and 10% [53-86 mmol/mol]), able to count their carbohydrate intake and vary their bolus insulin dose, having a body mass index between 18 and 35 kg/m², and using a suitable (iOS 9 or Android 4.1. and higher) mobile phone or tablet. Participants had to be able to speak, read and understand Dutch.

Exclusion criteria were people with serious diabetes complications: severe retinopathy with poor vision (visual acuity <0.5), renal failure (glomerular filtration rate <30 mL/min/1.73 m²), foot amputation, recent (<6 months) myocardial infarction or stroke, any serious comorbidity deemed to significantly affect participation, a history of severe hypoglycemia (requiring third-party assistance) over the past 3 years, pregnancy or aiming for pregnancy, or total insulin need greater than 1 U/kg/day.

Eligible people with diabetes were identified by their treating physician and invited to participate by letter. Subsequently, they were contacted by phone and, if they were willing to participate and had a suitable mobile phone, they received an extensive information package. A total of 144 potential participants were invited, of whom 20 participated. Reasons for not participating were perceived burden due to participation in the study, lack of a suitable mobile phone, or inability to attend 1 of the 3 introduction meetings. The institutional review board of the Radboud University Medical Center approved the study, and participants signed an informed consent form at entry into the study (ID: 2015-2013).

Study Procedures

We asked participants to record their blood glucose levels as usual and register hypoglycemic events in a personal diary in the 4 weeks prior to the start of the study. They were asked to keep a glucose (food and carbohydrate intake) and insulin dose diary for 5 days before starting to use the app. Participants visited 1 kickoff group meeting in which the app was installed and personalized by the nurse based on the diaries. Participants completed 3 validated questionnaires to assess diabetes-related emotional stress, fear of hypoglycemia, and diabetes self-care. After approximately 1 week of using the app, participants were contacted once for technical or medical support. In addition, medical support was available at all times for urgent matters, similar to regular care. After approximately 6 weeks of use, participants returned to the study center, where they repeated the questionnaires, including an additional survey about the usability of the app. Then, the app was removed from the device and respondents were interviewed individually. Before and at the end of the study period, we determined HbA_{1c}.

Measurements

We compared the hypoglycemic event rate during the 4 weeks before use of the app versus the hypoglycemic events recorded in the app and those logged by participants. The criterion for a

hypoglycemic event was a measured blood glucose level below 4 mmol/L, with or without symptoms.

We measured diabetes-related emotional distress using the Problem Areas in Diabetes (PAID) scale, consisting of 20 items concerning negative emotions related to diabetes, resulting in a score from 0 to 100. The cutoff score for serious emotional distress is 40; average reported scores are 24.6 (SD 18.7) for type 1 diabetes [13].

The Hypoglycemia Fear Survey (HFS) [14] (in Dutch: *Angst voor Hypoglycemie Vragenlijst*) consists of 13 items, exploring worries and fears related to hypoglycemia. The sum of the scores is calculated, and higher scores indicate greater fear of hypoglycemia. The range is 0 to 52, and the cutoff score is 21 [13].

The Confidence in Diabetes Self-Care (CIDS) scale (in Dutch: *Diabetes zelfzorg vragenlijst*) [15] consists of 21 items and measures diabetes-specific self-efficacy—that is, the level of confidence that people with type 1 diabetes have to perform diabetes-specific self-care activities. It results in a score from 0 to 100, with higher scores indicating more trust. The questionnaire assesses trust or confidence in self-care, not whether the activities are actually done.

Participants completed the System Usability Scale (SUS) after the test period. The SUS provides a global view of subjective assessments of usability [16]. This short questionnaire consists of 10 items with 5 response options and results in a score from 0 to 100. The mean usability score for a system is 68; systems scoring 70 or above are considered to have acceptable usability, and those scoring above 72 are considered to have good usability [17].

Semistructured Interviews

We held semistructured interviews at the end of the study to evaluate participants' experiences with the app. These interviews focused on the advantages and disadvantages of using the app in daily practice, and on participants' expectations for the future. An interview guide, based on guidelines for implementation and a framework for the evaluation of information systems in health care, was used [18,19]. This framework contains three domains: human, technology, and organization. In addition, we asked participants whether they would like to continue using this app and to rate the app on a scale from 1 (very poor) to 10 (excellent). All interviews lasted approximately 30 minutes and were performed face-to-face, recorded, and transcribed verbatim.

Analysis

We performed analysis and statistics using IBM SPSS Statistics version 20 (IBM Corporation) and R version 3.2.0 (R Foundation). We did not calculate a formal sample size, given that we considered this to be an exploratory study; the aim was to include 20 participants in total. Normally distributed continuous variables were described as mean (SD). Median and interquartile values were determined when variables were not normally distributed. Qualitative or categorical variables (ie, baseline parameters) were described as frequencies and percentages. HbA_{1c} and survey scores for the PAID, HFS, and CIDS questionnaires before and after use of the app were

compared by paired *t* tests. *P* values <.05 were regarded as statistically significant. We performed subgroup analyses based on activity: we calculated the number of median entries and created a least active group and a most active group, determined by the number of actions in the app.

We analyzed qualitative data using standard qualitative research methods. Two researchers independently analyzed the transcripts to identify barriers and facilitators that could affect use of the app, and perceived positive and negative effects of the app. They identified advice or suggestions for improving the next version of the app. All results were discussed until consensus was reached. Predefined tables were used to present results. Barriers and facilitators are presented following the framework of Gagnon et al [20]; positive and negative effects are presented according to Donabedian's framework for quality of health care

[21]. This framework distinguishes between process (eg, improved communication), structure (eg, hospital buildings), and outcomes (eg, death) of health care.

Results

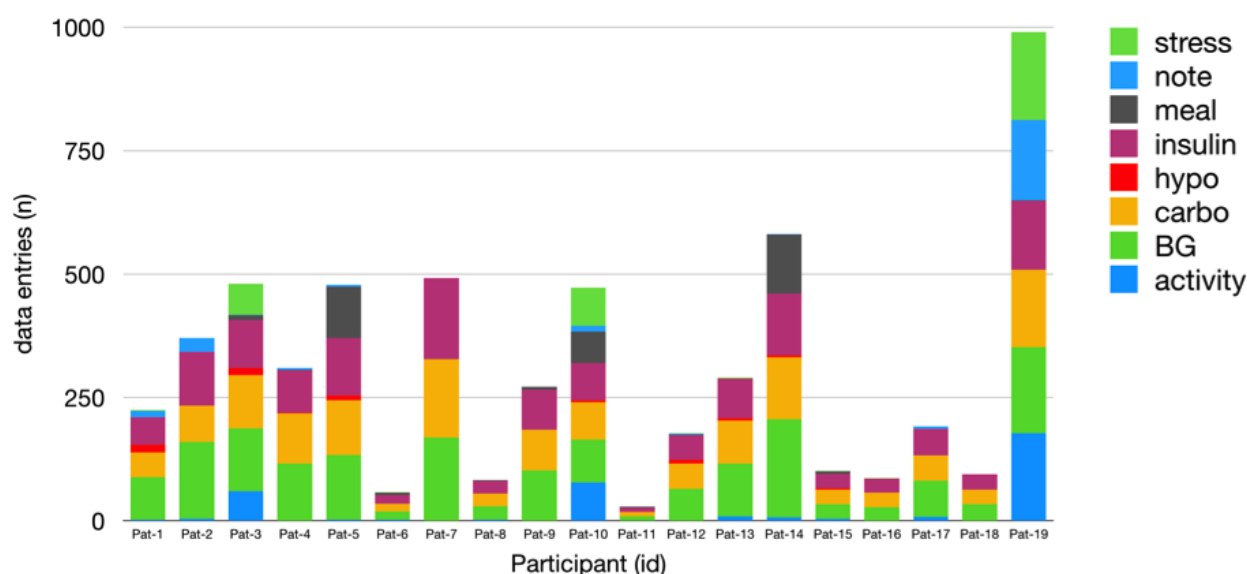
General Results

In total, 20 people with diabetes were included, of whom 19 completed the study. We excluded 1 participant on the first day of the test, because of an ineligible mobile phone. Table 1 shows the participants' characteristics. As intended, the study population was heterogeneous with respect to age, diabetes duration and glucose control, frequency of hypoglycemic events, and treatment: 12 people were on basal bolus, 7 on pump therapy, 3 used continuous glucose measurement, and 4 used a bolus calculator.

Table 1. General characteristics of the study population (n=19).

Characteristics	Values
Age (years), mean (SD)	43.8 (14.1)
Sex, n (%)	
Male	7 (37)
Female	12 (63)
Body mass index (kg/m ²), mean (SD)	25.7 (3.4)
Duration of diabetes mellitus (years since diagnosis), mean (SD)	22.8 (14)
Hemoglobin A_{1c}	
%	7.9
mmol/mol, mean (SD)	62.3 (7.8)
Insulin dose, U/day (range)	50 (11-100)
Insulin regimen, n (%)	
Basal bolus	12 (63)
Pump therapy	7 (37)

Figure 1. Use of app features by individual users. BG: blood glucose measurement; carbo: carbohydrate intake; hypo: hypoglycemic event.



App Use

Over the study period (up to 6 weeks), a total of 5782 data entries were recorded, ranging from 29 data entries by the least active user to 990 data entries by the most active user (median 272). On average, participants recorded 6.8 logging entries during working days and 8.5 during weekend days. The proportion of active users decreased from 100% (19/19) in week 1 to 78% (15/19) after 4 weeks ([Multimedia Appendix 2](#)). The most frequently logged data were blood glucose (n=1740), insulin (n=1378), and carbohydrates (n=1366). [Figure 1](#) presents participants' use of the various app features.

Pre- Versus Poststudy Comparison

Over the study period, mean HbA_{1c} dropped from 7.9% (62.3, SD 8 mmol/mol) to 7.6% (59.8, SD 7 mmol/mol; $P=.047$). The incidences of hypoglycemic events were 0.31 per participant per day at baseline and 0.27 per participant per day during the study period ($P=.21$). Basal to bolus ratio did not change over the study period.

[Table 2](#) shows results of the questionnaires on disease burden. Mean diabetes-related emotional problems (PAID scale scores) decreased from 14.4 (SD 10.0) to 12.2 (SD 10.3; $P=.04$). Based on the dichotomized PAID score, 4 of the 19 respondents (21%) were at risk for emotional burnout (all scores ≥ 40), decreasing to 1 of 19 after the intervention period (5%). The score on the CIDS scale seemed to increase during the study period. The scores on the other PAID subscales, HFS, and CIDS scale did not change notably over the intervention period. The mean SUS score was 75.5 (SD 16.7, range 47.5-97.5) at the end of the study (n=19), indicating good usability. [Multimedia Appendix 3](#) provides a comparison between more active and less active app users.

Qualitative Results

Semistructured interviews led to several insights. All users rated the app, resulting in a mean score of 6.7 (on a scale from 1 to

10). A total of 8 respondents reported that they would prefer to continue to use the app if this were possible.

Frequently reported facilitators were the graphic display of blood glucose (trend) and ease of use of the app. However, a frequently mentioned barrier was also related to complexity of the app or that it was not easy to use. Another frequently mentioned barrier was that retrospective data entry was not possible in the app (although this was actually possible). [Table 3](#) lists all reported facilitators and barriers for using the app.

Perceived positive and negative effects are presented according to the Donabedian framework for the quality of care. Among the six potential positive effects was that the app made participants more aware of their own situation and more conscious in managing their disease. The two negative effects that were mentioned were anxiety due to a bolus suggestion that did not reflect their personal view and the (risk of) more hypoglycemic events. [Table 4](#) presents a complete overview of perceived positive and negative effects.

Other benefits that participants described from using the diabetes app were that it was a "wake-up call" and "refreshing," since they had insufficient knowledge especially regarding carbohydrate counting. A total of 11 respondents indicated that they wished for a system with better (wireless) connections, such as a Bluetooth connection, between their blood glucose meter and the app, allowing for measurements to be imported, or even with a connection with their insulin pump. Independently of the app, 5 respondents also noted that they would like to have a continuous blood glucose sensor, allowing them to respond in a timelier manner. Regarding the possibility to share data from the app, 6 respondents mentioned that they would prefer better sharing options, such as easy exporting of data, use of cloud solutions, or a connection with their personal health record. The respondents would also have appreciated a more advanced way of presenting results in the app with graphs. Finally, respondents stated that the bolus suggestions could be more specific for different activities: 5 respondents mentioned that they were missing a sports mode function in the app.

Table 2. Results of Problem Areas in Diabetes (PAID), Hypoglycemia Fear Survey (HFS), and Confidence in Diabetes Self-Care (CIDS) questionnaires (n=19).

Instrument	Score, mean (SD)		P value
	Before	After	
PAID scale	20.0 (14.9)	17.2 (14.8)	.11
Diabetes-related emotional problems	14.4 (10.0)	12.2 (10.3)	.04
Treatment-related problems	2.1 (3.0)	1.3 (2.0)	.19
Food-related problems	2.9 (2.6)	2.8 (3.0)	.82
Social support-related problems	0.6 (1.0)	0.9 (1.4)	.24
HFS-Worry Scale ^a	25.4 (6.4)	25.3 (7.0)	.89
CIDS scale ^b	79.6 (11.3)	82.0 (10.9)	.13

^an=18, as 1 respondent did not answer item 12.

^bn=17, as 1 respondent did not answer item 5 and 1 respondent did not answer item 10.

Table 3. Frequencies of barriers and facilitators for using the app.

App-related factors	Barrier	Facilitator
Design and technical concerns	9	4
No internet access	2	0
Adding medication: can add only half numbers or units (eg, 0.5)	1	1
Retrospective data entry not possible	5	0
Lack of notifications	1	0
Graphic display of blood glucose (trend)	0	3
Characteristics of the innovation	18	3
Ease of use or complexity		
Meal picker complex or not intuitive	2	0
Sliders too sensitive	2	0
Complexity of app, easy to use (NFS ^a)	10	2
Relative advantage (usefulness) or lack		
No need to use additional booklet to register values	0	1
NFS	4	0
Validity of resources	9	2
Content available (completeness of meal picker)	3	1
Frequency of advice (eg, lacking between 2 meals)	2	0
Bolus suggestion		
Does not take into account blood glucose trend	1	0
Incorrect, does not correspond to personal view	3	0
Also bolus suggestion, even when blood glucose is (too) low	0	1
System reliability	3	0
Restarting the app takes too long	1	0
Login issues	1	0
Crashing (of app)	1	0

^aNFS: not further specified.

Table 4. Frequencies of perceived positive and negative effects according to the Donabedian model for quality of care.

Outcome	Positive	Negative
Processes	21	0
Effects on psychological domains		
More aware or conscious of disease (self-)management	12	0
Regularity: more frequent measurements	1	0
More precise adjustments	1	0
More frequent blood glucose checks	4	0
Reduced number of corrections needed	1	0
Patient education: better insulin advice, better than blood glucose meter	2	0
Outcomes	18	3
Medication: reduced insulin use	1	0
Health status		
Weight loss	1	0
More stable values (blood glucose, carbohydrates)	5	0
Lower blood glucose levels, reduced number of high peaks	5	0
Improved hemoglobin A _{1c}	1	0
Satisfaction: feeling more confident	3	0
Knowledge: better knowledge about own glucose levels (graphs)	2	0
Effects on psychological domains: anxiety, due to bolus suggestion that does not correspond to own estimation	0	1
Health status: (risk of) more hypoglycemic events	0	2

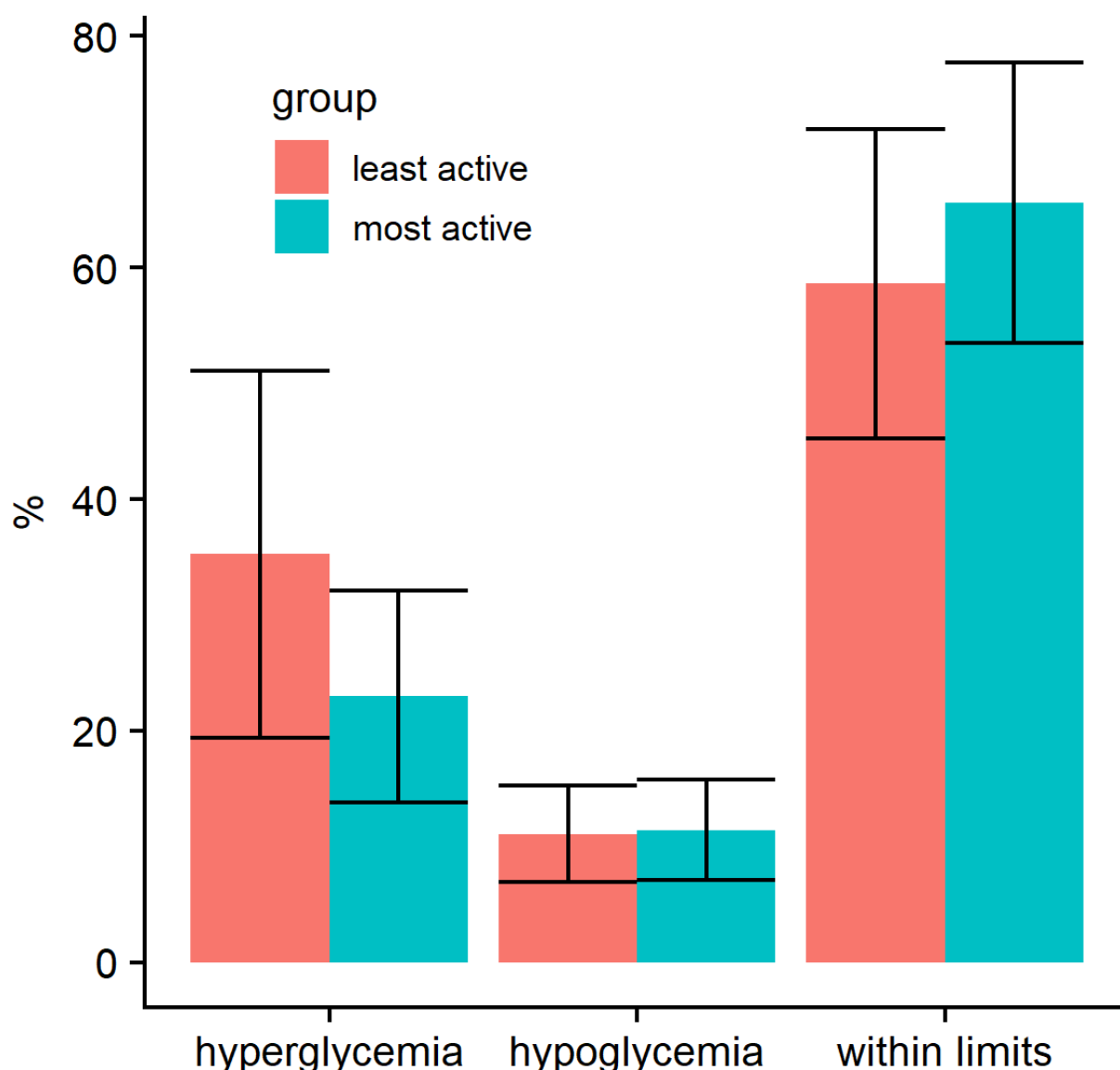
Bolus Suggestion

Logging and cloud storage allowed for subsequent analysis of several components of self-management. Of a total of 1378 insulin entries, 842 could be compared with the bolus calculator outputs. In 569 cases, the user accepted the bolus suggestion, whereas they reduced the suggested insulin dose in 101 cases and increased the insulin dose in 172 cases.

The logged dataset enabled us to compare glucose profiles after a bolus given according to the bolus suggestion versus boluses that were lower or higher than recommended, which were not different in this data set. More active users appeared to have more stable blood glucose levels, carbohydrate intake, and medication use (Figure 2). Compared with the least active participants, active participants tended to spend less time in hyperglycemia and more within the normal range (Figure 3). There were no differences in the drop in HbA_{1c} and disease burden between the least active and most active users.

Figure 2. Blood glucose levels, carbohydrate intake, and insulin use per day in the study, for all participants (left) and stratified by user app activity: most and least active participants (right).

Figure 3. Percentage of blood glucose readings within normal limits, hyperglycemia, and hypoglycemia, stratified by user app activity: most and least active participants.



Discussion

Principal Findings

This exploratory study with a prototype integrated mobile diabetes app in a heterogeneous sample of people with type 1 diabetes provided a detailed, in-depth, before-and-after analysis in an area with very limited evidence. The app, which uses the most relevant factors for diabetes self-management to provide a bolus suggestion, has the potential to benefit self-management, improve glucose control, and decrease disease burden. Logging and cloud storage allows for subsequent analysis of several components of self-management and potential feedback. The study revealed several barriers related to use of the app and identified high-priority areas for further development.

Over the short study period of 6 weeks, we noticed a significant improvement in glucose control with reduced hypoglycemia frequency and a significant decrease in disease burden. While this may have been an effect of using the app, the changes in glucose control could also be explained by a study effect. Participating in a study, keeping a diary, and discussing bolus settings increase the time and attention people with diabetes devote to their treatment. Measurement of disease burden did confirm the high burden associated with diabetes. While the decrease in disease burden may also have been a study effect, it has also been reported that PAID scores do not easily change over time [22]. Even when the changes are caused by a study effect, use of the app can apparently catalyze more attention toward diabetes management, without increasing disease burden.

The app combines several features, many of which are found in other diabetes devices, such as insulin pumps and glucose

meters, or offered as stand-alone functions in mobile apps. Still, to our knowledge, the combination of most functions that are considered basic for self-management, including blood glucose logging, insulin dosage, carbohydrate measurement, exercise, graphics, and chat and direct contact with health care providers on a mobile phone app, is unique to this app [9]. The participants were generally positive about the app, with most (79%) still actively using it after 4 weeks, and a large proportion stating that they would prefer to continue using it after the study. More specifically, the bolus calculator was evaluated as a relevant feature, and the app made them more aware of their diabetes self-management. These results are in line with findings of a qualitative study among adults with type 1 diabetes, which found that users of an app with bolus suggestion generally trusted the suggestion [23]. The bolus suggestion function was new to most study participants, while 2 participants already using a bolus calculator also reported that their personal settings as added by the nurse needed to be updated. This illustrates one of the problems of the bolus calculator: optimal use requires, first, an appropriate determination of the insulin to carbohydrate ratio and a correction factor and, subsequently, frequent and repeated fine-tuning of the settings. While the use of a bolus calculator has been associated with a slight improvement in glucose control [24], particularly among pump users [25], not all authors have identified benefits [26], and patients not on a pump rarely use a bolus calculator. In another study, our own group found improvements in neither glucose control nor disease burden after a structured introduction of a bolus calculator to experienced pump users versus carbohydrate and ratio education alone [27]. In this study, the bolus suggestion seemed to provide an educational element in reinforcing the relationship between insulin use and carbohydrate intake.

Our study identified several educational gaps among the participants, particularly at the level of carbohydrate counting. While all participants had followed a structured diabetes education, including dietary aspects and carbohydrate counting, which had generally been repeated over time, detailed discussion of diaries unmasked a lack of knowledge or wrong understanding. This is not unusual among people with long-standing diabetes, and particularly detailed carbohydrate counting is challenging and requires a substantial time investment. For some, this may be more than they can or are willing to invest in the disease management. While more intense and repeated education may be required, use of an integrated app preferably with detailed feedback may present an opportunity to provide tailored education.

Other Studies

Given the dearth of available apps for diabetes management, the lack of supporting scientific evidence is compelling. Appropriate studies on relevant outcome parameters are scarce, particularly in type 1 diabetes. In addition, most studies have focused on improvements in glucose control (HbA_{1c}). Our primary aim was to support people with diabetes in proper decision making, hopefully resulting in decreased disease burden. A recent review by Hood et al of studies that reviewed apps, both controlled and uncontrolled [10], identified that several studies in which HbA_{1c} was significantly reduced were

of poor quality. Brzan et al reviewed 9 of approximately 500 diabetes apps available in the Apple App Store, and identified 1 app containing a bolus calculator that had been shown to prevent hypoglycemic events [9]. A meta-analysis [12] summarizing controlled app studies identified 3 apps for type 1 diabetes, with 2 having no effect and 1 having a nonsignificant effect on HbA_{1c} . Effects on other parameters were not studied. Logging and cloud storage of data allows for subsequent analysis of several components of self-management and potential feedback. In our study, we analyzed the use of the bolus suggestion, the glucose pattern, insulin use, and carbohydrate intake before and after a hypoglycemic event and the differences between most frequent and least frequent users. Given the relatively small sample size and short study duration, the additional analyses allowed for only limited conclusions. Nevertheless, we think this possibility has great potential in identifying individual profiles, particularly when combined with personalized feedback. While more authors are identifying these potentials, this area is still in its infancy. More robust study designs including a control group are needed to formally assess the effects of self-monitoring apps.

Our study also identified several barriers to using the app, most of which were related to usability issues, such as lack of direct connectivity with devices. Another known barrier is the time needed to add information about nutrition and insulin [9]. Although we did not calculate the specific time needed, our qualitative analysis revealed that users found it time consuming, which could negatively influence app use. Future development should aim for automatic connections; this seems to be feasible with measuring devices (see below) and is already customary with pumps. Recent developments of Bluetooth-connected insulin pens [28] may further complement automatic input. Finally, optical recognition of numbers on glucose meters does not work properly under circumstances of decreased light. It should also be realized that in current practice the choice of a given glucose meter heavily depends on reimbursement issues. While input through a ruler was rapid and convenient, direct connection would still be optimal. The emergence of continuous glucose sensors that can directly connect to mobile apps may help in overcoming these barriers.

Strengths and Limitations

Our study had several limitations that are related to the exploratory design. These include the small sample size, open uncontrolled study design, and relatively short duration of follow-up. Obviously, mobile phone use and brand version determine patient selection. Intentionally, we did not select study participants based on treatment (pump or multiple daily injections) or technical savvy. Strengths of the study are that the app contains all of the basic features for optimal self-management and our use of the mixed-methods approach, which allowed for both comparison of objective measures before and after the study and assessment of subjective user experiences. Furthermore, the large (logged) complete data set allowed for a wealth of valuable analyses.

Conclusion

This study suggests that an integrated mobile phone app has the potential to benefit self-management, improve glucose control,

and decrease disease burden. It may help to better integrate glucose measurements, carbohydrate intake, physical activity, and insulin dose and can identify educational gaps. Logging and cloud storage allows for subsequent analysis of several components of self-management and potential feedback. Finally,

the study revealed several barriers to the use of the app and identified high-priority areas for further development. Clearly, further work is needed to advance digital support for people with type 1 diabetes.

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Authors' Contributions

CJT and THvdB designed the study, with input from BH, MMHJvG, and LJLPGE. BH and GJL assisted in the measurement experiments and collection of data. CJT, MMHJvG, DDM, and THvdB analyzed the data and wrote the manuscript. All authors discussed the results and implications and commented on the manuscript at all stages. CJT and THvdB are the guarantors of this work and, as such, had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Conflicts of Interest

DDM is an employee of Royal Philips.

Multimedia Appendix 1

App screenshots.

[[PDF File \(Adobe PDF File\), 923KB - diabetes_v3i4e17_app1.pdf](#)]

Multimedia Appendix 2

App use (6 weeks).

[[PDF File \(Adobe PDF File\), 155KB - diabetes_v3i4e17_app2.pdf](#)]

Multimedia Appendix 3

Least and most active app users.

[[PDF File \(Adobe PDF File\), 21KB - diabetes_v3i4e17_app3.pdf](#)]

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Abbreviations

- CIDS:** Confidence in Diabetes Self-Care
HbA_{1c}: hemoglobin_{1c}
HFS: Hypoglycemia Fear Survey
PAID: Problem Areas in Diabetes
Radboudumc: Radboud University Medical Center

SUS: System Usability Scale

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Original Paper

Prediction of Glucose Metabolism Disorder Risk Using a Machine Learning Algorithm: Pilot Study

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Abstract

Background: A 75-g oral glucose tolerance test (OGTT) provides important information about glucose metabolism, although the test is expensive and invasive. Complete OGTT information, such as 1-hour and 2-hour postloading plasma glucose and immunoreactive insulin levels, may be useful for predicting the future risk of diabetes or glucose metabolism disorders (GMD), which includes both diabetes and prediabetes.

Objective: We trained several classification models for predicting the risk of developing diabetes or GMD using data from thousands of OGTTs and a machine learning technique (XGBoost). The receiver operating characteristic (ROC) curves and their area under the curve (AUC) values for the trained classification models are reported, along with the sensitivity and specificity determined by the cutoff values of the Youden index. We compared the performance of the machine learning techniques with logistic regressions (LR), which are traditionally used in medical research studies.

Methods: Data were collected from subjects who underwent multiple OGTTs during comprehensive check-up medical examinations conducted at a single facility in Tokyo, Japan, from May 2006 to April 2017. For each examination, a subject was diagnosed with diabetes or prediabetes according to the American Diabetes Association guidelines. Given the data, 2 studies were conducted: predicting the risk of developing diabetes (study 1) or GMD (study 2). For each study, to apply supervised machine learning methods, the required label data was prepared. If a subject was diagnosed with diabetes or GMD at least once during the period, then that subject's data obtained in previous trials were classified into the risk group ($y=1$). After data processing, 13,581 and 6760 OGTTs were analyzed for study 1 and study 2, respectively. For each study, a randomly chosen subset representing 80% of the data was used for training 9 classification models and the remaining 20% was used for evaluating the models. Three classification models, A to C, used XGBoost with various input variables, some including OGTT data. The other 6 classification models, D to I, used LR for comparison.

Results: For study 1, the AUC values ranged from 0.78 to 0.93. For study 2, the AUC values ranged from 0.63 to 0.78. The machine learning approach using XGBoost showed better performance compared with traditional LR methods. The AUC values increased when the full OGTT variables were included. In our analysis using a particular setting of input variables, XGBoost showed that the OGTT variables were more important than fasting plasma glucose or glycated hemoglobin.

Conclusions: A machine learning approach, XGBoost, showed better prediction accuracy compared with LR, suggesting that advanced machine learning methods are useful for detecting the early signs of diabetes or GMD. The prediction accuracy increased when all OGTT variables were added. This indicates that complete OGTT information is important for predicting the future risk of diabetes and GMD accurately.

KEYWORDS

diabetes; machine learning; 75-g oral glucose tolerance test; XGBoost

Introduction

The incidence of diabetes has been increasing for the last decade and is expected to continue to increase in the future [1-3]. At present, diabetes is diagnosed and predicted based on fasting plasma glucose (FPG), glycated hemoglobin (HbA_{1c}), and plasma glucose levels 2 hours after a 75-g oral glucose tolerance test (OGTT) [4]. In an OGTT, a patient is asked to ingest a glucose drink, and their plasma glucose (PG) levels and immunoreactive insulin (IRI) levels are measured before and at intervals after the glucose drink is consumed. Although OGTT provides important information regarding pathological conditions of glucose metabolism, many diabetes survey tools predict the risk of diabetes development based only on noninvasive information, such as self-administered questionnaires [5]. The combination of parameters used to diagnose diabetes helps to identify individuals with a high risk of developing diabetes in the future. Heianza et al [6] showed that the combination of HbA_{1c} and FPG is useful for finding patients with a high risk of developing diabetes. Fujibayashi et al [7] used HbA_{1c} values, FPG levels, and 2-hour PG to predict instances of high future risk of developing diabetes. Complete data, including 1-hour and 2-hour PG and IRI values obtained by OGTT, may improve the prediction accuracy for diabetes risk.

Previously, logistic regression (LR) analyses were used as initial screening tests [5,8-10]. Recently, studies have demonstrated new methods, including machine learning algorithms, big data mining approaches, and genomic information, for the improved screening and prediction of diabetes [11,12]. Machine learning methods using all relevant information from OGTTs may be able to more accurately predict the risk of developing diabetes and prediabetes. The goal of this study was to verify this hypothesis. To our knowledge, no previous study has predicted the development of diabetes using all of the information from OGTTs combined with machine learning.

We used XGBoost [13,14] for machine learning, an advanced algorithm known for obtaining the winning solutions in data competitions such as Kaggle. In addition, XGBoost has been applied to other medical fields [15-17]. Gao et al [15] compared model-based approaches (such as LRs) and model-free approaches (including using XGBoost) for the task of forecasting falls by patients with Parkinson disease. The authors reported that the model-free approach provided more reliable forecasting. Nishio et al [16] applied XGBoost and support vector machine methods to the computer-aided diagnosis of lung nodules. The authors reported that XGBoost was generally

superior to support vector machine methods. Qiao et al [17] applied XGBoost and recurrent neural networks to a task of emergency room visit prediction. The authors reported that the nonlinear models had better performance than linear models.

Methods

Ethics Statement

This study was conducted using data from comprehensive periodic medical examinations at the Center for Preventive Medicine, NTT Medical Center Tokyo, from May 2006 to April 2017. In Japan, employers are required by the Industrial Safety and Health Law to commission medical examinations once a year to ensure the health of their employees. The Center for Preventive Medicine has been contracted by a telecommunications company, Nippon Telegraph and Telephone Corporation (NTT), to provide periodic medical examinations to their employees to comply with this law. This program involves comprehensive periodic medical examinations as well as many services beyond those mandated by law. The data used in this study were collected as part of this general health check-up program at the center. We retrieved subject clinical data from an institutional database, although the examinations were not specifically intended to collect new data for our study. Our research plan was announced on the websites of both our facility and the Center for Preventive Medicine. All subjects were informed that the clinical data obtained by the program would be retrospectively analyzed and published. In addition, it was announced that subjects could withdraw from our research study at any time. The study protocol was approved by the ethical review board of Juntendo University (No. 2017114) and the institutional ethics committee at the Center for Preventive Medicine (No. 17-664).

Study Population

Most of the study subjects were volunteers from among the employees of NTT and their families. They were primarily healthy office workers ranging in age from 40 to 60 years, with more male subjects than females. Our investigation focused on subjects who underwent a 75-g OGTT at the center between May 2006 to April 2017. Subjects without serious diabetes or advanced renal failure were assessed regarding the status of their glucose metabolism using the OGTT.

A total of 20,458 OGTT trials were collected from 9906 subjects during the period at the center. Table 1 shows the distribution of subjects with the number of OGTT trials obtained for each during the period. Overall, 6437 subjects underwent OGTT only once, while 1 subject had 12 OGTTs.

Table 1. Distribution of subjects according to the number of oral glucose tolerance test trials.

Trials undergone, n	Subjects, n
1	6437
2	1157
3	736
4	459
5	331
6	251
7	172
8	143
9	93
10	81
11	45
12	1

Data Collection

The examinations were performed on 2 consecutive days. On the first day, each patient's weight and height were measured after the removal of shoes and heavy clothing, and blood pressure was measured with an automatic monitor with the person in the sitting position. In addition, serum samples were collected from each participant after overnight fasting and immediately subjected to biochemical analysis. The blood samples were also used to determine each subject's HbA_{1c} level, which was measured using high-performance liquid chromatography with an automatic analyzer. On the second day, the subjects underwent an OGTT. We obtained the subjects' FPG levels along with 1-hour and 2-hour postloading PG IRI levels during the OGTT. The Japan Diabetes Society (JDS) HbA_{1c} values were converted to National Glycohemoglobin Standardization Program values using the formula developed by the JDS [18]: $HbA_{1c} = [HbA_{1c}(JDS)(\%) \times 1.02 + 0.25(\%)]$. Insulin sensitivity was calculated with the insulin sensitivity index (ISI; composite) [19,20]: $ISI(\text{composite}) = [10,000 / \sqrt{(\text{FPG level}(\text{mg/dL}) \times \text{fasting IRI level}(\mu\text{U/mL}) \times 2\text{-hour PG level}(\text{mg/dL}) \times 2\text{-hour IRI level}(\mu\text{U/mL}))}]$. The sum of plasma glucose (SPG) is defined as $SPG = \text{FPG levels} + 1\text{-hour PG level} + 2\text{-hour PG level}$. The sum of immunoreactive insulin (S-IRI) is defined as $S\text{-IRI} = \text{fasting IRI level} + 1\text{-hour IRI level} + 2\text{-hour IRI level}$.

We defined diabetes, normal glucose tolerance (NGT), and prediabetes according to the American Diabetes Association guidelines [4]. Diabetes is defined as subjects with an FPG level ≥ 126 mg/dL, a 2-hour postloading PG level ≥ 200 mg/dL, or an HbA_{1c} concentration $\geq 6.5\%$. NGT is defined as subjects with an FPG level < 100 mg/dL, a 2-hour postloading PG level < 140

mg/dL, and an HbA_{1c} level $< 5.7\%$. Prediabetes is defined as subjects without diabetes who failed to have NGT. In our study, we defined glucose metabolism disorders (GMD) as either diabetes or prediabetes.

Data Handling

Inclusion and Exclusion Flow

Initially, a total of 20,458 OGTT trials across all subjects were included. Data were removed based on the inclusion and exclusion criteria as shown in Figure 1. First, 6437 subjects who underwent OGTT only once during the period were excluded to increase the reliability of the data. Second, missing data were excluded, and the remaining number of trials was 14,020. Then, 2 studies were conducted: predicting the future risk of developing diabetes (study 1) or GMD (study 2).

Study 1. Prediction of Future Risk of Developing Diabetes

Study 1 was aimed at predicting the future risk of developing diabetes. To apply supervised machine learning to the data, data labels (at risk: $y=1$, not at risk: $y=0$) were required for each OGTT trial. It is widely known that diabetes can recur even after remission. In addition, women with a history of gestational diabetes have a high risk of developing diabetes in the future [21]. We considered that subjects with a diagnosis of diabetes in the past had a high risk of developing diabetes in the future. Because of this hypothesis, we defined the risk group as follows: a subject was in the risk group ($y=1$) for diabetes if he or she was diagnosed with diabetes at least once during the period. We defined a subject to be in the nonrisk group ($y=0$) if he or she did not belong to the risk group. From 14,020 trials, 439 data points from patients diagnosed with diabetes were excluded to focus only on nondiabetic subjects.

Figure 1. Inclusion and exclusion criteria.

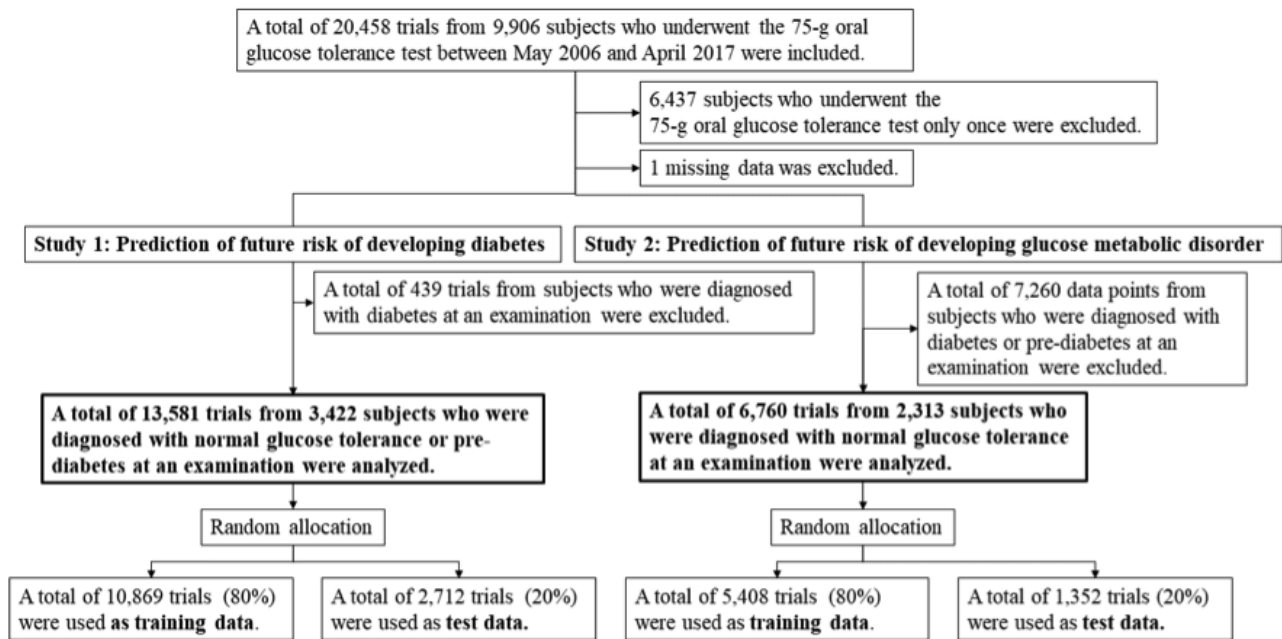
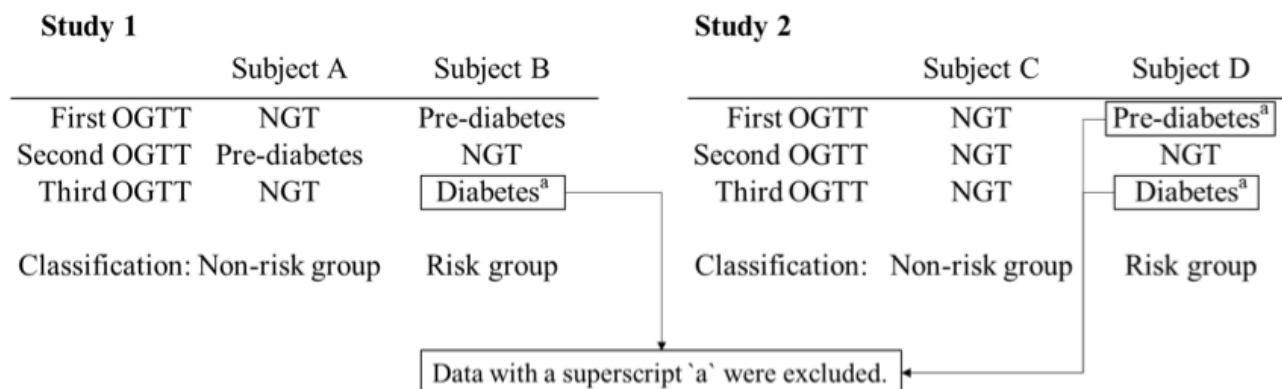


Figure 2. Examples of risk group and nonrisk group classifications. OGTT: oral glucose tolerance test, NGT: normal glucose tolerance.



Examples of the risk group and nonrisk group for diabetes are shown in Figure 2 (left). Subjects A and B underwent OGTT 3 times. Subject B was diagnosed with prediabetes, NGT, and diabetes in the first, second, and third OGTTs, respectively. Thus, Subject B was classified into the risk group, since he or she was diagnosed with diabetes at least once during the period. The third OGTT data point, which occurred after the diagnosis (marked with superscript a), is removed to focus only on nondiabetic data. Subject A was diagnosed with NGT, prediabetes, and NGT in the first, second, and third OGTTs, respectively. Subject A was classified into the nonrisk group, since he or she was never diagnosed with diabetes during the period.

At the end, we had a total of 13,581 OGTT trials of patients who were diagnosed with NGT or prediabetes, each of which was labeled with future risk information ($y=0$ or $y=1$). We randomly selected 10,869 (80%) for the training data and used

the remaining 2712 (20%) for test data. A classification model was trained using the training data, and the prediction accuracy was evaluated with the test data. Nine classification models were trained, as described below. Table 2 shows a summary of the analyzed OGTT data. No significant differences were observed between the training and test data.

Study 2. Prediction of Future Risk of Glucose Metabolism Disorders

Study 2 was aimed at predicting the future risk of developing GMD, which includes either diabetes or prediabetes. Similar to study 1, we defined a subject as being in the risk group ($y=1$) for GMD if he or she was diagnosed with GMD (prediabetes or diabetes) at least once during the period. We defined a subject to be in the nonrisk group ($y=0$) if he or she did not belong to the risk group for GMD. From 14,020 trials, 7260 data points from patients diagnosed with GMD were excluded to focus only on NGT subjects.

Table 2. Statistical summary of the analyzed oral glucose tolerance test data (study 1).

Data points	Training data (n=10,869)	Test data (n=2712)	P value ^a
Age, years, mean (SD)	49.78 (9.27)	49.71 (9.16)	.71
Sex, male, n (%)	9998 (91.99)	2509 (92.51)	.61
Body mass index (kg/m ²), mean (SD)	23.43 (3.00)	23.35 (2.98)	.21
Glycated hemoglobin (%), mean (SD)	5.50 (0.32)	5.49 (0.31)	.21
FPG ^b (mg/dL), mean (SD)	96.59 (8.31)	96.47 (8.35)	.50
1-hour PG (mg/dL), mean (SD)	145.82 (40.67)	146.91 (40.55)	.21
2-hour PG (mg/dL), mean (SD)	111.07 (26.62)	111.26 (26.32)	.73
SPG ^c (mg/dL), mean (SD)	353.48 (63.99)	354.63 (63.51)	.40
Fasting IRI ^d (IU/mL), mean (SD)	6.41 (3.65)	6.40 (3.44)	.89
1-hour IRI (IU/mL), mean (SD)	55.50 (37.16)	55.04 (35.21)	.55
2-hour IRI (IU/mL), mean (SD)	41.95 (32.59)	41.32 (31.01)	.34
S-IRI ^e (IU/mL), mean (SD)	103.87 (64.95)	102.76 (61.65)	.41
ISI ^f (composite), mean (SD)	8.39 (5.27)	8.34 (4.89)	.59
Systolic BP ^g (mm Hg), mean (SD)	125.38 (17.65)	125.68 (17.37)	.42
Diastolic BP (mm Hg), mean (SD)	79.74 (11.22)	80.13 (11.21)	.10
Total cholesterol (mg/dL), mean (SD)	200.80 (30.95)	200.17 (31.01)	.35
HDLC ^h (mg/dL), mean (SD)	58.27 (14.39)	58.10 (14.45)	.59
LDLC ⁱ (mg/dL), mean (SD)	118.37 (28.12)	117.83 (28.40)	.38
Triglyceride (mg/dL), mean (SD)	115.07 (79.98)	114.07 (73.87)	.54
Uric acid (mg/dL), mean (SD)	6.20 (1.27)	6.17 (1.30)	.24
UN ^j (mg/dL), mean (SD)	13.70 (3.18)	13.57 (3.14)	.05
Serum creatinine (mg/dL), mean (SD)	0.88 (0.14)	0.88 (0.15)	.29
GOT ^k (IU/L), mean (SD)	24.02 (9.24)	23.81 (9.28)	.29
GPT ^l (IU/L), mean (SD)	25.56 (16.44)	24.95 (15.43)	.07
γ - GTP ^m (IU/L), mean (SD)	47.05 (53.13)	46.55 (48.97)	.64
Serum albumin (g/dL), mean (SD)	4.51 (0.26)	4.50 (0.26)	.11

^aUsed *t* test or chi-square test.

^bFPG: fasting plasma glucose.

^cSPG: sum of plasma glucose.

^dIRI: immunoreactive insulin.

^eS-IRI: sum of immunoreactive insulin.

^fISI: insulin sensitivity index.

^gBP: blood pressure.

^hHDLC: high-density lipoprotein cholesterol.

ⁱLDLC: low-density lipoprotein cholesterol.

^jUN: serum urea nitrogen.

^kGOT: serum glutamic oxaloacetic transaminase.

^lGPT: serum glutamic pyruvic transaminase.

^m γ - GTP: serum γ -glutamyl transpeptidase.

Figure 2 (right) shows examples of the risk group and nonrisk group for GMD. Subjects C and D underwent OGTT 3 times. Subject D was diagnosed with prediabetes, NGT, and diabetes

in the first, second, and third OGTTs, respectively. Subject D was classified into the risk group of GMD, since he or she was diagnosed with prediabetes at least once during the period. The

first and third OGTT, which were diagnosed with prediabetes and diabetes, respectively, were removed to focus only on NGT data. Subject C was diagnosed with NGT all 3 times. Therefore, subject C was classified into the nonrisk group, since he or she was never diagnosed with prediabetes or diabetes during the period.

Finally, we had 6760 OGTT trials of patients who were diagnosed with NGT, each of which was labeled with future risk information ($y=0$ or $y=1$). We randomly selected 5408 (80%) for training data, and used the remaining 1352 (20%) for test data. A classification model was trained using the training data, and the prediction accuracy was evaluated using the test data. Nine models were trained, as detailed in the Classification Models section. Table 3 shows a summary of the analyzed data. No significant differences were observed between the training and test data.

Statistical Analysis

XGBoost

XGBoost [13] is open-source software [14] that provides a machine learning method of regression and classification using ensemble learning with gradient tree boosting (GTB) [22]. XGBoost is well known for obtaining the winning solutions in data competitions. Chen and Guestrin [13] reported that “Among the 29 challenge-winning solutions published on Kaggle’s blog during 2015, 17 winning solutions used XGBoost.” Applications of XGBoost include practical tasks such as “store sales prediction, high energy physics event classification, Web text classification, customer behavior prediction, motion detection, ad click-through rate prediction, malware classification, product categorization, hazard risk prediction, and massive on-line course dropout rate prediction.” See Chen and Guestrin [13] for details of the applications. In addition, XGBoost has been applied to medical fields [15-17].

XGBoost (or GTB) learns a regression and classification function in the data space by sequentially optimizing weak learners, called regression trees. The parameters of a regression tree consist of the tree structures and the weights of the leaf nodes. They are sequentially optimized to minimize an objective function, consisting of a fitting loss term plus a regularization term, using gradient methods. XGBoost software is designed to increase the scalability and acceleration of optimized computation for practical use. See Chen and Guestrin [13] for technical details. The underlying GTB algorithm is briefly discussed in Multimedia Appendix 1. XGBoost includes several hyperparameters—including the maximum depth of regression trees, number of weak learners, learning rate, and regularization parameters—which need to be tuned.

Classification Models

To predict the future risk of diabetes (study 1) or GMD (study 2), we developed 9 classification models (A to I) with different input variables, shown in Table 4.

Models A, B, and C used XGBoost. For comparison, models D to I used LR, which is traditionally used in medical research studies. For each classification model, the input variables were set as follows. Model A inputs some basic variables relevant to diabetes or GMD, without OGTT variables. Model B inputs OGTT variables (1-hour PG, 1-hour IRI, 2-hour PG, and 2-hour IRI), as well as the variables of model A. Model C inputs all the measured variables. Blood pressure, lipid parameters, uric acid values, markers of liver function, and markers of kidney function are parameters related with metabolic syndrome, fatty liver, and chronic kidney disease. These conditions are associated with diabetes and were included as variables [23-25]. Models D to F served as baselines using the well-known biomarkers FPG and HbA_{1c} . Models G to I used the same variables as models A to C to directly compare the performances of XGBoost and LR.

Evaluation

To evaluate the 9 trained classification models, we used the receiver operating characteristic (ROC) curves and their area under the curve (AUC) values computed from the test data [26,27]. ROC curves have commonly been used in diabetes prediction research. In addition, we report the sensitivity and specificity at the cutoff values determined by the Youden index.

Hyperparameter Tuning of XGBoost

As mentioned, XGBoost includes several hyperparameters such as maximum depth of the regression trees, number of weak learners, learning rate, and regularization parameters that need to be tuned.

We tuned the parameters using a grid search to maximize the mean AUC value computed from 5-fold cross validation on the training data. Specifically, the training data were divided into 5 subsets at random: 4 subsets were used for training XGBoost and the other subset was used for validation. The ROC curve and AUC value can be evaluated from the validation subset. This procedure was repeated 5 times with different validation subsets. The mean AUC value can be computed by averaging the 5 AUC values. We tuned the hyperparameters, including the regularization parameters, with a grid search method to maximize the mean AUC value. After finding the optimal values of the hyperparameters, XGBoost was trained using the entire training data set. The final ROC and AUC values were then evaluated with the test data.

Given a ROC curve, a cutoff value is required to compute the sensitivity and specificity. The cutoff value was determined by averaging 5 cutoff values computed from the Youden index from 5-fold cross validation.

Table 3. Statistical summary of analyzed oral glucose tolerance test data (study 2).

Data points	Training data (n=5408)	Test data (n=1352)	P value ^a
Age, years, mean (SD)	47.13 (8.75)	46.93 (8.70)	.43
Sex, male, n (%)	4853 (89.74)	1210 (89.50)	.83
Body mass index (kg/m ²), mean (SD)	22.71 (2.70)	22.72 (2.70)	.89
Glycated hemoglobin (%), mean (SD)	5.32 (0.23)	5.31 (0.23)	.43
FPG ^b (mg/dL), mean (SD)	91.46 (4.99)	91.41 (5.01)	.74
1-hour PG (mg/dL), mean (SD)	129.47 (33.10)	128.86 (31.48)	.53
2-hour PG (mg/dL), mean (SD)	99.89 (18.41)	99.73 (18.34)	.77
SPG ^c (mg/dL), mean (SD)	320.81 (45.05)	320.00 (43.52)	.54
Fasting IRI ^d (IU/mL), mean (SD)	5.66 (3.13)	5.59 (2.71)	.47
1-hour IRI (IU/mL), mean (SD)	51.06 (33.02)	49.20 (31.85)	.06
2-hour IRI (IU/mL), mean (SD)	34.16 (22.88)	33.45 (21.68)	.28
S-IRI ^e (IU/mL), mean (SD)	90.88 (51.66)	88.24 (49.38)	.08
ISI ^f (composite), mean (SD)	9.93 (5.50)	9.98 (5.35)	.77
Systolic BP ^g (mm Hg), mean (SD)	121.77 (16.63)	121.97 (16.01)	.68
Diastolic BP (mm Hg), mean (SD)	77.55 (10.82)	77.38 (10.51)	.59
Total cholesterol (mg/dL), mean (SD)	196.35 (30.13)	196.35 (30.28)	>.99
HDLC ^h (mg/dL), mean (SD)	59.53 (14.30)	60.25 (15.01)	.11
LDLC ⁱ (mg/dL), mean (SD)	114.88 (27.66)	113.94 (27.93)	.27
Triglyceride (mg/dL), mean (SD)	101.64 (63.13)	102.36 (77.61)	.75
Uric acid (mg/dL), mean (SD)	6.05 (1.28)	6.06 (1.31)	.70
UN ^j (mg/dL), mean (SD)	13.35 (3.04)	13.43 (2.99)	.36
Serum creatinine (mg/dL), mean (SD)	0.87 (0.14)	0.87 (0.14)	.95
GOT ^k (IU/L), mean (SD)	22.96 (8.20)	22.81 (8.42)	.55
GPT ^l (IU/L), mean (SD)	23.12 (13.91)	22.72 (13.13)	.32
γ - GTP ^m (IU/L), mean (SD)	40.74 (45.54)	39.87 (46.02)	.53
Serum albumin (g/dL), mean (SD)	4.50 (0.26)	4.49 (0.27)	.47

^aUsed *t* test or chi-square test.

^bFPG: fasting plasma glucose.

^cSPG: sum of plasma glucose.

^dIRI: immunoreactive insulin.

^eS-IRI: sum of immunoreactive insulin.

^fISI: insulin sensitivity index.

^gBP: blood pressure.

^hHDLC: high-density lipoprotein cholesterol.

ⁱLDLC: low-density lipoprotein cholesterol.

^jUN: serum urea nitrogen.

^kGOT: serum glutamic oxaloacetic transaminase.

^lGPT: serum glutamic pyruvic transaminase.

^m γ - GTP: serum γ -glutamyl transpeptidase.

Table 4. List of trained classification models.

Model	Algorithm	Input variables
A	XGBoost	Sex, age, BMI ^a , HbA _{1c} ^b , FPG ^c , and fasting IRI ^d
B	XGBoost	Variables in model A, 1-hour PG, 2-hour PG, 1-hour IRI, and 2-hour IRI
C	XGBoost	Variables in model B, SPG ^e during the 75-g OGTT ^f , S-IRI ^g during the OGTT, simple ISI ^h (composite), systolic blood pressure, diastolic blood pressure, total cholesterol, HDLC ⁱ , LDLC ^j , triglyceride, uric acid, UN ^k , serum creatinine, GOT ^l , GPT ^m , γ - GPT ⁿ , and serum albumin
D	LR ^o	FPG
E	LR	HbA _{1c}
F	LR	FPG, HbA _{1c}
G	LR	Sex, age, BMI, HbA _{1c} , FPG, and fasting IRI
H	LR	Variables in model A, 1-hour PG, 2-hour PG, 1-hour IRI, and 2-hour IRI
I	LR	Variables in model B, SPG during the 75-g OGTT, S-IRI during the OGTT, simple ISI (composite), systolic blood pressure, diastolic blood pressure, total cholesterol, HDLC, LDLC, triglyceride, uric acid, UN, serum creatinine, GOT, GPT, γ - GPT, and serum albumin

^aBMI: body mass index.

^bHbA_{1c}: glycated hemoglobin.

^cFPG: fasting plasma glucose.

^dIRI: immunoreactive insulin.

^eSPG: sum of plasma glucose.

^fOGTT: oral glucose tolerance test.

^gS-IRI: sum of immunoreactive insulin.

^hISI: insulin sensitivity index.

ⁱHDLC: high-density lipoprotein cholesterol.

^jLDLC: low-density lipoprotein cholesterol.

^kUN: serum urea nitrogen.

^lGOT: serum glutamic oxaloacetic transaminase.

^mGPT: serum glutamic pyruvic transaminase.

ⁿ γ - GPT: serum γ - glutamyl transpeptidase.

^oLR: logistic regression.

Results

Study 1. Prediction of Future Risk of Developing Diabetes

Figure 3 shows the 6 ROC curves for models A to I. Similarly, Multimedia Appendix 2 shows the corresponding curves for models A to F. The horizontal axis represents the false positive rate, and the vertical axis represents the true positive rate. The 3 solid lines (models A, B, and C) show the ROC curves obtained from XGBoost. The dashed lines (models G, H, and I) show the ROC curves obtained from LR.

The AUC values for the 9 classification models are shown in Table 5. For each model, we also show the sensitivity and specificity as determined by the Youden index. We observed that XGBoost had superior performance compared with LR. The AUC value increased with the number of input variables. Models B and C, which exploit XGBoost and complete OGTT information for input variables, showed the best AUC values, 0.90 and 0.93, respectively.

In addition, XGBoost provides an importance score for each input variable. The importance value for each input variable in models A to C are shown in Multimedia Appendix 3 (left), Multimedia Appendix 4 (left), and Multimedia Appendix 5 (left), respectively. In model B, we observed that the OGTT variables (1-hour PG, 1-hour IRI, 2-hour PG, and 2-hour IRI) were more important than FPG or HbA_{1c}. In model C, we observed that SPG and 2-hour PG were more important variables than FPG or HbA_{1c}, although multicollinearity needs to be considered.

Study 2. Prediction of Future Risk of Glucose Metabolism Disorders

Figure 4 shows the 6 ROC curves for models A to I. Similarly, Multimedia Appendix 6 shows the corresponding 6 ROC curves for models A to F. The 3 solid lines (models A, B, and C) show the ROC curves obtained from XGBoost. The dashed lines (models G, H, and I) show the ROC curves obtained from LR.

Figure 3. Receiver operating characteristic curves obtained for the prediction of diabetes.

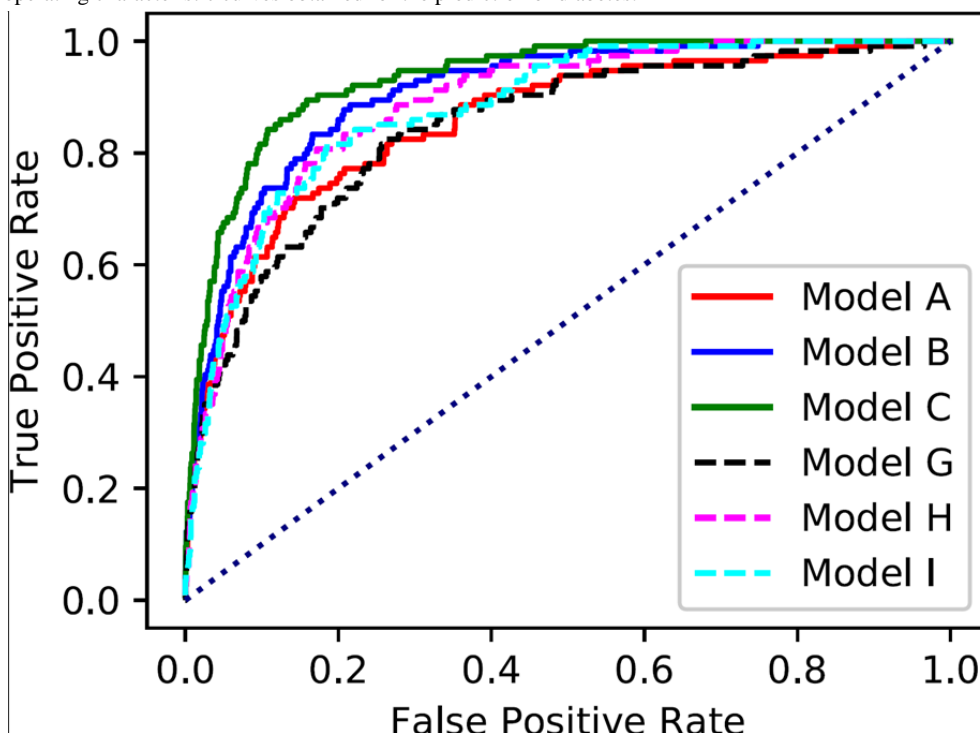


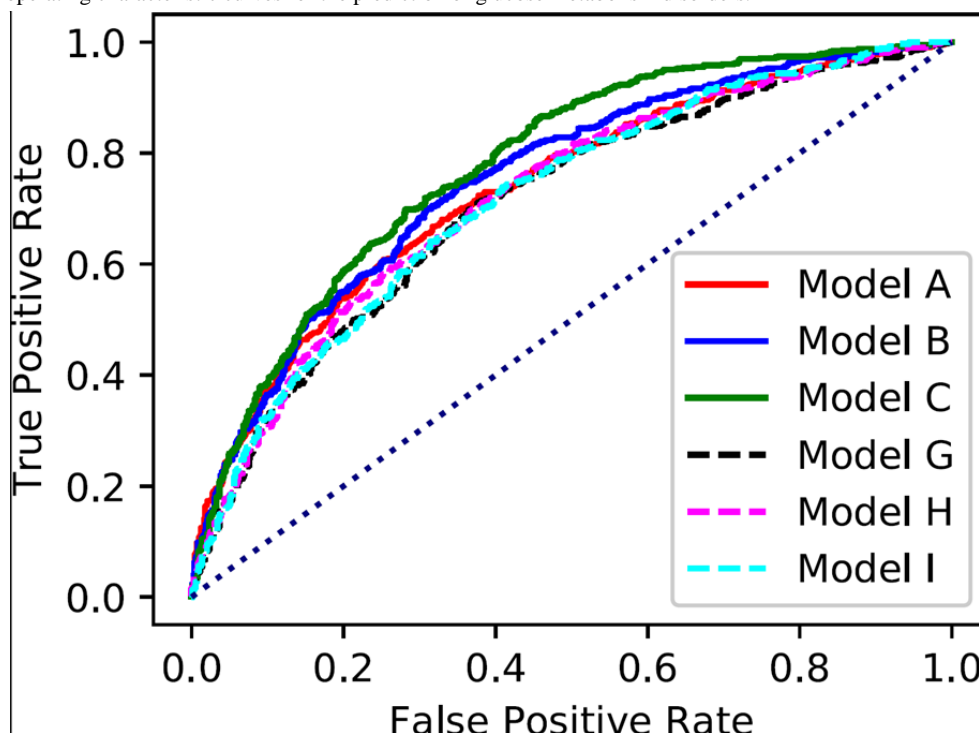
Table 5. Area under the curve, sensitivity, and specificity for predicting diabetes.

Type and model	AUC ^a	Sensitivity (%)	Specificity (%)
Machine learning			
Model A	0.86	36.8	97.2
Model B	0.90	40.4	97.4
Model C	0.93	39.5	98.4
Logistic regression			
Model D	0.80	12.3	99.4
Model E	0.78	6.1	99.9
Model F	0.84	41.2	95.2
Model G	0.85	38.6	95.9
Model H	0.88	37.7	96.1
Model I	0.88	40.4	96.5

^aAUC: area under the curve.

The AUC values for the 9 models are shown in Table 6. The sensitivity and specificity, as determined by the Youden index, are also shown in Table 6. Similar to study 1, we observed that XGBoost had better performance than LR. The AUC values also increased with the number of input variables. Models B and C, which exploit XGBoost and complete OGTT information as input variables, displayed the highest AUC values, 0.75 and 0.78, respectively.

The importance score of each input variable for models A, B, and C are shown in Multimedia Appendix 3 (right), Multimedia Appendix 4 (right), and Multimedia Appendix 5 (right), respectively. In model B, we observed that the OGTT variables (1-hour PG, 1-hour IRI, 2-hour PG, and 1-hour IRI) were more important than FPG or HbA_{1c}. In model C, we observed that the OGTT variables (1-hour PG, 1-hour IRI, 2-hour PG, 2-hour IRI, and SPG) were more important variables than FPG or HbA_{1c}, although multicollinearity needs to be considered.

Figure 4. Receiver operating characteristic curves for the prediction of glucose metabolism disorders.**Table 6.** Area under the curve, sensitivity, and specificity for predicting glucose metabolism disorders.

Type and model	AUC ^a	Sensitivity (%)	Specificity (%)
Machine learning			
Model A	0.73	34.3	90.9
Model B	0.75	31.6	91.8
Model C	0.78	33.7	92.2
Logistic regression			
Model D	0.65	6.6	97.3
Model E	0.63	21.3	91.6
Model F	0.69	6.6	98.4
Model G	0.71	27.6	78.9
Model H	0.72	27.1	91.6
Model I	0.72	41.3	84.9

^aAUC: area under the curve.

Discussion

Principal Findings

In this study, we reported on 2 results for predicting the future risk of diabetes or GMD using complete OGTT information and machine learning.

A feature of our study is that we used a large-scale dataset that included thousands of Japanese OGTT trials, even though OGTT is expensive and invasive. The amount of data enabled us to use a machine learning approach. It is known that one of the earliest detectable abnormalities in the development of diabetes is the deterioration of the early insulin response after glucose loading [28], and the aggravation of insulin sensitivity affects

the development of diabetes [7,29-32]. Data obtained from OGTT provide important pathological glucose metabolism information. We believe that the data obtained from OGTT contributed to the improvement in prediction of future risk of diabetes and GMD.

Another feature of our study is that we used an advanced and powerful machine learning method, XGBoost, which resulted in better performance compared with LR. Many previous diabetes risk assessment tools used LR analyses. Recently, various machine learning algorithms have been used for the screening and prediction of diabetes [12,33-35]. Linear approaches are generally unsuited for prediction models with complex correlations. We believe that XGBoost plays an important role in improving the prediction of the future risk of

developing diabetes or GMD. To our knowledge, no previous study combined large-scale Japanese OGTT data and XGBoost.

By observing the importance scores ([Multimedia Appendix 3](#)-[Multimedia Appendix 5](#)) of the input variables computed from XGboost, the OGTT variables (1-hour PG, 1-hour IRI, 2-hour PG, 2-hour IRI) were found to be more important predictors than FPG or HbA_{1c} for the future risk of diabetes or GMD, although multicollinearity needs to be taken into account. The progress of the PG level after loading can reflect abnormalities in the insulin response. Simultaneous measurement of PG and IRI levels can help evaluate the insulin sensitivity. Although multiple collinearity affects the results, PG and IRI levels after loading appeared to be more important than FPG or HbA_{1c}.

Limitations

Our research had several limitations. First, we did not use any information obtained from questionnaires in our research. This was because we were concerned that subject recall bias may impact the accuracy of the predictions [36]. As far as we know, previous diabetes risk assessment tools were based on information obtained from questionnaires such as family history and lifestyle habits [5,8-10,37]. Because of this, our results could not be easily compared with these reports. A previous study showed that combining the results of blood tests and questionnaire information improved the prediction accuracy of diabetes risk assessment [37]. We will attempt to improve the accuracy of diabetes risk prediction by integrating information obtained from blood tests and questionnaires. Second, we merged data from subjects who underwent OGTT different numbers of times. That is, we handled data from subjects who had 2 OGTT trials in the same manner as subjects with 10 OGTT trials. Data from subjects who had frequent OGTT trials may have impacted the calculation. Finally, our subjects were affected by selection bias, specifically, the “healthy worker”

effect. More than 70% of our participants were healthy male office workers who ranged in age from 40 to 60 years. Thus, the limited sample might not accurately represent the entire population. In addition, we believe that our method is not suitable for predicting rapidly progressing diabetes, as with type 1 diabetes. Also, validation is still required using other data sets.

Comparison With Prior Work

Thoopputra et al [5] considered many diabetes risk assessment tools developed worldwide. In the review, although there a few that used OGTT data or decision tree algorithms, many diabetes risk assessment tools used only noninvasive information and LR analyses. Values for the AUC ranged from 62% to 87%. In Japan, Nanri et al [37] reported a risk score showing an AUC value of 0.882 for predicting type 2 diabetes based on noninvasive information, FPG level and HbA_{1c}, using an LR analysis. Recently, studies have demonstrated new methods, including machine learning algorithms, big data mining approaches, and genomic information, for the screening and prediction of diabetes [11,12]. Habibi et al [34] developed a model with an AUC value of 0.875 when screening for type 2 diabetes that used a decision tree method and did not require any laboratory tests. López et al [12] reported a model for diabetes prediction having an AUC value of 0.89 that used genetic information and a random forest algorithm.

Conclusion

Our predictions for the future risk of developing diabetes or GMD, using data from thousands of OGTT trials and the machine learning program XGBoost, resulted in higher accuracy compared with traditional LR analysis. Combining complete OGTT information with advanced machine learning algorithms may be useful for detecting the future risk of diabetes or GMD more accurately.

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Conflicts of Interest

This study was funded by Novartis Pharma KK.

Multimedia Appendix 1

Brief review of gradient tree boosting algorithms.

[[PDF File \(Adobe PDF File\), 57KB - diabetes_v3i4e10212_app1.pdf](#)]

Multimedia Appendix 2

Receiver operating characteristic curves in study 1, comparison with reference models D-F.

[[PPTX File, 237KB - diabetes_v3i4e10212_app2.pptx](#)]

Multimedia Appendix 3

Importance of variables in model A.

[[PPTX File, 58KB - diabetes_v3i4e10212_app3.pptx](#)]

Multimedia Appendix 4

Importance of variables in model B.

[[PPTX File, 68KB - diabetes_v3i4e10212_app4.pptx](#)]

Multimedia Appendix 5

Importance of variables in model C.

[[PPTX File, 124KB - diabetes_v3i4e10212_app5.pptx](#)]

Multimedia Appendix 6

Receiver operating characteristic curves for study 2, comparisons with reference models D-F.

[[PPTX File, 240KB - diabetes_v3i4e10212_app6.pptx](#)]

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Abbreviations

- AUC:** area under the curve
- BMI:** body mass index
- BP:** blood pressure
- FPG:** fasting plasma glucose
- GMD:** glucose metabolism disorders
- GOT:** serum glutamic oxaloacetic transaminase
- GPT:** serum glutamic pyruvic transaminase

GTB: gradient tree boosting
HbA_{1c}: glycated hemoglobin
HDLC: high-density lipoprotein cholesterol
IRI: immunoreactive insulin
ISI: insulin sensitivity index
JDS: Japan Diabetes Society
LDLC: low-density lipoprotein cholesterol
LR: logistic regression
NGT: normal glucose tolerance
NTT: Nippon Telegraph and Telephone Corporation
OGTT: oral glucose tolerance test
PG: plasma glucose
ROC: receiver operating characteristic
S-IRI: sum of immunoreactive insulin
SPG: sum of plasma glucose
UN: serum urea nitrogen
γ - GTP: serum γ-glutamyl transpeptidase

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Original Paper

Transition Education for Young Adults With Type 1 Diabetes: Pilot Feasibility Study for a Group Telehealth Intervention

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Abstract

Background: Young adults with type 1 diabetes (T1D) experience a decline in glycemic outcomes and gaps in clinical care. A diabetes education and support program designed for young adults was delivered through group videoconference and mobile Web.

Objective: The objective of our study was to assess the feasibility, acceptability, and preliminary efficacy of the program as measured by attendance and webpage views, satisfaction, and pre- and postintervention psychosocial outcomes, respectively.

Methods: Young adults aged 18-25 years were recruited to attend five 30-minute group diabetes education videoconferences during an 8-week period. Videoconferences included an expert presentation followed by a moderated group discussion. Within 48 hours of each videoconference, participants were sent a link to more information on the study website. Feasibility was assessed using data on videoconference attendance and webpage views. Acceptability was assessed via a Satisfaction Survey completed at the conclusion of the study. Descriptive statistics were generated. Preliminary efficacy was assessed via a survey to measure changes in diabetes-specific self-efficacy and diabetes distress. Pre- and postintervention data were compared using paired samples *t* tests.

Results: In this study, 20 young adults (mean age 19.2 [SD 1.1] years) attended an average of 5.1 (SD 1.0) videoconferences equivalent to 153 (SD 30.6) minutes of diabetes education per participant during an 8-week period. Average participant satisfaction scores were 62.2 (SD 2.6) out of a possible 65 points. A total of 102 links sent via text message (short message service) or email resulted in 504 webpage views. There was no statistically significant difference between pre- and postintervention diabetes-specific self-efficacy or diabetes-related distress.

Conclusions: Delivery of diabetes education via group videoconference using mobile Web follow-up is feasible and acceptable to young adults with T1D. This model of care delivery has the potential to improve attendance, social support, and patient-reported satisfaction. Nevertheless, further research is required to establish the effect on long-term psychosocial and glycemic outcomes.

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KEYWORDS

diabetes education; mobile phone; telehealth; type 1 diabetes; young adult; transition

Introduction

Clinic-based transition support for young adults with type 1 diabetes (T1D) remains inadequate despite expert consensus guidelines published by the American Diabetes Association in 2011 [1-4]. Many young adults with T1D experience gaps in care, have poor glycemic control, and are, thus, at risk for acute and long-term diabetes-related complications. In a large clinical registry based in the United States, only 13% of young adults with T1D achieved the recommended glycosylated hemoglobin (HbA_{1c}) target of 7%, with HbA_{1c} peaking at an average of 9.2% at the age of 19 years [5,6]. This decline in glycemic control occurs as many young adults move away from home and lose access to their established diabetes support system [7,8]. Recent efforts to provide clinic-based structured transition support for young adults with T1D have been associated with improved glycemic control, reduced hypoglycemia, and improved psychological well-being [9,10]. Telemedicine visits have been successfully used in lieu of in-clinic visits to improve adherence to clinical attendance standards for pediatric patients with diabetes in rural settings [11], and an innovative pilot study found group medical appointments for young adults with T1D conducted using Web-based videoconference technology to be feasible and acceptable [12]. However, the use of Web-based group videoconferences to provide a transition-focused diabetes self-management education and support (DSMES) program has not been studied. The purpose of this pilot study was to test the feasibility, acceptability, and preliminary efficacy of a telehealth transition education program designed for young adults with T1D as a first step in our efforts to evaluate its potential for integration into the clinical care paradigm.

Methods

Following the institutional review board (IRB) approval, participants were recruited via fliers at the University of Florida outpatient diabetes clinic. Upon enrollment, participants completed surveys on paper to obtain demographic data, diabetes history, technology acquisition, and communication preferences. Participants then completed the Problem Areas in Diabetes (PAID) Scale to assess baseline levels of diabetes-specific distress [13,14] and the Confidence in Diabetes Scale (CIDS) to assess baseline levels of diabetes-specific self-efficacy [15]. The PAID Scale consists of 20 items; potential scores range from 0 to 80, with higher scores indicating higher levels of distress. The instrument has demonstrated high internal reliability (Cronbach alpha=.90) as well as reasonable (Spearman ρ =.83) 2-month test-retest reliability and correlates strongly with a wide range of theoretically related psychosocial constructs in diabetes (eg, distress, depression, self-care behaviors, coping, and health beliefs). The CIDS survey has 20 items; potential scores range from 20 to 100, with higher scores indicating higher levels of self-efficacy. The instrument has demonstrated high internal consistency (alpha=.90) and test-retest reliability (ρ =.85, P <.001).

Once the surveys were completed, participants were asked to indicate which 5 group diabetes education videoconferences they preferred to attend over the 8-week study period. Each

topic was offered a total of 5 times (5 different dates or times). A maximum of 5 participants per videoconference was set to facilitate dialogue and minimize the risk for technical challenges. After participants indicated topical preferences, a study coordinator contacted them to assist with scheduling. Vidyo software (Vidyo, Inc, Hackensack, NJ, USA) was used as the videoconference platform; it allows end users to participate via a smartphone, tablet, laptop, or desktop. Each 30-minute videoconference included a brief (10-15 minute) expert presentation by a pediatric endocrinologist, nurse practitioner (NP), certified diabetes educator (CDE), psychologist, or registered dietitian (RD). At the beginning of each videoconference, a moderator read a scripted, IRB-approved statement regarding privacy and respecting the privacy of all study participants. Only first names were used during group education sessions. Participants had the option to enable or disable video streaming during all videoconferences. The moderator's introduction was followed by the expert presentation, and then a moderated discussion among participants to foster peer-learning and social support. Table 1 summarizes the diabetes education topics available during the study.

Within 48 hours of each videoconference, attendees were sent a link to additional content on a section of the study website specifically for young adults with T1D and their parents (Figure 1). The study website was developed and reviewed by a multidisciplinary team of CDEs, pediatric endocrinologists, NPs, psychologists, RDs, registered nurses, parents, and people with diabetes. The website provides information on basic diabetes management, diabetes technology, and additional content tailored to young adults with T1D. Of note, the website was not publicly available during the study and could only be reached via links sent to participants. Web analytics for the site were monitored and analyzed, with particular attention to relevant page views and increases in website traffic during the 48 hours following the distribution of links via short message service (SMS) text message or email to participants.

At the end of the 8-week study, participants completed the PAID Scale, the CIDS Scale, and a Satisfaction Survey to assess acceptability and usability. The Satisfaction Survey was designed for the study and included 16 questions (13 closed-ended and 3 open-ended) to obtain end-user feedback about the usability and acceptability of the program. Potential scores on the closed-ended questions ranged from 13 to 65, with higher scores indicating higher levels of satisfaction. Answers to open-ended questions were reviewed and coded to inform future iterations of the educational content and clinical model. At the completion of study procedures, a US \$75 gift card was provided to participants. Participants were given information about the US \$75 gift card at the time of informed consent.

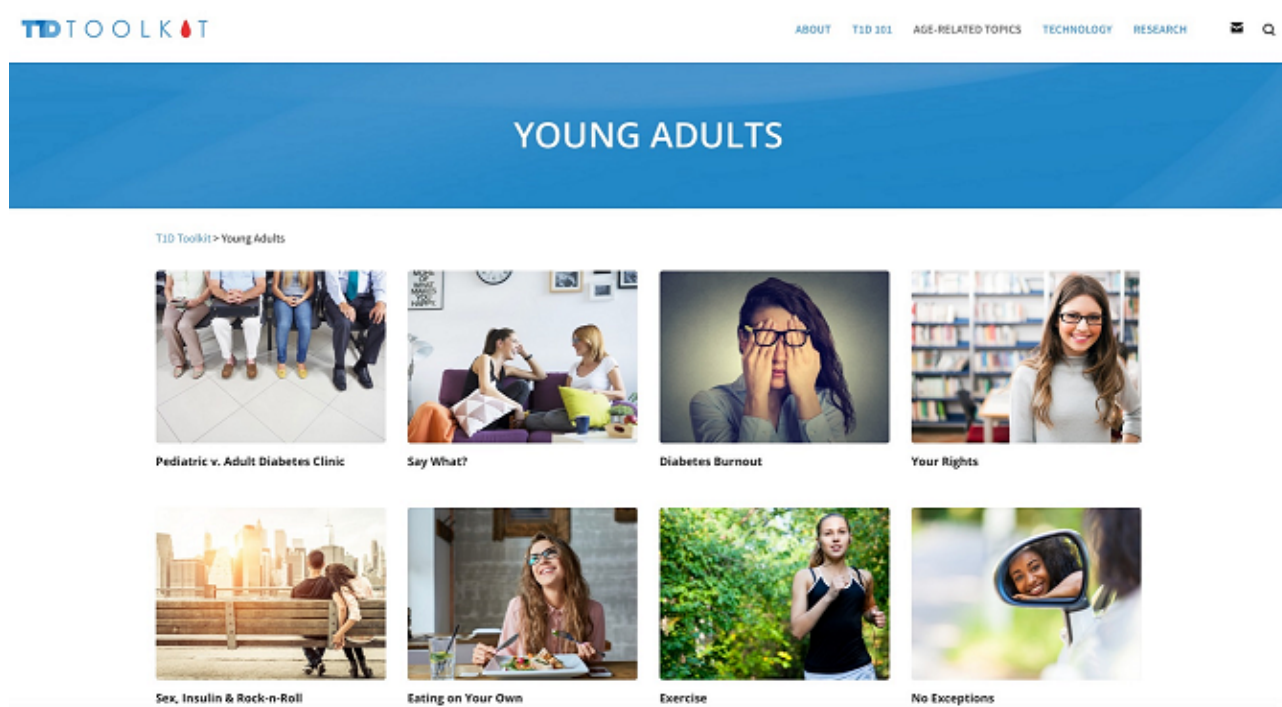
Quantitative data from the Demographic, Communication Preferences, and Satisfaction surveys were analyzed using SPSS, v.25, software (IBM Corp, Armonk, NY) to generate descriptive statistics. Results are expressed as mean (SD) and as frequencies and percentages for categorical variables. Pre- and postintervention scores on the CIDS and PAID scales were analyzed using paired samples t test. A P <.05 was considered statistically significant. Web analytics were reviewed and

pageview data were analyzed to describe participant traffic on the study website, T1DToolkit.org.

Table 1. Diabetes education topics.

Videoconference topic	Description
Pediatric versus Adult Diabetes Clinic	What to expect, how to prepare for transition
Say What?	How to have the “Diabetes Talk”
Your Rights	Reasonable work and school accommodations
Sex, Insulin, and Rock-n-Roll	Exploring “taboo” subjects related to real life with type 1 diabetes
Exercise and Nutrition	Optimizing activity and nutrition
Diabetes Burnout and Sources of Support	Identifying burnout, burnout versus depression, and how to find help
New and Emerging Diabetes Technologies	Insulin pumps, continuous glucose monitors, automated insulin delivery

Figure 1. Screenshot of the young adult section of the study website. Source: T1D Toolkit.



Results

We approached 21 participants to participate in this study. All enrolled, but 1 participant withdrew immediately following enrollment citing a busy high school sports schedule. Mean age of participants was 19.2 (SD 4.39) years, and 80% (16/21) participants were females. Mean diabetes duration was 10.21 (SD 4.39; range, 2-17) years; mean age at diagnosis was 9 (SD 4.42; range, 3-17) years, and 80% (16/20) participants were insulin pump users. [Table 2](#) provides additional demographic data. All participants had access to a smartphone (20/20, 100%) and most had access to a computer, laptop, or tablet. A majority (9/20, 45%) of participants preferred to receive notifications via both SMS text message and email, with 40% (8/20) preferring SMS text message only and 15% (3/20) email only ([Table 3](#)).

Mean attendance was 5.1 (SD 1.0; range, 2-7) diabetes education videoconferences per participant, which is equivalent to an average of 153 (SD 30.6; range, 60-210) minutes of diabetes

education per participant. The most popular sessions included Diabetes Burnout (n=17), Your Rights (n=15), Diabetes Technologies (n=15), and Exercise and Nutrition (n=15); these were followed by Transition to Adult Clinic (n=14); Sex, Insulin, and Rock-n-Roll (n=14); and Say What? (n=12). A minimum of 2 and a maximum of 5 participants participated in each of the 35 videoconferences offered during the study. The mean score on the Satisfaction Survey was 62.2 (SD 2.6; range, 57-65). Overall, 95% (19/20) participants responded that they would be “extremely interested” or “very interested” in participating in a similar program in the future. Representative positive responses to the open-ended questions included, “I really enjoyed participating in this study. I got to talk about things that I don’t really talk about with my doctor. And the topics that I have discussed with my doctor, it was interesting to hear different opinions.” Suggestions to improve the program included, “Add a better way to manage all questions from larger groups of people” and “Only one session had technical difficulties where no one could log on. It was fixed quickly.”

The mean scores for diabetes-related distress declined; however, there was no statistically significant reduction when comparing the mean baseline (mean 20.4 [SD 15.0]) and postintervention (mean 17.2 [SD 15.3]) scores on the PAID Scale ($t_{19}=1.04$, $P=.09$). Mean scores for diabetes-specific self-efficacy

increased; however, there was no statistically significant increase when comparing the mean baseline (mean 87.0 [SD 7.4]) and postintervention (mean 88.2 [SD 6.9]) scores on the CIDS Scale ($t_{19}=-0.79$, $P=.44$; Table 4).

Table 2. The description of study participants.

Characteristics	Values
Age in years, mean (SD)	19.2 (4.39)
Age at diagnosis in years, mean (SD)	9 (4.42)
Type 1 diabetes duration in years, mean (SD)	10.21 (4.39)
Insulin regimen, n (%)	
Pump	16 (80)
Multiple daily injections	4 (20)
Gender, n (%)	
Male	4 (20)
Female	16 (80)
Ethnicity, n (%)	
Asian	3 (15)
Hispanic black	1 (5)
Non-Hispanic black	1 (5)
Hispanic	1 (5)
Non-Hispanic white	14 (70)
Residence, n (%)	
Independent	14 (70)
Parent or guardian	6 (30)
Level at school, n (%)	
College	17 (85)
High School	3 (15)
Employment, n (%)	
Full time	4 (20)
Part time	10 (50)
None	6 (30)

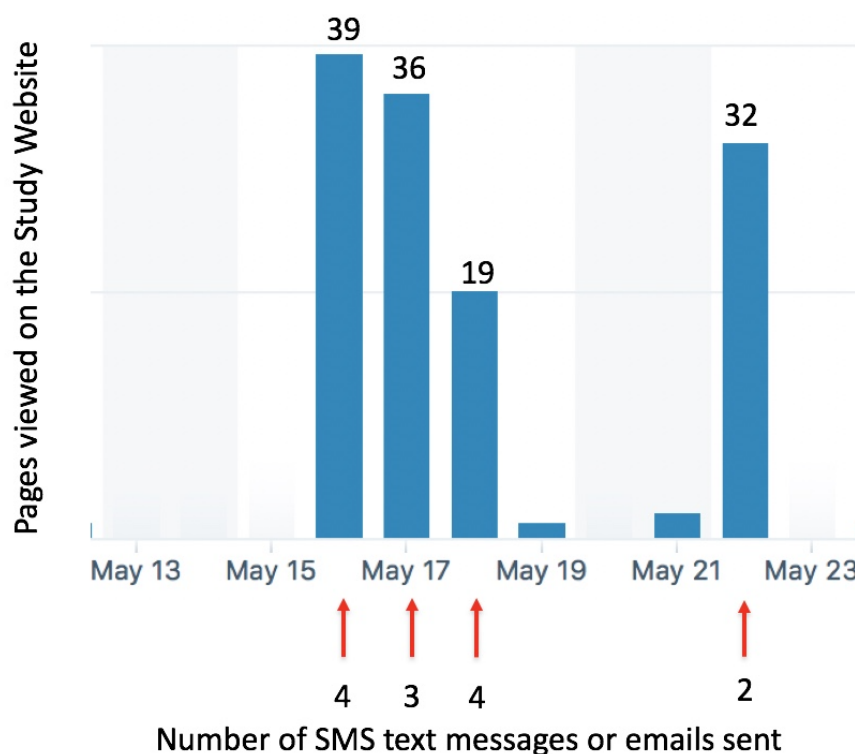
Table 3. Technology acquisition and communication preferences.

Characteristics	Values
Technology acquisition, n (%)	
Smartphone	20 (100)
Tablet	7 (35)
Laptop	19 (95)
Desktop	6 (30)
Communication preference, n (%)	
Email only	3 (15)
Short message service (SMS) text message only	8 (40)
Email and SMS text message	9 (45)

Table 4. Psychosocial outcomes.

Construct	Measure	Mean (SD)		<i>t</i> statistic	<i>df</i> ^a	<i>P</i> value
		Pre	Post			
Diabetes-related distress	Problem areas in Diabetes Scale	20.4 (15.0)	17.2 (15.3)	0.79	19	.09
Diabetes-related self-efficacy	Confidence in Diabetes Scale	87 (7.4)	88.2 (6.9)	1.04	19	.44

^a*df*: degrees of freedom.

Figure 2. Dose-response example of pushed links and website page views. SMS: short message service.

A total of 102 emails or SMS text messages with links to the study website were sent to participants, resulting in 504 page views. The timing of website page views was strongly linked to the date the links were pushed to participants; this indicates a high level of engagement in the educational content by participants. [Figure 2](#) provides a sample of the dose-response feedback.

Discussion

This pilot study with young adults with T1D demonstrated high feasibility for providing diabetes education and support via group videoconference and strong participant engagement in Web-based follow-up. Participants reported high levels of acceptability as measured by user satisfaction. In terms of the preliminary efficacy, there was no statistical difference in pre- and postintervention psychosocial outcomes; however, on average, we observed improved scores for both diabetes-related self-efficacy and diabetes-related distress. The findings support results from previous studies that have demonstrated high attendance and satisfaction with individual clinic visits and group medical appointments provided via telehealth to youth and young adults with T1D [11,12].

The implications of these results should be considered in the context of the study's limitations. Owing to the brief duration of and limited funding for the study, other efficacy-related outcome measures including glycemic control and diabetes knowledge attainment were not assessed. Recruitment took place at a university-based diabetes clinic, where patients may be more highly motivated to attend diabetes education visits. In addition, despite the ubiquity of mobile technology, patients with limited data plans or access to wireless networks may not find participation as feasible without financial support to cover the cost of a mobile data plan.

Nonetheless, the outcomes suggest that this delivery model for diabetes education and support has the potential to increase contact with the clinic, improve access to diabetes education, and provide peer and social support for young adults who have become disconnected from their diabetes network. Future randomized studies that include a control group should explore the intermediate and longitudinal effect of the model on glycemic control, diabetes knowledge attainment, clinic attendance, and psychosocial outcomes. In addition, future studies should measure provider satisfaction and explore the feasibility of reimbursement for telehealth group videoconference education sessions. Convenient,

comprehensive, yet tailored diabetes care, education, and support is required to keep young adults engaged in their diabetes management to reduce gaps in care and to mitigate the decline in glycemic control commonly experienced by this patient population. As T1D management becomes more technically

complex, videoconference and Web-based models of diabetes care and education delivery can be leveraged to connect patients to providers and educators at a reduced cost with improved convenience and without a decline in patient satisfaction.

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Conflicts of Interest

None declared.

Authors' Contributions

AAO, NT, and MJH designed the study. AAO, GB, MJH, SCW, and NT enrolled subjects and delivered the educational content. AAO, GB, and NT collected the data. AAO and MJH designed and performed the analysis. AAO, NT, and MJH wrote the manuscript. SCW, NJ, and DS reviewed and edited the manuscript.

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Abbreviations

CDE: certified diabetes educator

CIDS: Confidence in Diabetes Scale

DSMES: diabetes self-management education and support

HbA_{1c}: glycated hemoglobin

IRB: Institutional Review Board

NP: nurse practitioner

PAID: Problem Areas in Diabetes Scale

RD: registered dietitian

SMS: short message service

T1D: type 1 diabetes

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Original Paper

Promoting Self-Care of Diabetic Foot Ulcers Through a Mobile Phone App: User-Centered Design and Evaluation

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Abstract

Background: Without effective self-care, people with diabetic foot ulcers (DFUs) are at risk of prolonged healing times, hospitalization, amputation, and reduced quality of life. Despite these consequences, adherence to DFU self-care remains low. New strategies are needed to engage people in the self-care of their DFUs.

Objective: This study aimed to evaluate the usability and potential usefulness of a new mobile phone app to engage people with DFUs in self-care.

Methods: We developed a new mobile phone app, MyFootCare, to engage people with DFUs through goals, progress monitoring, and reminders in self-care. Key features included novel visual analytics that automatically extract and monitor DFU size information from mobile phone photos of the foot. A functional prototype of MyFootCare was created and evaluated through a user-centered design process with 11 participants with DFUs. Data were collected through semistructured interviews discussing existing self-care practices and observations of MyFootCare with participants. Data were analyzed qualitatively through thematic analysis.

Results: Key themes were as follows: (1) participants already used mobile phone photos to monitor their DFU progress; (2) participants had limited experience with using mobile phone apps; (3) participants desired the objective DFU size data provided by the tracking feature of MyFootCare to monitor their DFU progress; (4) participants were ambivalent about the MyFootCare goal image and diary features, commenting that these features were useful but also that it was unlikely that they would use them; and (5) participants desired to share their MyFootCare data with their clinicians to demonstrate engagement in self-care and to reflect on their progress.

Conclusions: MyFootCare shows promising features to engage people in DFU self-care. Most notably, ulcer size data are useful to monitor progress and engage people. However, more work is needed to improve the usability and accuracy of MyFootCare, that is, by refining the process of taking and analyzing photos of DFUs and removing unnecessary features. These findings open the door for further work to develop a system that is easy to use and functions in everyday life conditions and to test it with people with DFUs and their carers.

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KEYWORDS

mobile apps; foot ulcer, diabetic; self-care (rehabilitation); therapeutic adherence and compliance; patient engagement; podiatry

Introduction

Diabetic foot ulcers (DFUs) are common, costly, and take a toll on patients, families, and communities [1]. It is estimated that at any one time, DFUs affect between 3 million to 49 million people worldwide [1]. In Australia alone, each day, 50,000 people suffer from a DFU, 1000 are hospitalized, 12 have an amputation, and 4 die because of a DFU, leading to an estimated annual cost of Aus \$1.6 billion [2,3].

DFUs often result from a combination of diabetes-related peripheral neuropathy (loss of protective sensation as well as changes in gait) and mechanical pressures (from walking or external trauma) [1]. When DFUs are complicated by peripheral artery disease and infection, they may take months or even years to heal and often lead to hospitalization, amputation, and even death [1]. In addition, DFUs impact the physical and mental quality of life of patients and their partners and families, with patients frequently describing a loss of independence over basic activities of living and a disruption to their sense of self as a result of the ulcer [4].

Best practice treatment of DFUs requires biweekly multidisciplinary team treatment in specialized clinics, with various clinicians working together to provide effective clinical care [5]. However, this treatment also relies on self-care away from the clinic: patients need to prevent excessive moisture, change wound dressings regularly, ensure cleanliness, moisturize, check their feet to identify changes in the wound and any potential infection, and, perhaps most importantly, adhere to wearing offloading devices at all times to relieve mechanical pressures and protect the ulcer [5]. These self-care practices are typically established in consultation between patients, carers, and multiple clinicians.

Unfortunately, adherence to self-care practices has been found to be typically low [6]. Patients often have a limited understanding of diabetes, foot ulcers, and the significance of self-care [7]. Furthermore, several studies have shown that knowledge alone is not enough for people to adhere to new practices [4,8]. Patients and their families also need to have the ability to enact care in terms of skills, time, finances, and resources [8,9]. In addition, and perhaps most importantly, patients need to be motivated to enact self-care consistently over months of DFU treatment [10]. Unfortunately, many patients view self-care practices as a further diminishment to their quality of life, such as wearing an offloading device at all times, while improvements to their ulcer when adhering to this care can be difficult to detect on a daily basis [4]. Hence, experts recommend that new strategies are needed to help motivate patients and engage them in self-care away from the clinic [6].

Mobile health apps hold great promise for people with diabetes, but few apps seek to engage people in their DFU self-care. A variety of apps for people with diabetes are available on the Google Play Store and the Apple App Store. These commercial apps provide health information or allow tracking of blood glucose levels, eating habits, and physical activity [11-13], but they do not target DFU care. Several apps are being developed to measure DFU size [14-17], recognize signs of infection [18], identify spots where new DFUs are likely to develop [19], and

assess patients remotely [20], but these apps are targeted at clinicians rather than patients. A notable exception is the work by Boodoo and colleagues [21], who are working toward a DFU monitoring tool for patients. However, their tool relies on a near-infrared light attachment to the mobile phone, which limits accessibility for patients.

We recently developed a mobile app prototype called *MyFootCare*, designed for patients to motivate and engage them in their self-care [22]. *MyFootCare* encourages patients to use their own mobile phone to take photos of their feet. The app applies novel visual analytics to these photos to extract DFU size information that lets patients and their carers track their DFU healing progress [22]. Furthermore, *MyFootCare* highlights personal goals to help motivate patients and provides reminders to enact care on a regular basis [22]. The aim of this study was to evaluate the usability and potential usefulness for promoting self-care of an interactive prototype of *MyFootCare* with people with DFUs, based on a user-centered approach.

Methods

MyFootCare Prototype

The overall goal of *MyFootCare* is to be a mobile phone app that optimizes the engagement of people with DFUs in their self-care away from the clinic. *MyFootCare* was conceived by the research team based on their experience in the treatment and study of people with DFUs (JJvN and PAL) and in the design and implementation of mobile health technologies (BP and RB). The team developed multiple features within *MyFootCare* to engage people with DFUs, including the ability to visualize personal goals, self-monitor their DFU through ulcer photos and ulcer size information, a diary to foster reflection, and reminders to enact self-care [22].

The prototype presented in this study was the result of an iterative, user-centered design process. [Multimedia Appendix 1](#) shows our initial prototype, which was implemented in Axure (Axure Software Solutions) [23], a prototyping software to generate interactive screen mock-ups to gather feedback from prospective users. On the basis of patient feedback, we refined the design and implemented a fully functioning Android app to demonstrate the feasibility of our approach. The Android app was based on Java frameworks and open source computer vision library (OpenCV) [24], a free real-time computer vision development library. A morphological watershed algorithm [25] provided by OpenCV was used to segment the foot from the image background and then the ulcer from the foot. The app relied on a small (1 cm diameter) green sticker on the foot to provide a scale for calculating the ulcer wound size [14]. The mobile phone flash was used to control lighting during image capture, that is, to illuminate the foot and keep the background dark. The prototype was developed and evaluated on a Samsung Galaxy S4 mobile phone.

The primary aim of this prototype and study was to demonstrate the feasibility of DFU monitoring to patients during an interview to obtain feedback on usability and potential usefulness. Hence, the following sections describe the features of the app and how

participants in this study could interact with it during the interview.

Goal Image

The home screen (Figure 1) shows an image to visualize a goal a patient wishes to achieve when their DFU has healed. This feature was included because setting a realistic goal is typically one of the first steps in a therapy process to direct the treatment plan and to motivate patients to enact the plan [26,27]. The aim of this feature was not to quantify goals set with clinicians but to provide motivation. By having this image on the home screen, patients would be reminded each time they opened the app of their long-term goal of trying to achieve healing in a positive way.

Participants in this study could change the goal image by clicking on the image itself. They could choose from several photos provided in the app such as to enjoy gardening or to play with grandchildren. Alternatively, they could set a personal photo taken through the mobile phone camera or transferred from another device.

Capture Foot Photo and Analyze Ulcer Size

Figure 2 shows the 2 steps involved in the feature capturing photos of the foot and analyzing ulcer size. First, patients need to take a photo of the whole foot. We expected that photos will usually be taken by a family member because even for healthy adults, it is difficult to take a photo of the plantar side of the foot.

For patients living on their own, we devised a voice assistance mechanism to help patients take photos without assistance from

other people. People place the phone on the floor and hover their foot over the phone. The app guides the patient through voice feedback; specifically, the app vocalizes the phrases *higher* and *lower*. The guidance is based on image analysis through OpenCV. The app guides the patient to center the foot over the camera at an appropriate distance and then automatically takes a photo without the patient having to touch the phone. Finally, MyFootCare vocalizes *image successfully captured* to provide explicit feedback (Figure 2 leftmost image).

During the interview, the voice assistance feature was demonstrated by the researcher by hovering his foot over the phone and allowing the participants to hear the voice feedback to understand the concept. Although this feature was not accurate enough for patients to take photos themselves, we wanted to investigate if such voice assistance would be useful for patients.

Next, we developed a visual analytics feature (again based on OpenCV) to detect the ulcer and calculate its size. To evaluate this feature, participants used a test image that had been uploaded to the phone before the interview (as illustrated in Figure 2). To segment the ulcer and calculate its size, participants had to roughly draw on the image around the ulcer to denote skin tissue to the feature and then inside the ulcer using their finger on the screen of the phone to denote ulcer tissue (Figure 2 third image from left). The last image in Figure 2 (rightmost image) shows how the visual analytics feature then automatically segments the ulcer tissue from the foot image using an automated green line.

Figure 1. MyFootCare home screen showing a photographic image at the top to visualize a patient's goal (eg. to enjoy gardening again) and access to all features.



Figure 2. Photos can be captured with voice assistance. The analysis is based on circling around and inside the wound image to segment the ulcer from the foot.

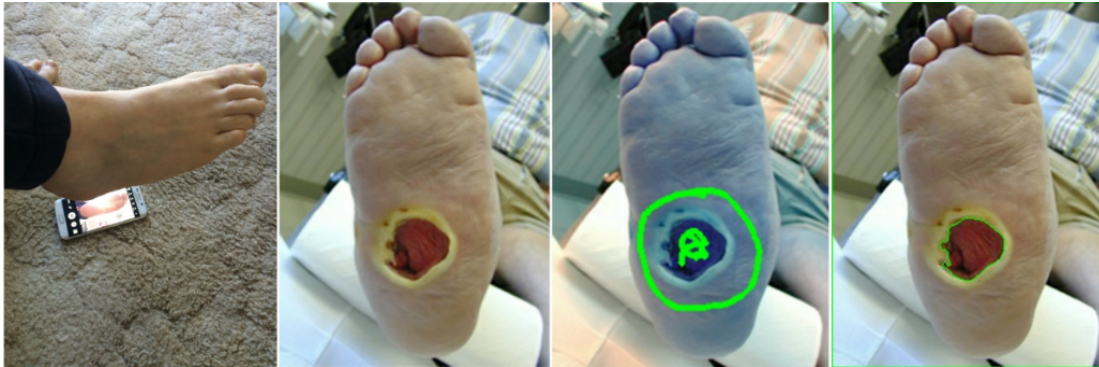


Figure 3. Patients can track the healing process in terms of wound size.



Wound Progress

On the basis of the ulcer detected in the image, MyFootCare calculates the size of the ulcer as a proportion of the size of the foot and presents the progress through a graph (Figure 3). Through this graph, patients can track their DFU healing process, which is often difficult to detect to the naked eye over weeks and months of the typical ulcer healing duration. This approach is inspired by popular self-tracking [28], quantified self [29] and personal informatics [30] approaches, which argue that personal health data can foster personal reflection and behavior change. Although it often takes a long time to heal ulcers, prior research suggests that the progress (or lack thereof) during the first 4 weeks provides a clear indication as to whether the ulcer care is effective (>50% reduction in ulcer area in the first 4 weeks of care has been found to be a surrogate marker

of effective DFU healing [31-34]). Participants in this study could view the graph, which included the information generated by the researchers before the interview, as well as the information generated by the participants during their analysis of a test image.

Diary

The diary feature was incorporated to encourage reflection on self-care and well-being more broadly. Although we initially considered structured questions to help inform the therapy process, we eventually designed the diary in an open-ended manner so that patients can reflect on experiences that matter to them. Smiley faces were also added to let people add an entry quickly without having to type an entry (Figure 4). Participants were asked to add a diary entry during the interview and to comment on what information they would diarize, if any.

Figure 4. Patients can diarise information to reflect on their well-being and self-care.

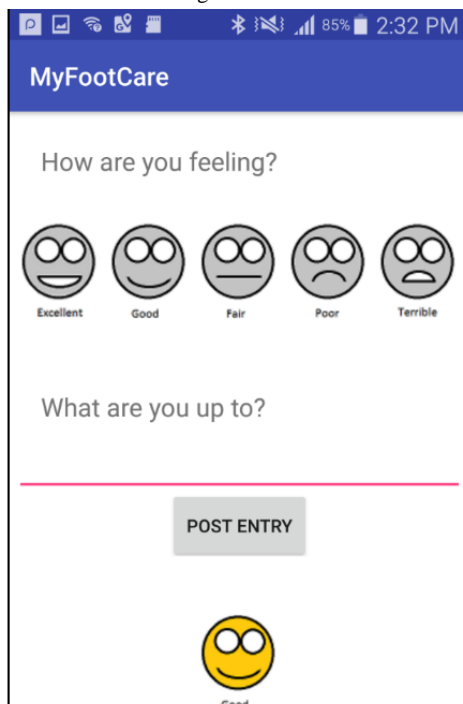


Figure 5. Image gallery allowing patients, carers, and clinicians to review ulcers visually.

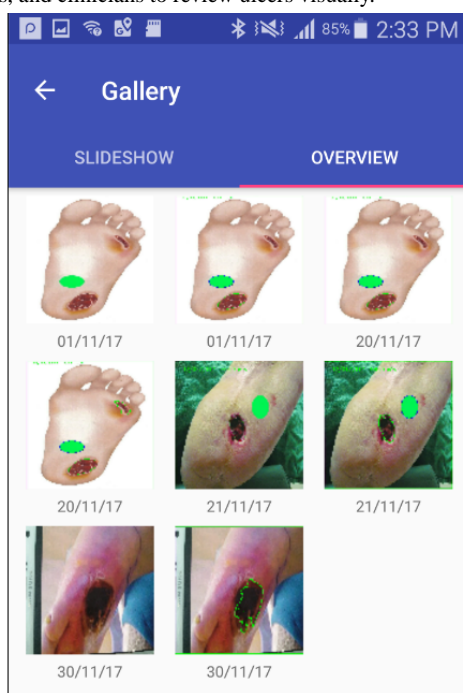


Image Gallery

An image gallery allowed patients to review images and to see progress in the healing of their ulcer over time, in addition to the aforementioned graphing of progress. This image gallery was separated from the image gallery on the phone because patients may not want their ulcer images alongside other personal photos. We added the gallery feature to let patients revisit their images and also so that they can show their images to carers and clinicians (Figure 5). Participants in this study

could browse through a gallery that contained sample images provided by the research team.

Reminder Notifications

The app also provides patients with notifications to remind them to enact their dressing changes, take ulcer photos, or to make an appointment with their clinician. We added this feature because behavior change theory [10] suggests that even if people have sufficient knowledge and motivation, they may forget or run out of time and therefore need a reminder to enact behaviors. Reminders are implemented using a simple dialogue under

settings, defining the intervals for reminding the patient to take photos and use features in the app (Figure 6).

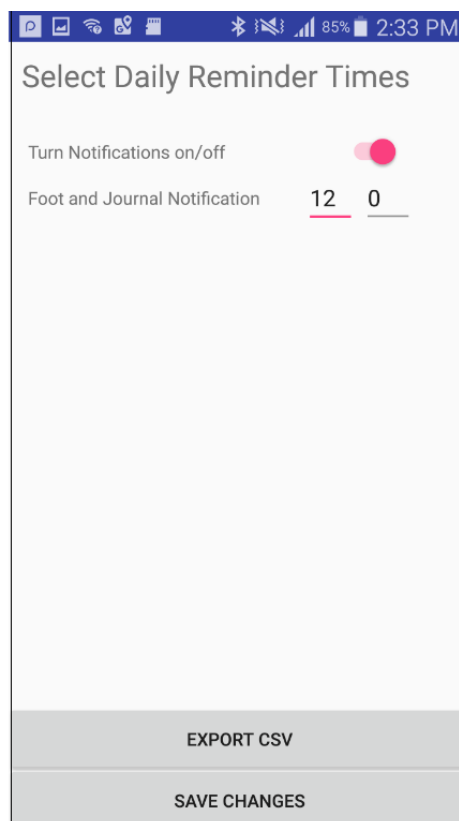
Participants were asked to set the time for notifications, which prompted discussion about the potential usefulness of notifications and its contents. Furthermore, participants could view a sample notification on the Android lock screen that stated *Time to check your foot*, which they could double-tap to open MyFootCare.

Study Participants

Eligible participants were people with a DFU being treated at a diabetic foot clinic and who owned a mobile phone. DFUs were defined as a full-thickness wound on the foot (ie, below the malleoli) of a person with diagnosed type 1 or type 2 diabetes mellitus [1]. An internet-enabled mobile phone was a requirement so that participants would have some familiarity with mobile phone apps and potentially be willing to use it on their own phones. Recruitment was conducted through a large community diabetic foot clinic in Brisbane, Australia.

In all, 11 participants took part in this study (10 men and 1 woman who were aged between 43 and 74 years). All participants had had foot ulcers for extended periods, ranging from 3 months (P11) to recurring ulcers for 7 years (P5). All 10 male participants (P1-10) had a spouse or child who helped them care for their ulcer, whereas participant 11 looked after her own ulcer. The carer of participant 4 also joined the interview to provide an additional perspective. All participants owned mobile phones, but only 6 of them regularly used apps on their phone (P1, 3, 4, 5, 6, and 8).

Figure 6. App reminder configuration interface.



Data Collection

We conducted a qualitative evaluation through semistructured interviews to explore how people with DFUs would use MyFootCare and to what extent the app could enhance their self-care practices. The interviews took place in a meeting room at the clinic where participants received their foot care and lasted 30 to 60 min per participant. Ethics approval was obtained from The Prince Charles Hospital's human research ethics committee (#17/QPCH/14).

The evaluation followed a standard procedure. First, a background interview was conducted to learn about their ulcer history, clinical care and self-care practices, and mobile phone usage. Second, we conducted observations of patients exploring each of the MyFootCare features. The participants were given a mobile phone with the MyFootCare prototype. They were instructed to think aloud to get a better understanding about their impressions of each feature, any questions or expectations that they may have, and whether they would try out this feature on their own phone. Participants were free to try features in any order they wished, and questions were asked accordingly. Finally, through a semistructured interview, the participants were asked to compare and rate the features in terms of usefulness for their DFU care. These ratings were used as prompts to discuss how the app could be integrated with their self-care practices and the potential impact on improving their therapy process. Each evaluation was conducted by the same researcher (LSDS) and was audio-recorded and transcribed verbatim for later analysis.

Data Analysis

The data were analyzed qualitatively, following a thematic analysis approach [35]. The authors read through all transcripts and coded the data to identify the various uses for each app feature as well as areas for improvement. Data were coded by the authors (BP, JJvN, and LSDS) through SaturateApp, a Web-based tool for collaborative qualitative analysis [36]. In total, 54 codes were generated about the existing mobile phone practices, 97 codes about MyFootCare features, and 57 codes about the potential use in daily life. These codes were collated into 5 themes that describe existing care and mobile phone practices and how MyFootCare could support them, and they are presented in the Results section.

Results

Theme 1: Participants Already Use Mobile Phone Photos to Monitor Diabetic Foot Ulcer Progress

Mobile phones were already an integral part of self-care for many participants. Overall, 8 out of the 11 participants had photos of their ulcers on their mobile phone. This suggests that MyFootCare can build on well-established practices among people with DFUs.

The main motivation for participants to take these photos was to monitor progress. Participants found progress difficult to assess on a day-to-day basis for several reasons: they could not feel the ulcer because of peripheral neuropathy and participants also found it difficult to see their ulcer by themselves as their ulcers were on the plantar side of their foot and typically covered by dressings or a cast. Hence, participants often relied on others to take a photo at times of wound dressing changes:

I get the wife to take the photos. When they were changing the cast at the hospital I'd ask the nurse to take a photo so I could see what state my foot was in. [P9]

More importantly, healing takes weeks or months, and hence, improvements are difficult to ascertain without a record, as pointed out by participant 7:

See the thing is with wound care you just, I can't tell the difference; you see it every day you might not notice the changes. [P7]

Progress information from photos was important for participants as well as their carers (most often their partners):

I've quite often scrolled back through the photos looking for an older one just to, so that I have a visual comparison. [Carer of P4]

Some participants found seeing progress in photos encouraging:

No one wants to see a photo of a chronic ulcer, but for me it shows where I've come from, what it looked like then, and what it looks like now. [P3]

Those participants who did not have photos of their ulcer on their phones (P5, 7, and 11) received photos from their podiatrist to check their progress. For example, participant 5 stated the following:

I do that every week when I come here [to the clinic].

They normally take a photo and then I can see it. [P5]

This highlights that all participants in this study were already relying on photos to monitor their progress.

However, we also found that ulcer photos were not taken in a systematic manner. Participants had only a few photos on their phones, although they had their ulcers for several months or even years. Photos appeared to have been taken in an ad-hoc manner at different angles, distances, and periods, rather than in a systematic way. The photos of participant 9 did not have the correct dates because they were taken by his wife and children on their own phones:

Mum sent a copy because she wasn't able to get up to the hospital with me, my son sent one, my daughter sent one and there's so many copies in there, they're all out of sequence. [P9]

Theme 2: Participants Have Limited Experience With Using Mobile Phone Apps

The widespread use of ulcer photos was encouraging, particularly because only 6 out of the 11 participants regularly used apps on their mobile phones. The remaining 5 participants stated that they used their mobile phone only to call other people and occasionally to send and receive short message service text messages. Participant 7 stated that he was "not a smartphone person." Some participants commented that they were too old. For example, participant 10, a 53-year-old man, commented the following:

I just haven't bothered with any of it; it's my age, I just don't [use apps]. [P10]

Participants also highlighted issues that limited their ability to access and use mobile phone apps in general. One difficulty was limited dexterity, which makes navigating and typing on a mobile phone cumbersome. For example, participant 2, a 74-year-old man, stated the following:

The problem I have is my hands, my dexterity's not that good [...] for me to type in the stuff it would take me 20 minutes or half an hour. [P2]

Furthermore, participants reported difficulties reading on mobile phones, which is not surprising considering people with diabetes often also develop diabetes-related complications of retinopathy and blindness. For instance, participant 9 stated the following:

...that's too small an interface for my eyes because I've had retinopathy, I've had laser surgery on both eyes, I've had cataracts removed off both eyes. [P9]

Theme 3: Participants Desire Objective Data From MyFootCare to Monitor Diabetic Foot Ulcer Progress

Feedback regarding MyFootCare was largely positive. Overall, 7 out of 11 participants said that they would be interested to try out the app on their own phones for several weeks to support their self-care.

The key benefit of MyFootCare for participants was that the app could provide objective data to monitor the progress of their ulcers. Participants could clearly see how they could monitor

progress by taking photos on a regular basis and by tracking the objective ulcer size information provided by the visual analytics feature. The participants highlighted that MyFootCare would make ulcer size more explicit:

It's so handy especially if you've got no idea. In my case I don't see a lot of the wound so knowing the size is handy because then I can tell whether it's actually a problem or becoming more of a problem than you know just going along and all of a sudden, and I've done it before, going along well and all of a sudden my wound's fifteen by three or something, which is not ideal. [P5]

Seeing progress through the app is particularly important because ulcers often heal slowly. Hence, participants often felt demotivated by the lack of visible progress, which they hope would be addressed by being able to track ulcer size over several weeks or months with MyFootCare:

If I took a photo of something every day I'd get frustrated 'cause look now, it's not changed. But if you do it a week apart, you just have to [see change]. [P7]

The desire for seeing progress and the potential motivation to keep up good self-care was highlighted several times:

Just proving to yourself that the ulcer is getting better. [P11]

You can see the progress; and when you can see progress you're more inclined to keep doing the right thing. [P9]

Importantly, participants regarded the data on MyFootCare as objective data, independent from their own subjective well-being, as highlighted by participant 1:

It's not going to lie. It's going to ask the same questions each time and it's going to be yes/no answer basically. Is it bigger? No, it's not. Is it smaller? Yes, it is. [P1]

It is also important to note the limitations pointed out by participants. First, participants recognized that taking photos of the plantar side of their foot to provide such objective data may be difficult, but that the automated image taking feature contained in MyFootCare may provide a solution to this difficulty. Images need to be consistently taken at a certain angle and at a certain distance to provide accurate data:

I'd say with certain parameters within [the app] that recognises that OK you're holding it at this angle or that angle and that's why it's saying no take the photo again. Or you know it's supposed to be between ten and fifteen centimetres or what have you so it can do all the calculations. [P1]

Although the researcher could demonstrate the image-taking process during the interview, participants and their carers noted that taking an image at home might be difficult and that assistance from another person might be needed:

It's probably not so much a case of [P4] taking the photos himself but one of us doing it for him because

yeah it's too hard to manoeuvre with one hand. [Carer of P4]

Second, not all participants were interested in trying out MyFootCare. As discussed above, participants 2, 7, and 10 stated that they did not use any mobile phone apps and hence would not use MyFootCare either. Participants 5 and 10 felt that their ulcers were healing well and said that they did not see the need for additional support through an app:

If they got bad yeah, I could see it; but because we're onto it straight away I really haven't had a problem. [P10]

Participant 7 stated that he did not see the need for MyFootCare because clinicians were already taking photos for him:

Every two weeks they take a photo and they can, that's all on file, well you know the folder. And you go back all this time you can see what my foot was doing a year ago, what it was doing six years ago, six months ago, what it was doing six weeks ago. [P7]

Theme 4: Participants Were Ambivalent About the MyFootCare Goal Image and Diary Features

Participants felt ambivalent about the goal image and diary features. They could see the potential benefit of using these features to find motivation and to reflect on factors that may influence their self-care and their progress. At the same time, however, many participants stated that it was unlikely that they would use these features in daily life.

Goal setting is an integral part of any therapy. However, the feedback on the MyFootCare feature to set an image that represents their goal was mixed. Participant 7 highlighted that goals are important to stay motivated to look after the foot:

You definitely need motivation; You're going through these emotional ups, lows and that really, no that's, motivation is always good. [P7]

Discussing this feature with participants has also highlighted the various goals that they were pursuing. The main priority for most participants was for the ulcer to heal or to avoid amputation:

I want to heal the ulcer in the shortest possible time, I don't want to have to wear medical grade footwear, I don't want to have to wear a crow boot. My motivation is to have the problem resolved in five or six months for argument's sake. Some of us might put unrealistic expectations on that and if we don't get it done. Yeah but my motivation comes down to I want to live a long life with my legs. I don't want to lose them. [P9]

Participants also highlighted activities that were important for them and motivated them to get their ulcer healed, such as being able to shower, engaging in physical activity, and playing with their children:

I would like to go swimming with my kids and not have to worry about the foot getting wet or the bandage getting wet. [P8]

Moreover, 6 of the participants also highlighted that (unlike the ability to monitor progress) having an image on the app is not essential to the app. They stated that they were aware of their goals and did not need them visualized:

Having progress is probably more important, giving an idea of where you're going. But I don't know that motivation, I think most people try and be motivated by some form so I don't know that that's a huge thing. [P2]

The diary also received mixed feedback. Some participants (P1, 3, 4, 7, 9, and 10) pointed out that it provides a useful feature to reflect on contextual factors that might impact progress. Participant 1 recognized that the diary can provide context to the ulcer measurements (as provided by the visual analytics feature) and that it can aid personal reflection on factors that influence healing:

You know that's a diary, you put in comments that you want to, you might get "OK ulcer grew this week but decided to go for a walk around IKEA." So you know like you know that you did have a problem but you're also putting sort of like the reason why. And so you can sort of possibly learn the things to avoid and what have you, how to adapt your lifestyle for better healing so to speak. [P1]

Participant 9 indicated the potential value of the diary to aid reflection during consultations with podiatrists:

I come along to you to get my foot done and you're saying what did you do, well I can't remember, look up my diary. [P9]

Despite recognizing these benefits, participants stated that it would be unlikely that they use the diary. Participant 6 stated the following:

Well it's not a bad idea with the journal but I probably wouldn't use it myself. [P6]

Participants mentioned that it would require effort:

The diary is good providing you do it every time [...] it can be a bit laborious. [P2]

Furthermore, the personal benefit of the diary was not clear to participants:

From my point of view I don't see that as an advantage, probably might be for the healthcare worker. [P11]

Theme 5: Participants Desire to Share MyFootCare Data With Their Clinicians

Overall, 9 out of 11 participants pointed out that MyFootCare data would be useful for discussion with their clinician. Although this was not an explicit feature of the app, participants suggested that the information available through MyFootCare would be useful for consideration during consultations with their podiatrists and general practitioners (GPs):

That would be good because then I could show my doctor and say look this is the progress we're having. If I see another podiatrist, I mean I know it's in my

file, but it's a nice easy way for them to look at it and go hey look OK right-o! [P3]

The photos, progress charts, and diary information have the potential to provide clinicians with information about the participant's well-being in their everyday life environments:

It would give the podiatrist a better feel of what's going on I think. They see what's happening at home, they see what's happening when you're not here [in the clinic]. You get to see them for ten/fifteen minutes, there's not a lot of time. And because that's because there are so many people with this problem. So that would give them a weekly feedback on what's been happening during the week, how your toes have been looking or your ulcers are looking when you've been changing the dressing. [P3]

Furthermore, 5 participants also expressed a desire to digitally share MyFootCare data with a clinician outside of consultations. Participants pointed out that sharing information from MyFootCare would allow them to keep their GPs and podiatrists up-to-date with their progress in between consultations:

With your health care provider being able to send [to] them, let them know the sizes or the images, that's very important. [P8]

In addition, participants pointed out that they would like to share MyFootCare with a clinician to determine if they need to see them in response to a deterioration of their DFU. For example, participant 3 suggested adding a feature to contact a clinician for advice based on the photos and graphs:

A section, like a messenger, where you get online help if you've got a question; for example, "I noticed a different colour ooze coming out of the wound." You can share the photo and ask, "should I contact my podiatrist or can it wait to the next appointment?" [P3]

Participant 1 said that used this way, MyFootCare would allow patients and clinicians to be more proactively engaged in their care:

It's being nearly proactive rather than reactive. [P1]

Discussion

Principal Findings

This study showed that people with DFUs perceive a mobile phone app such as MyFootCare as useful to engage them in the care of their ulcers. Despite technological advancements and despite the burden of the complication, mobile phone apps are hardly used by patients in their management or prevention of DFUs. Some pilot research in this area focused on mobile phone apps that use thermal cameras attached to mobile phones to detect signs of possible ulcers early on [19] or to manage active ulcers [21]. Unlike these apps, however, our design works with standard mobile phone cameras, which makes it potentially available to anyone owning such a mobile phone without further cost or work. In addition, other apps are being developed mainly to measure DFU size [14-17], but these apps are targeted at clinicians treating patients rather than patients engaging in their

own care. Our app differs by being patient-focused, including a patient-oriented design, involving patients from the start of the research, and aiming to improve patients' motivation by developing an app for them to use rather than keeping the app in the hands of the clinician.

Patients perceived the main benefit of MyFootCare was its visual analytics feature that provides objective data about the size of ulcers from photos of the foot. This information was seen as valuable because patients typically cannot feel or see their ulcer, and even if they could see their ulcer (on photos or in person), they could not detect if it was improving or deteriorating. In addition, the participants regarded the information provided by the app as objective and hence put more faith in this information than in their own or their carer's subjective accounts. Importantly, the app may address a lack of motivation by patients by showing them progress in their healing process [10]. This may encourage patients and their carers to continue self-care practices in a consistent manner.

Many patients in our study already used mobile phone photos (mostly taken by others) to inspect their ulcers. Although related work shows that people with diabetes take photos of the food they have eaten and share them with dieticians [37,38], our study now shows that many people have also already adopted mobile phones to take images of the foot to share with relevant others (either clinicians or carers). This also makes it more likely that people will use MyFootCare to take photos and track their healing process in real life.

Although feedback on MyFootCare was largely positive, we also identified several challenges. First, using an app does constitute additional work for the patient and thereby increases the already significant workload involved in their ulcer care and diabetes management. Monitoring progress was seen as valuable, but participants also indicated that further reflection through goals and diaries might not be worthwhile enough to warrant the extra work. Goal images were included because reflection on goals and progress data can be empowering, as it helps explain the relationship to people of how their care activities can impact their progress and ultimately their goal [39]. Writing a diary was included as it can help people to come to terms with difficult issues [40] such as the disruption caused by a DFU. However, the participants in this study were ambivalent about the goal and diary features. They could see potential benefits, for example, by providing more detailed information to their clinicians, yet they also felt that the effort would not be justified by these benefits. In future iterations of MyFootCare, we recommend to potentially remove these features and keep the focus on self-tracking.

Second, many people with DFUs find mobile phone apps difficult to use. Although we recruited only mobile phone owners, many of them did not use apps on their phone, and some participants found apps inaccessible because of limited vision and dexterity. This finding is consistent with other studies of mobile phone apps for people with diabetes. Despite increasing availability of diabetes apps, they are often not well designed to support the needs of people with diabetes, that is, for older adults [11-13]. In moving forward in the development of the app, we will continue to explore further guidance in the

image capture process, for example, through voice assistance mechanisms or selfie sticks to control distance and lighting between phone and the foot, through boxes to rest the foot for image capture [16], or through consistent *ghost* outlines of the foot on the camera screen each time an image is taken to keep photos consistent in angle and distance [17]. We will also explore the use of tablet computers, which may provide a better grip and a larger surface area to make the app more accessible for people with limited vision and dexterity. In exploring these options, it is important to continue working with people with DFU of all ages and their carers to ensure that the design allows them to easily read and navigate information.

Finally, we found that many participants wished to share their data with their clinicians. This is both a challenge and an opportunity. On one hand, the desire to share information aligns with growing trends in digital and participatory health care [41,42], where patients increasingly take control of their own health and related information. Photos are particularly popular in participatory health care approaches because they are easy to generate and interpret [43-45]. At the same time, however, sharing information with clinicians creates challenges in terms of information ownership, security, and privacy [46]. It also raises the question of feasibility, with previous studies highlighting that mobile phone images of DFUs in isolation may not be sufficient for clinicians to make reliable diagnosis [20]. Furthermore, it would also require a change in organizational practices, where clinicians receive time and remuneration for reviewing such information without the presence of patients. To overcome barriers to sharing data electronically, we recommend patients keep their data on their own mobile phones. Patients can then choose what data they show to clinicians during consultations, which avoids technical and legal pitfalls and allows patients to remain in control of their data.

Limitations

First, the findings from this study come from a small cohort and may not be representative of all patients with DFUs. We only recruited patients who already owned mobile phones, and still, some patients within our cohort did not use apps at all. During our recruitment phase, we found that many patients did not have mobile phones, which is supported by survey studies showing that mobile phone ownership among individuals with diabetes is lower than that in the general population, especially among older adults and people with low incomes [47]. Although this may change in the future, it is important to note that the encouraging findings presented here do not reflect the opinions of all DFU patients.

Second, the accuracy of MyFootCare has not been evaluated. The aim of this app prototype was to demonstrate the feasibility of monitoring DFUs to patients to obtain feedback on the potential usefulness for self-care. Now that we understand that patients desire objective data from MyFootCare to monitor DFU progress, our future research will focus on iteratively evaluating and improving the accuracy of the app. Evaluations will be performed by comparing MyFootCare measurements with measurements performed by clinicians using ruler measurements [14], wound tracings [16], or gold standard digital wound

imaging instruments [48,49]. Accuracy will be improved by working with patients to assist them in controlling factors such as light, distance, and angle of the foot during image capture. We will continue to refine the voice assistance and also explore alternatives, for example, selfie sticks, light boxes [16], and *ghost* outlines of the foot [17].

A third limitation of this study lies in the ecological validity. The findings from this interview study provide rich insights into the potential uses of a mobile phone app to support self-care in people with DFU. However, they only express opinions on potential use based on trying out the app with the assistance of a researcher. Such evaluations of technology prototypes through interviews are an important step in a user-centered design process and commonly reported in the health informatics literature, including in the area of diabetes (eg, [21,50-53]). A critical next step is a deployment study where patients and their carers can use and evaluate the app over several weeks or months in their daily lives to quantify app engagement and to evaluate the actual impact on self-care.

Conclusions

MyFootCare, a mobile phone app that seeks to engage patients through goals, progress monitoring, and reminders, shows promising features to engage people in DFU self-care. The patients in this study expressed positive views on MyFootCare. The features perceived most useful were (1) taking photos of foot ulcers to assess healing and (2) the ability to monitor changes in the size of their ulcers through wound size data generated from such photos. More work is needed to improve the usability and accuracy of MyFootCare, that is, by refining the process of taking and analyzing wound photos. This study enhances our understanding of opportunities and challenges for mobile health technologies, especially through medical photography, to support people with diabetes and DFUs. The findings open the door for further work to develop an app that is accurate, reliable, and easy to use in daily life and to test it with people with DFUs and their carers. The app presented in this study works on standard mobile phones without requiring a separate camera. With mobile phones becoming more widely used among people with diabetes, MyFootCare has the potential for widespread impact.

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Authors' Contributions

This research project has been conceptualized and led by BP, RB, JJvN, and PAL. BP, RB, and JJvN designed the MyFootCare prototype. The study has been designed and conducted by BP, JJvN, LSDS, and PAL. The paper was drafted by BP. All authors took part in editing this paper and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

MyFootCare Axure prototype.

[PDF File (Adobe PDF File), 875KB - [diabetes_v3i4e10105_app1.pdf](#)]

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Abbreviations

DFU: diabetic foot ulcer

GP: general practitioner

OpenCV: open source computer vision library

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Original Paper

Improved Diabetes Care Management Through a Text-Message Intervention for Low-Income Patients: Mixed-Methods Pilot Study

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Abstract

Background: Diabetes is a major contributor to global death and disability. Text-messaging interventions hold promise for improving diabetes outcomes through better knowledge and self-management.

Objective: The aim of this study was to examine the implementation and impact of a diabetes text-messaging program targeted primarily for low-income Latino patients receiving care at 2 federally qualified health centers (FQHCs).

Methods: A mixed-methods, quasi-experimental research design was employed for this pilot study. A total of 50 Spanish or English-speaking adult patients with diabetes attending 2 FQHC sites in Los Angeles from September 2015 to February 2016 were enrolled in a 12-week, bidirectional text-messaging program. A comparison group (n=160) was constructed from unexposed, eligible patients. Demographic data and pre/post clinical indicators were compared for both the groups. Propensity score weighting was used to reduce selection bias, and over-time differences in clinical outcomes between groups were estimated using individual fixed-effects regression models. Population-averaged linear models were estimated to assess differential effects of patient engagement on each clinical indicator among the intervention participants. A sample of intervention patients (n=11) and all implementing staff (n=8) were interviewed about their experiences with the program. Qualitative data were transcribed, translated, and analyzed to identify common themes.

Results: The intervention group had a mean glycated hemoglobin (HbA_{1c}) reduction of 0.4 points at follow-up, relative to the comparison group ($P=.06$). Patients who were more highly engaged with the program (response rate \geq median of 64.5%) experienced a 2.2 point reduction in HbA_{1c}, relative to patients who were less engaged, controlling for demographic characteristics ($P<.001$). Qualitative analyses revealed that many participants felt supported, as though “someone was worrying about [their] health.” Participants also cited learning new information, setting new goals, and receiving helpful reminders. Staff and patients highlighted strategies to improve the program, including incorporating patient responses into in-person clinical care and tailoring the messages to patient knowledge.

Conclusions: A diabetes text-messaging program provided instrumental and emotional support for participants and may have contributed to clinically meaningful improvements in HbA_{1c}. Patients who were more engaged demonstrated greater improvement. Program improvements, such as linkages to clinical care, hold potential for improving patient engagement and ultimately, improving clinical outcomes.

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KEYWORDS

diabetes mellitus, type 2; text messaging; telemedicine; health education; qualitative research; poverty; Hispanic Americans

Introduction

Background

An estimated 29.1 million people have diabetes in the United States [1] and over 2.3 million adults in California report being diagnosed [2]. As one of the most common chronic illnesses, diabetes leads to an estimated US \$245 billion in economic costs annually and doubles the risk of death for those affected [1]. Furthermore, the prevalence of diabetes among Latinos is almost double than that of non-Latino whites, and rates of diabetes are also much higher among people with lower incomes and education [3]. In addition to higher rates of disease, evidence suggests that low-income patients also experience worse complications resulting from diabetes [4].

Objectives

Text-messaging interventions for people with diabetes hold promise for improving patient satisfaction and intermediate health outcomes through better knowledge and self-management. In particular, there is evidence that text-messaging programs can improve glycated hemoglobin (HbA_{1c}) levels in people with diabetes [5-8]. Following participation in these types of programs, patients have reported high levels of satisfaction and changes to their diet and other behaviors, which should lead to improved management of their diabetes [9-11].

Despite the benefits of these interventions in broader populations, studies have found that patient engagement and the resulting health effects can be worse for people who are nonwhite, have lower literacy, and/or are older [12-14]. However, there is potential to improve the effectiveness of diabetes interventions through culturally sensitive adaptations [15]. This fact, coupled with the higher prevalence of diabetes among Latino and low-income populations, highlights the importance of targeting the interventions to Latino populations and examining their impact on care. To contribute to this aim, *we studied the impact of a pilot diabetes text-messaging program targeted primarily for low-income Latino patients, receiving care in federally qualified health centers (FQHCs).*

In addition to assessing the pilot program's impact, *we also examined implementation barriers and facilitators through interviews with patients and staff.* Identifying the operational- and patient-factors influencing implementation effectiveness can inform the effective scale-up of similar text-messaging interventions in other clinics and health systems caring for patients who are Latino and/or have low income.

Methods

Overview

This study employed a mixed-methods, quasi-experimental design to examine the effectiveness and implementation of a pilot 3-month short message service intervention for adult patients with diabetes, which sent automated, interactive text messages focused on diabetes self-management. Quantitative

data included program and clinical indicators, and qualitative data included semistructured interviews of patient participants and clinic staff.

Setting

Participants (n=50) were Spanish- (n=33) or English-speaking (n=17) adult patients with diabetes attending 2 sites of ChapCare, an FQHC in Los Angeles, from September 2015 to February 2016. From October to December 2015, enrollment in the pilot intervention was offered to all adult patients with type 2 diabetes with an HbA_{1c} value above 8.5% that presented for an appointment at either of the 2 participating ChapCare clinics. The HbA_{1c} cutoff was suggested by the clinical staff, as they felt these patients might benefit most from the intervention. However, in January and February 2016, due to limited enrollment, patient eligibility was expanded to include all adult patients with type 2 diabetes who presented for an appointment, until intervention group enrollment reached 50 participants. Enrollment procedures and staff involved in the intervention were determined by the clinic administration and are examined in the implementation component of this study. Clinic front desk staff identified eligible patients with diabetes from a preprinted list when they checked in for their appointment. The patient was then referred to an AmeriCorps volunteer, who explained the text-messaging program and offered to help them enroll. To enroll, patients had to have their own mobile phone with text-messaging capabilities. Out of 65 patients who were approached, 77% (50/65) enrolled in the text-messaging program. For the 15 patients who declined to enroll in the intervention, the following reasons were given: no mobile phone (27%, 4/15), not comfortable with text messaging (20%, 3/15), not interested in receiving health information via text (40%, 6/15), and already comfortable with managing their diabetes (13%, 2/15). No compensation was given to participants for participating in the text-messaging program. The sample size of 50 intervention participants and the follow-up period was selected based on earlier studies of text-messaging programs for patients with diabetes that examined HbA_{1c}, body mass index (BMI), and blood pressure (BP) as outcomes [5] and to limit disruption to the pilot clinics.

A comparison group (n=160) of adult patients with type 2 diabetes was constructed through chart review. All patients with type 2 diabetes who attended the clinics during the study period but were unexposed to the intervention and attended a follow-up visit before August 2017 were eligible for inclusion in the comparison group.

Intervention

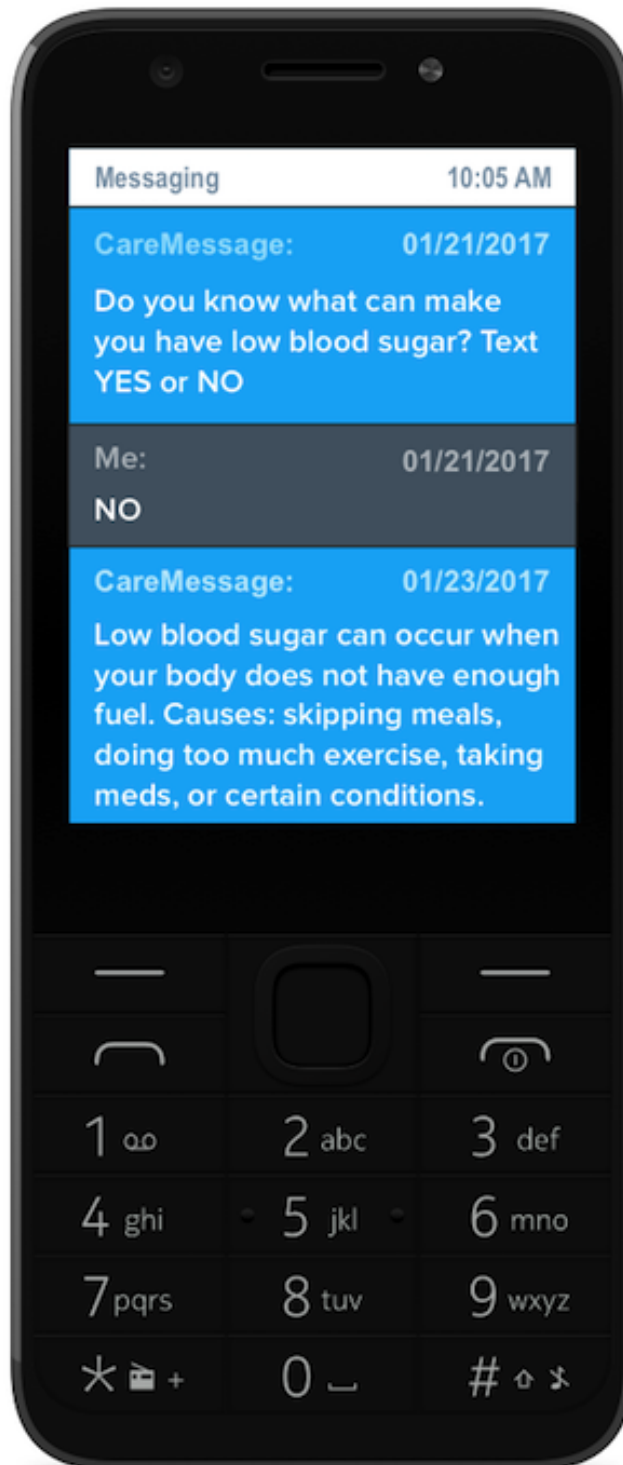
The text-messaging intervention was designed for adults with diabetes using a proprietary platform from CareMessage, a nonprofit organization that designs mobile health tools. The 12-week intervention consisted of 3 to 4 educational text messages per week in either Spanish or English, depending on the participants' preference. Most of the messages were bidirectional: 31% were multiple-choice and 24% asked yes/no

or true/false questions, similar to the example message in [Figure 1](#). If a participant answered incorrectly, they would receive a gentle response with the correct answer. If the participant answered correctly, they received a response affirming that their answer was correct. The remaining 45% of messages were unidirectional (eg, a health tip or reminder).

The program was targeted at low-income patients, and the Spanish-language version was further targeted at Latino patients. The Spanish program was not a direct translation of the English

program, but instead it was developed from the beginning of the program's conceptual design stages in Spanish. The development of both programs was informed by observing patients in one-on-one and group education sessions conducted by CareMessage in community clinics. In addition, CareMessage conducted focus groups with patients with diabetes after they received the messages as part of a 3-month feasibility study in San Francisco in 2014. Following this product development research, the messages were targeted to address participants' concerns and culture.

Figure 1. Sample text message.



For example, Spanish-speaking patients more often discussed how family and traditional foods sometimes made it difficult to change their behavior; therefore, the Spanish messages were adapted to address this topic and to include foods that may be prevalent in Latino populations. Some messages were also adapted to incorporate income level into recommendations for exercise and disease management. For example, patients expressed concerns about being able to afford test strips and therefore, with guidance from a physician, the message was adapted to state they could potentially skip a day so they did not run out of test strips as quickly.

The messages address 10 overall themes: understanding diabetes, medication adherence, nutrition, exercise, mental health, resources, managing blood sugar levels, ABCs (A_{1c} , BP, and cholesterol), foot care, and annual exams (eye, kidney, and dental). The messages were developed using the American Diabetes Association guidelines for disease self-management along with input from the health care providers at implementing clinics and oversight of the staff physician at CareMessage. The average-grade reading level of the unique messages in the program is 6.2, according to the Flesch-Kincaid Grade Level test [16].

Quantitative Program Data

Collection

At baseline, intervention participants answered 5 questions about diabetes-related emotional distress, Problem Areas in Diabetes questionnaire (PAID-5) in person with the AmeriCorps member, right after registering for the text-messaging program [17]. Throughout the 12-week program, the text-messaging platform recorded patient response rates (calculated by dividing the number of valid responses from the patient by the total number of questions requiring a response, multiplied by 100). At the end of the program, the follow-up PAID-5 questions and a user satisfaction survey were administered via text message. Demographic and clinical data were extracted by chart review from Chapcare's electronic health record. These data included pre- and postintervention measures of HbA_{1c} , BMI, and BP. Premeasurements and demographics were taken from visits to the clinic immediately before the start of the intervention. A single postmeasurement was taken for each patient whenever they presented for their next follow-up visit, sometime between the end of the intervention and up to 1 year from the study commencement date (ie, between February and September 2016). These data from charts were merged with the program data for the intervention group and deidentified before being shared with the research team. A deidentified dataset with the same demographic and clinical measures for the comparison group was also provided to the research team, and the 2 datasets were integrated for analyses.

Analysis

First, descriptive statistics were examined for all study variables. This included mean, median, and SD for all continuous variables and frequencies, proportions, and CIs for all categorical variables. Baseline characteristics were compared between the intervention and comparison groups and between patients with missing and complete datasets using chi-square tests for

categorical variables and 2-sample *t* tests with unequal variances for continuous variables. The analysis was then restricted to patients with complete baseline and follow-up measures of the dependent variables (HbA_{1c} , BP, and BMI). This resulted in listwise deletion of 25 observations (12 from intervention group and 13 from comparison group). Next, propensity score weights were calculated using gender, age, race/ethnicity, and baseline HbA_{1c} . A further 8 observations (all from the comparison group) were dropped because of missing data on race/ethnicity, which are needed to calculate the propensity score. Changes in clinical outcomes were compared between groups using individual fixed-effects linear regression models with an ordinary least squares estimator. A sensitivity analysis was run with multiple imputations to handle missing data on the independent variable of race/ethnicity for 8 observations (all from the comparison group). The chained equations method was used, under the missing-at-random assumption, to generate 10 imputed datasets. Propensity score weighting was then conducted for each of the 10 imputed datasets, and the results were combined in the subsequent analysis using Rubin combination rules [18]. Next, the individual fixed-effects linear regression models were run, and results were compared with the main analysis.

The final set of analyses was conducted on the data from the intervention group only. To examine associations between clinical indicators by time-invariant characteristics among intervention participants, population-averaged linear models were estimated with generalized estimating equations. These models facilitated the examination of differential effects of patient engagement on improvements in clinical outcomes among the intervention participants.

An additional post hoc regression model was run to examine any associations between satisfaction with the program and personal characteristics, including patient engagement among the intervention participants.

All models were run with cluster robust SEs to correct for heteroscedasticity and were clustered by patient identity document (to account for the fact that pre/post observations were clustered under each patient). Analyses were conducted with StataSE v.13 (StataCorp).

Qualitative Program Data

Collection

All intervention participants were invited to complete a phone interview to provide feedback on the program in March 2016 (depending on when they enrolled, this ranged from right after the end of the messages to up to 8 weeks after the end of the messages). A total of 11 out of the 50 (22%) participants agreed to be interviewed in their primary language, either Spanish ($n=6$) or English ($n=5$). In addition, all 8 staff members participating in the implementation of the program were invited to participate in a phone interview to provide feedback on the program implementation in March 2016 (after enrollment ended in their clinics), and all agreed to participate.

Verbal consent was obtained from all interview participants, and all of them received a gift card as a token of appreciation for their time. Structured interviews lasted up to 45 min and

were recorded with the participants' permission. Interviews were conducted via phone by a researcher in either English or Spanish, depending on the participants' preference. The structured question guide, with probes, was used to facilitate discussion. The interview guide for participants asked questions aimed at understanding their experience with the program, such as "Describe your first encounter with the text messages. What did you think?" The staff interview guide focused on implementation of the program and asked questions such as "How easy or difficult has it been to incorporate CareMessage into your workflow?" The full interview guides in English are available in [Multimedia Appendix 1](#). The university's review board for research with human subjects approved the research study.

Analysis

Interview recordings were professionally transcribed and when applicable, were translated from Spanish to English by a bilingual member of the research team. A preliminary codebook was developed by 1 researcher, drawing upon the existing literature on text messages for health as well as the Health Belief Model [19] and related theory. Coding of all patient interviews was then performed by 2 researchers, using ATLAS.ti software (ATLAS.ti Scientific Software Development GmbH). The coding process was iterative, and the codebook grew throughout the analysis as additional codes were added based on the data. If a quote emerged that did not fit the preliminary codebook, a new relevant code was generated and discussed with the other researcher. For example, 1 patient explained that they thought the messages were automatically generated but sounded like they came from a person. Preliminary codes only included "automatically generated" or "from a person," so this data point generated a new code to accommodate this finding. Coding of staff interviews was performed by 1 researcher. After coding was complete, common themes were identified. New concepts and themes were discussed among the research team until the codebook was finalized and all themes had been identified.

Results

Quantitative Results

Though demographic ([Table 1](#)) characteristics of patients in both the intervention and comparison groups were mostly comparable at baseline, there were some nonstatistically significant differences between groups. Among the groups, 55.7% (117/210) of patients were primarily Spanish speaking. In addition, 69.0% (145/210) of participants were of Hispanic or Latino ethnicity. Participants ranged widely in age, and there were more female participants (62.4%, 131/210) than males (37.6%, 79/210) in both groups. There was a higher proportion of English speakers and females in the comparison group than the intervention group; however, the differences were not statistically significant. Propensity score weighting resolves

imbalances of unweighted analyses and helped to further reduce overall mean bias on these observable characteristics by 5.2% and overall median bias by 7.9%.

Most participants (86%, 43/50) in the intervention group responded to at least 1 question with a valid answer (ie, 1 of the multiple-choice options provided). Participants received an average of 31.8 (interquartile range 28-35) questions requiring an answer over the course of the program. The average number of days that participants were enrolled in the program was 79.5 (SD 11.4), with only 3 participants leaving the program before 80 days. No reason was given when participants withdrew—they only had to text the word "STOP" or to tell the clinic staff member who enrolled them that they wished to stop receiving messages. The overall mean response rate was 57.1% (calculated by dividing the number of valid responses from the patient by the total number of questions requiring a response, multiplied by 100), but it varied widely (SD 33.2%).

[Table 2](#) outlines self-reported health indicators from participants in the intervention group, including the levels of diabetes-related distress (PAID-5) that participants were experiencing at baseline and follow-up (after the text-messaging program). Response rates to the follow-up PAID-5 text-message survey were relatively low, ranging from 12% to 54% (depending on the question), and therefore, may not be representative of all participants' experiences. Most participants reported being in fair or poor health (80%, 39/49) at baseline. In addition, most participants indicated some problems with feeling scared about living with diabetes (54%, 27/50), feeling depressed about living with diabetes (52%, 26/50), worrying about the future (74%, 37/50), and other measures of diabetes-related distress at baseline.

Following propensity score weighting, clinical indicators of patients ([Table 3](#)) in the intervention and comparison groups were similar at baseline. The intervention group had slightly higher HbA_{1c} at baseline than the comparison group (8.7 vs 8.0), but the difference was not statistically significant ($P=.07$).

To check for systematic differences between patients who were excluded due to missing outcome data ($n=25$), their baseline demographics and clinical indicators were compared with the other patients in their respective group using chi-square tests for categorical data and t tests for continuous data (results not shown in table). No statistically significant differences in age, gender, race/ethnicity, smoking status, baseline HbA_{1c}, baseline diastolic BP, or baseline BMI were detected. However, excluded patients were statistically significantly more likely to speak English than those remaining in both the intervention (58% vs 26%, $P=.04$) and comparison groups (77% vs 45%, $P=.03$). In addition, patients excluded from the comparison group had statistically significantly higher baseline systolic BP than those remaining in the comparison group (144.2 vs 125.8, $P=.01$).

Table 1. Baseline characteristics of participants.

Variable	Unadjusted		<i>P</i> ^a value	Before PSW ^b		After PSW, comparison mean (n=140)	<i>P</i> ^c value
	Intervention frequency (n=50), n (%)	Comparison frequency (n=160), n (%)		Intervention mean (n=38)	Comparison mean (n=140)		
Clinic			<.001				<.001
Site 1	18 (36)	21 (13.1)	— ^d	0.37	0.12	0.12	—
Site 2	32 (64)	139 (86.9)	—	—	—	—	—
Age group, in years			.53				—
18-44	12 (24)	28 (17.5)	—	0.29	0.17	0.19	.19
45-54	16 (32)	50 (31.2)	—	0.32	0.31	0.32	<.001
55-64	22 (44)	82 (51.3)	—	0.39	0.52	0.49	.29
Gender			.16				.67
Male	23 (46)	56 (35.0)	—	0.42	0.35	0.38	—
Female	27 (54)	104 (65.0)	—	—	—	—	—
Primary language			.09				.08
English	17 (34)	76 (47.5)	—	0.26	0.45	0.42	—
Spanish	33 (66)	84 (52.5)	—	—	—	—	—
Race and ethnicity			.43				
Hispanic or Latino	37 (74)	108 (67.5)	—	0.79	0.69	0.74	.50
White	5 (10)	18 (11.3)	—	0.05	0.12	0.10	.32
Other	8 (16)	26 (16.3)	—	0.16	0.16	0.16	>.99
Missing	0 (0)	8 (5.0)	—	—	—	—	—
Smoking status			.53				.34
Current nonsmoker	48 (96)	147 (91.9)	—	0.03	0.07	0.07	—
Current smoker	2 (4)	13 (8.1)	—	—	—	—	—

^a*P* values are for chi-square tests or Fisher exact test where cell frequencies are less than 5.

^bPSW: propensity score weighting.

^c*P* values are for *t* tests.

^dNot applicable.

Table 2. Self-reported health indicators of intervention group.

Indicators	Baseline, n (%)	Follow-up, n (%)
Overall health	N=49	
Poor	6 (12)	— ^a
Fair	33 (67)	—
Good	8 (16)	—
Very good	2 (4)	—
Excellent	0 (0)	—
Feeling scared when I think about living with diabetes	N=50	N=27
Not a problem/minor problem	33 (46)	12 (44)
Moderate/somewhat serious/serious problem	27 (54)	15 (56)
Feeling depressed when I think about living with diabetes	N=50	N=15
Not a problem/minor problem	24 (48)	7 (47)
Moderate/somewhat serious/serious problem	26 (52)	8 (53)
Worrying about the future and possible serious complications	N=50	N=11
Not a problem/minor problem	13 (26)	3 (27)
Moderate/somewhat serious/serious problem	37 (74)	8 (73)
Diabetes takes up too much of my mental and physical energy	N=50	N=11
Not a problem/minor problem	19 (38)	4 (36)
Moderate/somewhat serious/serious problem	31 (62)	7 (64)
Coping with complications of diabetes	N=50	N=15
Not a problem/minor problem	19 (38)	4 (27)
Moderate/somewhat serious/serious problem	31 (62)	11 (73)
In the past week, how many times have you had a low blood sugar reaction (sweating, weakness, anxiety, trembling, hunger, or headache)?	N=50	N=14
0	20 (40)	4 (29)
1-3	26 (52)	8 (57)
4 or more	4 (8)	2 (14)

^aNot applicable.

Table 3. Propensity score weighted diabetes clinical indicators at baseline and follow-up.

Variable	Baseline			Follow-up			Mean difference	
	Intervention (n=38), mean	Comparison (n=140), mean	<i>P</i> ^a value	Intervention (n=38), mean	Comparison (n=140), mean	<i>P</i> ^a value	Intervention (n=38)	Comparison (n=140)
Glycated hemoglobin	8.7	8.0	.07	8.4	8.3	.63	-0.3	0.3
Systolic blood pressure	124.2	124.6	.88	126.6	127.1	.89	2.4	2.5
Diastolic blood pressure	77.1	77.3	.91	77.5	75.4	.23	0.4	-1.9
Body mass index	32.7	33.5	.59	32.4	33.3	.53	-0.3	-0.2

^a*P* values are for two-tailed, 2-sample *t* tests.

Individual fixed-effects linear regression models (Table 4) on the propensity score weighted data indicate that the intervention group had an average estimated reduction in HbA_{1c} of 0.40 points at follow-up, relative to the comparison group (*P*=.06). This comparison is illustrated graphically in Figure 2. No significant differential reductions were found for BP or BMI.

The sensitivity analysis, using multiple imputations for missing independent variables followed by propensity score weighting, produced similar results to the main analysis (results not shown in table). However, baseline balance between groups was not achieved, and bias increased on some variables following propensity score weighting.

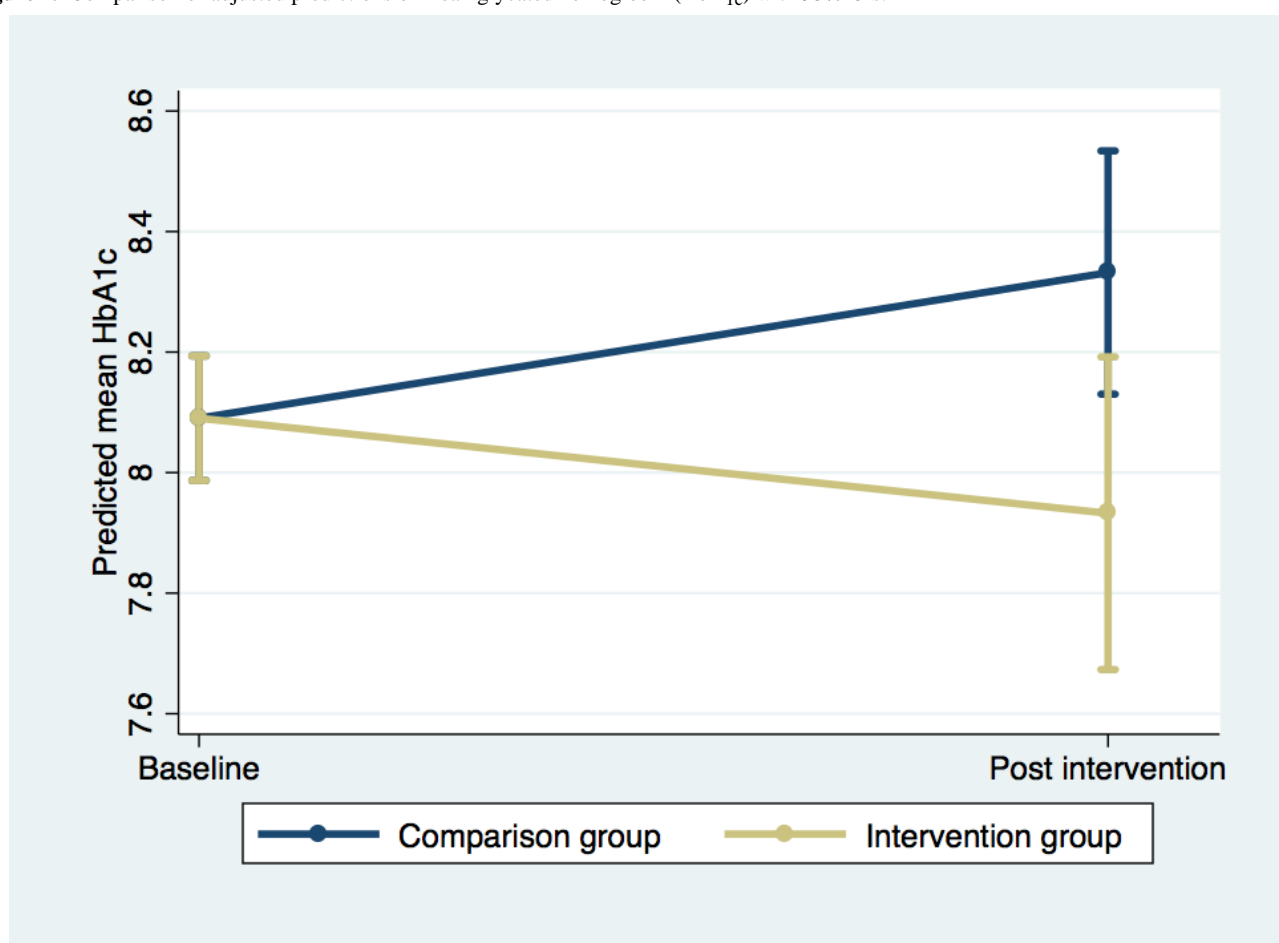
Table 4. Comparison of change in clinical indicators from baseline to follow-up between intervention and comparison groups.

Coefficient	Glycated hemoglobin (n=185)			Systolic BP ^a (n=185)			Diastolic BP (n=185)			Body mass index (n=185)		
	Estimate	SE ^b	P value	Estimate	SE ^b	P value	Estimate	SE ^b	P value	Estimate	SE ^b	P value
Constant	8.09	0.05	<.001	124.93	0.84	<.001	76.86	0.63	<.001	32.96	0.08	<.001
Time	0.24	0.13	.06	2.43	1.29	.06	-1.89	0.98	.06	-0.13	0.15	.39
Intervention group × time	-0.40	0.21	.06	-1.02	3.38	.76	3.17	2.53	.21	-0.13	0.33	.70
Within-cluster SD	0.95	— ^c	—	3.37	—	—	2.86	—	—	1.08	—	—

^aBP: blood pressure.

^bCluster-robust standard errors.

^cNot applicable.

Figure 2. Comparison of adjusted predictions of mean glycated hemoglobin (HbA_{1c}) with 95% CIs.

Population-averaged linear models (Table 5) found that among the intervention participants, higher engagement (modeled through response rate to questions requiring a response) was associated with greater reductions in HbA_{1c}, controlling for clinic site, age, gender, primary language, and race. In particular, highly engaged patients (defined as having a response rate \geq the median of 64.5%), experienced a mean 2.23 point reduction in HbA_{1c} relative to less-engaged patients (response rate <64.5%), controlling for demographics ($P < .001$; Model A). To illustrate the relationship between patient engagement and HbA_{1c}, Figure

3 shows the changes in unadjusted mean HbA_{1c} values between highly engaged and less-engaged patients. As a sensitivity test, a population-averaged linear model was also run with a continuous, standardized response rate variable (Model B). This model found that an increase of 1 SD in response rate over the mean was associated with a mean 0.93 point reduction in HbA_{1c}, controlling for demographics ($P = .001$), again supporting the findings that higher engagement was associated with greater reductions in HbA_{1c}. Subsequent sensitivity analyses were also run using the lower and upper quartiles of engagement as cutoff points.

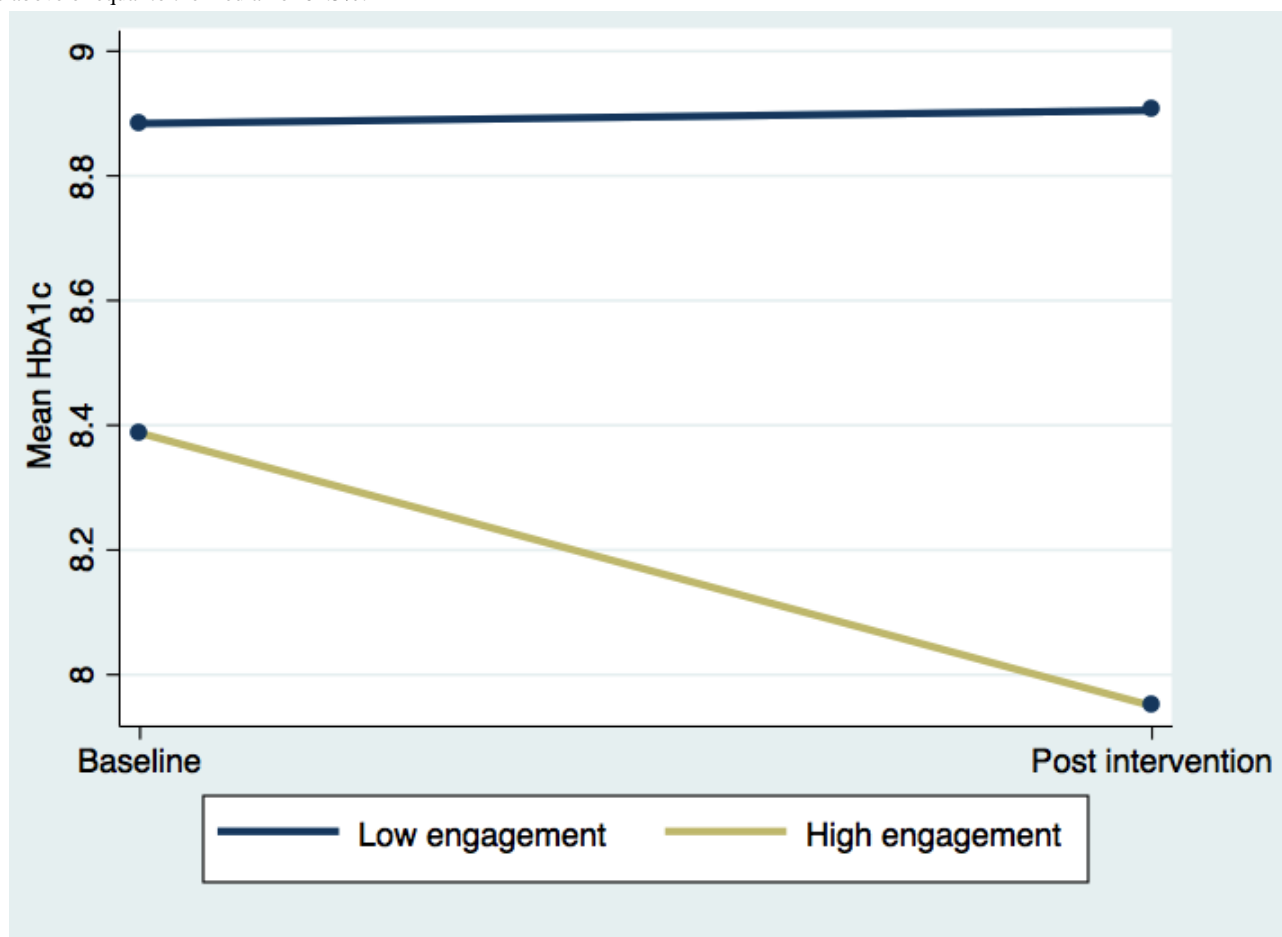
Table 5. Associations between patient characteristics and glycated hemoglobin.

Variable	Estimate	SE ^a	P value
Model A with categorical response rate variable			
Clinic			
Site 1	0.25	0.50	.62
Site 2	Reference	Reference	Reference
Age, in years			
18-44	Reference	Reference	Reference
45-54	1.38	0.57	.02
55-64	-0.45	0.49	.36
Gender			
Female	Reference	Reference	Reference
Male	-1.72	0.55	.002
Primary language			
Spanish	Reference	Reference	Reference
English	2.05	0.73	.005
Race/ethnicity			
White	Reference	Reference	Reference
Hispanic/Latino	-1.14	1.79	.52
Other	-2.43	1.65	.14
Engagement with program			
Low (response rate <64.5%)	Reference	Reference	Reference
High (response rate ≥64.5%)	-2.23	0.56	<.001
Constant	10.72	1.80	<.001
Model B with continuous, standardized response rate variable			
Clinic			
Site 1	0.22	0.51	.66
Site 2	Reference	Reference	Reference
Age, in years			
18-44	Reference	Reference	Reference
45-54	1.21	0.64	.06
55-64	-0.91	0.53	.09
Gender			
Female	Reference	Reference	Reference
Male	-1.27	0.47	.007
Primary language			
Spanish	Reference	Reference	Reference
English	1.72	0.62	.006
Race/ethnicity			
White	Reference	Reference	Reference
Hispanic/Latino	-1.64	1.74	.35
Other	-2.68	1.63	.10
Engagement with program			
Standardized response rate	-0.93	0.28	.001

Variable	Estimate	SE ^a	P value
Constant	10.14	1.75	<.001

^aCluster-robust standard errors.

Figure 3. Change in unadjusted mean glycosylated hemoglobin (HbA_{1c}) by patient engagement level. High engagement is defined here as having a response rate above or equal to the median of 64.5%.



When defining highly engaged patients as those with a response rate above 32% (the bottom quartile), no statistically significant change in HbA_{1c} was found between highly engaged and less-engaged patients (results not shown in table). However, when defining highly engaged patients as those with a response rate above 86% (the top quartile), highly engaged patients experienced a mean 2.0 point reduction in HbA_{1c} relative to less-engaged patients ($P=.001$, results not shown in table).

Among intervention participants, being male was associated with a statistically significant decrease in HbA_{1c} relative to female participants, controlling for other demographic characteristics and patient engagement rate. In addition, speaking English as a primary language was associated with a statistically significant increase in HbA_{1c} relative to primarily Spanish-speaking participants, controlling for other demographics and response rate.

Table 6 presents findings on patient satisfaction with the text-messaging program. The overall response rate was 50%, due to substantial drop-off in responses as the text-message

survey progressed to question 5. Among those who responded, satisfaction with the program was high: 78% (28/36) of respondents felt that they learned useful information from the text messages, and 89% (25/28) felt that the text messages helped them to better manage their diabetes. A post hoc regression model with cluster-robust SEs was run to examine any associations between satisfaction with the program and personal characteristics, including patient engagement among the intervention participants, but no statistically significant associations were found.

Qualitative Results

Participants' Feedback on the Program

Most participants (81%, 9/11) in the text-messaging program felt that the messages were positive. One participant stated:

...[the program was] positive, because it was telling us...what we have to do in our daily lives, and how a diabetic can't be hopeless because it is a disease that can be controlled.

Table 6. Intervention group satisfaction with text-messaging program.

Statements and responses	n (%)
I learn useful information from the text messages (n=36)	
Strongly agree/agree	28 (56)
Not sure	1 (2)
Disagree/strongly disagree	7 (14)
I find the text messages annoying (n=29)	
Strongly agree/agree	6 (12)
Not sure	4 (8)
Disagree/strongly disagree	19 (38)
The text messages help me better manage my diabetes (n=28)	
Strongly agree/agree	25 (50)
Not sure	1 (2)
Disagree/strongly disagree	2 (4)
The text messages are clear and easy to understand (n=27)	
Strongly agree/agree	25 (50)
Not sure	2 (4)
Disagree/strongly disagree	0 (0)
I would recommend the texting program to a friend with diabetes (n=25)	
Strongly agree/agree	23 (46)
Not sure	2 (4)
Disagree/strongly disagree	0 (0)

In addition, several participants explained that the program made them feel supported. This theme was especially common among Spanish-speaking participants (66%, 4/6). For example, 1 participant said:

The messages were helping me because these messages were as [if] a person was speaking to me, telling me what I should do, as if that message was from someone that was thinking of me and was telling me that I have to do this for my wellbeing.

Another participant said:

It felt good...because I knew that someone was worrying about my health.

In addition to emotional support, all participants (n=11) cited learning new information and setting new goals as a result of the program. Some participants felt the messages provided more detailed information than they get in medical appointments, and the text message format allowed them to refer back to the information. One participant said:

It's just that the messages explains things...better. Because when I go to an appointment and ask, then the doctors speak in English and if the girls that they provide interpret for you, [they] don't fully explain the conversation that you would have with a doctor.

Most participants also stated that they already knew some of the information (90%, 10/11), but many participants also struggled to recall specific content from the messages (63%,

7/11), suggesting that knowledge retention from the messages may be low.

Many felt that the messages provided helpful reminders (63%, 7/11) to check their blood sugar and/or to take their medication. All participants stated that the program led them to set new goals; to contemplate behavior change; or to change their behavior relating to their diet, medication, and/or exercise. For example, 1 participant reported taking their medication more regularly after the messages:

[The messages] said that you're supposed to take [medication] twice a day at about the same time, and so we instituted a little thing where I have the little days of the week [on a]...holder that says, "Noon, Morning, Evening, Night," and we put the pills in there so I take them on the right times...I'm doing it after the messages.

Some participants offered feedback to improve the program. A total of 2 participants felt that the times the messages were sent were not always convenient for them. Most participants wanted more messages, and 2 participants felt it would be helpful to tailor the program to participants' baseline diabetes self-management knowledge levels. Additional quotes from the interviews with participants organized by theme are provided in [Multimedia Appendix 2](#) for interested readers.

Implementing Staff Feedback on the Program

Staff who implemented the program identified key facilitators and barriers to the program's success. The major facilitator cited by the staff was that this text-messaging program allowed them to provide health education to patients using relatively few resources, making implementation more feasible for a resource-limited FQHC. However, they also identified some barriers to program success, particularly for scale-up beyond the initial implementation for this effectiveness-implementation study. The clinic administration chose to use temporary staff (AmeriCorps volunteers) to enroll participants for this pilot, which minimized the program's disruption to the clinic workflow but also limited integration into routine clinical practice. Interviewees suggested that no staff outside of those directly involved in management or enrollment (ie, none of the clinical providers) knew about the program. In addition, there was no systematic monitoring of patient responses, in part, because the text-messaging platform was not integrated with the electronic medical record system in the clinic. Similarly, identifying patients with diabetes eligible for the intervention was a challenge, requiring the clinic staff to print lists of eligible patients, cross-check them with the clinic schedule, and to identify patients when they presented for appointments. Much of the work to identify patients was done by the AmeriCorps volunteers, but these activities would likely be burdensome for permanent clinic staff if the program were to be scaled up to more patients with diabetes in the future.

Finally, staff also provided some feedback to improve the program in the future. A total of 2 staff members suggested that including more clinical staff could improve the program. One suggested that having clinicians mention the text messages during visits could give the program more "standing" with patients. Staff also suggested hosting an in-person meeting at the start of the program to ensure all involved staff understand the project and their roles.

Overall, despite some of implementation barriers cited by staff, most felt the program worked well and had the potential to help patients with diabetes; some felt the program provided an easier-to-understand and more accessible form of health education than the brochures or written materials usually provided by FQHCs.

Discussion

Principal Findings and Comparison With Prior Findings

Participants of a diabetes text-messaging program described the program as providing instrumental and emotional support, and higher engagement with the program was associated with improvements in HbA_{1c}. Earlier studies have found evidence of reductions in HbA_{1c} in broader populations who received a text-messaging intervention [5-7]. A recent randomized controlled trial of a text-messaging program in a similar low-income, Latino, diabetic population also found evidence of improved glycemic control following participation, though the program also collected patient-reported glucose levels via text message, unlike the CareMessage program [8]. We also

examined BMI and BP, but no significant improvements were observed. This could be due to the relatively short duration of the study and/or the intervention's emphasis on glycemic control for diabetes, rather than weight loss or BP specifically. Our findings suggest that text-messaging interventions for diabetes management might be effective among low-income Latino patients, if adapted appropriately. This finding is especially relevant given that earlier studies have found that these groups can have lower engagement with text-messaging programs and smaller health effects than other patient groups. We also found evidence that patients who are more engaged with the program might experience greater improvements to HbA_{1c}, suggesting that encouraging patient participation could lead to greater health effects more broadly.

These findings indicate that this diabetes-management text-messaging program has the potential to improve HbA_{1c}. The effect sizes seen in this study have potential to be clinically meaningful based on earlier studies. A meta-analysis of 5 earlier randomized controlled trials reported that a mean 0.9 point reduction in HbA_{1c} significantly reduced events of nonfatal myocardial infarction by 17% and events of coronary heart disease by 15% [20]. Therefore, applying these estimates to our findings, a mean improvement of 0.4 points (from the individual fixed-effects models, Table 4) could result in up to an 8% reduction in nonfatal myocardial infarction and a 7% reduction in coronary heart disease events. Among highly engaged participants, these effects could be even larger, where a mean reduction of 2.2 points in HbA_{1c} (from population-averaged linear models, Table 5) could result in up to a 40.8% reduction in nonfatal myocardial infarction and a 36% reduction in coronary heart disease events.

Qualitative analyses highlight the potential mechanisms that could lead to improved intermediate outcomes for people with diabetes participating in the program. Many participants cited receiving both instrumental and emotional support from the program. First, participants described how the messages reminded them to take their medication or to check their blood sugar. These descriptions evoked "cues to action" as described by the Health Belief Model and found by other studies of similar interventions [14]. Though the constructs of this model were not assessed directly in this study, the CareMessage text-messaging platform was informed by the Health Belief Model, and patient interviews explored these concepts. Then, participants also described feeling that someone was thinking or worrying about them, suggesting that they received emotional support from reading and responding to the messages, particularly among Spanish-speaking participants. These results aligned with earlier findings that text messages for diabetes management were able to produce greater positive and optimistic feelings in patients as well as reducing denial of diabetes among patients participating in these types of programs [11]. Similar findings have also been observed among Spanish-speakers in a text-messaging intervention for depression [21].

The interviews of patients and staff identified some facilitators and barriers to the implementation of this program. The ease of reaching many patients at once with diabetes self-management information made this program significantly more feasible for

a resource-limited FQHC. However, the clinic experienced challenges of integrating the program into their routine care processes. Recommendations to facilitate implementation and improve patient experiences include adapting the messages to baseline patient knowledge and linking in-person clinical care with the text-messaging program. These types of improvements could have positive effects on patients' satisfaction with the program as well as patients' engagement with the program, which could lead to improved self-management and outcomes of care, but they would also require changes in provider behavior and clinical workflow.

Limitations

This study has important limitations. First, because the text messages were implemented for this pilot study within the participating clinics' constraints, the analytic sample is modest. The comparison group patients were also not aware of the intervention or the analysis of their deidentified data, so there is a likelihood that any observed improvements to intervention participants' HbA_{1c} could have been due to the Hawthorne effect. In addition, operational constraints were not conducive to randomizing patients to the intervention and comparison groups, which could have improved causal inference. As a result of the lack of randomization, we cannot conclusively determine that the intervention caused any observed differences between the groups. However, we were able to use propensity score weighting to balance confounding factors between groups, reducing concerns about selection bias. A second limitation of this study is missing data. Despite the use of a long observation period following the intervention (1 year), about 22% of the intervention group did not attend a follow-up visit in that period, leading to missing outcome data. However, when comparing the baseline HbA_{1c} of patients who came for a follow-up visit with those who did not, we found no evidence of a statistically significant difference in HbA_{1c} among nonreturning patients, reducing concerns about bias. If the long follow-up period had any effect on the results, it would have had an attenuated effect

on the intervention group's outcomes, biasing our results toward the null. A third limitation to this study is that the qualitative interviews were only conducted with patients who volunteered to participate and therefore, might not be representative of all patients' experiences with the program. Interviewed patients, however, provided critical feedback to improve the program. Another important limitation is that the follow-up patient satisfaction questions and diabetes-related distress (PAID-5) had low rates of response, likely due to the delivery via text message late in the program and the large number of questions delivered. In the future, response rates could potentially be improved by delivering this survey in person during a visit to the clinic (as was done with the PAID-5 measure at baseline) or by incentivizing completion. Finally, we do not have data on the proportion of messages actually received and read by participants, and there is a possibility that mobile phone plans or changes to phone numbers could have affected receipt of the messages. However, 100% of the messages were reported as delivered by the text-messaging platform, and 86% of participants responded to at least 1 question with a valid answer, suggesting that if there were patients who did not receive the messages, it was not a widespread issue.

Conclusions

This study contributes to our understanding of the effectiveness of diabetes management text-messaging programs among patients who have low income and are mostly Latino. We found evidence that glycemic control of adult patients of FQHCs with diabetes might be improved through participation in a text-messaging program for diabetes self-management. The findings also suggest that patient engagement with the program could contribute to improved self-management and clinical outcomes. By supporting patients with education, reminders, and positive messages during the course of their daily life, diabetes management text-messaging programs have the potential to increase and sustain healthy behaviors and improve clinical outcomes among low-income patients with diabetes.

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Conflicts of Interest

AA has received consulting fees from CareMessage. The other authors declare that they have no conflicts of interest.

Multimedia Appendix 1

English versions of the interview guides used for patient and staff qualitative data collection.

[[PDF File \(Adobe PDF File\), 34KB - diabetes_v3i4e15_app1.pdf](#)]

Multimedia Appendix 2

Additional quotes from the qualitative interviews, organized by theme.

[PDF File (Adobe PDF File), 157KB - [diabetes_v3i4e15_app2.pdf](#)]

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Abbreviations

BMI: body mass index

BP: blood pressure

FQHC: federally qualified health center

HbA_{1c}: glycated hemoglobin

PAID-5: Problem Areas in Diabetes questionnaire (short form with 5 questions)

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Review

Patient Portal Use in Diabetes Management: Literature Review

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Abstract

Background: Health information technology tools (eg, patient portals) have the potential to promote engagement, improve patient-provider communication, and enhance clinical outcomes in the management of chronic disorders such as diabetes mellitus (DM).

Objectives: The aim of this study was to report the findings of a literature review of studies reporting patient portal use by individuals with type 1 or type 2 DM. We examined the association of the patient portal use with DM-related outcomes and identified opportunities for further improvement in DM management.

Methods: Electronic literature search was conducted through PubMed and PsycINFO databases. The keywords used were “patient portal*,” “web portal,” “personal health record,” and “diabetes.” Inclusion criteria included (1) published in the past 10 years, (2) used English language, (3) restricted to age ≥ 18 years, and (4) available in full text.

Results: This review included 6 randomized controlled trials, 16 observational, 4 qualitative, and 4 mixed-methods studies. The results of these studies revealed that 29% to 46% of patients with DM have registered for a portal account, with 27% to 76% of these patients actually using the portal at least once during the study period. Portal use was associated with the following factors: personal traits (eg, sociodemographics, clinical characteristics, health literacy), technology (eg, functionality, usability), and provider engagement. Inconsistent findings were observed regarding the association of patient portal use with DM-related clinical and psychological outcomes.

Conclusions: Barriers to use of the patient portal were identified among patients and providers. Future investigations into strategies that engage both physicians and patients in use of a patient portal to improve patient outcomes are needed.

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KEYWORDS

patient portal; diabetes mellitus; personal health records; electronic health records

Introduction

Background

Diabetes mellitus (DM) is a significant public health problem associated with many debilitating health conditions [1]. Prevalence data indicate that approximately 1 of every 10 adults in the United States has diabetes, with predictions that the

number will triple by 2050 [2]. The economic burden of diabetes and its complications to the US health care system are enormous. Every 1 in 4 health care dollars is spent for the care of people with diabetes [3]. Thus, the steady increase in the prevalence of diabetes and the substantial associated costs make this one of the most pressing public health concerns in the United States.

Effective diabetes management requires continuous collaboration between individuals and their providers [4], yet the infrastructure of current health delivery systems does not fully support the needs of patients with chronic conditions [5]. A call has been sounded to redesign the care delivery systems to improve chronic disorder care [6]. The Chronic Care Model (CCM) was developed in 1998 to reorganize care delivery to improve functional and clinical outcomes for people with chronic disorders [7]. A primary focus of the CCM is on creating productive interactions between informed patients and a prepared care team [7]. To achieve this, patients need to have the knowledge and skills to make informed decisions, and care teams need to be able to provide relevant patient information, resources, and decision support at the point of encounter. Health information technologies, such as patient portals, can facilitate these activities within health care systems.

Patient portals, often referred to as tethered personal health records (PHRs), provide Web-based platforms for patients' access to their health information from a health organization's electronic health record (EHR). Patient portals were widely adopted by health care organizations in the late 1990s and gained greater attention when the Medicare and Medicaid incentive programs for EHR (a.k.a. Meaningful Use) implementation was initiated in 2011 [8]. Today, the PHR adoption rate by consumers is rapidly increasing. It is estimated that the percentage of people who will have a PHR is expected to exceed 75% by 2020 [9]. Patients can perform a variety of medical-related tasks within the portal. For example, most portals permit patients to view laboratory results, receive visit summaries, manage appointments, and electronically communicate with health care providers. More advanced portals enable individuals to record their symptoms and test results, such as blood glucose or blood pressure (BP) readings, data that can be viewed for decision making, and changes in therapy by providers [10]. Health care organizations have commonly adopted patient portals as an essential strategy to provide patient-centered care and engage patients for the purpose of improving clinical outcomes.

Purpose

Given the continuous increase in the prevalence of diabetes and the increasing development of patient portal applications, a review of the literature on the current use of patient portals in supporting patients with diabetes can be informative. In this review, we identified studies that used qualitative or quantitative methods to describe the state of science in the use of patient portals for diabetes management. Specifically, we evaluated the use of patient portals by patients with diabetes, including the portal functionalities, predictors of portal use, and the effects of portal use on diabetes-related outcomes. These findings provide opportunities for further approaches to improve diabetes management through the use of a patient portal.

Methods

Search Strategies

Electronic literature searches were conducted through PubMed and PsycINFO databases. Keywords included "patient portal*," "web portal," "personal health record," and "diabetes." Additional articles were searched by identifying similar articles in PubMed and manually reviewing the bibliography of published papers in relevant articles. The literature search was limited to publications in the English language and peer-reviewed articles, but no restrictions as to the country in which the study was conducted were imposed.

Inclusion and Exclusion Criteria

Articles selected were based on the following inclusion criteria: (1) published in the past 10 years (2007-2017), (2) used the English language, (3) study participants were adults (ie, age ≥ 18 years), and (4) available in full text. Studies using both quantitative and qualitative methods were included in this review. The focus of the selected articles was a patient population of adults with either type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM). Studies were excluded if the portal was designed for parents of children with diabetes.

Data Extraction

The initial search from PubMed and PsycINFO retrieved 128 articles after filtering out 11 articles that did not meet the inclusion criteria. We removed 8 duplicates, which reduced the number to 120 articles for review of the title and abstract. The assessment of these 120 articles resulted in a further removal of 74 articles, including 63 that were not relevant, 5 articles that focused on children, and 6 articles that applied mobile apps for diabetes management. Thus, a review of full text was conducted on 46 articles based on the aforementioned inclusion criteria, and 17 were excluded because of the use of stand-alone Web portals that were not connected to any health care organizations, and, in addition, 2 review papers were excluded. We later added 3 additional articles by searching the bibliography of previously published literature reviews. Therefore, a total of 30 articles were included in our study (see [Figure 1](#)), including 6 randomized controlled trials (RCTs), 16 observational studies, 4 qualitative studies, and 4 mixed-methods studies. RCTs and observational studies were summarized based on the following categories: authors and country, study aims and design, sample size and retention, intervention (only for experimental studies), PHR features, measures, and findings. Studies that used qualitative methods or mixed methods were summarized based on study aims, study design, sample, PHR features, measures or questions, and findings (see [Tables 1 and 2](#); [Multimedia Appendix 1](#)).

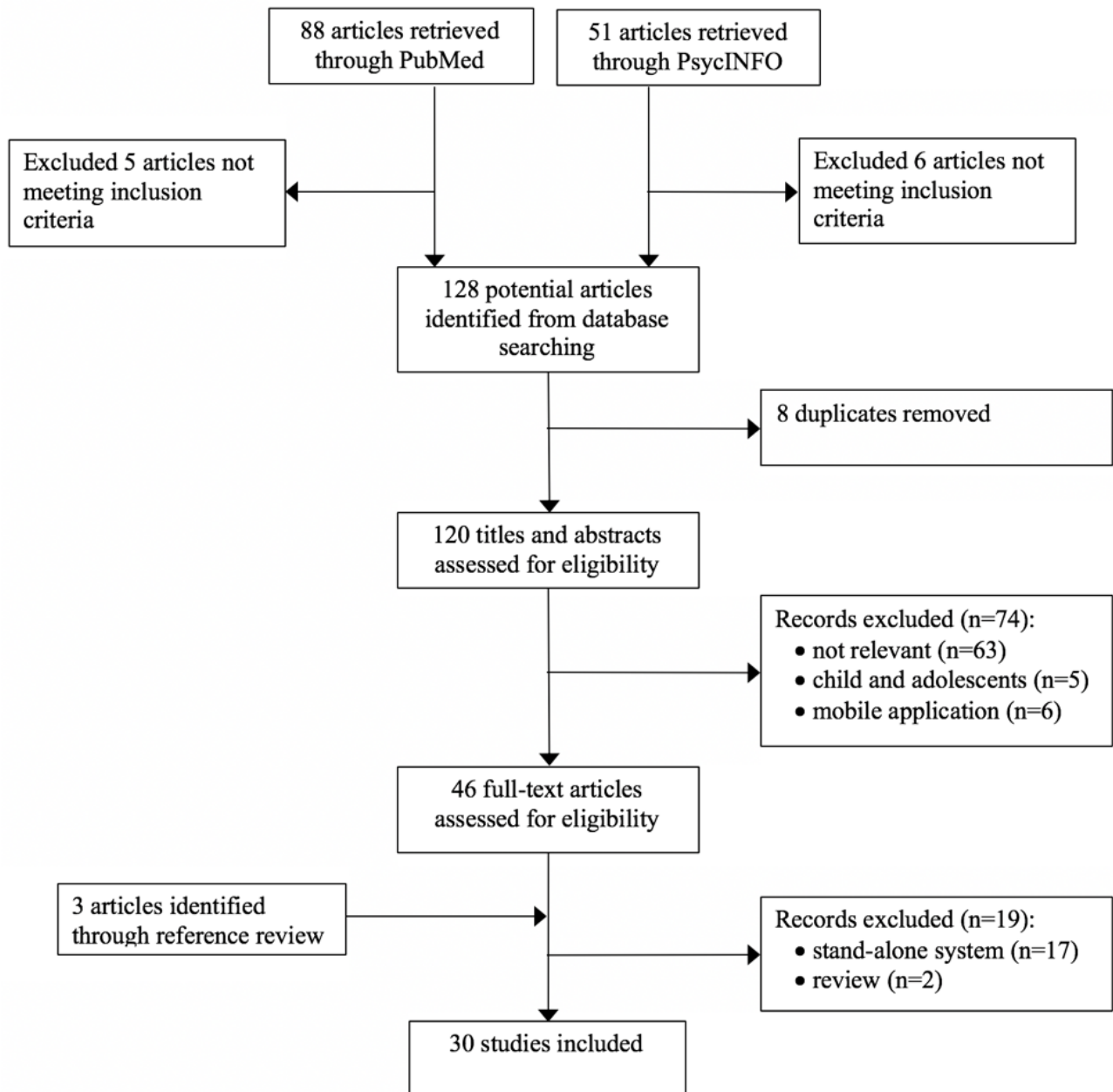
Figure 1. Flow diagram for paper selection process.

Table 1. Randomized controlled trials examining patient portal for diabetes management.

Authors, country	Study aims, design, and level of evidence	Sample and retention	Patient portal features	Intervention	Outcomes (portal related)	Findings
van Vugt et al (2016) [11], Netherlands	2-group study, 6-month randomized controlled trial (RCT) to study the uptake and effects of e-Vita with a self-management support program (SSP) and personalized coaching for patients (Ps) with type 2 diabetes mellitus (T2DM); Evidence: Grade A	N=132; males: 59.1%; white: 91%; age: 67.9 (SD 10.4) years; body mass index (BMI): 30.2 (SD 5.2); glycated hemoglobin (HbA _{1c}): 6.6%; retention: Coaching group (CG): 43.9%; non-coaching group (NCG): 59.1%	e-Vita (diabetes mellitus [DM]-specific) by VU University Medical Center allows Ps to access diabetes education; access data from electronic medical records (EMRs) of primary care physicians (PCPs); receive messages from providers; receive SSP	CG (n=66): Personal health record (PHR)+SSP+coaching; NCG (n=66): PHR+SSP	HbA _{1c} , BMI, systolic blood pressure (SBP), diastolic blood pressure (DBP), cholesterol, diabetes self-care, diabetes-related distress, and PHR and SSP use	Intention-to-treat (ITT) was applied. PHRs were assessed by 128 Ps, of which 59 Ps never returned to the PHR. The use declined over time. The SSP was used by 5 Ps in the CG and 1 patient in the NCG group, 3 of whom asked a coach for feedback. Ps recently diagnosed actively used the SSP; no differences were observed on outcome measures between baseline (BSL) and 6 months for the 2 groups.
Tang et al (2013) [12], United States	2-group study, 12-month RCT to evaluate an Web-based disease management system by Ps with uncontrolled T2DM; Evidence: Grade A	N=415; Intervention (Int) vs Control (Con): males: 58.9% vs 61%; white: 60% vs 58%; age: 54 (SD 10.7) vs 53.5 (SD 10.2) years; weight: 215.3 (SD 49.4) vs 218.4 (SD 51.3) pounds; HbA _{1c} : 9.24 (SD 1.59) vs 9.28 (SD 1.74); Retention: 87%	Web-based diabetes management system (DM specific) by Palo Alto Medical Foundation allows Ps to monitor glucose remotely; view summary report; document nutrition and exercise; record insulin; communicate with the health team; receive advice; personalized education	Int (n=202): access to Web-based disease management system for diabetes; Con (n=213): usual care	HbA _{1c} , BP, low-density lipoprotein (LDL), health care utilization, diabetes knowledge, diabetes treatment satisfaction, and depression screening	ITT was applied. Int had reduced HbA _{1c} at 6 months (-1.32% Int vs -0.66 Con, <i>P</i> <.001), but not at 12 months. The Int had better LDL control at 12 months (<i>P</i> =.001), but no difference for BP or weight. Ps in the Int had a lower distress score (<i>P</i> <.001), better knowledge of glucose testing (<i>P</i> =.004), better understanding of diabetes (<i>P</i> <.001), greater treatment satisfaction (<i>P</i> <.001). No differences were noted in the depression screening or health care utilization.
Fonda et al (2009) [13], United States	2-group study, 12-month RCT to examine changes in Problem Areas in Diabetes (PAID), and its association with use of an internet-based diabetes care management (IBCM) program; Evidence: Grade A	N=104; males: 99%; white: 76.7%; age: 60.9 (SD 10.3) years; HbA _{1c} : 9.9 (SD 0.9%); Retention not reported	IBCM (DM specific) by VA Boston Healthcare System allows Ps to transmit BP and glucose data from devices; view BP and glucose data; message care managers; access diabetes education	Int (n=52): access to the IBCM program; Con (n=52): usual care	Diabetes distress (PAID), and pattern of usage	The decline in PAID score was significant for sustained users of the portal but not for nonusers in the Int group. Sustained users (n=27) had lower PAID scores at baseline.

Authors, country	Study aims, design, and level of evidence	Sample and retention	Patient portal features	Intervention	Outcomes (portal related)	Findings
McCarri-er et al (2009) [14], United States	2-group study, 12-month RCT to test whether a diabetes case management program can improve glycemic control and self-efficacy in adults with T1DM; Evidence: Grade A	N=77; males: 67.5%; white: 96.1%; age: 37.3 (SD 8.09) years; HbA _{1c} : 8%; Retention: 83%	Web-based program (DM specific) by University of Washington (UW) General Internal Medicine Clinic allows Ps to view EHR data; upload glucose readings; enter medication, nutrition, and exercise; create action plans; access education	Int (n=41): usual care+Web-based case management program; Con (n=36): usual care	HbA _{1c} , diabetes-related self-efficacy, and usage	ITT was applied. A nonsignificant decrease in HbA _{1c} in the Int compared with the Con group (-0.48%, 95% CI -1.22 to 0.27) between groups. The Int group had an increase in self-efficacy compared with the Con group (95% CI 0.01 to 0.59, <i>P</i> =.04). The log-in rate was 61%, and averaged 3.3 log-ins per patient. Emails were sent by 44% users, with a mean of 5.0 messages.
Ralston et al (2009) [15], United States	2-group study, 12-month RCT to test Web-based care management of glycemic control using a shared EMR in Ps with T2DM; Evidence: Grade A	N=83; Int vs Con: females: 47.6% vs 51.2%; white: 89.7% vs 73% (<i>P</i> =.06); age: 57 vs 57.6; Glycohemoglobin (GHb): 8.2% vs 7.9%; Retention: 89.2%	Web-based diabetes support program (DM specific) by UW General Internal Medicine Clinic allows Ps to access EHR data; communicate with providers; send glucose readings; enter exercise, diet, and medication data; access education	Int (n=42): usual care+Web-based case management program; Con (n=41): usual care	GHb, total cholesterol, SBP, DBP, health care utilization, and usage	ITT was applied. More change in GHb among the Int group compared with the Con group at 12 months (change -0.7%, <i>P</i> =.01). SBP, DBP, total cholesterol levels, and use of in-person health care services did not differ between groups. EHR was accessed 76%, 69% emailed, and 33% entered data. Number of page views was not associated with GHb improvement.
Grant et al (2008) [16], United States	2-group study, 12-month RCT to evaluate the impact of a PHR for T2DM; Evidence: Grade A	N=244; Int vs Con: females: 43% vs 56% (<i>P</i> =.04); white: 93% vs 84% (<i>P</i> =.04); age: 58.8 vs 53.3 years (<i>P</i> <.001); HbA _{1c} : 7.3% vs 7.4%; Retention: 50.4%	Patient Gateway by Partners Health care system allows Ps to update registration information; send messages; confirm appointments; request prescription refills; access DM modules	Int (n=126): access to a DM-specific PHR (ie, review mediations, and access decision support and care plans); Con (n=118): non-DM-specific PHR	HbA _{1c} , BP, and LDL	ITT was applied. More Ps in the Int group had DM treatment adjusted compared with the Con group (53% vs 15%; <i>P</i> <.001). There was no difference in HbA _{1c} between groups (Int vs Con: 7.1% vs 7.2%) after 1 year. BP and LDL showed similar patterns at BSL and follow-up between groups.

Table 2. Qualitative or mixed methods studies on patient portal for diabetes management.

Authors, country	Study aim	Study design	Sample	Portal features	Measures or questions	Findings
Sieverink et al (2014) [17], Netherlands	To explore factors associated with diffusion of a personal health record (PHR) for patients with type 2 diabetes mellitus (T2DM) in primary health care workers	Semistructured interview with primary care nurses: qualitative	N=11	e-Vita (diabetes mellitus [DM]-specific) by the Diabetes Center in Zwolle allows patients (Ps) to access diabetes education; access electronic health record (EMR) data; receive messages from providers	What are the reasons for using a PHR?; What training do you receive?; How to embed PHR in your daily routine?; What are the barriers and facilitators for embedding PHR in daily routine?; What are your expectations?	Practice nurses indicated barriers for using a PHR: lack of integration with work routines, time constraints, and experience usability problems.
Osborn et al (2013) [18], United States	To understand Ps with T2DM who use MyHealthAtVanderbilt (MHAV) and reasons for use and nonuse, how users are using a portal to manage medications, and explore ideas for functionality improvement	Focus groups and medical chart review: mixed methods	N=75; females: 67%; white: 63%; age: 56.9 (SD 8.8) years	MHAV by Vanderbilt University Medical Center (VUMC) allows Ps to access EHR data; message providers; manage appointments; assess risks; access education	Do you use MHAV or not? How and why?; What could be added to MHAV to help manage medications?; What do you think about an email reminder to refill or dose reminders?	Users were more likely to be white, have higher incomes, and be privately insured. Reasons for nonuse: unaware of the portal (n=3), no access to a computer (n=3), and helped by a family member (n=1). Users used the portal to request prescription refills and view medication list, and Ps were enthusiastic about the idea of adding refill reminder functionality, alerting providers to fill or refill nonadherence, and providing side effects and interactions.
Wade-Vuturo, et al (2013) [19], United States	To explore how Ps with T2DM use and benefit from secure messaging within a patient portal	Focus group and patient survey: mixed methods	N=54; females: 65%; white: 76%; age: 57.1 (SD 8.4) years; body mass index (BMI): 34.4 (10.2); HbA _{1c} : 7.0 (SD 1.4)	MHAV by VUMC allows Ps to access EHR data; message providers; manage appointments; assess risks; access education	HbA _{1c} , self-reported frequency of use, benefits and barriers to use messaging	Greater use of messaging to schedule an appointment was associated with patients' glycemic control ($r=-.29$, $P=.04$). Benefits of messaging: improved patient satisfaction, enhanced efficiency and quality of face-to-face visits, and access to care. Barriers to use messaging: negative experiences with messaging. Ps' assumptions about providers' opinion and instruction.
Urowitz et al (2012) [20], Canada	To evaluate the experience of Ps with T1DM or T2DM and providers using a Web-based diabetes management portal	Telephone interview and open-ended questionnaire: qualitative	Ps (n=17); females: 53%; providers (n=64)	Patient portal by the Waterloo Wellington Local Health Integration Network allows Ps to access DM education; access EHR data	Telephone interview with Ps and open-ended questionnaires with providers	17 Ps were interviewed. Facilitators of disease management: increase awareness of their disease, access to educational information, and promote behavior change. Barriers to portal use: poor usability, not useful, challenges with physician engagement, and lack of understanding. Recommendations for portal improvements: more Web-based tutorial about the portal content, improve usability.

Authors, country	Study aim	Study design	Sample	Portal features	Measures or questions	Findings
Mayberry et al (2011) [21], United States	To examine the role of health literacy, numeracy, and computer literacy on usage of a patient Web portal (PWP) in Ps with T2DM	Focus group and patient survey: mixed methods	N=75; females: 68%; white: 47%; age: 56.9 (SD 8.8) years	MHAV by VUMC allows Ps to access DM education; access EHR data	Health literacy, numeracy, computer literacy, self-report usage of PWP and health information technology (HIT)	Lower health literacy was associated with less use of a computer for searching diabetes medications or treatments, but not usage of a PWP. Numeracy and computer literacy were not associated with PWP use. Family members' support facilitated Ps usage of both PWP.
Bryce et al (2008) [22], United States	To rate the potential or actual usefulness of 15 features of a Web-based portal for diabetes management	Focus group and patient survey: mixed methods	Preportal group (n=21) vs portal-user group (n=18): nonwhite: 33% vs 22%; age: 53 (SD 13) vs 55 (SD 11) years	HealthTrak by University of Pittsburgh Medical Center (UPMC) allows Ps to access EMR data; schedule appointments; message providers; access education; logbooks	The study asked how the portal affected management of diabetes, Ps' experiences in using the portal and communicating with physicians	Features rated most favorably were: calculator to estimate blood glucose control (74%), appointment reminder (74%), email to health team (74%), personal tracking logs (69%), and scheduling (69%). More patients from the preportal group than the portal-users group favored personal logs ($P=.02$) and opportunities to form interest groups ($P=.03$).
Zickmund et al (2008) [23], United States	To examine the impact of the provider-patient relationship on interest in using the patient portal	Focus group: qualitative	N=39; white: 72%; males: 52%; age: 54 (SD 12)	HealthTrak by UPMC allows Ps to access EMR data; schedule appointments; message providers; access education; logbooks	Topics included the relationships with providers, and feedback on the patient portal	Interest in the portal was linked to dissatisfaction with provider responsiveness, unable to obtain medical information, and logistical problems. Disinterest in the portal was linked to satisfaction with the provider communication, difficulty in using the portal, and fear of losing connections with providers. No patient identified email communication through the portal was helpful
Hess et al (2007) [24], United States	To assess the impact of HealthTrak on patient-provider communication during September 2004-January 2007	Focus groups: qualitative	N=39; males: 51%; white: 72%; age: 54 (SD 12) years	HealthTrak by UPMC allows Ps to access EMR data; schedule appointments; message providers; access education; logbooks	Discussion around living with diabetes, desired information about diabetes, current sources of information about diabetes, doctor-patient communication, and reaction to the portal	The number of patient visits or telephone calls received did not change, but the number of HealthTrak messages increased. Participants felt that the system enhanced communication. Having access to laboratory tests was preferred. They became frustrated when test results were not released, or messages were not answered by providers.

Quality Assessment

The quality of the reviewed studies that used quantitative methods was assessed using the evidence grading system developed by the American Diabetes Association. An evidence grade of A, B, C, or E is assigned depending on the quality of the evidence. A grade A evidence is considered optimal because it is derived from large, well-designed clinical trials or

meta-analyses; it is estimated to have the best chance to improve outcomes when applying the treatment to the appropriate population. Grade B ratings indicate supporting evidence from well-conducted cohort studies or case-control studies. Grade C ratings indicate supporting evidence from poorly controlled or uncontrolled studies. A separate category E is applied to papers reporting expert opinions or clinical experience when there is no evidence from clinical trials.

Results

Description of Included Studies

We reviewed 30 studies focusing on 13 different portals from 3 countries—10 from the United States, 2 from the Netherlands, and 1 from Canada. Of these 13 portals, 5 were designed for patients with diabetes and functioned as a component in Web-based diabetes management programs. These 5 DM-specific patient portals were from the Palo Alto Medical Foundation, VA Boston Healthcare System, University of Washington General Internal Medicine Clinic, the VU University Medical Center, and the Diamuraal of the Netherlands. Almost half of the included studies ($n=13$) focused on patients with T2DM, 1 on patients with T1DM, 6 included both types, and 10 did not specify.

Of all the studies included, 6 [11-16] were RCTs (Table 1). These studies examined the effect of a DM-specific patient portal on diabetes-related outcomes. The sample sizes for the RCTs ranged from 77 to 415, with the number of subjects in 2 studies being less than 100 [14,15] and in 1 study more than 400 [12]. The study duration in the 5 RCTs was 12 months [12-16], with the duration of the remaining RCTs being 6 months [11]. Of 6 RCTs, 5 reported a retention rate range of 50.4% to 89.2% and employed an intention-to-treat approach to handle protocol deviations [11,12,14-16]. These 6 RCTs studied an array of diabetes-related outcomes, including glycated hemoglobin (HbA_{1c}) or glycohemoglobin (GHb), systolic blood pressure (SBP) and diastolic blood pressure (DBP), body mass index (BMI reported as kg/m^2), total cholesterol, and low-density lipoprotein (LDL). The psychological outcomes that were examined included diabetes-related distress and diabetes-related self-efficacy.

There were 16 observational studies [25-40] identified, which included 3 retrospective cohort studies [25,29,38] and 13 cross-sectional studies (Multimedia Appendix 1). The sample sizes of these studies were variable; 7 studies [25,29,31,33,35,37,39] had more than 10,000 participants, and 5 studies [26,30,34,36,40] had less than 1000. The data only obtained from the EHR were examined in 7 studies [25,29,30,33,34,38,39], and 9 studies [26-28,31,32,35-37,40] combined data collected from the EHR and patient surveys. The association between patient portal use and diabetes-related outcomes was investigated in 5 studies; 1 of the studies examined the overall portal use [33], whereas the other 4 studies investigated only certain features within the portal, such as secure messaging [25,39,41] or medication refills [25,29]. The remaining 11 studies examined the usage of the patient portal and factors associated with portal use [26-28,30-32,35-38,40].

Qualitative methods were used in 4 studies [17,20,23,24], and 4 additional studies used mixed methods [18,19,21,22] to address the benefits and barriers of using patient portals (Table 2). Focus group was used in 6 studies [18,19,22,23,42,43], of which 4 [18,19,22,42] also used patient surveys. The sample sizes in the 6 studies using focus groups ranged from 39 to 75 [18,19,21-24]. In 1 study, semistructured interviews with 11 primary care nurses were conducted [30]. Another study conducted telephone interviews with 17 patients and collected

qualitative data using open-ended questionnaires from 64 providers [20].

Features Provided in Patient Portals

Features offered in patient portals varied across systems. Most portals allowed patients to access a component of the EHR data (eg, visit summary, medical history, physical examination results, lab results), receive general health education, request prescription refills, and communicate with health care providers. In the DM-specific portals, patients were able to perform more activities such as wirelessly uploading their blood glucose readings assessed via home-monitoring devices [12-15,26]. The education provided in these DM-specific portals was specifically related to patients' conditions and prescribed medications [12-16]. A few portals also enabled patients to enter lifestyle data such as diet and exercise [12,14,15,25]. In 4 RCTs, the interventions included access to the portal and assigned case managers (nurses, dietitians, or pharmacists) to assist patients in using the Web-based portal, responding to messages, reviewing blood glucose levels and food intake, and adjusting medications as appropriate [12-15].

Patient Usage of the Portals

The percentage of patients with diabetes who registered for a portal account ranged from 29% to 46% [28,30,37,39]. Among patients with portal accounts, 27% to 76% actually logged on to the portal at least once [13,27,28,30,35,37]. However, 50% (3/6) of these studies indicated a response rate of less than 50% [27,28,30]. In 2 studies, an initial high log-in frequency was observed that declined over time [11,30].

Patients logged on to portals for various tasks. Of all included studies, 1 study identified viewing laboratory results as the most frequently used feature, followed by requests for medication refills, sending and reading messages, and making appointments [35]. Another study reported similar findings, with checking which laboratory tests were ordered by providers being the most frequent activity, followed by reading messages from providers and reviewing laboratory results [33].

Patient Characteristics of Portal Users and Nonusers

Significant differences between portal users and nonusers have been identified. Portal users were more likely to be younger [25,27,32,33,35,38], white [18,25,33,35], and male [25,32,38] with higher incomes [18,33,38] and greater educational attainment [27,32,33,35]. Other factors reported to be associated with portal use were higher health literacy [37] and higher morbidity [38]. Ronda et al found that insulin use, T1DM, longer duration of diabetes, polypharmacy, and treatment by an internist were associated with using the portal [26,27,32].

Impact of Patient Portals on Glycemic Control

The impact of DM-specific patient portals on glycemic control was investigated in 5 RCTs. Of these, 4 targeted patients with T2DM and yielded inconsistent results. Tang et al randomized 415 patients to either the usual care group or the intervention group. The results demonstrated reductions in HbA_{1c} in the intervention group, where patients had access to a Web-based diabetes management system, compared with that of the usual care group (-1.32% vs -0.66% , $P<.001$) at 6 months, but the

difference between groups was no longer significant at 12 months (-1.14 vs -0.95% , $P=.13$) [12]. Ralston et al observed that the intervention group ($n=42$) in which patients were introduced to the Web-based diabetes support program had a greater decline in GHb than the usual care group ($n=41$) at 12 months (difference in mean change between groups= -0.7% , $P=.01$) [15]. Another 2 RCTs provided patients with access to portals in both groups. The only difference between groups in the study conducted by Grant et al was the content of the module that was diabetes related in the intervention group but not the control group [16]. In the study by Vugt et al, patients in the intervention group, but not in the control group, were able to request feedback from a health coach [11]. Both these studies failed to observe changes in HbA_{1c} over time in either group [11,16]. The study by McCarrier et al, which examined 77 patients with T1DM, did not find a significant decrease in the average HbA_{1c} in the intervention group with a Web-based management program when compared with the usual care group over 12 months [14].

There were 3 observational studies that used data from EHR as well as an audit of portal registration and usage to examine the association of portal use with glycemic control. Of these 3 studies, 2 studies focused on single features (ie, secure messaging, Web-based medication refill). The 5-year retrospective cohort study conducted by Shimada et al in 111,686 veterans demonstrated that patients with HbA_{1c} $\geq 7\%$ at baseline tended to achieve HbA_{1c} $< 7\%$ with 2 (odds ratio [OR] 1.24, 95% CI 1.14 to 1.34) or more (OR 1.28, 95% CI 1.12 to 1.45) years of messaging use. Use of Web-based medication refills was not associated with changes in glycemic control [25]. An earlier study of 15,427 patients that examined the messaging feature revealed that frequent use of messaging (ie, ≥ 12 threads) was associated with HbA_{1c} less than 7% (relative risk [RR] 1.36, 95% CI 1.16 to 1.58) [39]. Another study of 10,746 adults, which investigated the association between overall portal use and diabetes quality measures, observed a minimum decrease in HbA_{1c} was associated with an increase in portal use (0.02%, $P<.01$) [33].

Impact of Patient Portals on Other Diabetes-Related Outcomes

In addition to glycemic control, researchers also explored other diabetes-related physiological outcomes. The RCT by Tang et al found that patients who had Web-based access to the diabetes management system had better control of LDL, but not BP or weight, when compared with patients in the usual care group at 12 months ($P=.001$) [12]. A significant decline in LDL and BP was observed in 2 retrospective cohort studies that examined single features in the portal [25,29]. Sarkar et al focused on individuals with diabetes who were prescribed statins. They observed that for patients with poor adherence to a statin medication at baseline ($n=3887$), those who requested all their medication refills on the Web during the 5-year study period had a 2.1 mg/dL decrease in LDL compared with nonusers (95% CI -4.4 to 0.18). This decrease in LDL can be explained by the improved statin adherence [29]. Shimada et al demonstrated that both secure messaging use and Web-based medication refill requests were associated with lower LDL at follow-up. Patients

with uncontrolled BP at baseline tended to achieve better control at follow-up, if they used the Web-based medication refill function for 2 (OR 1.07, 95% CI 1.01 to 1.13) or more years (OR 1.08, 95% CI 1.02 to 1.14) [25]. Significant associations between portal use and improved physiological measures were reported by 2 other cross-sectional studies [33,39]. Tenforde et al reported that portal users ($n=4036$), compared with nonusers ($n=6170$), had a small difference in SBP (by 1.13 mm Hg, $P<.01$) and DBP (by 0.54 mm Hg, $P<.01$) [33]. In the Harris et al study of 15,427 patients, a small but significant association was observed between secure messaging use and LDL < 100 mg/dL ($P<.001$) [39]. Other studies did not find a difference in total cholesterol [11,15], LDL [15,16,33], BP [11,12,15,16,39], or BMI [11] between groups.

Several studies also assessed changes in psychological measures, including diabetes-related distress and self-efficacy for managing diabetes. Data on diabetes-related distress as measured by the Problem Areas in Diabetes (PAID) questionnaire were reported in 4 studies. Of these studies, 1 study using an RCT design found a lower distress score in the intervention group ($n=202$) compared with the usual care group ($n=213$, 0.6, SD 0.8, vs 1.0, SD 1.0, $P<.001$) at 12 months [12]. No significant differences were found between treatment groups in the PAID scores in 3 other studies, including 2 RCTs [10,12] and 1 observational study [31].

Self-efficacy between groups was assessed in 2 studies. In an RCT by McCarrier et al ($n=77$ patients with T1DM), the intervention group had a significant increase in diabetes-related self-efficacy compared with the control group ($P=.04$) [14]. The study from the Netherlands analyzed data from 1390 respondents and found a significantly higher self-efficacy score for portal users (ie, patients with at least 1 log-in, 79.5, SD 15.8) than nonusers (ie, patients without a log-in, 72.7, SD 17.8) among patients with T2DM ($n=1262$, $P<.001$) but not T1DM ($n=128$) [32].

Qualitative Studies Reporting Benefits and Barriers to Using Patient Portals

There were 8 studies that evaluated patient portals by applying qualitative methods—6 used focus groups, 1 used face-to-face interviews, and 1 used telephone interviews. Qualitative responses revealed that patients favored features that allowed them to view summaries, request prescription refills, receive reminders for medical appointments, access laboratory results, and communicate with providers [18,22,24]. Patients stated that benefits of using the portal included more awareness of their disease, increased access to care outside of office visits, enhanced communication and satisfaction, and promotion of behavior change [19,20,24].

Patients who never used the portal provided the following reasons for not requesting a log-in: unawareness of the existence of the portal, no use of computers, family members as delegates, slow response from physicians or nurses, and poor usability of the portal [18,20,24]. Mayberry et al highlighted the role of family members in supporting patients' access to and use of the portal, especially for those with limited health literacy, numeracy, or computer literacy. Family members taught the patient how to use each function in the portal, and some acted

as delegates for patients by managing their health conditions [21]. Several studies also identified that physician engagement in using the portal remains challenging. Providers with negative attitudes toward the portal listed lack of integration with work routine, minimal knowledge about the portal, limited time, and usability problems as reasons for not using the portal [20,30].

Discussion

Principal Findings

This literature review reports on the current evidence on EHR portal use in the clinical management of patients with diabetes. The 13 patient portals that were represented in the 30 studies showed wide variability in features examined and provided across portals, evaluated diabetes outcomes, and whether the technology resources were applied in combination with a disease management program for diabetes. These variabilities increased the difficulty of performing a meta-analysis and generating any conclusions about the effectiveness of patient portals for diabetes management. In our review of the RCTs, we found inconsistent findings regarding the effect of the portal use on diabetes outcomes. Observational correlational studies also yielded mixed findings regarding the association between portal use and diabetes outcomes. However, we were able to identify that the patient portal, which leverages strong patient-centered principles (eg, DM education, tailored feedback on patient's DM-related health data), performed better in improving patient outcomes. The DM-specific portals enabled patients to receive personalized education, send blood glucose readings, and obtain individualized feedback from the health team.

Although we observed more favorable outcomes associated with using the DM-specific portals, the effect sizes in the studies reviewed were small. This may be due to several challenges associated with the use of patient portals. The design of the majority of the patient portals currently available was not patient-centered, meaning that features provided do not align with patient expectations, and in many cases were not evidence based. For a self-management intervention to be effective, appropriate theories of engagement and implementation should be in place to support the evidence-based intervention. For example, to ensure the effective application of a system, the system needs to provide a complete feedback loop, which consists of multiple components that include monitoring and transmission of patient status, data interpretation in comparison with personalized goals, adjustment of treatment regimen based on patient status, timely communication with individualized recommendations, and repetitiveness of this cycle [44]. However, from the studies reviewed, current patient portals often provided only one of these functions or a subset of them, which may contribute to the less robust favorable results. To significantly improve diabetes management, patient portals need to do more than provide convenient services such as requesting medication refills or reviewing laboratory results. They should also integrate more evidence-based strategies, such as patient education, to enhance patient engagement.

The current state of low engagement by patients in portal use may interfere with the ability to achieve meaningful clinical benefits. Initial high log-in rates followed by a rapid decline in

portal use suggest that multifaceted barriers prevent patients from engaging in the long-term use of patient portals. These barriers are technology-related (eg, functionality, usability), patient-related (eg, access to the internet or a computer, low health literacy, perceived usefulness, sociodemographic and clinical characteristics), and provider-related (eg, provider engagement).

A recently published review indicated that endorsement from providers was one of the most influential factors that contributed to patients' accepting the portal and using it as a tool for diabetes self-management [8]. However, health care providers commonly expressed concerns toward using a patient portal such as a disruption of their workflow and time constraints. These challenges may limit physicians' adoption and engagement of portal use and lead to minimal improvement in patient outcomes [45]. Future research needs to focus on addressing these barriers to promote more physician involvement in using the portal.

Limitations

There were several noted limitations of this review. First, our findings lacked sufficient quality evidence; the results of this review are not well-supported by level A evidence, with the majority of studies graded as the B or C level. It is no longer feasible to randomly assign patients to either portal use or nonuse group as individuals have the right to access their health information, but studies could consider examining different designs or additional features, given the necessary health information included in the portal. Second, this literature review only included studies explicitly concerned with patient portals and diabetes, studies evaluating patient portals for multiple chronic disease management that may include diabetes were not included. Finally, only 1 person was involved in the selection of the studies for inclusion in our review. Future studies should consider using a multiple-rater approach for study evaluation and data extraction.

Conclusions

In conclusion, this review identified several opportunities that could potentially improve diabetes outcomes through a patient portal. Because the majority of the studies examined the overall effect of patient portals, future investigations should consider investigating single features to understand the contribution of each component and understand which component is more influential than others in helping patients manage their diabetes. Moreover, a conceptual framework is needed to standardize an approach to guide the design and evaluation of patient portals. Specifically, functionalities need to be specified to provide guidance on system requirements for patient portal developers. Moreover, a set of evaluation metrics needs to be developed for the evaluation of patient portals to enable them to be compared and ranked. To further improve diabetes outcomes, continued investigation of strategies that could potentially enhance the implementation of the patient portal (eg, portal design, implementation strategy) may enable the patient portal to reach its fullest potential in supporting diabetes management and increasing patient engagement. At the same time, physicians' perceptions of portal use need to be assessed, and potential barriers need to be addressed to foster physicians' engagement in patient portals.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Observational studies examining patient portals for diabetes management.

[[PDF File \(Adobe PDF File\), 53KB - diabetes_v3i4e11199_app1.pdf](#)]

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Abbreviations

BMI: body mass index
BP: blood pressure
CCM: chronic care model
DBP: diastolic blood pressure
DM: diabetes mellitus
EMR: electronic medical record
EHR: electronic health record
GHb: glycohemoglobin
HbA_{1c}: glycated hemoglobin
LDL: low-density lipoprotein
PAID: Problem Areas in Diabetes
PHR: personal health record
RCT: randomized controlled trial
SBP: systolic blood pressure

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Original Paper

Crossing the Digital Divide in Online Self-Management Support: Analysis of Usage Data From HeLP-Diabetes

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Abstract

Background: Digital health is increasingly recognized as a cost-effective means to support patient self-care. However, there are concerns about whether the “digital divide,” defined as the gap between those who do and do not make regular use of digital technologies, will lead to increased health inequalities. Access to the internet, computer literacy, motivation to use digital health interventions, and fears about internet security are barriers to use of digital health interventions. Some of these barriers disproportionately affect people of older age, black or minority ethnic background, and low socioeconomic status. HeLP-Diabetes (Healthy Living for People with type 2 Diabetes), a theoretically informed online self-management program for adults with type 2 diabetes, was developed to meet the needs of people from a broad demographic background.

Objective: This study aimed to determine whether there was evidence of a digital divide when HeLP-Diabetes was integrated into routine care. This was achieved by (1) comparing the characteristics of people who registered for the program against the target population (people with type 2 diabetes in inner London), (2) comparing the characteristics of people who registered for the program and used it with those who did not use it, and (3) comparing sections of the website visited by different demographic groups.

Methods: A retrospective analysis of data on the use of HeLP-Diabetes in routine clinical practice in 4 inner London clinical commissioning groups was undertaken. Data were collected from patients who registered for the program as part of routine health services. Data on gender, age, ethnicity, and educational attainment were collected at registration, and data on webpage visits (user identification number, date, time, and page visited) were collected automatically by software on the server side of the website.

Results: The characteristics of people who registered for the program were found to reflect those of the target population. The mean age was 58.4 years (SD=28.0), over 50.0% were from black and minority ethnic backgrounds, and nearly a third (29.8%) had no qualifications beyond school leaving age. There was no association between demographic characteristics and use of the program, apart from weak evidence of less use by the mixed ethnicity group. There was no evidence of the differential use of the program by any demographic group, apart from weak evidence for people with degrees and school leavers being more likely to use the “Living and working with diabetes” ($P=.03$) and “Treating diabetes” ($P=.04$) sections of the website.

Conclusions: This study is one of the first to provide evidence that a digital health intervention can be integrated into routine health services without widening health inequalities. The relative success of the intervention may be attributed to integration into routine health care, and careful design with extensive user input and consideration of literacy levels. Developers of digital health interventions need to acknowledge barriers to access and use, and collect data on the demographic profile of users, to address inequalities.

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KEYWORDS

type 2 diabetes mellitus; self-management; patient education; internet; digital divide; social class; health literacy; computer literacy

Introduction

Background

Health systems internationally are struggling with the challenges posed by rising demand and increasing costs of health care due to an aging population, the increase in the prevalence of long-term conditions, and changing patient expectations [1-3]. This challenge has been clearly articulated in the English National Health Service (NHS), with an explicit commitment to improving the quality and efficiency of care delivered by the NHS, within a tightly controlled budget [4]. Two strategies which have been identified are increasing provision of digital health and promoting self-care by patients [5-9]. The expectation is that, where health care can be effectively delivered through digital means, it will be more cost-effective than face-to-face health care delivery, because of the scalability and low marginal costs per additional user of digital health interventions. There is also an expectation that improving patients' ability to self-care will reduce health care costs and improve health outcomes.

Although there are some data to support both these contentions [4,10-12], there are also anxieties about the extent to which such policies will widen health inequalities [13]. There are concerns about the "digital divide," defined as the divide between those who do and do not make regular use of digital technologies and the internet [14,15]. Overall, internet use is high in the United Kingdom (UK), with 90% of the population having access in 2017, and one of the most common reasons for using the internet is to access health-related information or services [16]. However, there are still 4 million households without internet access, and those without access are often those who are most in need of health care, including older people, people with disability, and people with lower socioeconomic status (SES) [17]. Data from the Office for National Statistics show that adults aged over 75 years are the lowest users of the internet [16], and the proportion of adults who are recent internet users is lower for disabled people than it is for able-bodied people [18]. Buying and accessing computer equipment is costly, which presents a barrier to access for people with lower SES.

The digital divide is about more than just access. The 2014 Government Digital Inclusion Strategy identified 3 additional challenges, which were (1) not having the skills or capacity to use the internet (computer literacy), (2) not having the motivation to go online, and (3) lack of trust in internet security [19]. Thus the "digital divide" is closely related to general literacy and health literacy. Health literacy has been defined as "the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health" [20]. People with low health literacy are less able to access and use health information effectively and have poorer health outcomes [21,22].

Similarly, there are concerns that programs which aim to promote self-care by patients, such as the expert patient program, may widen health inequalities as people with higher levels of

self-efficacy, and better access to social, economic, and practical resources, may be better able to engage with such programs and adopt the behaviors required for effective self-management [23,24].

In this paper, we present registration and usage data from a digital program designed to support self-management of type 2 diabetes mellitus (T2DM), known as Healthy Living for People with type 2 Diabetes (HeLP-Diabetes). We collected data on age, gender, ethnicity, and educational attainment. Educational attainment was used as a marker of SES, as is common in epidemiological research [25,26], and also digital and health literacy. Low health literacy has been found to be more common among older people, people from black and minority ethnic (BAME) backgrounds, people with lower incomes, and people with lower educational attainment [27-29]. Lower digital literacy has also been found to be associated with lower educational attainment [30].

Data on ethnicity were collected due to the higher prevalence of low health literacy, and the concern about health inequalities, among BAME groups. Inequalities in health have been documented across ethnic groups in the United States and the United Kingdom, with Bangladeshi and Pakistani people reporting the poorest health, followed by Caribbean, Chinese, and Indian people [31,32]. White people have the best health [31,32]. Factors underlying these differences include SES, genetic, and cultural factors [33].

Considerable effort was invested during the development of HeLP-Diabetes to ensure that the program was accessible, relevant to, and met the needs of, people from a wide range of demographic backgrounds. The development of HeLP-Diabetes is described in more detail elsewhere [34]. It is a theoretically-informed, evidence-based online program developed using participatory design techniques and extensive user input, which has demonstrated efficacy in improving glycemic control [34,35].

The text for HeLP-Diabetes was written for people with a reading age of 12 (80% of UK population achieve this) [36]. All essential information was provided in a video as well as text, and personal stories were included, as people with low literacy prefer this method of learning [37-39].

HeLP-Diabetes was commissioned by 4 inner London clinical commissioning groups (CCGs) during the data collection period and offered to patients with T2DM as part of routine care. Hence there was a unique opportunity to gather real-world data on whether this intervention was being used across the digital divide. As the use of the program was a necessary prerequisite for patients obtaining health benefits [34], it was a relevant outcome for exploring whether the program was reaching the target audience.

Aims

The overall aim of the study was to determine whether there was evidence of a digital divide when a Web-based

self-management program for T2DM was integrated into routine care. Specific objectives were to determine:

1. Whether the demographic characteristics of people who registered to use the program differed from the target population, and if so how
2. Whether once registered, specific demographic groups were more likely to use the program
3. Whether there were different patterns of use by specified demographic characteristics

Methods

Design

A retrospective analysis of data on the use of HeLP-Diabetes in routine clinical practice in 4 inner London CCGs was undertaken.

Setting

General Population of Study Setting

HeLP-Diabetes was commissioned by 4 inner London CCGs (CCG 1, 2, 3 and 4). All 4 CCGs have young, multicultural communities. They are densely populated and have relatively high levels of deprivation [40]. The educational attainment in the 4 CCGs is polarized. The proportion with degree level or above education attainment is higher than the national average. In contrast, 34%-42% of 19-year-old individuals do not have

A-level qualifications (postsecondary nontertiary education) [41,42].

Diabetes Population of Study Setting

The target population of the HeLP-Diabetes program was adults with T2DM (see Table 1). There is a higher percentage of people in the 40-64 age group with T2DM in England (42.8%) and all 4 CCGs (range 49.3%-54.4%), than any other age group. More than 48% (range 48.3%-62.6%) of people with T2DM in the 4 participating CCGs are of BAME origin, reflecting the ethnic diversity of these areas [43].

Intervention

HeLP-Diabetes is described in detail elsewhere [34]. It is an evidence-based, theoretically informed online self-management program for adults with T2DM. Content is based on the Corbin and Strauss [44] theory for living with long-term conditions which takes a holistic approach to diabetes management, incorporating the disease process (adopting healthy behaviors, working with health professionals, and taking medicines), the emotional consequences (the negative emotions associated with being diagnosed with a long-term condition), and the changes that occur in daily life (including the impact of a diagnosis on relationships with friends, family, and colleagues). Information is divided into 8 sections (see Table 2). Patients with T2DM were referred to the program by health care professionals, or made aware through flyers in waiting areas and texting from practices.

Table 1. Diabetes population of the clinical commissioning groups compared with England (prevalence is given as a percentage, because the numbers are not publicly available).

Population demographic characteristic	England	CCG ^a 1	CCG 2	CCG 3	CCG 4
QoF ^b total type 1 and type 2 diabetes prevalence, n (%)	3,116,399 (6.7)	15,213 (6.2)	10,368 (5.0)	18,274 (5.5)	16,663 (6.5)
T2DM^c prevalence, (%)					
Age (years)					
<40	3.9	4.6	4.8	4.9	4.8
40-64	42.8	50.4	49.3	54.4	51.4
65-79	38.0	32.8	32.2	29.2	31.0
>80	13.8	10.0	10.6	9.6	11.0
Gender					
Male	55.8	51.9	52.5	52.5	51.7
Female	48.1	44.2	47.5	47.5	48.3
Race					
White	64.4	33.8	49.2	31.3	41.4
BAME ^d	19.3	60.5	48.3	62.6	55.8

^aCCG: clinical commissioning groups.

^bQoF: quality and outcomes framework in population >17 years of age.

^cT2DM: type 2 diabetes mellitus.

^dBAME: black and minority ethnic.

Table 2. Healthy Living for People with type 2 Diabetes (HeLP-Diabetes) website sections.

Section	Content
Understanding diabetes	<ul style="list-style-type: none"> • Common diabetes questions • How my body can be affected • Quick guides
Staying healthy	<ul style="list-style-type: none"> • Why is lifestyle important? • Looking after yourself • Physical activity • Taking medicines • Eating and drinking • Alcohol • Smoking • Working with my diabetes team
Treating diabetes	<ul style="list-style-type: none"> • How is type 2 diabetes treated? • Tests to monitor diabetes • Medicines • Surgery • Complimentary medicine • Vaccinations and immunizations • How the National Health Service can help
Living and working with diabetes	<ul style="list-style-type: none"> • Food • Relationships • Work • Social life • Travel • Driving • Financial support • Ramadan
Managing my feelings	<ul style="list-style-type: none"> • Understanding my moods • My mood tools
My health record	<ul style="list-style-type: none"> • My diabetes care plan • My appointments • My health tracker • My test results • My medicines • My reminders
News and research	<ul style="list-style-type: none"> • News • Research • Concerns about specific medicines
Forum and help	<ul style="list-style-type: none"> • Forum • Useful resources • People's stories • Frequently asked questions

The intervention was offered to patients with T2DM as a routine service in clinical practice. Practices placed flyers and posters in waiting areas informing patients about the program. Health care professionals were able to offer it to patients in consultations, and some practices wrote or sent texts to patients inviting them to register. Data were not recorded on how many patients were offered the program by health care professionals, and so this was not included in the analysis.

Ethics and Privacy

Details of the people who used the HeLP-Diabetes website were automatically pseudoanonymized with a user identification. Pseudoanonymized data were collected by the server side of

the website and subsequently exported by the research team to Microsoft Excel and then Tableau reader for analysis. Secondary analysis of information collected for service evaluation is excluded from an ethics committee review by the NHS Research Ethics Committees (RECs), as long as patients were not identifiable [45]. Formal ethical approval was therefore not needed.

Data Collection

The demographic characteristics of everyone who registered to use the program were collected at the point of registration. Initially, people were registered and given access to the website by a member of the HeLP-Diabetes administrative team, and

later a self-registration page was added to the website to allow people to register themselves. The demographic data collected at registration included gender, age, ethnicity, and education level. Education level was categorized using UK and US qualifications, and the International Standard Classification of Education [42].

The server side of the website automatically collected data on visits to the HeLP-Diabetes website. The data collected were: user ID, date and time of login, and page visited. These data were chosen as measures of use following best practice [46]. Alternative measures such as time can be prone to error as people may leave browsers on while engaged in alternative activities. The data presented here were collected between November 2015 and January 2017. During this time, 343 people registered to use the website, but not everyone who registered gave complete data on gender, ethnicity, education level and age. Therefore, the numbers provided in the results (n) are the numbers of people providing data for each demographic factor, and the totals are less than 343.

Analysis

For the analysis, web page visits were grouped into 11 sections. Eight of these are the sections of the website (see Table 2), and the remaining 3 are other web pages that the user may have visited outside the 8 information sections of the HeLP-Diabetes website. These comprise of (1) the homepage, (2) miscellaneous articles, and (3) HeLP-Diabetes: Starting Out (a structured program for people newly diagnosed with T2DM based on the content of HeLP-Diabetes). The profile, administration, logout, and registration pages were excluded from the analysis. Statistical analysis was carried out using Stata (version 14.1) [47].

The analysis addressed each of the 3 research questions listed under the aims.

Question 1: Did the Demographic Characteristics of People Who Registered to Use the Program Differ From the Target Population, and If so How?

The percentage of people who registered to use HeLP-Diabetes from each gender, ethnic, education, and age group was calculated to address this question. The target population was examined using the Public Health England data (see Table 1). A statistical analysis to compare the characteristics of the user population and the target population could not be carried out as the data were categorized differently. Instead of carrying out statistical analyses, we described the demographic characteristics of the registered users by stating the percentage of registered users in specified gender, ethnicity, education level and age groups. We have compared the percentage of male and female registered users with the percentage of males and females with T2DM in the 4 CCGs and compared the percentage of BAME registered users with the proportion of BAME people with

T2DM in the 4 CCGs narratively. We were able to comment on which age group had the highest proportion of registered users.

Question 2: Was There Evidence of the Digital Divide in Overall Use?

The term “use” was defined as logging in to the HeLP-Diabetes website at least twice. This was in order to determine who returned to the website, rather than just visiting once. The percentage of people who visited the website at least twice was calculated for each demographic group. Logistic regression analyses were performed to look for evidence of an association between the binary dependent variable (use/nonuse) and each of the covariates (gender, ethnicity, education level, and age group).

Question 3: Was There Evidence of Differential Use by Demographic Characteristic?

The number of users who visited each of the 11 sections of the website and the number of visits to each section were categorized by demographic group. The Wilcoxon signed rank test was used to determine if there was an association between age and the number of visits to each section of the website. The Kruskal-Wallis equality of populations rank test was used to determine if there was an association between ethnicity, education, and the number of web page visits per user to each section of the website.

Results

Question 1: Was There Evidence of the Digital Divide in People Registered to Use the Program?

The mean age (see Table 3) was 58.4 years (SD 28.0). The age group with the highest proportion of people registered to use HeLP-Diabetes is the 51-60-year-olds (101/334, 30.2%), followed by the 61-70-year-olds (80/334, 24.0%), and 71-80-year-olds (56/334, 16.8%). Of the people with T2DM in the general population of the 4 CCGs (see Table 1), the highest proportion (range 49.3%-54.4%) of people was in the 40-64-year-old age group. This suggests that the age of the registered users reflected the target population. The most common education level was a bachelor's degree or equivalent (102/299, 34.1%), followed by a general certificate of secondary education (GCSE)/high school diploma (89/299, 29.8%).

Males represented 55.5% (176/317) of registered users. Public Health data on the 4 CCGs the program was offered in, shows 51%-53% of people with T2DM in these areas are male. A total of 180/330 (54.5%) of the registered users were BAME, and 48%-60% of people with T2DM in the 4 CCGs are BAME. This suggested that the gender and ethnicity of people who registered to use the program reflected the target population in the 4 CCGs.

Table 3. Demographic characteristics of people who registered at clinical commissioning group 1 (n=97), 2 (n=51), 3 (n=154), and 4 (n=41) to use Healthy Living for People with type 2 Diabetes (HeLP-Diabetes).

Demographic characteristic	n (%)
Gender (n=317)	
Male	176 (55.5)
Female	141 (44.5)
Ethnicity (n=330)	
White	150 (45.5)
Black	117 (35.5)
Asian	46 (13.9)
Mixed	17 (5.2)
Education level (n=299)	
GCSE ^a /high school	89 (29.8)
A-level/postsecondary	64 (21.4)
Bachelor's degree or equivalent	102 (34.1)
Master's or doctoral degree or equivalent	44 (14.7)
Age group (n=334)	
18-30	6 (1.7)
31-40	20 (6.0)
41-50	55 (16.5)
51-60	101 (30.2)
61-70	80 (24.0)
71-80	56 (16.8)
81-90	13 (3.9)
≥91	3 (0.8)

^aGCSE: general certificate of secondary education.

Q2. Was There Evidence of the Digital Divide in Overall Use?⁴⁴

Ninety-two of 150 (61.3%) white, 70/117 (59.8%) black, and 28/46 (60.9%) of Asians who registered to use HeLP-Diabetes, visited the website at least twice (see Table 4). This was lower in the mixed group (5/17 (29.4%)), odds ratio (OR)=0.26, 95% CI=0.09-0.78). The median age of people who visited the website at least twice was 59 years (lower quartile=50, upper quartile=70), and age groups were categorized into quartiles for this analysis. Visits to the website by the different age groups ranged from 46.7% (50/107) in those aged 60-69 years to 55.9% (62/111) in those aged 51-59 years. There was no significant difference in usage for gender, education level or age.

Q3. Were There Different Patterns of Use by Demographic Characteristics?

Overall, the 2 sections of the website that were most visited were (1) My health records and (2) Staying healthy. There was

no evidence of differential use of the program by any demographic group, apart from education level, where there was weak evidence of an association between education level and visits to the “Living and working with diabetes” section with $P=.03$ (Figure 1), and the “Treating diabetes” section with $P=.04$ (Figure 2). The difference between visits by people with high school diplomas and a tertiary education level was small, as 34.3% (24/70) of visits to the “Living and working with diabetes” were by users with a bachelor's degree or equivalent, while 32.9% (23/70) of visits were by users with high school diplomas. Also, 34.9% (22/63) of visits to the “Treating diabetes” section were by users with a bachelor's degree or equivalent, compared to 33.3% (21/63) of visits by users with high school diplomas. The proportion of users who visited both sections with postsecondary nontertiary education level or master's or doctoral degrees or equivalent was much lower (see Multimedia Appendices 1-4 for details).

Table 4. Proportion of people registered to use HeLP-Diabetes who visited at least twice.

Demographic characteristics	n/N ^a (%)	Odds ratio (95% CI)	P value
Gender (n=317)			
Female	77/141 (54.6)	1.00	.19
Male	109/176 (61.9)	1.35 (0.86-2.12)	
Ethnicity (n=335)			
White	92/150 (61.3)	1.00	.12
Black	70/117 (59.8)	0.94 (0.57-1.54)	
Asian	28/46 (60.9)	0.98 (0.50-1.93)	
Mixed	5/17 (29.4)	0.26 (0.09-0.78)	
Education level (n=299)			
GCSE ^b /high school	53/89 (59.6)	1.00	
A-level/postsecondary	36/64 (56.3)	0.87 (0.46-1.67)	
Bachelor's degree or equivalent	61/102 (59.8)	1.06 (0.59-1.90)	
Master's degree, doctoral degree or equivalent	26/44 (59.1)	0.98 (0.47-2.05)	.95
Age group (n=334)			
22-50	49/96 (51.0)	1.00	.54
51-59	62/111 (55.9)	1.21 (0.70-2.10)	
60-69	50/107 (46.7)	0.84 (0.49-1.46)	
70-93	44/80 (55.0)	1.17 (0.65-2.13)	

^aThe proportion who visited the website at least twice (n)/everyone in this demographic group who registered (N).

^bGCSE: general certificate of secondary education.

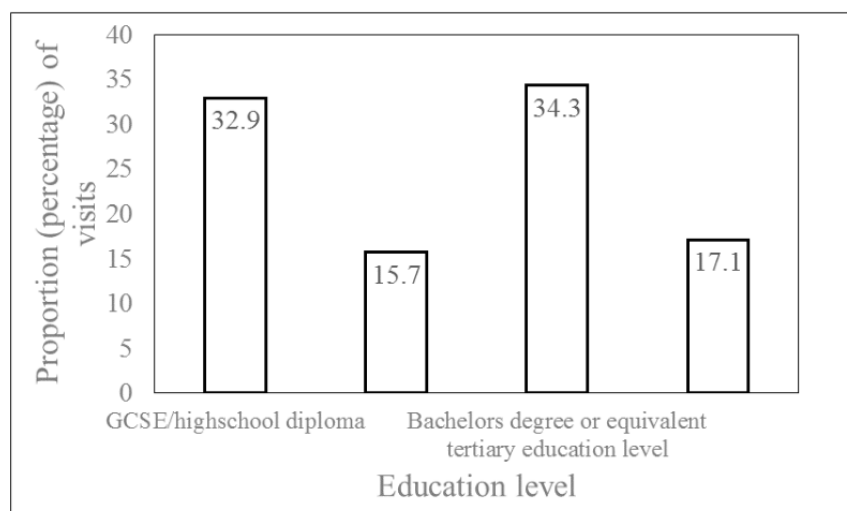
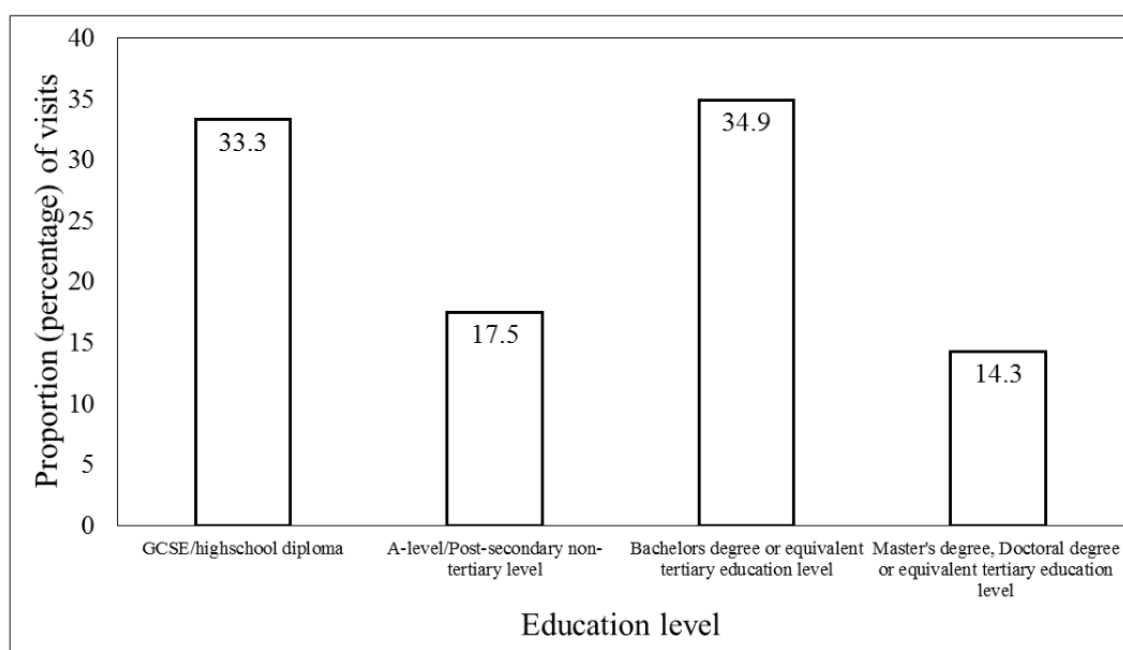
Figure 1. Proportion of visits to the "Living and working with diabetes" section of the website. GCSE: general certificate of secondary education.

Figure 2. Proportion of visits to the "Treating Diabetes" section of the website. GCSE: general certificate of secondary education.



Discussion

Principal Results

This study is one of the first to explore whether there is evidence of a digital divide in the use of a digital health intervention integrated into routine health care. As such it makes a substantial addition to the literature on whether digital health is likely to increase or decrease health inequalities. Reassuringly, we found no strong evidence of differential patterns of registration, or patterns of use by age, gender, educational attainment or ethnicity. There was weak evidence that people from the mixed ethnicity group were less likely to use the program than the white group (OR=0.26, 95% CI=0.09-0.78, $P=.12$). There was also weak evidence of differences in visits to the "Living and working with diabetes" ($P=.03$) and "Treating diabetes" ($P=.04$) sections of the website by education level. The highest proportion of users who visited these sections of the website were those with a bachelor's degree or equivalent, but people with high school diplomas closely followed.

Comparison With Prior Work

These findings make a significant contribution because the literature on the use of digital health interventions suggests higher use among younger, well-educated, higher income, nonBAME individuals, which is a pattern that is likely to increase health inequalities. For example, a systematic review of electronic portal (an online electronic health records system) usage among patients with diabetes found that higher education, younger age, higher income, and nonHispanic, nonblack race were associated with higher portal utilization [48].

A second systematic review of patterns of user engagement with mobile and Web-based self-care interventions for adults with T2DM [49], also found that use was higher among younger people. However, 1 study included in the review showed that

use of a mobile Health medication adherence promotion intervention for low-income adults with T2DM increased from 25 to 50 years of age, then decreased as age increased [50].

Our findings are also in keeping with a qualitative study of people with high and low levels of health literacy about a digital intervention to promote physical activity for diabetes in 5 countries [51]. Participants in that study were from areas with high levels of deprivation and had a mean age of 62 years and most found the design of the intervention was acceptable and engaging. Findings from both our study and this qualitative study suggest that it is possible to design digital health interventions that appeal to a diverse population, including people with low literacy and health literacy levels.

Strengths and Limitations

A strength of the research is that individuals were offered HeLP-Diabetes as an NHS service, and not as a research study. This provides us with data on "real world" use of the program and not data generated from a highly controlled research setting. Actual website visits were automatically measured rather than using self-reported use of the program, which relies on memory and may result in bias from social desirability. A variety of engagement measures were analyzed including numbers who registered, the proportion who actively used the program, and the number of page visits. There are other measures of engagement including the duration of time spent using the website per visit, and the duration of time between visits to the website. The number of visits was considered to be a more reliable measure of engagement.

A limitation of the research is the total number of participants ($n=343$). This may limit the power of the study to detect significant differences between demographic groups. The 95% CI was provided in addition to P values in recognition of the

fact that a *P* value by itself provides limited information [52]. Where the *P* value and 95% CI do not agree, this has been stated.

Implications

The findings of this study suggest that digital health interventions can be designed to be used by people of different demographic backgrounds. This is important to enable equitable access to health information and support, and to prevent worsening health inequalities.

Developers of digital health interventions should be mindful of the needs of different demographic groups in their design process and involve users of different backgrounds at each stage of development. Research on the evaluation of digital health interventions should include the collection of data on the demographic profile of users, and the use (or other engagement measure) of the intervention by different demographic groups.

Developers also need to acknowledge and address barriers to the use of digital health interventions such as low health literacy and poor computer literacy. The 2014 Government Digital Inclusion Strategy has identified lack of computer skills, not having the motivation to go online, and lack of trust in internet security as additional challenges to internet use, in addition to lack of access [19]. Possible reasons for our relative success in crossing the digital divide are twofold. First, full integration into routine health care, with a recommendation for use from health care professionals. This improved motivation to go online and use the intervention, and trust in the security of the

intervention [53]. Second, careful design of the intervention to make it fully accessible to a wide range of people. HeLP-Diabetes was designed using participatory design techniques, extensive user input, and consideration of literacy levels and use of audio-visual media [34]. These techniques make the program more accessible to people with lower health literacy and computer literacy.

Conclusion

This study is one of the first to provide evidence that health inequalities are not necessarily widened when a digital health intervention was integrated into routine health care. Weak evidence of a difference in overall use was identified for ethnicity (less use by the mixed-race ethnic group). There was also weak evidence of differences in the use of the “Living and working with diabetes” and “Treating diabetes” sections of the website (the highest proportion of visits were by people with a bachelor’s degree) but the proportion of visits by people with high school diplomas was very similar). The relative success of the intervention may be attributed to integration into routine health care, and recommendation from health care professionals, but also careful design with extensive user input and consideration of literacy levels. Developers of digital health interventions need to acknowledge barriers to access and use including health literacy, computer literacy, motivation and concerns about internet security if they are to navigate and reduce health inequalities successfully.

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Conflicts of Interest

Elizabeth Murray is Managing Director of HeLP-Digital, a not-for-profit Community Interest Company that exists to disseminate digital interventions, including HeLP-Diabetes and HeLP-Diabetes Starting Out to the NHS. She has not, does not, and will not take any remuneration for this work.

Multimedia Appendix 1

Total number of visits to each section of the HeLP-Diabetes website by female and male users.

[PDF File (Adobe PDF File), 25KB - [diabetes_v3i4e10925_app1.pdf](#)]

Multimedia Appendix 2

Total number of visits to each section of the HeLP-Diabetes website by users of different education levels.

[PDF File (Adobe PDF File), 28KB - [diabetes_v3i4e10925_app2.pdf](#)]

Multimedia Appendix 3

Total number of visits to each section of the HeLP-Diabetes website by users of different age groups.

[PDF File (Adobe PDF File), 30KB - [diabetes_v3i4e10925_app3.pdf](#)]

Multimedia Appendix 4

Total number of visits to each section of the HeLP-Diabetes website by users of different ethnic groups.

[PDF File (Adobe PDF File), 27KB - [diabetes_v3i4e10925_app4.pdf](#)]

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Abbreviations

- BAME:** black and minority ethnic
CCG: clinical commissioning group
GCSE: general certificate of secondary education
HeLP-Diabetes: Healthy Living for People with type 2 Diabetes
NHS: National Health Service
SES: socioeconomic status
T2DM: type 2 diabetes mellitus

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Original Paper

A Web-Based Coping Intervention by and for Parents of Very Young Children With Type 1 Diabetes: User-Centered Design

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Abstract

Background: Management of type 1 diabetes (T1D) among children aged <6 years is exceptionally challenging for parents and caregivers. Metabolic and psychosocial outcomes among very young children with T1D (YC-T1D) are tightly associated with their parents' ability to meet these challenges. There is scant research testing interventions targeting these issues and few resources to equip health care providers with feasible and effective coping strategies for these parents. User-centered design (UCD) of a continuously accessible Web-based resource could be a mechanism for helping parents of YC-T1D cope more effectively with the complex challenges they face by providing them with information, solutions, and emotional support.

Objective: The objectives of this paper are to (1) describe the application of UCD principles to the development of a Web-based coping intervention designed by and for parents of very young children (<6 years old) with T1D; (2) illustrate the use of crowdsourcing methods in obtaining the perspectives of parents, health care providers, and Web development professionals in designing and creating this resource; and (3) summarize the design of an ongoing randomized controlled trial (RCT) that is evaluating the effects of parental access to this resource on pertinent child and parent outcomes.

Methods: This paper illustrates the application of UCD principles to create a Web-based coping resource designed by and for parents of YC-T1D. A Web-based Parent Crowd, a Health Care Provider Crowd, and a Focus Group of minority parents provided input throughout the design process. A formal usability testing session and design webinars yielded additional stakeholder input to further refine the end product.

Results: This paper describes the completed website and the ongoing RCT to evaluate the effects of using this Web-based resource on pertinent parent and child outcomes.

Conclusions: UCD principles and the targeted application of crowdsourcing methods provided the foundation for the development, construction, and evaluation of a continuously accessible, archived, user-responsive coping resource designed by and for parents of YC-T1D. The process described here could be a template for the development of similar resources for other special populations that are enduring specific medical or psychosocial distress. The ongoing RCT is the final step in the UCD process and is designed to validate its merits.

KEYWORDS

coping; mobile phone; parenting; social media; type 1 diabetes

Introduction

Type 1 diabetes (T1D) is increasing in prevalence among children aged <6 years [1-3]. Daily T1D care is immensely challenging for parents and caregivers, and the adequacy of parental coping is intertwined tightly with their children's metabolic and psychosocial outcomes [4-14]. Yet, there are few resources that specifically target the unique needs of this population or that equip health care providers to offer feasible and effective coping strategies to these parents and caregivers [15,16].

The development, evaluation, and dissemination of digital health interventions for promoting healthy lifestyle and improved management of chronic medical conditions [17-23] are growing. These include websites [24-26], smartphone apps [27,28], and innovative devices [29] designed to assist people in achieving specific health goals. The development of these interventions is labor-intensive and costly. Hence, developers of these resources would be prudent to include targeted end users throughout the design process to ensure the utility and uptake of new interventions.

Many have advocated the application of user-centered design (UCD) in the development of digital health resources. Roberts et al [30] advocated for the application of design thinking in the area of innovations in health care management. Maher et al [31] described their process of developing a roadmap for bone marrow transplant patients built largely on input from patients who represented end users of this tool. LeRouge and Wickramasinghe [32] reviewed research applying UCD principles in the design and development of diabetes-related consumer health information technology initiatives and platforms. The authors concluded that few projects have verified the use of UCD principles throughout the entire life cycle from conceptualization to implementation of the end product. Devito-Dabbs et al [33] illustrated the merits of UCD in their development of a "Pocket Personal Assistant for Tracking Health" device for the promotion of self-management behaviors in lung transplant patients. The UCD principles that drove their design process were (1) Focus on Users and Tasks; (2) Measure Usability Empirically; and (3) Design and Test Usability Iteratively. The authors demonstrated how these UCD principles could guide the development of a wide range of digital health interventions. This paper illustrates how we applied these same UCD principles to the entire life cycle of our design and the development of a Web-based coping resource created by and for parents of very young children with T1D.

Extensive research shows that effective management of pediatric T1D requires substantial involvement of patients and family members, and outcomes are heavily dependent on how families accommodate the demands of T1D to their daily lives. This point is especially salient for parents of very young (<6 years old) children with T1D (YC-T1D) because YC-T1D lack the

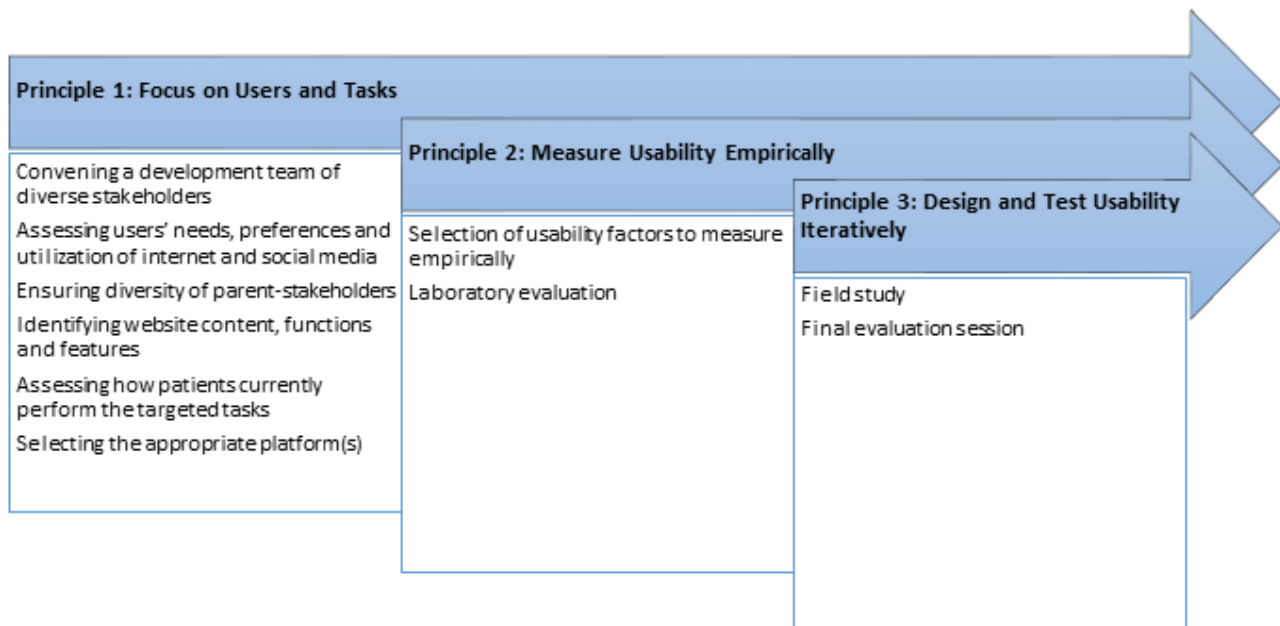
cognitive, behavioral, and emotional self-regulation skills that are prerequisites for T1D self-management. Hence, YC-T1D are prone to display difficulties adapting to the demands of care, as manifest in resistance to painful procedures, mealtime behavioral problems, anger over perceived differential treatment relative to peers or siblings, etc [4-16]. Parents of YC-T1D are overwhelmed, anxious, and prone to fatigue owing to their pervasive worry about their children, constant vigilance about their children's blood glucose levels, and reluctance to place their children in the care of others [9,10]. Multifamily support groups that specifically target these parents encounter barriers such as the low incidence of T1D in very young children, frequent acute childhood illnesses, caregiving duties for other young children, interference with children's early bedtimes, and hesitation about others caring for their children. While many centers offer general support groups for children and teens with T1D, they do not address the unique issues faced by parents of YC-T1D. Since this population of parents tends to be heavy internet and social media users [34], it seems plausible that they could benefit from a Web-based coping resource.

This paper describes the application of UCD principles [30-33,35] to the development of a Web-based coping intervention "by and for" parents of YC-T1D. This paper illustrates the application of UCD principles by engaging many parents of YC-T1D, health care providers, and experts in T1D medical and psychosocial care (JML, TW, and JP), qualitative research (KA), Web development (LM and CC), and usability testing (TM) in this initiative. The research team relied extensively on crowdsourcing methods to facilitate the UCD process. Crowdsourcing, a flexible Web-based activity [36] that has been applied to problems in diverse fields, comprises 4 elements [37]: (1) an organization that has a task it needs to be performed (eg, design an internet resource meeting parents' specifications); (2) a community, or crowd, that contributes to meeting those specifications; (3) a Web-based environment that enables collaboration between the crowd and the organization; and (4) mutual benefit for the organization and the crowd (eg, better child health and quality of life, less family distress). Crowdsourcing methods enabled the researchers to efficiently capture the perspectives of parenting roles and challenges from a relatively large and diverse group of parents of YC-T1D, ensuring that the design process was consistent with the "by parents, for parents" approach. With extensive stakeholder engagement, the researchers developed a continuously accessible resource that provides credible information and social support and offers searchable content that evolves in response to ongoing needs and preferences of the user group. The development of the Web-based resource is now complete, and recruitment of participants for a randomized controlled trial (RCT) has begun.

Methods

Figure 1 depicts the multistep, UCD process employed here, followed by more detailed treatment of those elements.

Figure 1. User-centered design principles applied in this project.



Principle 1: Focus on Users and Tasks

Convening a Development Team of Diverse Stakeholders

Parents of YC-T1D and health care providers served multiple roles on the development team, with a corresponding range of engagement methods. Constitution of the development team began during the earliest stages of the grant application that supports this work. Using a variety of recruitment approaches (nominations by T1D professionals, referrals from diabetes advocacy groups, and internet advertising), 5 parents of YC-T1D agreed to serve as Family Advisors to the research team in preparing the project plan and securing funding for the project. They met with the first 2 authors approximately monthly during the preparation of the project plan to provide stakeholder input. The process of securing funding for the project required about 9 months, during which time there was an interlude in any activity involving the Family Advisors. Once funding was secured for the project, the team recruited a Web-based community ("crowd") of many parents of YC-T1D to guide the planning of the website and reconstituted the group of Family Advisors. Of the original Family Advisors, 3 committed to continuing in that role, and the researchers recruited 3 additional Family Advisors, comprising a team of 6 that would advise the researchers throughout the remainder of the design and development of the Web-based resource, as well as the implementation of the RCT to follow.

Based on the Family Advisor input, the team began the design process with a systematic effort to characterize the parents' perspectives of challenges their families faced in meeting the unique needs of YC-T1D, while also addressing their other personal, marital, family, and vocational priorities. The intent of this step was to provide a broad perspective of the

psychological landscape faced by these families to guide future iterative interaction with a larger Web-based parent community to progressively refine and validate this framework. Using recruitment methods similar to those employed in recruiting the Family Advisors, we then assembled a Web-based Parent Crowd, who were interested in assisting the researchers in designing and building the Web-based resource. Parents were eligible if they were parents or legal caregivers of a child who was diagnosed with T1D before the age of 6 years and was aged <10 years at the time of recruitment. Relying on both direct contact with parents of YC-T1D at the host institution and contact through a variety of resources comprising the "Diabetes Online Community" [38], a group of 170 parents enrolled as Parent Crowd members, of whom 153 participated actively in the design of the Web-based resource as described below. Although it might have been valuable to characterize these parents in terms of the type and quality of T1D care received by their children, the researchers did not attempt to collect that type of information. The parents' children received care at numerous different centers, and self-report by parents is probably not the most accurate way to characterize a given center's clinical resources and practices. The depth and quality of parents' responses to the researchers' Web-based qualitative questions suggest a sample of parents that were receptive to T1D technology and highly engaged in their children's care.

Conference calls between the Family Advisors and the researchers occurred every 2-4 weeks throughout the project phase, contributing a wide range of input into various project decisions and plans and ensuring that those plans adequately reflect broader Parent Crowd input. For example, Family Advisors reviewed and edited the instructions for several Parent Crowd tasks, detailed below, to ensure they were easily

comprehensible; reviewed the list of parent-generated and health care professional-generated articles written for the website and suggested additional articles to be written; and reviewed and confirmed that changes made to the website following usability testing (see Principle 2 below) were consistent with the preferences specified by Parent Crowd members. Parent Crowd members strongly recommended that the website should be structured so that parents of newly diagnosed children would not be overwhelmed by the magnitude and scope of many challenges that they, their children, and their other family

members would now face. As a result of this input, parents who log in to the website for the first time receive a prompt asking whether their child is very recently diagnosed. Those who respond affirmatively are directed to content that was specifically selected by the Parent Crowd and research team as being most appropriate for these parents. This content included opportunities for basic education about T1D, diagnosis stories submitted by Parent Crowd participants, and a variety of articles about getting through the early weeks and months after the diagnosis.

Textbox 1. Open-ended questions distributed to the Parent Crowd via Yammer for written replies.

1. In what ways has your life changed since your child was diagnosed with type 1 diabetes?
 2. What challenges are you facing in managing your child's diabetes? If your child is currently 6 or older, please answer this question about the challenges you experienced when he/she was 5 or younger.
 3. What do you do now that helps you cope with the challenges you described in Question 2? If your child is currently 6 or older, what did you do to cope when he/she was 5 or younger?
 4. How does/did being a parent of a very young child with diabetes affect your relationships with others?
 5. In what ways has your child's life changed since he/she was diagnosed with T1D?
 6. How does your child's behavior or temperament affect your ability to take care of diabetes? Please remember to answer this question about your experience when your child was 5 or younger.
 7. How has taking care of your child's diabetes affected your other children, if you have any? Please remember to answer this question about your experience when your child was 5 or younger.
 8. How do you fit diabetes care into your daily family life? If your child is currently 6 or older, how did you fit diabetes care into your daily family life when he/she was 5 or younger?
 9. How have you fit your child's diabetes care into special occasions (holidays, birthdays, travel)? If your child is currently 6 or older, how did you fit diabetes care into special occasions when he/she was 5 or younger?
 10. What could your diabetes care team do to be more helpful to you in caring for your child? If your child is currently 6 or older, please answer this question about what your health care team could have done when your child was younger than 6.
 11. Looking back, is there some aspect of caring for your child that you could have been better prepared for?
 12. Knowing what you know now, what is the most important advice you would give to a parent whose young child was just diagnosed?
 13. What advice or information about treating young children, toddlers, and infants with T1D would you give to your child's doctor or health care team? What would you like them to know?
 14. In what ways, if any, has raising a young child with diabetes been a positive experience for you?
 15. In what ways, if any, has diabetes been a positive experience for your young child?
 16. What else would you like us to know about your experience raising a young child with T1D that wasn't address in the questions you have already answered?
- 17-19. Intimacy questions (Sent via email rather than posted on Yammer given private nature of content)
- Are you married or living with a partner?
- If YES:
- How do you and your spouse or partner divide responsibility for your child's diabetes care? How acceptable is this arrangement to each of you?
 - In what ways has your child's diabetes affected the emotional intimacy or closeness of your relationship with your spouse or partner?
 - In what ways has your child's diabetes affected the physical intimacy or closeness of your relationship with your spouse or partner?
- If NO:
- How successful have you been in finding others who you trust to care for your child with T1D?
 - In what ways do you do things just for yourself, to give yourself a break?
 - In what ways has your child's diabetes affected your life in the areas of dating and romance?

Assessing Users' Needs, Preferences, and Utilization of the Internet and Social Media

Based on the Family Advisor input, the researchers' knowledge of the pertinent research evidence base, and with consultation from a qualitative research expert (KA), the researchers developed 16 a priori open-ended questions for distributing among the Parent Crowd through a private social network, Yammer. The questions sought to characterize the challenges faced while parenting YC-T1D in terms of its impact on YC-T1D, parents, marital and family issues, extrafamilial social relationships, workplace and career issues, and interactions with the health care community. Three additional open-ended questions were developed as the team gained experience with this subject matter, addressing marital intimacy, workplace issues, and relationships with health care providers in more depth. For the 19 open-ended questions, shown in [Textbox 1](#), participants responded by entering written replies that were available to all Parent Crowd members, providing opportunities for interactions among Parent Crowd members about their perspectives and experiences. The researchers distributed 15 other polls and surveys designed to characterize their use of the

internet in general and specific to T1D, use of social media as a means of obtaining T1D information and support, use of other sources of T1D information, and experiences in multifamily T1D support groups. These efforts yielded a Social Ecological Model ([Figure 1](#)) that provided a taxonomy for organizing the functional domains that should be addressed by the planned Web-based resource [9].

Certain proposals raised by the Parent Crowd members, such as broadening intended website users to include parents of older children with T1D and providing T1D educational games for children on the website, indicated that the Parent Crowd's work could proceed most efficiently if it could become more focused. The Family Advisors and the investigators proposed that the group should develop a formal Vision, Mission, and Operating Principles document to ensure consistency of the group's purposes and strategy and to more clearly define the nature of the end product that should result from this work. Over several iterations, the participants prepared successive drafts of a Vision, Mission, and Operating Principles document. The final document, ratified by a Parent Crowd vote, is shown in [Textbox 2](#), and it is posted prominently on the completed website.

Textbox 2. Vision, Mission, and Operating Principles document.

Vision

Our vision is to provide a comprehensive internet resource designed by parents for parents of infants, toddlers, and preschoolers with type 1 diabetes (T1D).

Mission

The dual mission of this website is as follows:

- To ensure parents and caregivers have the information, resources, and support they need to promote the health and well-being of their child(ren) with T1D
- To provide parents and caregivers of children with T1D the information, support, and resources that they can use to enhance their own physical and mental health and well-being.

Operating Principles

1. The website content and features will be managed by the Website Committee, comprising the Researchers and Family Advisors. In all of its activities, the committee will ensure that the website is developed "by parents for parents."
2. Anyone can submit content or suggestions to the Website Committee for possible posting on the website.
3. To the extent possible, the website will offer a "one-stop" resource for parents (or other caregivers) of infants, toddlers, and preschoolers with T1D.
4. The website will offer both informational and social media resources.
5. The website will help parents and caregivers connect with others who share similar circumstances or concerns.
6. The website will provide links to reputable and helpful external resources (eg, websites, books, and agencies), its content will be kept current and will grow in response to users' needs, and all medical information on the website will be accurate and credible.
7. Users will respect each other by being polite and accepting others' diverse experiences and opinions.
8. The website will enable parents and caregivers to set their own preferences for safeguarding their privacy and confidentiality.
9. The website content will be accessible and useful to parents, providing a wide range of reading and internet use skills.
10. Although the informational content on the website will be in English, it will enable people who prefer other languages to connect with each other.

Table 1. Demographic characteristics of young children with T1D whose parents who took part in specific website development components.

Characteristics	Parent crowd group (n=153)		Diversity focus group (n=13)		Usability test participants (n=10)	
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
Child characteristics						
Age (years)	139 (90.8)	5.50 (2.00)	8 (62)	4.75 (1.39)	7 (70)	5.05 (2.61)
Age at diagnosis (years)	138 (90.2)	2.63 (1.45)	8 (62)	2.63 (1.30)	7 (70)	2.87 (1.37)
Duration of type 1 diabetes (years)	138 (90.2)	2.43 (1.97)	8 (62)	1.63 (1.19)	7 (70)	2.17 (2.89)
Most recent hemoglobin A _{1c} (%)	134 (87.6)	7.69 (0.92)	7 (54)	8.43 (0.09)	6 (60)	8.48 (1.79)

Table 2. Demographic characteristics of young children with T1D whose parents who took part in specific website development components.

Characteristics	Parent crowd group (n=153)	Diversity focus group (n=13)	Usability test participants (n=10)
Gender, n (%)	N=137	N=8	N=7
Male	65 (47.4)	3 (37.5)	4 (57.1)
Female	72 (52.5)	5 (62.5)	3 (42.9)
Race, n (%)	N=138	N=8	N=7
Caucasian	123 (88.5)	2 (25.0)	5 (71.4)
African American	2 (1.4)	5 (62.5)	1 (14.3)
Other or multiple	13 (9.4)	1 (12.5)	1 (14.3)
Ethnicity, n (%)	N=133	N=8	N=7
Hispanic	9 (6.8)	3 (37.5)	2 (28.6)
Non-Hispanic	124 (93.2)	5 (62.5)	5 (71.4)
Insulin regimen, n (%)	N=136	N=8	N=7
Insulin pump	94 (69.1)	3 (34.5)	1 (14)
Multiple daily injections	38 (27.9)	5 (62.5)	4 (57)
Conventional or sliding scale	4 (2.9)	0 (0)	2 (29)
Use of continuous glucose monitor, n (%)	N=138	N=7	N=7
Yes	96 (69.6)	5 (62.5)	4 (57.1)
No	42 (30.4)	2 (29)	3 (57.1)

Ensuring Diversity of Parent Stakeholders

Since the Parent Crowd members were disproportionately Caucasian, married, and college educated and had above average in household income, the research team constituted a 13-member Diversity Focus Group, essentially doubling minority representation on the project team, ensuring that the design process reflected the perspectives of racially, ethnically, and economically diverse parents. The Diversity Focus Group participated through videoconference from 1 of the 3 locations. The researchers condensed the 19 open-ended questions previously distributed to the Parent Crowd to 6 summative

questions posed to the Diversity Focus Group. The Focus Group results supported the working Social Ecological Model and confirmed the previous findings from the Parent Crowd. Some new examples of specific issues emerged, but the research team concluded that the perspectives of the Diversity Focus Group were very similar to those of the Parent Crowd.

Tables 1-3 summarize the demographic characteristics of the Parent crowd, participants in the Diversity Focus Group, participants in a usability testing session described below, and their YC-T1D. Usability testing participants were more diverse than the Parent Crowd members, particularly in the inclusion of 50% male caregivers within that sample.

Table 3. Demographic characteristics of parent participants who took part in specific website development components.

Characteristics	Parent crowd group (n=153)	Diversity focus group (n=13)	Usability test participants (n=10)
Parent age (years), mean (SD)	36.34 (5.6)	34.4 (7.0)	35.5 (5.2)
Relationship with child, n (%)^a			
Biological mother	129 (84.6)	8 (61.5)	6 (60.0)
Biological father	22 (14)	3 (23.1)	3 (30.0)
Other	2 (1)	2 (15.4)	1 (10.0)
Education, n (%)^a			
HS diploma	12 (7.8)	4 (33.3)	0 (0)
Some college or technical school	41 (26.8)	5 (41.7)	10 (100.0)
Bachelor's degree	54 (35.3)	1 (8.3)	0 (0)
Advanced degree	45 (29.4)	2 (16.7)	0 (0)
Occupation, n (%)^a			
Not employed outside home	44 (28.8)	4 (33.3)	3 (30.0)
Operational or technical level	29 (19.0)	4 (33.3)	0 (0.0)
Managerial level	48 (31.4)	3 (25.0)	4 (40.0)
Professional level	26 (17.0)	1 (8.3)	3 (30.0)
Household annual income, n (%)^a			
<US \$50K	32 (20.9)	5 (41.7)	2 (20.0)
US \$51K-US \$100K	63 (41.2)	5 (41.7)	8 (80.0)
US \$101K-US \$150K	34 (22.2)	2 (16.7)	0 (0.0)
>US \$150K	17 (11.1)	0 (0.0)	0 (0.0)
General internet use, n (%)^a			
Daily	103 (67.3)	4 (33.3)	7 (70.0)
Often	23 (15.0)	2 (16.7)	1 (10.0)
Sometimes	19 (12.4)	4 (33.3)	2 (20.0)
Never	3 (2.0)	1 (8.3)	0 (0)
Type 1 diabetes-related internet use, n (%)^a			
Daily	60 (29.2)	2 (16.7)	5 (50.0)
Often	45 (29.4)	1 (8.3)	1 (10.0)
Sometimes	27 (17.6)	5 (41.7)	3 (30.0)
Never	11 (7.2)	2 (16.7)	1 (10.0)

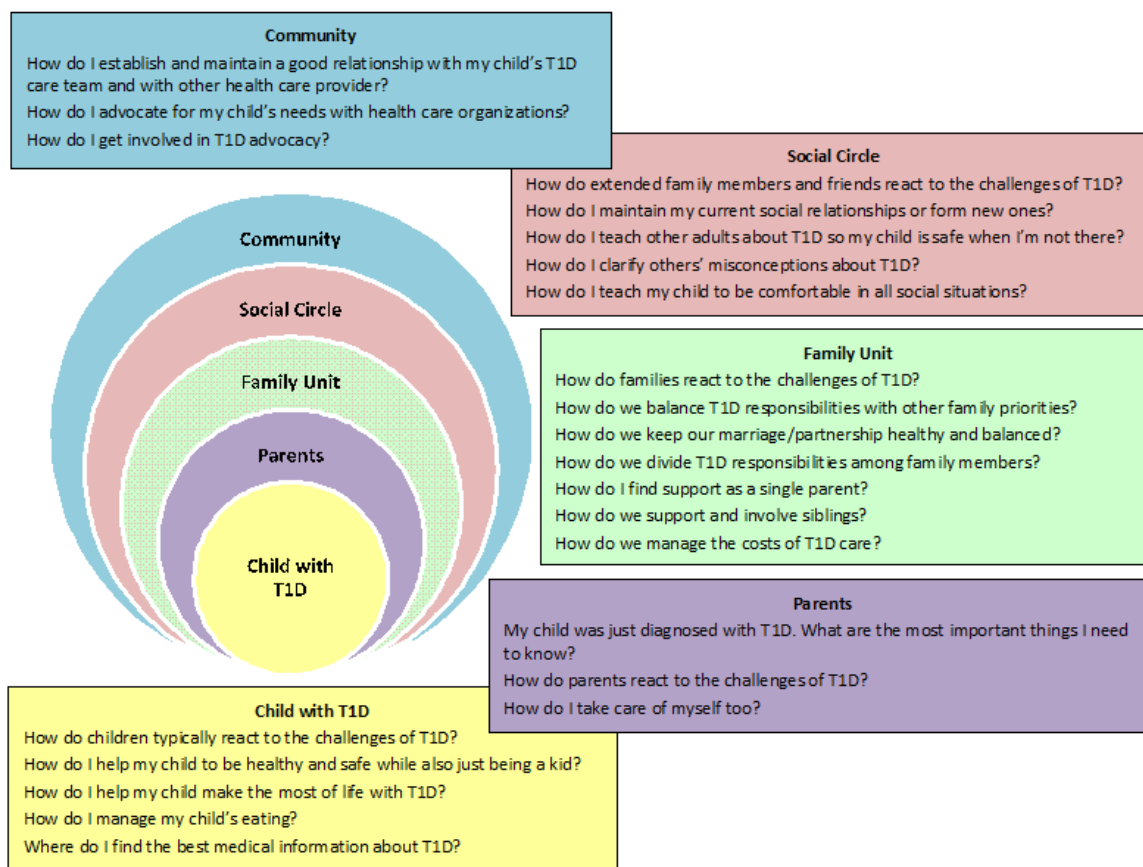
^aPercentages were calculated using a denominator consisting of the number of parents reporting on the dimension of interest. Hence, the denominators varied among the different demographic characteristics.

Identifying Website Content, Functions, and Features

As delineated in [Textbox 1](#), the Parent Crowd's responses to the 19 open-ended questions yielded voluminous information about the many ways in which raising a YC-T1D impacted every corner of their lives. The Parent Crowd then assisted the research team in condensing the perspectives they contributed into a set of 23 parenting challenges that the Web-based resource should help users address. Specifically, an initial draft of these issues was posted to the Parent Crowd members who were asked

to rate the clarity of each challenge and to provide feedback about each challenge. These challenges, shown in [Figure 2](#) as questions, served as a guide to developing the website's features, functions, and information architecture. The team also used these challenges to generate topics for parent-authored and health care professional-authored articles for the website. Furthermore, Parent Crowd members submitted "Questions for the Experts" that were compiled into topics, and then the researchers recruited specific health care professionals to contribute additional articles on those topics.

Figure 2. A social ecological taxonomy of influences on family management of type 1 diabetes (T1D) in very young children.



Assessing How Patients Currently Perform the Targeted Tasks

A very high proportion of the Parent Crowd indicated weekly or more frequent use of the internet or social media for both general and T1D-specific purposes. However, the Parent Crowd members expressed considerable dissatisfaction with the availability of credible information on the internet that is specific to YC-T1D. They also reported receiving limited T1D-specific, in-person support because of friends and family members not being able to understand the complexities of raising YC-T1D. Hence, the Parent Crowd members tended to describe themselves as socially isolated, as having relatively little contact or support from other parents in their situation and as being largely alone in finding solutions to T1D challenges. Based on this input, the research team reasoned that the needs of parents of YC-T1D could be well served if they had continuous access to a Web-based resource that provides them with the information and support they need to optimize their children's health and development, while also preserving their own health and well-being.

Selecting the Appropriate Platform(s)

The development team elected to develop the Web-based resource using responsive Web design so it could be accessible by the full range of devices and screen sizes, including smartphones, desktop and laptop personal computers, notebooks, and tablet devices.

Principle 2: Measure Usability Empirically

Selection of Usability Factors to Measure Empirically

Since 94% of 18-29 year olds and 89% of 30-49 year olds use smartphones [39], the research team decided to focus its usability testing work on that platform. Other reasons for deciding to focus first on the mobile phone platform rather than on the personal computer or notebook platforms were that the Web developers asserted that it is easier and less expensive to "scale up" the mobile phone platform rather than to "scale down" other platforms, that the project lacked the funds to conduct usability testing for all 3 platforms, and that the mobile phone platform was more likely to reveal navigation problems than the other 2 platforms. An expert in user-centered website design guided the team's specification of activities for parents to perform on the website. The team assessed participants' perspectives of the nature and purposes of the website and ease of navigation for common tasks and the degree to which the architecture and features were intuitive.

Laboratory Evaluation

The formal usability testing session targeted the assessment of these activities by parents of YC-T1D without prior knowledge of the team's development of this resource. With an expert in usability testing, the team compiled a 46-item structured agenda (Multimedia Appendix 1) for the testing sessions. The team completed 1-hour individual usability testing sessions with 10 parents over 2 days at a marketing research firm. Participants used their own mobile phones to log in to a website prototype

and then completed the usability testing session. After a brief orientation, the facilitator placed the parent's mobile phone in a frame that held it stationary. A video camcorder placed above the phone recorded participants' actions in response to the instructions. Participants were asked to describe aloud their reasoning as they navigated through these tasks. Other members of the research team observed the session through a one-way vision screen and could prompt the facilitator to ask follow-up questions. Each parent received US \$125 compensation for their efforts.

Each session began with ascertaining participants' general and T1D-specific life circumstances, asked individuals to complete various tasks, and concluded with an overall evaluation of the website's clarity and ease of use, as well as suggested changes to the website. The tasks that each individual was asked to perform included the following: carrying out instructions related to logging into the website; navigating to several different components of the website; reading and reacting to several different articles on the website; after exploring the website, inferring the website's intended users and objectives; demonstrating how to submit an article, photo, or video clip for posting on the website; returning to the home page from varied locations; and using the website "Search" function.

Each session was videorecorded and audiorecorded for subsequent analysis. Based on the usability testing results, the team incorporated 26 design improvements to the final website appearance, structure, and functions. These included the following: changing the icon signifying the "menu" function to a more intuitive icon; making navigation to the home page more salient; reducing wordiness and font size to limit the need for scrolling; eliminating the prompt for "newly diagnosed" after each user's first log-in; reducing the size of parent quotes on home page as it occupied too much space; emphasizing the "Contact Us" link by moving the tab to the home page menu bar; making article overviews as brief as possible; and other similar changes.

Principle 3: Design and Test Usability Iteratively

Field Study

As the website design proceeded, the research team delivered 3 webinars over about 3 months to the Parent Crowd to collect and integrate their feedback on the website structure, features, and content. The content and topics of the 3 sequential webinars provided the following: Webinar 1, review of the site map and wireframes; Webinar 2, review of the home page and article page; and Webinar 3, a tour of the completed website. Parents could access the webinars in real time (permitting the submission of written comments or questions to the presenter) or through a recording of the session. After each webinar, the Parent Crowd members responded to open-ended questions, and the responses were integrated into the working prototype. These sessions also confirmed that the website development was congruent with the Parent Crowd's specifications and with the Website Vision, Mission, and Operating Principles, shown in [Textbox 2](#). One parent expressed impatience with the duration of the design and development process, which required about 21 months rather than the projected upper limit of 18 months.

Final Evaluation Session

The final webinar demonstrated the completed website to Parent Crowd members who participated in either the live or recorded session at their convenience. The purpose of the webinar was to notify parents of the completion of the website, to invite them to register as users, and to request their input after exposure to the website. About 2 weeks after the webinar, the researchers distributed 9 pertinent open-ended, qualitative questions to the parents who had used the website. Transcripts of the verbatim responses were coded by trained members of the research team and interpreted by the investigators in consultation with an expert qualitative researcher. Parents' responses confirmed that the website met their expectations; was user-friendly and engaging, contained appropriate content; was positive and encouraging in tone; and was free of difficult, confusing, or tangential information. The parents did not identify any substantial flaws in the website design or functionality.

Now that the website is functional, the research team has begun recruiting eligible parents to enroll in an RCT comparing usual care for T1D with and without access to the website. The RCT will enroll parents of patients from Nemours Children's Health System by direct contact, as well as eligible parents of YC-T1D who receive care elsewhere, using T1D-focused social media groups, websites, and blogs. Regardless of the recruitment method, parents' informed consent and participation in the RCT will occur solely over the Web. Outcome measures will include indices of parental and child outcomes measured at 0, 6, and 12 months. Parental outcomes include measures of their adjustment for managing their children's T1D, treatment adherence, quality of life, psychiatric symptoms, social support, parenting self-efficacy, T1D family routines, fear of hypoglycemia, and benefit finding. Child outcome measures include hemoglobin A_{1c} and general and T1D-specific behavior problems. Members of the Parent Crowd who guided the creation of this resource can continue using the website during the RCT, but they will not otherwise participate in the research procedures.

Results

The research team demonstrated serious and continuing engagement of key stakeholders through a Web-based community of 153 parents of YC-T1D supplemented by a Diversity Focus Group comprising 13 parents representing racial and ethnic minorities, as well as the involvement of health care professionals specializing in T1D and experts in qualitative research, Web development, and usability testing. The consistent involvement of 6 Family Advisors, who were also members of the Parent Crowd, ensured that design decisions reflected the parents' perspectives and preferences. This work thoroughly characterized the pervasive challenges faced by these parents in their daily lives and yielded a taxonomy based on a socioecological model that drove the design of the structure, content, and functionality of a Web-based coping resource designed by and for these parents.

The collaborative adoption of a Website Mission, Vision, and Operating Principles document clarified the goals of the design and development phase of this initiative. Results of 15 polls

and surveys distributed to the Parent Crowd characterized the internet access and utilization habits of this population and identified specific website content and features that parents nominated as being potentially helpful. For example, the Parent Crowd members ranked their 5 favorite T1D Web-based resources and their preferences for the website's social networking platform (ie, a built-in platform vs a Facebook group). A structured process for naming the website resulted in the selection of "The New Normal" as the main website name, "The New Normal: A Community of Parents of Young Children with Type 1 Diabetes" as the home page by-line, and "TheNewNormalT1D.com" as the domain name. Finally, formal user testing and periodic webinar demonstrations of design progress further engaged the Parent Crowd in the website design process. This work yielded a functioning, private website that the researchers are now evaluating formally. All users must be authenticated to access the website with secure credentials provided by site administrators. The site is also hosted on enterprise-level cloud hosting that includes a firewall to protect against website hacks and attacks. The site has recurring backups to ensure data security.

The home page for The New Normal website, shown in [Figure 3](#), demonstrates the functions, history, and development of the website; guidance on using the website's features; articles written by parents or health professionals on topics suggested by parents; links to T1D-related news articles; and the Parent-to-Parent Forum, a private social media platform enabling parents to interact around topics of shared interest or discuss website articles. Other features include parent-contributed diagnosis stories and open letters to other parents, a photo gallery, a glossary of T1D technical terms, and a "Contact Us" utility that provides users with a variety of options such as offering the suggested content for articles, submitting news items, or reporting potentially erroneous statements that appear on the website. When a parent first accesses the website, an alert appears asking users if one or more of their children were recently diagnosed with T1D. If the parent clicks on "Yes," links appear to content suitable to parents who are new to this role, including opportunities for learning or reviewing the fundamentals of T1D care, articles that describe typical reactions and adjustment to this experience, and articles that provide alternative methods for parent and child coping with the new diagnosis.

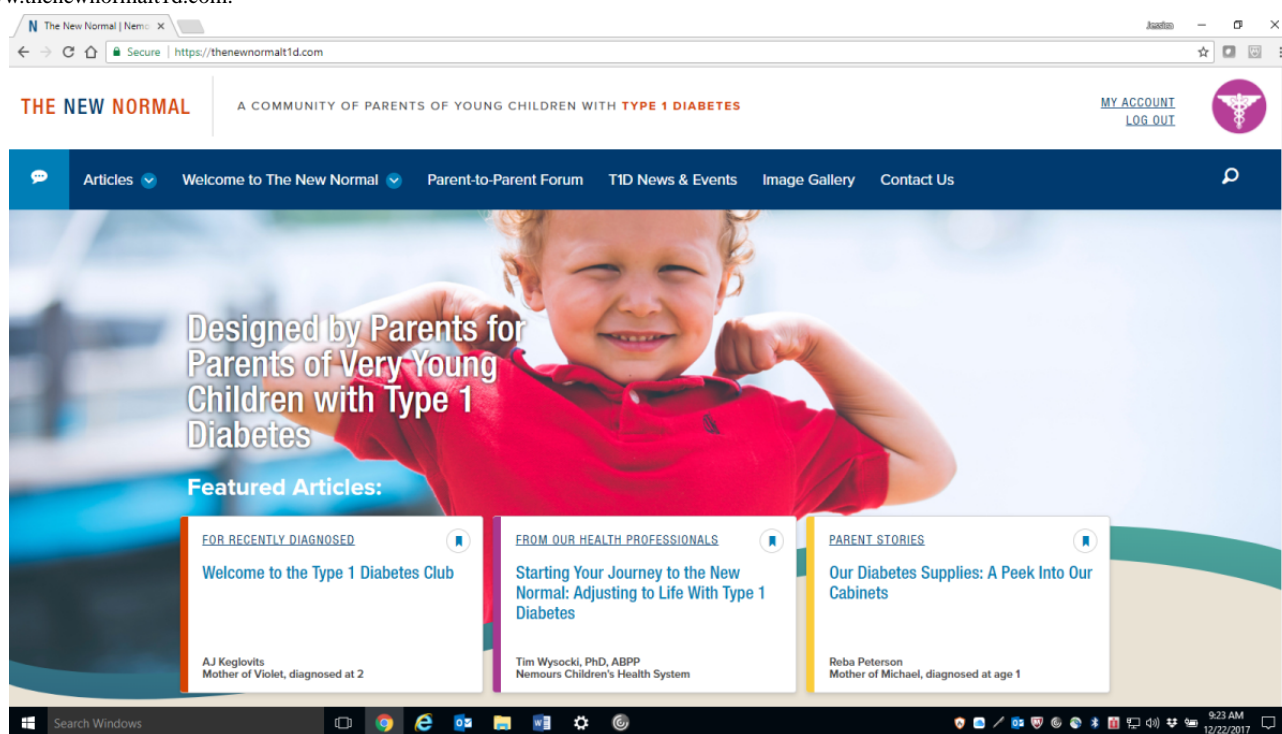
The Parent Crowd, in accord with the team's professional Web development partners, advocated for continuously evolving content such that the website could be responsive to parent users' needs; fresh and engaging to invite users to return repeatedly; and relevant to current developments in diabetes

research, treatment, and health care policy. Consequently, the researchers designed the site to enable such features as archiving of discussion threads on the Parent-to-Parent Forum, multiple mechanisms for parent users to offer suggestions for new article topics, regular refreshing of news articles highlighted on the site, and periodic refreshing of photo images displayed on the site. The researchers regularly recruit professionals to contribute articles for the website on their areas of expertise and parents to write articles on special issues, such as one mother's efforts to obtain a dog for her son trained to detect his hypoglycemic episodes. Articles or other website features that are not visited frequently will be removed, edited, or replaced.

The website utilizes the Woopra platform to track, compile, and analyze users' patterns of website use. These data can be viewed on aggregated, subgroup, or individual user levels to identify pages relative to the frequency of use, frequency of return visits, and compilation of comments about article content. Monitoring and analysis of these data in the RCT will permit a careful understanding of who does and does not use the website, what users are most attracted to access, and what kinds of content attract users to revisit the website.

All website content is searchable using tags drawn from parents' responses to the initial open-ended questions. The Parent Crowd expressed that the website should include strong safeguards to ensure that only medically accurate information appeared on the site. Assurance of medical credibility occurs during the editorial review of articles that parents or health professionals submit. Health professionals who are invited to contribute articles for the website are recognized experts in their respective disciplines. Articles submitted by either parent or professional authors are vetted, edited, and screened for scientific and medical credibility before posting on the website. The website manager, along with the website clinical directors, who are both pediatric psychologists with extensive T1D experience, conduct an initial review and then determine whether secondary review by the website medical advisor (JML) or another appropriate professional is needed. Additionally, the website includes a mechanism for parent users to report questionable content to the research team. Postings on the Parent-to-Parent Forum carry the highest risk of containing misleading or incorrect information, but several processes may prevent or reduce the appearance of inappropriate information on the website and ensure the prompt editing or removal of inappropriate content that is posted. These include parental self-policing, daily monitoring by the website manager and clinical directors, the Vision, Mission, and Operating Principles document that was adopted by the Parent Crowd and easily accessible on the forum, and the fact that this is a closed Web-based community.

Figure 3. Screenshot of the website homepage home page with a menu bar depicting key functions and featured articles. Source: www.thenewnormalt1d.com.



Discussion

This paper describes the application of principles of UCD to the crowdsourced creation of a Web-based coping resource developed by and for parents of YC-T1D. The design and development process sought extensive input from a Web-based community of parents that thoroughly characterized many challenges faced by these parents in seeking to preserve and optimize their children's health, well-being, and overall growth and development. The preliminary qualitative work laid the foundations for collaborative specification of the structure, features, and content of the website and included the drafting, refinement, and adoption of a Vision, Mission, and Operating Principles document. Formal usability testing and periodic demonstrations of website design progress ensured that the website structure, features, and content embodied the Parent Crowd's aspirations and preferences. The website is an organic resource that will continue to expand as parents contribute new articles, health care professionals contribute articles on topics requested by parents, and the use of the Parent-to-Parent Forum evolves over time.

An RCT is evaluating the potential benefits of website use in terms of the effects on child and parent outcomes. Unlike other interventions in which there is a specified number of sessions, doses, etc, there is no specified "end" to the use of the website, as it will be continuously updated. Thus, the research team also developed a website sustainability plan that includes a variety of initiatives designed to preserve the availability of this resource, including the submission of follow-up grant applications, solicitation of in-kind support for website hosting and maintenance from the host organization, cultivation of relationships with diabetes advocacy organizations that could assume responsibility for the website, and seeking philanthropic

support from potential donors or corporate sponsors. The website could easily be the "go-to" resource for all families with children aged <6 years having a diagnosis of T1D. It was designed to provide a one-stop source for accurate information, practical help, and mutual support for these parents, essentially constituting a continuously accessible, highly specialized diabetes support group in cyberspace. This study provides a template for developing Web-based resources targeting other life challenges such as medical conditions, traumatic injuries, major changes in life circumstances, or other stressful life events. In addition to its applications to the website development, clinical researchers could apply the basic approach employed here in the development and evaluation of other digital health apps for smartphones, desktop personal computers, or tablet platforms.

Although the UCD process capitalized on the input of 4 groups of potential users (ie, Family Advisors, Parent Crowd, Diversity Focus Group, and Usability Testing Participants), there are several limitations to the study. Compared with traditional qualitative research, the crowdsourcing data collection method engaged a larger, geographically diverse sample to obtain a holistic perspective of the complex challenges faced by parents of YC-T1D. However, the Parent Crowd was not so diverse in terms of race, ethnicity, or socioeconomic status, and the website design should anticipate the needs and preferences of users with varied characteristics. Although the Parent Crowd had limited racial or ethnic diversity, our Focus Group participants consistently confirmed the data obtained previously from the larger Parent Crowd sample. Additionally, the majority of parent participants had YC-T1D who used insulin pumps and continuous glucose monitors and also had a lower-than-average mean hemoglobin A_{1c} [40]. This limitation raises concerns about the generalizability of findings across parents who have YC-T1D

and are prescribed more conventional, less-intensive insulin regimens. However, a caveat that applies to UCD principles, as well as developing Web-based interventions for health, is that some populations may be more interested in and able to benefit from participating than others. Perrin and Duggan [41] recently reported the results of a Pew Research Center study on Americans' internet use from 2000 to 2015. The internet use had essentially reached saturation among younger, more educated, more affluent people by 2015, while internet access and use was lower, but increasing slowly among older, less-educated people from lower socioeconomic strata. Some subpopulations, thus, continue to be "digital have-nots" who lack access to the internet. A certain level of fluency is also required, both in terms of comfort with technology and average to above average command of written language. The final limitation is that about one-third of participants had children who were aged between 6 and 10 years and were asked to report on their experiences before their child turned 6. For these parents, data were retrospective, and this might have introduced response bias. Nonetheless, parents of younger children, as well

as the Family Advisors, often expressed that perspectives of parents whose children with T1D who were then aged >6 years was critical to the optimal design of the website.

UCD could play an important role in the ongoing development of such technologies as closed-loop insulin delivery systems [42], flash glucose monitoring [43], and cloud-based sharing of real-time blood glucose data [44]. These inventors and companies are not obligated to report on their engagement of key stakeholders from the beginning and throughout the completion of the design process and may choose to protect that information as proprietary. However, there would appear to be significant potential advantages to employing UCD principles, by ensuring that user perspectives precede, rather than follow, the design of the product in question. The engagement of stakeholders as key partners in the design of health interventions may slow the development process, but it may also yield interventions that are attractive and acceptable to end users, which they actually use and that achieve desired improvements in health and well-being.

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The authors thank the parents, health care providers, and Web development professionals who participated in the creation of the website. Interested readers can access a recording of the last webinar demonstrating the website's structure, features, and content by navigating to <https://vimeo.com/247426180> (Password: NewNormT1D!). This work was supported by a grant from the National Institutes of Health (Grant #1-DP3-DK108198) awarded to the first 2 authors (multiple principal investigators).

Conflicts of Interest

None declared.

Multimedia Appendix 1

Usability Testing Script.

[[PDF File \(Adobe PDF File\), 81KB - diabetes_v3i4e16_app1.pdf](#)]

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Abbreviations

- RCT:** randomized controlled trial
T1D: type 1 diabetes
UCD: user-centered design
YC-T1D: young children with T1D

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Original Paper

Content Analysis of Metaphors About Hypertension and Diabetes on Twitter: Exploratory Mixed-Methods Study

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Abstract

Background: Widespread metaphors contribute to the public's understanding of health. Prior work has characterized the metaphors used to describe cancer and AIDS. Less is known about the metaphors characterizing cardiovascular disease.

Objective: The objective of our study was to characterize the metaphors that Twitter users employ in discussing hypertension and diabetes.

Methods: We filtered approximately 10 billion tweets for keywords related to diabetes and hypertension. We coded a random subset of 5000 tweets for the presence of metaphor and the type of metaphor employed.

Results: Among the 5000 tweets, we identified 797 (15.9%) about hypertension or diabetes that employed metaphors. When discussing the development of heart disease, Twitter users described the disease as a journey (n=202), as transmittable (n=116), as an object (n=49), or as being person-like (n=15). In discussing the experience of these diseases, some Twitter users employed war metaphors (n=101). Other users described the challenge to control their disease (n=34), the disease as an agent (n=58), or their bodies as machines (n=205).

Conclusions: Metaphors are used frequently by Twitter users in their discussion of hypertension and diabetes. These metaphors can help to guide communication between patients and providers to improve public health.

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KEYWORDS

cardiovascular diseases; language; metaphor; social media; hypertension; diabetes mellitus

Introduction

Communicating About Health Through Metaphors

Humans often communicate about health using metaphors. Physicians were found to use metaphors in 64% of conversations

with patients with serious illness [1], and patients also use metaphors when discussing their own illnesses [2].

Prior work has focused on characterizing metaphors used to describe patients' experience of cancer, tuberculosis, and HIV [3-5]. Although cardiovascular disease affects more than 80

million Americans, less is known about the metaphors used by patients to describe heart disease [6]. Characterizing these metaphors might inform patient-provider communication by promoting understanding of the public's framing of disease.

Metaphor is an efficient way to link conceptual domains, which allows us to make inferences among seemingly unrelated items or events [7]. Taken in the aggregate, metaphors can help us understand higher-order cultural frameworks about ways that the world works. Finally, metaphors help to perform the task of analogic reasoning [8].

Objective

Prior work has evaluated health-related metaphors largely through surveys and patient recall. These approaches may miss the metaphors of day-to-day conversation between people. The social media network Twitter is increasingly used by researchers to analyze patient language around health [9]. Previously, we showed that almost half of a sample of cardiovascular-related tweets contained metaphorical language [10]. In this study, we expanded this work and characterized metaphors in tweets about hypertension and diabetes.

Methods

Study Design

This was a sequential, exploratory, mixed-methods study of Twitter data relating to hypertension and diabetes.

Data Source

Identification of Tweets

To identify tweets about hypertension and diabetes, we used the standard Twitter application programming interface (Twitter, Inc, San Francisco, CA, USA) [10].

From a random 10% sample of tweets over the 6-year period from July 2009 to February 2015, we searched approximately 10 billion tweets for keywords related to hypertension and diabetes [11,12]. To generate these keywords, we used the Unified Medical Language System, Consumer Health Vocabulary, and the agreement of study authors. Keywords identified were hypertension (high blood pressure) and diabetes (blood sugar, mellitus) [10-12].

We limited our analysis to English-language tweets that could be mapped to a US county. Additional details about Twitter processing and data extraction are described elsewhere [10].

Metaphor Coding

Metaphor was defined as a representation of a subject rather than the subject itself, or a non-reality-based statement with an analog in the real world.

To identify tweets containing metaphors, 2 coders (CLR and CM) evaluated a random subset of 1000 tweets about hypertension and 4000 tweets about diabetes for the presence of metaphor, adjudicating differences with a larger group that included 3 other authors. The characteristics of the metaphors were coded into metaphor types. These 5000 tweets represented approximately 1% of the total tweets returned using the search

strategy above. After coding 5000 tweets, total agreement in each category was greater than 90% with a kappa score of .77.

We performed data coding and analysis in NVivo version 10.0 (QSR International).

Results

Of the 4000 diabetes tweets, 12.1% (n=482) contained metaphors, while 31.5% (n=315) of the 1000 hypertension tweets contained metaphor. We further categorized metaphorical tweets into 2 groups: metaphors that described the development of disease and those that described the experience of disease.

Development of Disease

Four themes in the development of disease emerged: journey to disease, disease as transmittable, disease as object, and disease as actor (Table 1).

Journey to Disease

Many tweets described acquisition of the disease as a journey that originated with a "vector" and travelled along a path to the person (202/312, 64.7%). These tweets described the disease as being acquired through a single encounter (eg, "You can probably get high blood pressure from one large fry at McDonald's") or described developing the disease as a culmination of many influences (eg, the hashtag #roadtodabetes).

Disease as Transmittable

Other Twitter users described hypertension and diabetes as transmittable diseases (eg, "Don't talk to me, you're giving me diabetes" or "I have to avoid diabetes like the plague").

Disease as Object

Some users described the disease as an object that was tangible. Often these tweets contained metaphors about the disease existing within food (eg, "I could taste the diabetes"). This metaphor was more frequently used in the context of diabetes than in hypertension (48/211, 22.7% vs 1/101, 1.0%).

Disease as an Actor

Some tweets labeled diabetes and hypertension as sinister agents (eg, "Hypertension dangers lurking in obese kids").

Experience of Disease

Four themes in the experience of disease emerged: body as machine, disease as difficult to control, war and destruction, and disease as agent (Table 1).

Body as Machine

Many tweets represented the body as a machine and the disease as an interruption of the machine's functioning (eg, "Shuttling blood sugar into cells"). These mechanical metaphors were more frequently used to describe hypertension (167/214, 78.0%) than diabetes (38/271, 14.0%).

Disease as Difficult to Control

Some tweets used metaphors that helped to demonstrate the difficulty of controlling one's disease (eg, "Stepped care approach to tackle uncontrolled high blood pressure").

Table 1. Metaphors used in tweets to describe the development and experience of diabetes and hypertension^a.

Metaphor themes	Diabetes, n (%)	Hypertension, n (%)	Example tweets
Development of disease (diabetes: n=211; hypertension: n=101)			
Journey to disease	140 (66.4)	62 (61.4)	<ul style="list-style-type: none"> You can probably get high blood pressure from one large fry at McDonald's #roadtodiabetes Tips on how to prevent the path to diabetes Couples who develop diabetes together stay together! I really feel the diabetes coming
Transmittable	53 (25.1)	63 (62.4)	<ul style="list-style-type: none"> I'd rather catch diabetes than feels I have to avoid diabetes like the plague Stop! you'll give me diabetes... Don't talk to me, you're giving me diabetes. Salty enough to give high blood pressure
Disease as object	48 (22.7)	1 (1.0)	<ul style="list-style-type: none"> I could taste the diabetes Mountain dew tastes like diabetes and depression Diabetes for breakfast tomorrow yay I asked for a brownie and instead I got diabetes That's a nice cart full of diabetes you've got there
Disease as actor	12 (5.7)	3 (3.0)	<ul style="list-style-type: none"> Hypertension dangers lurking in obese kids When high blood pressure attack No diabetes allowed Like sugar? So does...diabetes Don't die on me! No diabetes allowed. LOL
Experience of disease (diabetes: n=271; hypertension: n=214)			
Mechanical	38 (14.0)	167 (78.0)	<ul style="list-style-type: none"> Actually, beer IS good for lowering high blood pressure Shuttling blood sugar into the cells My blood sugar drops drastically today...I feel like my energy has been drained. Still feeling weak until now. I be low then I be high it's like a battle knife to a gun fight no need to worry it's the story of my life blood sugar I just had a crazy blood sugar spike
Control	31 (11.4)	13 (6.1)	<ul style="list-style-type: none"> Control your high blood pressure Stepped care approach to tackle uncontrolled high blood pressure The best exercise to control high blood pressure seems to be virtually any exercise....Get up and get going! Telehealth may help patients control high blood pressure, but engagement is a barrier The message is to prevent and control diabetes
War	84 (31.0)	17 (8.0)	<ul style="list-style-type: none"> Diabetes destroyer In the fight against high blood pressure, potassium is a powerful weapon Simple Tips On How to Battle Diabetes The American Diabetes Association is leading the fight against the deadly consequences of diabetes Slash high blood pressure
Disease as actor	38 (14.0)	20 (9.3)	<ul style="list-style-type: none"> Hypertension is a silent killer Oh diabetes, you're the reason I don't sleep Diabetes messing with my eyes Diabetes doesn't define me, it explains me My blood sugar plays funny little tricks on me

^aPercentages equal more than 100%, as some tweets fit into more than one theme.

War and Destruction

Some tweets used militaristic metaphors, including words such as “destroyer,” “fight,” and “battle” (eg, “The American

Diabetes Association is leading the fight against the deadly consequences of diabetes”).

Disease as an Actor

As in the tweets describing the development of disease, in tweets about the experience of disease, users often represented diabetes or hypertension as agents of evil (eg, “Hypertension is a silent killer. Monitor your BP [blood pressure] now...”).

Discussion

Principal Findings

This study had two main findings. First, metaphor is a substantial part of how Twitter users communicate information about hypertension and diabetes. Second, the conceptualization of disease implied by the metaphors described often conflicts with biomedical understanding of the biological underpinnings of disease.

In the 1970s, Susan Sontag described the widespread use of metaphors in communication about cancer and HIV/AIDS [5]. She argued that the use of metaphorical language about illness could adversely influence public attitudes or clinicians’ practices and, in the end, patients’ experience.

In contrast, less has been studied about heart disease. A better understanding of metaphors about hypertension and diabetes offers promise for understanding what a population thinks about the etiology, treatment, and progression of disease. This “code” could provide insights into a disconnect between a health condition and its treatment and management.

Metaphors may be used by patients seeking to discuss their condition with family and friends and to relate to other patients experiencing the same disease. Patients affected by diseases associated with great morbidity and mortality may have greater motivation to formulate conceptual frameworks to explain their disease, allowing them to better cope with the complex, medical reality of their condition.

According to our results, the general population’s understanding of hypertension seems to be narrower than that of diabetes. A higher percentage of metaphors were employed in the sample of hypertension tweets than in the diabetes tweets, yet the majority of those metaphors associated hypertension with a purely mechanical understanding of the experience of the

disease, such as the raising or lowering of pressure within the body (167/214, 78.0%). Patients may have fewer approaches to thinking about hypertension because it is less salient than diabetes—that is, it is less likely to cause direct symptoms, less likely to require time-intensive management on the part of the patient, and less likely to be perceived as fatal.

While some of the metaphor themes we found have been previously described in the literature, others are newly described as metaphor, such as disease as object or disease as actor [5,13]. These metaphors may be new because of our focus on heart disease and diabetes rather than cancer or infectious disease, or perhaps because Twitter provides a window into the public’s spontaneous language about disease.

While some of the metaphors described here are consistent with our biomedical understanding of disease (eg, body as machine), other metaphors are incongruent with the pathophysiology of the disease (eg, disease as object, disease as transmittable). Many of these metaphors were employed in jest. It remains unclear whether the use of metaphors inconsistent with the medical community’s understanding of disease represents a misunderstanding to be corrected, or an effective rhetorical approach to be appropriated.

Limitations

This study had several limitations. This study characterized only US-based English-language tweets; additional metaphors would have emerged if we had studied a broader sample of tweets. While we removed duplicate tweets, we counted each retweet individually in this study, as we believed that the propagation of any given message reflects the salience of that metaphor.

Conclusions

Metaphors are windows into the shared understandings that laypeople have about illness. They have potential to provide physicians with tools to explain difficult scientific concepts in a culturally appropriate context. However, these benefits must be balanced with the potential harm that metaphors can induce by propagating inaccurate or potentially stigmatizing language [3].

Conflicts of Interest

None declared.

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Original Paper

The Phased Implementation of a National Telehealth Weight Management Program for Veterans: Mixed-Methods Program Evaluation

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Abstract

Background: The burden of obesity is high among US veterans, yet many face barriers to engaging in in-person, facility-based treatment programs. To improve access to weight-management services, the Veterans Health Administration (VHA) developed *TeleMOVE*, a home-based, 82-day curriculum that utilizes in-home messaging devices to promote weight loss in VHA patients facing barriers to accessing facility-based services.

Objective: The primary aim was to establish preliminary evidence for the program by comparing outcomes for *TeleMOVE* with standard, facility-based MOVE weight-management services (group, individual modalities) over the evaluation period based on the number of patients enrolled per site and the program's clinical effectiveness, as demonstrated by average weight lost per patient. The secondary aim was to understand factors influencing *TeleMOVE* implementation variability across demonstration sites to develop recommendations to improve national program dissemination.

Methods: We employed a formative mixed-methods design to evaluate the phased implementation of *TeleMOVE* at 9 demonstration sites and compare patient- and site-level measures of program uptake. Data were collected between October 1, 2009 and September 30, 2011. Patient-level program outcomes were extracted from VHA patient care databases to evaluate program enrollment rates and clinical outcomes. To assess preliminary clinical effectiveness, weight loss outcomes for veterans who enrolled in *TeleMOVE* were compared with outcomes for veterans enrolled in standard MOVE! at each demonstration site, as well as with national averages during the first 2 years of program implementation. For the secondary aim, we invited program stakeholders to participate in 2 rounds of semistructured interviews about aspects of *TeleMOVE* implementation processes, site-level contextual factors, and program delivery. Twenty-eight stakeholders participated in audio-recorded interviews.

Results: Although stakeholders at 3 sites declined to be interviewed, objective program uptake was high at 2 sites, delayed-high at 2 sites, and low at 5 sites. At 6 months post enrollment, the mean weight loss was comparable for *TeleMOVE* (n=417) and MOVE! (n=1543) participants at -5.2 lb (SD 14.4) and -5.1 lb (SD 12.2), respectively (P=.91). All sites reported high program complexity because *TeleMOVE* required more staff time per participant than MOVE! due to logistical and technical assistance issues related to the devices. High-uptake sites overcame implementation challenges by leveraging communication networks with stakeholders, adapting the program to patient needs whenever possible, setting programmatic goals and monitoring feedback of results, and taking time to reflect and evaluate on delivery to foster incremental delivery improvements, whereas low-uptake sites reported less leadership support and effective communication among stakeholders.

Conclusions: This implementation evaluation of a clinical telehealth program demonstrated the value of partnership-based research in which researchers not only provided operational leaders with feedback regarding the effectiveness of a new program

but also relevant feedback into contextual factors related to program implementation to enable adaptations for national deployment efforts.

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KEYWORDS

obesity; veterans health; telemedicine; adoption; qualitative research; self-management

Introduction

Background

In 2016, 42% of the patients receiving care in the Veterans Health Administration (VHA) were obese and 37% were overweight, putting these individuals at risk for obesity-related comorbidity, functional impairment, and diminished quality of life [1,2]. Since 2006, VHA patients have had access to an evidenced-based national weight-management program called MOVE! [1,3]. MOVE! programming relies heavily on group- or individual-based psychoeducational modes of delivery that require patients to visit a facility to receive face-to-face care [4,5]. However, for some veterans seeking phone-based counseling, many facilities have difficulty providing phone-based support due to insufficient staff time or training [6,7]. Furthermore, many patients have difficulty attending on-site programming due to barriers related to logistics (cost, distance, and time), transportation, weather, and conflicts with the scheduled times of available programming [8].

To address these access barriers, the VHA National Center for Health Prevention and Disease Prevention (NCP), which oversees MOVE!, collaborated with the VHA Telehealth Services Home Telehealth (HT) Program to develop a telehealth program called *TeleMOVE*. The goal of this joint effort was to combine MOVE! content with HT's strengths in deploying innovative health informatics, disease management, and telehealth technologies to overcome barriers to care by delivering coordinated and supportive care management through automated communication protocols [9,10]. *TeleMOVE* was created for delivery via asynchronous in-home messaging devices, which collect and transmit (store and forward) patient data from the patient to a care coordinator at the facility overseeing care. These devices enable clinicians to prospectively monitor and support patient self-management activities more efficiently and allow for a greater number of patients to engage in programming than relying on conventional face-to-face or phone-counseling protocols.

The impetus for rapid *TeleMOVE* implementation was driven by the need for the VHA to increase access to care services for veterans, particularly in rural regions, and less by the evidence for the application of telehealth technology to obesity treatment. The adoption of in-home messaging devices was informed by clinical evidence supporting the benefit of intensive monitoring for weight management through regular engagement in self-weighing, self-guided psychoeducational materials, and helping patients feel accountable to their health care team, particularly through regular brief motivational counseling phone calls with an interventionist such as an HT clinician [11-13].

Although there was evidence for the efficacy of individual voice recognition (IVR) and phone coaching for weight management, studies of in-home messaging devices had not been rigorously evaluated for health promotion application before *TeleMOVE* implementation. VHA policy leaders recognized that the implementation of this untested innovation would benefit from a systematic phased implementation in which VHA researchers employed pragmatic research methods to rapidly and rigorously evaluate the program to identify implementation barriers, assess clinical impact, and develop recommendations to inform national program dissemination efforts [14-16]. National leaders encouraged demonstration sites to adopt the mantra, "Learn, evaluate, and improve," consistent with the principles of a learning health care system [17].

Objectives

This implementation evaluation had 2 aims. First, we sought to establish preliminary evidence for the impact of *TeleMOVE* by measuring patient engagement (enrollment numbers), as well as to assess the program's clinical effectiveness to yield weight loss by comparing weight loss outcomes with similar patients enrolled in existing facility-based MOVE! weight management services at the participating demonstration sites. Second, we examined variability in *TeleMOVE* implementation across demonstration sites using qualitative methods to identify contextual factors that distinguished facilities with high program implementation compared with those with poor indicators of implementation. We hypothesized that sites with higher uptake of *TeleMOVE* would demonstrate greater levels of program enrollment, average weight loss per participant, and theory-based constructs of program implementation relative to low-uptake sites using the Consolidated Framework for Implementation Research (CFIR) [18,19] to assess 39 relevant constructs to the implementation of new interventions at 5 domains or levels of assessment (intervention characteristics; inner and outer setting in which the implementation occurs; characteristics of the individuals involved in the implementation; and the process of implementation itself). Ultimately, the goal of this partnership-based implementation evaluation was for researchers to provide policy leaders with insights into factors affecting implementation and sustainment of the innovation to improve program dissemination efforts throughout VHA.

Methods

Study Design

We used a formative mixed-methods design to evaluate implementation of *TeleMOVE* across 9 Veterans Health Administration medical centers (VAMC) over a 2-year period using a parallel in-person MOVE! cohort as a nonrandomized comparison group for quantitative analyses and qualitative

interview methods to understand how contextual organizational factors influenced variability in *TeleMOVE* implementation uptake across sites.

Setting

To facilitate organizational learning, *TeleMOVE!* was implemented in a systematic, multi-phased deployment that is described in Table 1. The first phase began with national operational stakeholders planning the program rollout in the first half of 2009 and recruiting a single VAMC that specialized in telehealth programming to carry out a 3-month single-site demonstration beginning in September 2009. Despite not being the focus of this evaluation, a summary of implementation activities from phase 1 are provided to illustrate the benefit of employing this single site to develop initial implementation toolkit resources to support scale-up and further iterative testing at additional demonstration sites. This study assessed program implementation at 9 VAMCs from 3 VHA regional health

networks in the northeastern, southeastern, and middle southern United States that volunteered to participate in phase 2 of the systematic implementation between October 1, 2009 and February 28, 2010. Follow-up data collection at these 9 sites continued until September 30, 2011 to evaluate long-term implementation outcomes.

Phase 2 began in October 2009, with an Web-based training conference about *TeleMOVE*. Patient enrollment began in the first week of November 2009 and continued up to February 2010. Biweekly calls were held between national program leaders and demonstration site personnel to share problems experienced in implementing *TeleMOVE* as well as solution strategies to overcome these challenges. The research team attended these calls to record process notes. All demonstration sites were asked to recruit at least 30 patients during phase 2 and to only use a single model of telemessaging device. In phase 3, the national rollout of the *TeleMOVE* program began in April 2010 and continues to the present.

Table 1. Summary of pilot phases of *TeleMOVE* implementation and stakeholders.

Phase	Participants	Implementation activity and evaluation method
Planning		
March 2009	<ul style="list-style-type: none"> NCP^a, TS^b, and regional network leaders 	<ul style="list-style-type: none"> Invitation for 10 HT^c programs to submit written intent to volunteer to pilot <i>TeleMOVE</i> Define collaborative roles and responsibilities for NCP/TS Create timeline for phased implementation plan Update implementation plan draft
July-August 2009	<ul style="list-style-type: none"> Staff from 1 VAMC^d NCP, TS, and regional network leaders 	<ul style="list-style-type: none"> Weekly planning meetings Track challenges and facilitators to <i>TeleMOVE</i> during pilot to develop implementation plan Review readiness of cross-training modules for <i>TeleMOVE</i> providers
Phase 1		
September-November 2009	<ul style="list-style-type: none"> 1 VAMC Local staff 	<ul style="list-style-type: none"> Enroll 30-45 patients to develop implementation methods and toolkit
Phase 2 training		
October 2009	<ul style="list-style-type: none"> Staff from 9 VAMCs NCP, TS, and regional network leaders 	<ul style="list-style-type: none"> Share early learnings/challenges from phase 1 site Disseminate program materials Share workflows and administrative procedures
Phase 2 start		
November-February 2010	<ul style="list-style-type: none"> Staff from 9 VAMCs 	<ul style="list-style-type: none"> Enroll 30-60 patients per medical center Monitor and troubleshoot pilot implementation Identify key learnings; develop solutions to barriers Refine implementation plan for national rollout
Phase 3		
April 2010-September 2011	<ul style="list-style-type: none"> Interested VA facilities 	<ul style="list-style-type: none"> National goal to enroll 10,000 patients per year Enroll panels of 80-120 patients per medical center Funding for care for up to 300 patients per network

^aNCP: National Center for Health Promotion and Disease Prevention.

^bTS: Telehealth Services.

^cHT: Home Telehealth.

^dVAMC: Veterans Health Administration medical centers.

Overview of the MOVE! and TeleMOVE Programs

MOVE! Weight Management Services

Standard MOVE! treatment services were implemented throughout VHA in 2006 as a comprehensive, evidence-based lifestyle approach to weight management for veterans [1,3]. In 2010, the core components of MOVE! included annual comprehensive screening for overweight and obesity and brief conversations between patients and clinicians about weight management that included the option for referral to MOVE!. Referred patients then completed a needs assessment called the MOVE!23 Questionnaire that helped clinicians to provide tailored written feedback and handouts on possible areas for lifestyle change. MOVE! featured a behavior-based diet and physical activity self-management support delivered through a variety of modalities that were predominantly facility-based, such as group 71.88% (393,774/547,790) and individual 20.50% (112,299/547,790) face-to-face counseling as well as telephone-based counseling 7.62% (41,717/547,790) [20]. These modalities were delivered by licensed providers from dietetics, nursing, psychology, physical therapy, and social work, utilizing didactic instructions, interactive exercises, and content based around a MOVE! handout booklet. Participants set personal goals with the help of clinicians and were given log sheets and pedometers to monitor behavioral and weight changes. Program staff assessed weights at encounters to monitor the patient's progress. Programming options varied across facilities due to staffing and space constraints but ranged in intensity from 6 to 12 structured sessions delivered over 4 to 8 weeks, with sessions ranging between 30 to 90 min in duration. In 2010, participants averaged 4.5 visits in MOVE! annually with the majority of visits occurring within 6 months of enrollment [20]. In 2008, VHA began developing *TeleMOVE* as a MOVE! treatment modality that helped patients overcome the barriers to participating in time-specific, facility-based programming via automated, asynchronous telehealth devices that offered patients a flexible and convenient approach to weight management. Notably, *TeleMOVE* excluded services delivered via clinical video telehealth technologies, such as live MOVE! group sessions, simultaneously broadcast to patients at a remote community-based outpatient clinic (CBOC).

Telehealth Device

TeleMOVE was implemented with the Health Buddy, an automated messaging device developed by the Bosch-Health Hero Network (Palo Alto, CA), which enabled daily communication between a *TeleMOVE* coordinator and the participant. The messaging device was the size of a clock radio and featured 4 buttons, a liquid crystal display screen, a speaker, and a connection to a landline phone. *TeleMOVE* utilized a disease management protocol (DMP) that featured daily communications based on a series of algorithmic interview questions delivered to patients in their homes via a display on the device that assessed patients' symptoms, health factors, educational needs, and self-management status. In the course of these interactive dialogues with the Health Buddy, patients entered weight information and any responses to daily prompts to be forwarded via landline phone each night to a vendor server

from where it was then forwarded to a *TeleMOVE* coordinator for review.

Intervention Program

Upon completing MOVE! enrollment activities, patients who elected to choose the *TeleMOVE* programming modality received a Health Buddy, MOVE! handout booklet, a pedometer to track daily ambulatory activity (steps), and a digital scale to use at home. The participant and a *TeleMOVE* coordinator then used the MOVE! booklet to develop a patient-centered treatment plan with specific weight and behavioral change goals to monitor progress. Once this plan was agreed upon, it was recorded in the patient's medical record. Following the installment of their device, a patient would commence participation in 82 daily communications or sessions at an agreed upon time. The DMP engaged the participant at their home, in a 5-min interactive educational module that was displayed on the device screen. These modules covered topics pertinent to weight management, such as nutrition, exercise, behavior modification, self-monitoring, and goal setting, adapted from the content used in the standard MOVE! booklet for in-person programming for individuals and groups. At the end of each module, the participant was prompted to answer a series of multiple-choice questions to evaluate user understanding. Correct answers were reinforced with positive affirmations and for incorrect responses, participants were encouraged to reference modules from the accompanying MOVE! booklet.

The Health Buddy prompted participants to provide daily weight readings from their digital scale to encourage tracking of weight management progress. If a participant went 30 days or longer without losing half to 2 lb per week or lost weight too quickly, a trigger alert for re-evaluation would occur. Participants received 10- to 20-min telephone calls from a *TeleMOVE* coordinator every 30 days that had the purpose of re-evaluating patient goals while providing motivational and problem-solving support. Coordinators also called participants for affirmative responses to *red alert* questions about increased pain or emotional distress. Finally, the 82 modules had to be completed within 90 days, at which point the participant would decide if they would like to repeat the program for a second cycle. Participants could pause the program for breaks up to a total of 7 days in case of acute illnesses or vacations. Although program duration spanned nearly 3 months, the total dose of patient participation was designed to be roughly equivalent to traditional clinician-delivered MOVE! modalities.

TeleMOVE Interventionists

The *TeleMOVE* implementation guide permitted the program to be administered flexibly either by the MOVE! or HT programs at each facility or a combination of both services. While most VHA telehealth programs were typically staffed by registered nurses, nurse practitioners, or social workers, the addition of the weight management DMP permitted other disciplines (eg, registered dietitians/nutritionists and psychologists) to deliver *TeleMOVE* to veterans, provided they agreed to complete local, regional network, and national training related to MOVE! and HT competencies. *TeleMOVE* participant materials were often distributed to patients through each hospital's prosthetics service. Given the potential

cross-disciplinary staffing complexities of *TeleMOVE*, the implementation guide provided detailed guidance regarding the methods to track workload, coordinate the distribution of program materials, and estimate staffing resources to meet projected needs of the facility's patient population.

Quantitative Evaluation

TeleMOVE Participants

The quantitative aspect of this mixed-methods study evaluated 2 cohorts of VHA patients who enrolled in either *TeleMOVE* or standard in-person MOVE! programming during fiscal years (FYs) 2010 and 2011 (October 1, 2009 to September 30, 2011) at each of the 9 demonstration sites. The in-person MOVE! cohort served as a parallel, nonrandomized comparison group to evaluate preliminary clinical outcomes for *TeleMOVE*. All VHA weight management program enrollment occurred through each site's MOVE! program, where each patient was required to complete a 23-item questionnaire called the MOVE!23 about their weight history [3,21] and to consult with a MOVE! clinician to discuss programming options before starting the treatment. Veterans eligible for MOVE! were those who were obese (body mass index, BMI ≥ 30) or who were overweight ($25 \leq \text{BMI} < 30$) with a weight-related health problem (diabetes, hypertension, degenerative joint disease, dyslipidemia, obstructive sleep apnea, or metabolic syndrome) [3]. Veterans could choose to enroll in standard MOVE! services or *TeleMOVE*. To enroll in *TeleMOVE*, patients had to meet additional criteria including not being enrolled in another HT program (eg, for noninstitutional care, acute care management, or chronic care management); having a working landline telephone; and having no plans to relocate during the 6 months of the initial enrollment in *TeleMOVE*. Patients enrolled in these program modalities were identified retrospectively using VHA Decision Support System identifier/stop codes to capture workload credit from administrative databases.

Quantitative Data Extraction and Analysis

Quantitative data was extracted from VHA patient care databases to describe patient characteristics, program use, and weight changes associated with program participation at each of the 9 demonstration sites. Participant demographic characteristics and program utilization data were extracted from the VHA Service Support Center-hosted visits ProClarity cube. Data pertaining to medical comorbidities and change in weight were extracted from the VHA Corporate Data Warehouse (CDW). Program use was characterized by 2 indicators: program enrollment and program engagement. Distinctions in program *enrollment* versus engaged *participation* were based on operational definitions developed by NCP [20]. Enrolled patients were required to have at least one visit within 180 days of the date of enrollment. As an indicator of more sustained program use, *engaged* participation was defined as patients having more than 2 visits within 180 days of enrollment. The primary quantitative outcomes for this evaluation were (1) cumulative number of patients *engaged* in *TeleMOVE* and MOVE! in FY 2010 and FY 2011 at each demonstration site defined by having greater than 2 visits over 180 days; (2) mean weight loss per patient achieved after 6 months of program participation; and (3) the percentage of participants with clinically meaningful

weight loss ($\geq 5\%$ body weight from enrollment to 6-month follow-up) [22]. Baseline weight was determined by extracting the closest clinical weight measure within ± 30 days of enrollment from vital status files in CDW. Follow-up weights were assessed at 180 days from enrollment using a 60-day window before and after the 180-day increment [20]. To provide a basis to interpret preliminary *TeleMOVE* effectiveness, we provided MOVE! statistics for FY 2010 to serve as nonstatistical comparator references for key weight loss outcomes, including average *national* mean values for weight loss, percentage of weight loss, change in BMI, and the proportion of participants achieving clinically significant weight loss ($\geq 5\%$ of pretreatment weight) [23].

Indicators of site implementation effectiveness were rated based on attaining targets for program enrollment *and* attaining average weight loss of at least one pound for program participants. For phase 2 pilot implementation, we assessed whether each demonstration site could enroll at least 30 patients over 4 months as an indicator of implementation effectiveness. As indicators of sustained implementation effectiveness, we evaluated whether each demonstration site could accumulate patient panels of at least 100 patients and attain average weight loss per participant by the end of FYs 2010 to 2011. Classification as a *high-uptake* site was based on attaining NCP/HT enrollment targets while also attaining an average weight loss per participant. *Low-uptake* sites were categorized by attaining only 1 or no indicators of program effectiveness (ie, low enrollment/high clinical effectiveness, high enrollment/low clinical effectiveness, or low enrollment/low clinical effectiveness). These program indicators were tracked over 2 years to assess the sustainability of early program adoption as well as to assess which contextual factors (as identified by the qualitative data) were correlated with program effectiveness to identify possible determinants of successful implementation. Descriptive statistics were used to summarize patient characteristics and program utilization patterns. Paired *t* tests were used to compare patient characteristics and change in weight status from baseline, adjusting for clustering by site. Quantitative data analysis was performed using SAS Version 9.2 (SAS Institute Inc, Cary, NC).

Qualitative Evaluation

Qualitative Stakeholder Interviews

The evaluation plan called for conducting 2 rounds of semistructured interviews at each of the 9 phase 2 demonstration sites. The first round of interviews was conducted by phone, 3 to 6 months after phase 2 (June-August 2010) and the second round of in-person interviews were conducted 6 months after the start of phase 3 (November 2010-April 2011) to capture the dynamic nature of the implementation process. Key facility- and regional-level managers and program staff involved in *TeleMOVE* implementation were invited by email to participate in the interviews, including *TeleMOVE* care coordinators, HT directors, MOVE! coordinators, MOVE! dietitians, physician program champions, program support assistants, regional data analysts, and regional network program coordinators. Participation in interviews was voluntary, and we asked for

additional names to ensure that we invited all individuals involved in *TeleMOVE*.

Verbal consent and permission to digitally audio-record interviews were obtained from participants at the start of their first interview. Staff at 3 sites declined to participate in both rounds of interviews. A total of 42 VHA stakeholders were invited to participate in an interview, and 66% (28/42) agreed to participate in at least one interview; 22 participated in the phone interviews, and 21 participated in on-site interviews. Interview ranged from 18 to 86 min in duration and was digitally audio-recorded and transcribed verbatim into Microsoft Word documents. Additionally, call minutes from biweekly conference calls held among the demonstration sites during the evaluation were analyzed to understand contextual factors affecting implementation effectiveness.

Qualitative Data Collection, Coding, and Analysis

The CFIR [18] was used to develop the 2 interview guides and offered a framework for qualitative coding and of those contextual factors that could affect implementation success [17,21,22]. See [Multimedia Appendices 1 and 2](#) for the interview guides. The CFIR organizes 39 constructs that influence implementation into 5 major domains: intervention characteristics, inner setting, outer setting, characteristics of the individuals involved in the implementation, and the process by which implementation is accomplished. Abbreviated definitions of CFIR constructs and domains are located in additional file 3 [24]. Interview transcripts were coded deductively using a codebook based on the CFIR and a descriptive content coding approach [19]. QSR International's NVivo software version 10 was used to facilitate coding. Each interview transcript was independently reviewed and coded by at least 2 members of the research team and a fourth coder helped achieve consensus in cases of disagreement (JCL) [25]. Codes were compared, and differences were resolved by a consensus discussion. A memo was created for each site to summarize the top 10 CFIR constructs mentioned by respondents that were strongly associated (positively or negatively) with implementation outcomes (enrollment process and weight loss). Memos were compared across sites to identify the constructs that were most consistently associated with high or low uptake of the intervention across sites. A fifth team member (CRR) performed a member check to verify the validity of the top themes identified by the team.

Human Subjects' Protection

This research study was approved by the VA Ann Arbor Healthcare System Institutional Review Board (2010-010042) with a waiver of signed informed consent for staff interviews and for secondary data analysis of deidentified patient-level outcome data.

Results

Quantitative Results

[Figure 1](#) presents a comparison of enrollment in *TeleMOVE* and standard in-person MOVE! at the 9 demonstration sites

during the first year of program implementation. Notably, among patients who enrolled and engaged in *TeleMOVE*, 93.9% (467/497) engaged in 2 or more visits over 6 months compared with 71.97% (1189/1652) for MOVE!.

[Figure 2](#) shows cumulative enrollment in *TeleMOVE* during the first year of implementation. Moreover, 3 sites attained the phase 2 goal of enrolling 30 or more patients, 3 sites enrolled less than 30 (mean=25), and 3 sites recruited between 0 and 6 patients. Following phase 2, 2 of the 9 sites attained cumulative enrollment levels of at least 100 patients by the end of FY 2010, and 4 sites attained this target in FY 2011.

There were significant differences in demographic characteristics between those who chose to enroll in each program modality (see [Table 2](#)). Both Hispanics and African Americans were more likely to choose in-person MOVE! than *TeleMOVE*, whereas there were no differences in enrollment based on sex. *TeleMOVE* enrollees were also older than those who chose in-person MOVE!, whereas rural veterans were more likely to choose *TeleMOVE* than urban veterans. Finally, *TeleMOVE* participants were significantly heavier than in-person MOVE! participants. However, there were no differences between program participants with respect to the burden of medical comorbidities as measured by the Charlson Comorbidity Index [26].

Preliminary indicators of clinical effectiveness are summarized in [Table 3](#). The average weight loss for both *TeleMOVE!* and standard MOVE! was at -5.2 lb (SD 14.4) and -5.1 lb (SD 12.2), respectively, with no statistically significant differences between the 2 delivery modalities ($P=.91$). At the demonstration sites, both program modalities slightly outperformed average national in-person MOVE! results with respect to weight loss. These preliminary weight loss outcomes suggest that the number of patients needed to treat by *TeleMOVE* to achieve clinically meaningful weight loss ($\geq 5\%$) is 5, which is indicative of a highly effective treatment.

[Multimedia Appendix 3](#) presents site-level indicators of *TeleMOVE* implementation. Although there was significant variability in baseline characteristics of demonstration sites with respect to patients served, rurality, and proportion of patients served older than 55 years, no discernible association could be made with these facility characteristics and indicators of enrollment and clinical effectiveness below. The table combines enrollment and weight loss outcomes to generate a combined indicator of implementation effectiveness. *High-uptake* sites 4 and 5 not only achieved phase 2 enrollment targets of ≥ 30 patients but also demonstrated the ability to sustain higher patient panel sizes during national rollout while providing clinical benefit. Sites 6 and 7 exemplified cases of *delayed* high-uptake in which effectiveness not was manifested until year 2, when enrollment numbers increased.

Low-uptake sites were broadly characterized by low enrollment at sites 1, 3, 8, and 9. However, site 2 was a low-uptake site that had high enrollment numbers without achieving meaningful weight loss outcomes. Notably, both sites 1 and 9 had low enrollment rates and displayed declines in weight loss outcomes.

Figure 1. Comparison of enrollment in evaluation cohorts for year 1 of implementation.

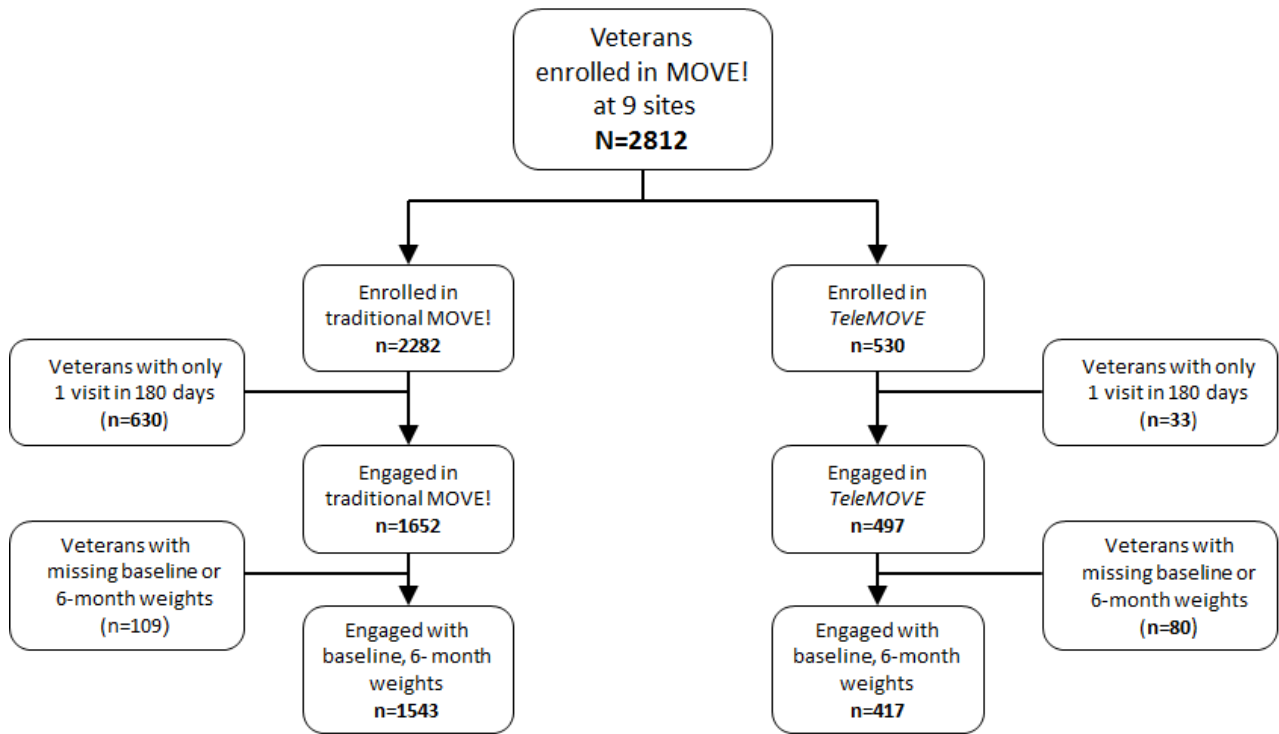


Figure 2. Cumulative enrollment across sites during year 1 of *TeleMOVE* implementation.

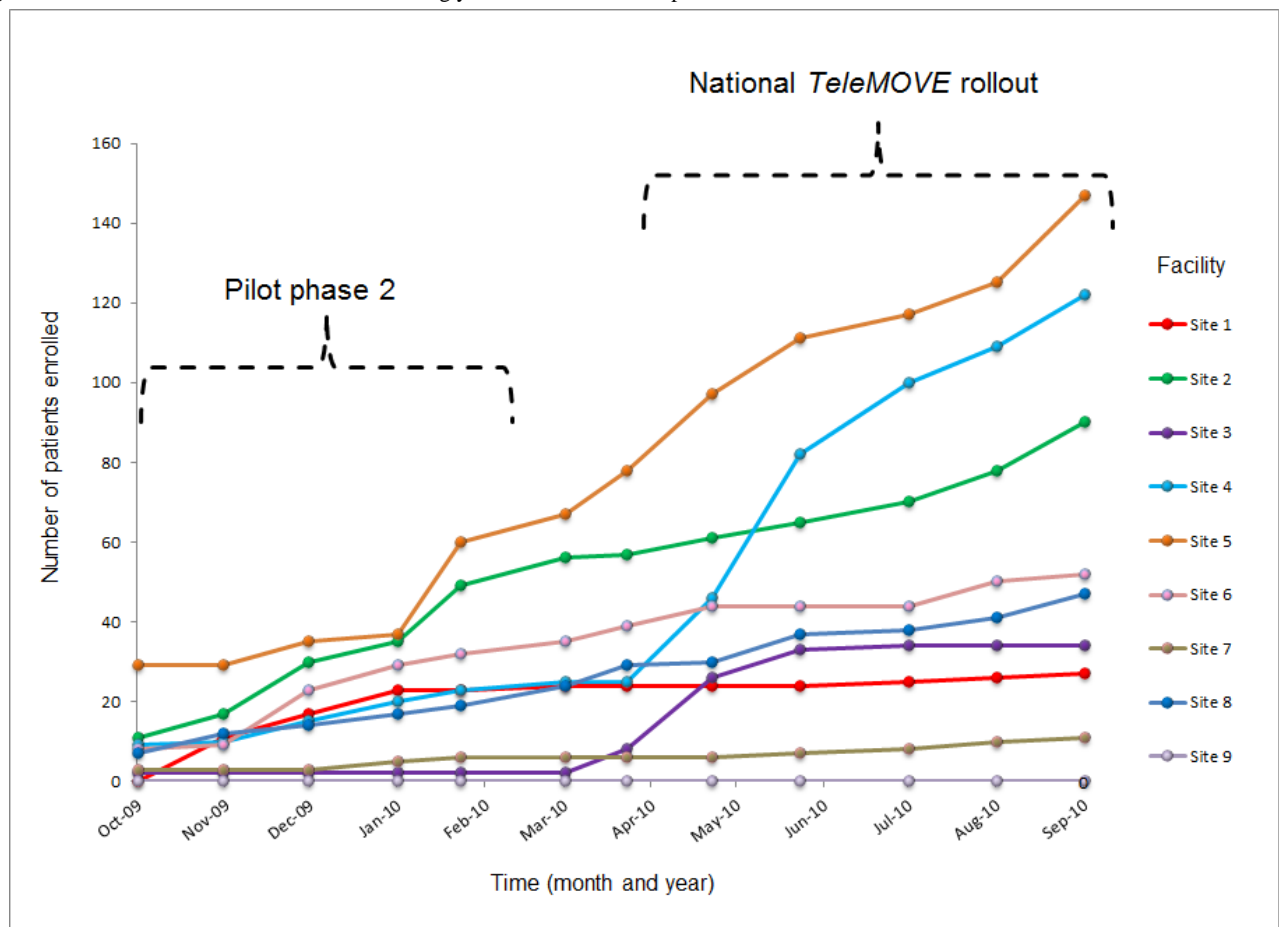


Table 2. Demographic characteristics of engaged *TeleMOVE* and MOVE! year 1 participants.

Characteristic	<i>TeleMOVE</i> (n=497)	MOVE! ^a (n=1648)	<i>P</i> value ^b
Age in years, mean (SD)	57 (9.5)	55 (11.0)	<.001
Male, n (%)	422 (84.9)	1434 (87.01)	.23
Race^b, n (%)			<.001
White	301 (80.1)	853 (65.31)	
Black	60 (16.1)	413 (31.62)	
Other	11 (3.1)	40 (2.96)	
Ethnicity ^c (Hispanic), n (%)	7 (1.7)	66 (4.88)	.006
Rural address, n (%)	287 (57.9)	691 (41.93)	<.001
Baseline (lb), mean (SD)	256 (51)	243 (49)	<.001
Baseline body mass index, mean (SD)	37.5 (6.9)	35.5 (6.3)	<.001
Charlson score, mean (SD)	1.7 (1.9)	1.6 (1.9)	.39

^aExcludes patients enrolled in *TeleMOVE* during the same time period.

^bPaired *t* test comparisons of patient characteristics were adjusted for clustering by site.

^cAvailable data to calculate % race/ethnicity variables were *TeleMOVE* (N=402) and MOVE! (N=1353).

Table 3. Comparison of weight change outcomes in year 1 for engaged participants.

Characteristics	National MOVE! cohort (N=31,854) fiscal year 10 ^a	MOVE! participants (N=1553)	<i>TeleMOVE</i> participants (N=417)	<i>P</i> value (MOVE! versus <i>TeleMOVE</i> ^b)
Six-month weight (lb), mean (SD)	-3.6 (0.1) ^c	-5.13 (12.4)	-5.22 (12.4)	.90
Six-month change (BMI ^d), mean (SD)	-0.5 (0.0) ^c	-0.75 (1.8)	-0.70 (2.4)	.72
Change in body weight, n (%)	-1.4 (0.1) ^c	-2.02 (5.0)	-2.01 (5.6)	.95
Number of patients with >5% weight loss, n (%)	5925 (18.60)	372 (24.11)	92 (22.1)	.31

^aNormative in-person averages from national FY 2010 MOVE! report [23].

^bPaired *t* test comparisons were adjusted for clustering by site.

^cNote, all fiscal year 10 national MOVE! statistics used SEs and not SD.

^dBMI: body mass index.

Qualitative Findings

Among the 6 sites that participated in qualitative interviews, we identified 5 CFIR constructs that illustrated key contextual factors that distinguished high from low implementation sites: complexity, patient needs and resources, networks and communications, leadership engagement, and reflecting and evaluating. [Table 4](#) provides illustrative quotes for each construct. [Multimedia Appendix 4](#) provides a detailed chronological summary of formative findings shared with operational partners over the course of the 2-year evaluation.

Complexity

Complexity refers to the perceived difficulty of implementing an intervention especially with respect to the duration, scope, disruptiveness, and intricacy of the steps involved. *TeleMOVE* was viewed as complex across all sites because it required (1)

several time-consuming and intricate logistical steps simply to enroll a patient, check devices, and mail the messaging device and program materials; (2) troubleshooting installation and resolving ongoing device issues with patients; and (3) resolving issues related to the messaging devices not being user-friendly for older patients or accessible for veterans without a landline phone.

Across all 6 sites, respondents felt that although *TeleMOVE* was a progress toward helping veterans access weight management services in their homes, the technical compatibility of the telehealth device with patients' home connectivity was an increasing barrier as telecommunications companies upgraded veterans' landline homes to digital technology. Many patients who were interested in *TeleMOVE* discovered that they no longer had a home landline phone to hook up the telehealth device because they relied primarily on either cellular or digital cable phone services.

Table 4. Qualitative data illustrating contextual factors distinguishing *TeleMOVE* uptake.

CFIR ^a construct	High-uptake site	Low-uptake site
Complexity	<ul style="list-style-type: none"> • <i>Making sure your clinics are started up right, making sure you've got everything in place before you get, take on your first patient, knowing how to enroll, knowing how to do the forms correctly, knowing how everything needs to run, getting the equipment to the patient, getting the program itself started...</i> • <i>If I get them [patients], I have them face to face; I have the screening right there...So we've eliminated the phone tag and they're right on board. So, when they get their equipment, I call them the next week. Most of them are already hooked up on the equipment.</i> 	<ul style="list-style-type: none"> • <i>There were all the hurdles in the world you could imagine. So the six months before [that?] I spent trying to contact everybody and their cousin trying to figure out how to make this happen, how to get the technology...just logistics, you know. How were the pedometers going to be issued turned into a big you know, issue.</i>
Patient needs and resources	<ul style="list-style-type: none"> • <i>...They always at least always get a phone call at least once a month even if they did fine,...because they like that accountability...the ones that participate...They like something that will help keep them focused. If they could come see me every day, they might do that. So, this is a way to keep them at home and keep them focused with the weight loss.</i> 	<ul style="list-style-type: none"> • <i>I would put more people on the Tele-Move program if I could but a lot of people do not have computers or land lines. All they have is cell phones.</i> • <i>...I would like to see...more initial face-to-face um, contact with the Veteran before they're actually in the program and issued the equipment...If we were able to arrange something like...the care coordinators physically go to those sites at the designated time to meet with the Veterans, to try and do a group enrollment to establish that rapport with that individual, I think you would probably get more buy in...The way that we're doing it right now is basically over the telephone...there's none of that face to face personal interaction.</i>
Networks and communication	<ul style="list-style-type: none"> • <i>...and every month we do a phone call conference with all our VISN, with all our care Tele-Move coordinators and stuff and keep them updated on anything that comes out even if it comes out beforehand they're always in the know. I mean I even get phone calls from other VISNs you know, about things you know, because...we're a little bit ahead of the game so I'm always trying to help and...give out anything that we develop and because there's no sense in rewriting the, reinventing the wheel when we already got it to help anybody out.</i> 	<ul style="list-style-type: none"> • <i>Well as a MOVE! coordinator and being on the calls I tried to solicit you know, the clinic space and the clinic profiles...I was not clear on the information that this was going to be completely within HT. Initially I thought that the HT Move was going to be within MOVE!...There were a lot of different people trying to you know, coordinate the program...But we were some time in before we clearly understood that all this stuff was going to be within HT you know.</i>
Leadership engagement	<ul style="list-style-type: none"> • <i>You know, they [facility leaders and managers] were really supportive and they always wanted to know what was going on you know, what kind of data and stuff we were getting.</i> 	<ul style="list-style-type: none"> • <i>Um no, leadership—I never felt supported at all for any of home Tele-Health with leadership at this hospital. With my immediate supervisor, yes but with senior management no...</i>
Reflecting and evaluating	<ul style="list-style-type: none"> • <i>This is what I send to CCHT Director every month is the non-responders because that's what my quality improvement deal is...I'm at average monthly compliance of 58, my goal is 80. Well every month we do a report...our chief has us do it; We have to do a weight loss report and weight gain percentage and all that kind of stuff...we get from our data warehouse and...we can pull triglycerides, HDL, blood pressures it kind of depends on whatever we want to be tracking. I can...see like where they were when they started until now to kind of see if there has been improvement on those ends...we always kind of we look at our numbers and stuff making sure. And we do monthly calls just here at our facility you know, to make sure we're all on the same page and not doing something completely different than the other...We're always trying to improve and do better.</i> • <i>It really has been good to go through the pilot and get a lot of feedback from the CCHT Coordinator because we were able to kind of stream line a lot of things.</i> 	<ul style="list-style-type: none"> • <i>...I don't write down or have any tracking system for how the patients are doing um, but I think we have few enough patients where I can almost just remember how each one is doing, at least of my patients. I haven't seen that [program feedback data] but I haven't asked for it either you know, so. I mean because I'm not supervising that...</i>

^aCFIR: Consolidated Framework for Implementation Research.

Although many patients were pleased with the telehealth devices, some patients were frustrated by connectivity issues and others were disappointed with the device's simple interface. Often, these dissatisfied patients chose not to use their device, thereby reducing program productivity due to the time needed for program coordinators to contact these patients, return the devices back to the VA hospital, and to repurpose the device for another patient.

Coordinators across sites spent considerable time in calling patients to provide technical assistance, particularly for older veterans who were less confident in using the telehealth devices despite the relatively simple device interface. Coordinators also noted the need to address the ongoing issue of false alerts for issues such as low self-reported mood or errors in the transmission of weight data due to issues with the interface of the digital scales with the Health Buddy. Many of these complexity issues stemmed from the fact that most sites initially attempted to conduct screening and enrollment over the phone rather than conducting face-to-face orientations. With thoughtful experimentation, high-uptake sites found better ways during the phased implementation to mitigate complexity barriers by proactively preparing patients for the device use, whereas low-uptake sites continued to struggle with these issues without re-examining their workflow to identify areas to mitigate problems.

Low-uptake sites also found the *TeleMOVE* implementation complex due to unanticipated issues with the device platform and adopting new administrative procedures. Meeting minutes from phase 2 implementation conference calls among demonstration sites revealed that the requirement to administer *TeleMOVE* using Health Buddy devices was particularly disruptive to sites 7, 8, and 9 that relied primarily on Viterion 100 messaging devices for HT programming (Viterion TeleHealthcare, LLC; Tarrytown, NY). The subsequent process to adopt another HT platform to implement *TeleMOVE* resulted in long delays. Additionally, low-uptake sites reported the process to adopt a new interdisciplinary method to assign workload credits among HT and MOVE! staff and have these changes approved by regional leadership slowed program uptake.

Patient Needs and Resources

This construct reflects the extent to which patients' needs, as well as barriers and facilitators to these needs are accurately known and prioritized by program staff. Accurately assessing patients' home connectivity was a critical component of the recruitment and enrollment process. Over time, higher performing coordinators developed in-person protocols that carefully assessed this issue during screening and enrollment, recording declined patients' names in a file for contact when *TeleMOVE* moved to more flexible platforms such as mobile phones, individual voice recognition, or the internet. Staff at high-uptake sites utilized these in-person orientations to explain how to use the messaging devices, set initial personalized program goals, and to anticipate requests for technical assistance or follow-up from patients. In comparison, less effective enrollment procedures at low-uptake sites caused the staff to

focus much of their attention on enrollment and reacting to technical assistance requests.

High-uptake sites were also more likely to report to patient needs by resourcing *TeleMOVE* with coordinators who possessed health-coaching expertise, which they utilized on both incidental and planned monthly action-planning calls to address patient problems, set goals, coordinate reported health issues with the patient's provider, and maintain patient engagement and motivation. In contrast, lower-uptake site respondents were less likely to mention personalized contacts to help patients feel engaged, accountable, and motivated. Coordinators across high and low uptake sites also noted that the criterion that veterans only participate in one HT program at a time was counterproductive, since many eligible *TeleMOVE* patients had obesity-related comorbidities such as diabetes, high blood pressure, or high cholesterol and could have benefited from concurrent participation in other HT programs addressing these risk factors in an integrated fashion. Finally, respondents across both high and low uptake sites observed that although patients were prompted regularly by their telehealth devices to provide program satisfaction feedback, vendors refused to share this information with VHA. This contractual dispute denied providers with regular and consistent ratings of program satisfaction that could help inform efforts to make the program more patient centered.

Networks and Communications

Strong formal and informal social networks of program staff and leaders were essential to effectively implement *TeleMOVE*. Failure to communicate effectively across services was more likely in low-uptake sites. In contrast, high-performing sites reported a high degree of cooperation between providers across programs and the ability to reach out to other services, providers, and leaders to gain support in planning and delivering the *TeleMOVE* program. One high-uptake site exhibited uniquely strong care management and coordination networks by consulting relevant providers to adjust patients' medications for blood pressure, cholesterol, diabetes, and psychiatric self-management in response to desirable reductions in weight and lifestyle improvements.

Leadership Engagement

The presence of strong commitment and support by leaders is an indicator of an organization's commitment to implementing an intervention. In contrast to low-uptake sites, among high-uptake sites, there was strong support by hospital leaders as well as by frontline supervisors and midlevel managers overseeing HT and MOVE! programming. This support was manifested by quick approvals for changes in workflows, staffing credit, and resources, with a shared consensus that *TeleMOVE* was viewed as a long-term addition to HT services. At low-performing sites, there was less shared consensus about the benefits of *TeleMOVE* across stakeholders, and facility-level leadership was frequently unaware of the existence of the program.

Reflecting and Evaluating

Effective implementations require the ability to regularly reflect and evaluate both quantitative and qualitative feedback regarding the progress and quality of an intervention implementation. This CFIR construct reflects a quality improvement mindset that was present to some degree in all high-uptake sites but absent at the low-uptake sites. High-uptake sites provided specific examples of monitoring various aspects of program implementation and then using these data to identify opportunities to improve care delivery and patient outcomes. Conversely, examples of reflecting and evaluating were largely absent at lower performing sites where program staff were more reactive and less innovative in identifying solutions to issues in implementing the program.

Discussion

Principal Findings

Our mixed-methods findings provide preliminary evidence for the clinical effectiveness of the *TeleMOVE* weight-management program for helping veterans lose weight while identifying key characteristics of program users and contextual factors for consideration in scale-up of the intervention at other VHA facilities. This evaluation study is important because it addresses 2 major reasons cited for the low use of mHealth and telemedicine programs in medical settings on a population level: (1) insufficient evidence for the efficacy of the telemedicine innovation and (2) poor insights into how organizational and social contextual factors influence the adoption and routine use of such new technologies [27,28]. This study underscores the benefit of partnerships between researchers and operational programs to rapidly evaluate promising technology innovations in medical settings to help ensure their widespread adoption and sustainability.

Our quantitative findings helped build a case for further adoption of *TeleMOVE* throughout VHA by demonstrating the clinical benefit of the program and by providing VA leaders with insights into likely program users. New telehealth programs are often given low relative priority for adoption [18,29] by health care leaders because it is unclear whether a new program is effective or provides a solution to a key clinical need or issue [27]. However, *TeleMOVE* simultaneously addressed the burden of obesity among veterans and access to weight management treatment services by leveraging existing HT infrastructure to provide a solution to these clinical priorities. Across the 9 demonstration sites, veterans averaged a 5.2 lb (2.4 kg) weight loss over 6 months using *TeleMOVE*, which was comparable with results achieved in standard in-person, facility-based *MOVE!* programming. These results have since been replicated in subsequent observational studies [30,31]. We also found that *TeleMOVE* users were more likely to be white, older, heavier, and living in rural areas than traditional *MOVE!* program participants. These characteristics are relevant to VHA clinical leaders because it is national VHA priority to reach the 25% of veterans who live in rural areas [32] with preventive services, and higher BMI levels among *TeleMOVE* participants indicate the program reaches patients likely to benefit from weight loss support. Enrollment figures also suggest that it was feasible for

the majority of demonstration sites to achieve patient panel sizes in the 80-120 patient range.

This evaluation benefited from the systematic assessment of stakeholders' perspectives regarding *TeleMOVE!* to identify contextual factors facilitating or impeding program uptake so that refinements to the implementation plan could be made in a timely manner. Notably, stakeholders observed that *TeleMOVE* was a logistically and technically complex intervention that did not result in decreased staff time per patient. Reflecting evaluations of similar telehealth programs [28,33-35], policy makers underestimated the time coordinators and program staff had to take to screen, enroll, and activate patients, including the considerable time for mailing devices, advising on installation, responding to red flag alerts, attempting to reach patients to answer questions, and reacquiring equipment from nonresponders. These logistical challenges reduced staff time for recruitment and enrollment as well as efforts to improve direct contacts with the patient during program participation, suggesting the need for a more cost-effective and user-friendly intervention delivery platform. Requiring demonstration sites to use only the Health Buddy messaging also revealed a key lesson for national implementation: make the *TeleMOVE* DMP interoperable across the different vendor devices to avoid delays in switching platforms.

Stakeholders told us that it is important to consider what the CFIR identifies as outer setting factors interacting with the *TeleMOVE* implementation, including understanding the needs, resources, and circumstances of patients using the program. *TeleMOVE* was implemented during a period when home connectivity was rapidly changing from landline phones to digital and cellular forms of connectivity [36,37]. Many eligible patients were turned away because they lacked a landline phone. Installation and use of the devices was intimidating for some older users while many potential participants had to be turned away because their household no longer had landline telephone access. Although some staff at some sites tried to enroll patients over the phone, face-to-face enrollment was essential to confirm patient expectations about the program and to identify patients most likely to engage in sustained participation over time as has been reported from prior VHA evaluations of telehealth programs for older veterans with chronic disease management needs [34,38]. As mHealth and eHealth interventions continue to advance at a rapid pace, it will remain essential to match patients to a user-friendly intervention platform and to ensure that patients understand how to engage with the intervention platform to attain clinical benefit.

Prior telehealth studies point toward leverage points to improve *TeleMOVE* over time to tailor the program to specific patient groups. Studies at this time reflect our results that those who were less likely to engage in the program were women, younger veterans, and those living in urban areas who may have preferred other telehealth platforms delivered by IVR or mobile phone apps [28,34,36]. These alternative platforms for *TeleMOVE* also reduce some of the logistical barriers that diminish the efficiency of relying on the in-home messaging devices and could allow clinicians at CBOCs in rural areas to enroll veterans rather than having enrollment controlled by program staff at a distant VA facility where HT services are centralized. However, high-uptake

sites adopted best telehealth practices to reduce logistical issues and increase patient engagement for older patients by using individual or group enrollment sessions to ensure users understood the DMP protocol, how to use and connect the telehealth device, and solve issues [34]. In addition, despite the automated nature of the DMP, high-uptake sites made a concerted effort to employ coordinators trained in motivational interviewing [39] and theory-based, patient-centered cognitive behavioral change strategies (eg, values clarification for goal setting, problem solving, personalized feedback, self-monitoring, and relapse prevention) to keep patients engaged through regular phone or in-person contacts [40–44].

Interviews also revealed how *TeleMOVE* implementation interacted at multiple levels within demonstration sites' inner setting. Notably, while demonstration sites already had robust HT programs and saw a value to volunteering for the phase 2 implementation, *TeleMOVE* caused stakeholders to interact with other services in new ways that were disruptive and challenging in some cases. For example, the process of staffing the program and adopting new billing codes to capture workload credits for low-uptake sites was slow and frustrating at sites with poor communication networks between services. Coordination of programming was further complicated by the fact that *TeleMOVE* was a stand-alone platform in which program data was maintained on a separate vendor database. Accordingly, data was not readily accessible to stakeholders (patients or providers) or integrated into the electronic medical record in a usable form [45]. This lack of interoperability from vendor databases to end users such as patients, providers, and program coordinators inhibits utilization for developing goals and monitoring results to make program improvements. High-uptake sites were characterized by coordinators who made an extra effort to organize program data to communicate to program stakeholders, to set performance goals, monitor progress, and share results with the patient, providers, and facility leaders to increase the perceived value of *TeleMOVE* for veteran care.

Limitations

This study is not without limitations. Notably, the study was a nonrandomized program evaluation of volunteer facilities to the implementation of clinical care program for an older generation of telehealth intervention platform. Generalizability was limited to a small number of sites and clinical stakeholders over a short period, and stakeholders at 3 sites with implementation challenges were unwilling to be interviewed regarding the specific barriers to implementing *TeleMOVE* at their site despite their initial enthusiasm to participate in the early phases of the implementation. Hence, results may not acknowledge significant organizational and contextual factors that may impede effective implementation at a health care facility despite enthusiastic support among some stakeholders. Quantitative analyses of program effectiveness were also limited in that the original design of the study did not call for cost-effectiveness analyses of *TeleMOVE* relative to standard *MOVE!* programming. Such analyses would be difficult because a number of indicators to program effectiveness are not readily accessible from vendor databases such as types of contacts between patients and *TeleMOVE* coordinators, frequency of

patient use, reliability indicators (eg, calls for troubleshooting device problems), and patient satisfaction data [46]. Telehealth interventions represent a significant investment, and it is particularly important to determine if devices and programs are user-friendly, well designed, and achieve clinically significant changes in clinical outcomes [46]. Currently, it is difficult to extract *TeleMOVE* data from VHA administrative databases to perform measurement-based care, monitor program process over time, and allow policy makers to make strategic funding decisions. Finally, results from this study may not generalize to other community-based settings that lack the integration of the VHA health care setting and the significant investment in telemedicine platforms.

Modifications to National Implementation Strategies

The formative nature of this phased implementation program evaluation enabled operational decision makers to obtain real-time feedback from VHA implementation researchers to make several significant modifications to the program implementation guide and toolkit. Below are the recommendations made to operational leaders to inform national implementation efforts that were derived from our mixed-methods evaluation:

- Conduct initial face-to-face screenings and enrollment sessions to assess patient ability and motivation, verify home connectivity status, and proactively address technical questions related to device use and installation.
- Ensure telehealth devices from multiple vendors could all work from the same basic *TeleMOVE* DMP.
- Allow patients to enroll in another HT DMP while in *TeleMOVE* to concurrently address weight-related comorbidities (eg, pain and diabetes).
- Revise implementation guides to emphasize the need for interservice care agreements between facilities *MOVE!* and HT services to answer and address specific implementation decisions regarding staffing, referrals, panel sizes, workload credit, staffing and funding needs, and procuring and mailing the telehealth and peripheral devices (scales and pedometers).
- Advocate local coordinators to assess staff competencies and encourage staff to undergo recommended standardized trainings in motivational interviewing.

These program modifications were incorporated into the implementation plan used in the subsequent national *TeleMOVE* rollout. Some recommendations could not be easily addressed. For example, staff recommended providing advanced training to HT staff in motivational counseling and in behavioral weight loss strategies. This increased level of training was not incorporated into the national implementation plan, but staff were encouraged to consult with local health behavior coordinators for assistance in these areas. There were also strong recommendations for the development of IVR software version of *TeleMOVE* to address the high number of interested patients without landline phones, but development of such a program was beyond the scope of the project. Finally, it has proven difficult to seamlessly update participants' medical records with progress data from online vendor monitoring databases.

Although the telehealth technology highlighted by this mixed-methods program evaluation may seem dated by today's standards, the barriers to implementation of new generations of eHealth and mHealth technologies largely remain the same [47]. Specifically, many technology intervention programs developed by researchers and commercial vendors face challenges with respect to interoperability with the electronic medical records and information networks of most health care providers [48,49]. Most interventions that do provide clinicians and patients with relevant data that inform clinical care decisions are likely unsustainable [50]. Furthermore, the adoption of new mHealth and eHealth technologies occur within an organizational environment in which contextual factors decide whether a promising technology is deployed and sustained over time in an organization and with technology users [51,52]. The present implementation evaluation provided VHA policy makers with proactive feedback on the limitations of *TeleMOVE* and helped clinicians adopt best practices from demonstration sites to help support the existing platform until a newer platform could replace the less efficient telemessaging devices. Consequently, *TeleMOVE* has evolved to meet patient and clinician needs by recently transitioning to an IVR technology to allow patients to use either a landline or cell phone or use a Web browser-based technology that enables patients to use their

personal computer or mobile phone (Medtronic Care Management Services, Dublin, Ireland). Although large health systems such as VHA lack the agility to rapidly change technology platforms, *TeleMOVE* exemplifies a case study where VHA's commitment to systematic, partner-based evaluations of technology implementation efforts has allowed such interventions to spread, evolve, and sustain in the face of dynamic technological environment.

Conclusions

We showed that an adaptation of telehealth technology could be adapted to promote clinically meaningful weight loss for veterans served by VHA, and formative qualitative data from program stakeholders could help guide national program implementation efforts when summarized by an implementation science framework. Our program evaluation highlights the benefit of implementation researchers partnering with operational initiatives to provide rigorous and rapid evaluation of the systematic deployment of promising innovation. This approach has direct application to the rapid scale-up of promising modes of telemedicine—mHealth and eHealth interventions that have the potential to help provide solutions to gaps in patient care and quality in a dynamic health environment.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Telephone interview guide evaluation of *TeleMOVE* program implementation.

[[PDF File \(Adobe PDF File\), 132KB - diabetes_v3i4e14_app1.pdf](#)]

Multimedia Appendix 2

Site visit follow-up interview guide evaluation of *TeleMOVE* program implementation.

[[PDF File \(Adobe PDF File\), 122KB - diabetes_v3i4e14_app2.pdf](#)]

Multimedia Appendix 3

Site-level indicators of *TeleMOVE* implementation over 2 years.

[[PDF File \(Adobe PDF File\), 45KB - diabetes_v3i4e14_app3.pdf](#)]

Multimedia Appendix 4

Summary of formative outcomes.

[[PDF File \(Adobe PDF File\), 67KB - diabetes_v3i4e14_app4.pdf](#)]

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Abbreviations

- BMI:** body mass index
CBOC: community-based outpatient clinic
CDW: Corporate Data Warehouse
CFIR: Consolidated Framework for Implementation Research
DMP: disease management protocol
FY: fiscal year
HT: Home TeleHealth
IVR: Individual Voice Recognition
NCP: National Center for Health Promotion and Disease Prevention
VA: Veteran Affairs
VAMC: VHA Medical Center
VHA: Veterans Health Administration

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Corrigenda and Addenda

Correction: A Feasible and Efficacious Mobile-Phone Based Lifestyle Intervention for Filipino Americans with Type 2 Diabetes: Randomized Controlled Trial

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The authors of the paper “A Feasible and Efficacious Mobile-Phone Based Lifestyle Intervention for Filipino Americans with Type 2 Diabetes: Randomized Controlled Trial” (*JMIR Diabetes* 2017;2(2)e30) made a mistake in the final stage of proofreading. The metadata incorrectly designated Linda G Park as a PNP instead of a PhD. Her correct designation is PhD, RN, FNP-BC, FAHA.

The correction will appear in the online version of the paper on the JMIR website on December 21, 2018, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article also has been resubmitted to those repositories.

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