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Contents

Original Papers

Viewpoint

Original Paper

Smartphone App Use for Diabetes Management: Evaluating Patient Perspectives

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Abstract

Background: Finding novel ways to engage patients in chronic disease management has led to increased interest in the potential of mobile health technologies for the management of diabetes. There is currently a wealth of smartphone apps for diabetes management that are available for free download or purchase. However, the usability and desirability of these apps has not been extensively studied. These are important considerations, as these apps must be accepted by the patient population at a practical level if they are to be utilized.

Objective: The purpose of this study was to gain insight into patient experiences related to the use of smartphone apps for the management of type 1 diabetes.

Methods: Adults with type 1 diabetes who had previously (or currently) used apps to manage their diabetes were eligible to participate. Participants (n=12) completed a questionnaire in which they were required to list the names of preferred apps and indicate which app functions they had used. Participants were given the opportunity to comment on app functions that they perceived to be missing from the current technology. Participants were also asked whether they had previously paid for an app and whether they would be willing to do so.

Results: MyFitnessPal and iBGStar were the apps most commonly listed as the best available on the market. Blood glucose tracking, carbohydrate counting, and activity tracking were the most commonly used features. Ten participants fulfilled all eligibility criteria, and indicated that they had not encountered any one app that included all of the functions that they had used. The ability to synchronize an app with a glucometer or insulin pump was the most common function that participants stated was missing from current app technology. One participant had previously paid for a diabetes-related app and the other 9 participants indicated that they would be willing to pay.

Conclusions: Despite dissatisfaction with the currently available apps, there is interest in using these tools for diabetes management. Adapting existing technology to better meet the needs of this patient population may allow these apps to become more widely utilized.

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KEYWORDS

type 1 diabetes; mobile health; smartphone

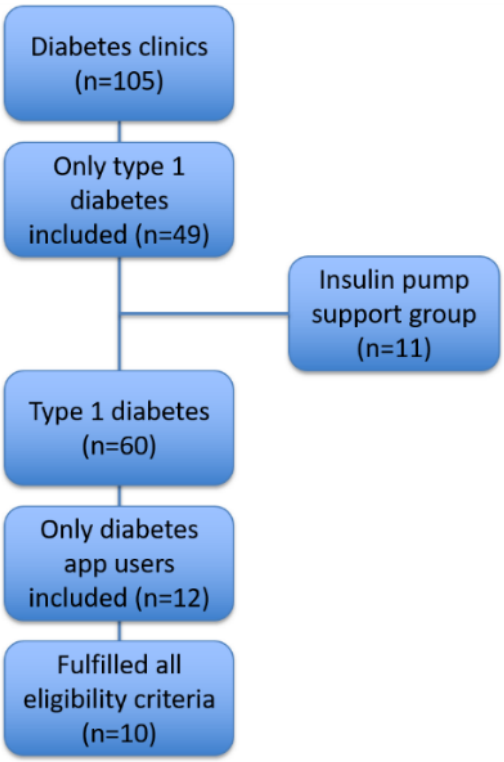
Introduction

Finding novel ways to engage patients in chronic disease management has led to an increased interest in the potential of mobile health (mHealth) technologies for the management of diabetes. There is currently a wealth of smartphone apps for diabetes management that are available for free download or purchase [1]. The functions of diabetes apps vary, with glucose tracking, calorie counting, activity tracking, and education among the many available features [2,3]. There is evidence from small studies that app use may have a beneficial effect on health outcomes [4], however user preferences and desired features of these apps is a topic in need of further study [5,6]. A previous systematic review on this topic demonstrated that the usability of many apps is suboptimal, and advocated for greater patient input in the development of such apps [1]. Conway et al [7] illustrated that preferences of diabetes app users may not be well represented in the available technology, as education features are highly desired, yet only present in a minority of apps. There also appear to be differences in user preferences according to gender [8] and age [1,9]. Other studies [9,10] have highlighted the importance of user satisfaction and ease of use in acceptance of apps as diabetes self-management tools. These are important considerations, as these apps must be accepted by the patient population at a practical level if they are to be utilized. The objective of this study was to gain insight into patient perspectives and experiences related to the use of available diabetes apps. Specifically, we were interested in which diabetes apps were being used, what features of these apps were valued by patients, and what perceived gaps exist in app technology.

Methods

The procedures followed in this study were in accordance with the ethical standards of the Conjoint Health Research Ethics Board. Over a period of 8 months we recruited patients from nine diabetes clinics, one diabetes and pregnancy clinic, and one insulin pump support group to participate in a short survey about their experiences using smartphone apps for diabetes. We used a purposive sampling strategy to target patients with a high probability of having sufficient experience with smartphone apps. Recent work with a patient portal at our center suggested that patients with type 1 diabetes have higher rates of e-literacy and diabetes self-efficacy than patients with type 2 diabetes. Based on this premise, we limited our recruitment to patients with type 1 diabetes. To be eligible for participation, patients had to have a diagnosis of type 1 diabetes mellitus, along with experience using smartphone apps for some aspect of their diabetes management. During recruitment, each clinic schedule was reviewed in advance to identify patients with type 1 diabetes. These individuals were then approached and screened for eligibility based on whether they had any experience using smartphone apps for diabetes self-management. A total of 60 patients were approached for recruitment from the clinics (n=49) and support group (n=11; Figure 1). The high number of patients that did not participate was due to ineligibility based on a lack of experience with smartphone apps; all eligible patients chose to participate. Our original targeted sample size was 20, but recruitment was stopped at 12 patients due to time constraints and the emergence of some consistent patterns.

Figure 1. Patient recruitment strategy.

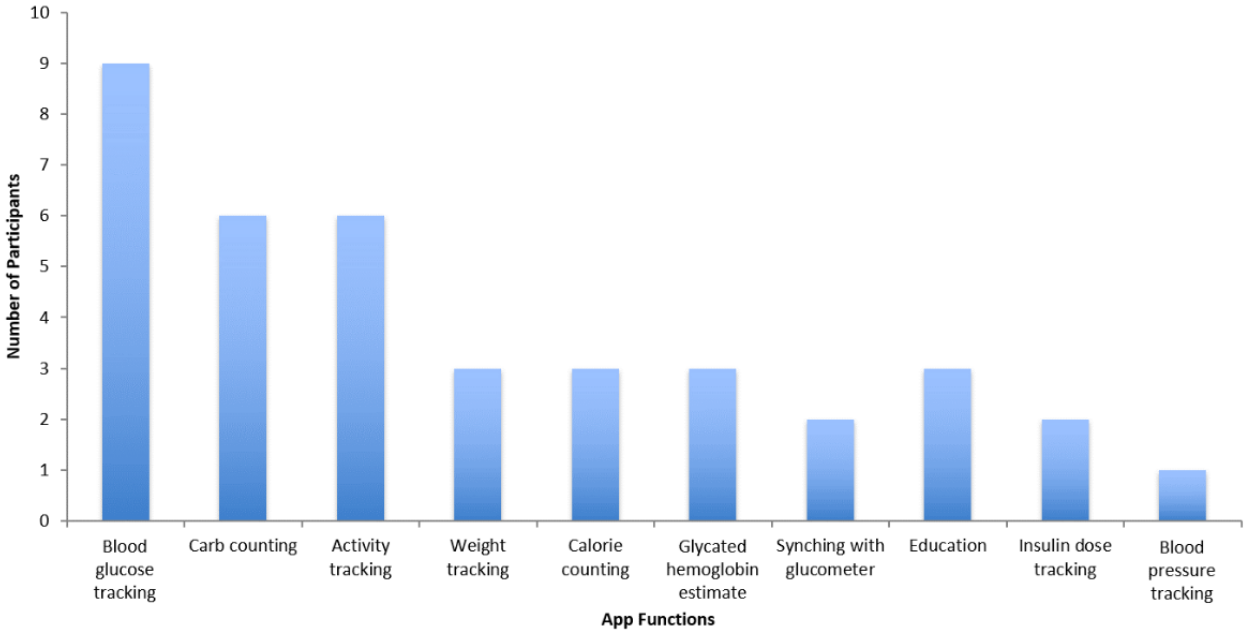


The 12 eligible participants answered a short questionnaire. Participants were required to provide demographic information including age, gender, number of years with type 1 diabetes diagnosis, number of years using a smartphone, and what type of smartphone they were using. Participants were asked to provide the specific names of up to 3 of the best apps they had encountered for managing their diabetes. From a list of known functions of available diabetes apps, participants were asked to indicate which features they had used. Participants were then asked if any of the apps they had encountered included all of the functions that they had used, and were asked to provide the names of any such apps. Participants were given space to make specific comments about app functions that they perceived were absent from currently available technology. Finally, participants were asked whether they had ever paid for an app, along with if (and how much) they would be willing to pay.

Results

Data was collected from 12 eligible participants, however 2 respondents were excluded from the final analysis, as incomplete data was provided. The age of participants ranged from 18 to 64 years (mean 34.5). We recruited 7 men and 3 women. The average length of time with a diagnosis of type 1 diabetes was 20.6 years. We did not collect data regarding the use of insulin pumps or continuous glucose monitors (CGMs). MyFitnessPal and iBGStar were the apps most commonly listed as the best available on the market; each was listed by 2 participants. The remainder of the apps that were listed included Diabetes App, Guide Resto, Glucose Buddy, Carb Control, Lose it, S health, Bike tracks, Mountain Bike Pro, and iPhone health App; each of these apps was listed by 1 participant. Two participants indicated that they were no longer using apps due to dissatisfaction with apps that they had previously used. In terms of functions used, blood glucose tracking, carbohydrate counting, and activity tracking were the most commonly used features (Figure 2). In response to whether any apps they had encountered included all functions that they were using, all participants answered *no*. The function most frequently indicated by participants as being absent from app technology was the ability to synch the app with a glucometer or insulin pump, which was a response given by 5 participants. *Reminder to check blood glucose* was indicated as a missing feature by 2 participants, *Canadian units for blood glucose values* was mentioned by 1 participant, and a *more comprehensive graphing function* was listed by 1 participant. Only 1 participant reported previously paying for an app related to diabetes management, and 9 patients indicated that they would be willing to pay for an app. Of the participants willing to pay, 8 stated that they would be willing to pay between Can $5 and $20, and 1 participant indicated that there was no upper limit to what they would be willing to pay.

Figure 2. Use of different app functions, as self-reported by participants.



Discussion

Despite the presence of hundreds of diabetes-related apps, recruiting patients that currently use these apps was a challenge. Furthermore, the apps that are currently being used do not meet all of the patients' expectations of a self-management tool. However, there remains a desire to continue using these apps despite their shortcomings, and a high willingness to pay for this technology.

We acknowledge that this study has some limitations regarding its generalizability. The collected data represent the views of a population of patients with type 1 diabetes, which may differ from patients with type 2 diabetes. These findings do not extend to mobile apps that might be part of a larger patient or electronic medical record platform. In our small study, we were not able

to make any specific correlations with the nature of app use and patient factors, such as duration of diabetes, gender, and concurrent use of insulin pump or CGM. Previous studies have shown that duration of diabetes diagnosis influences how patients engage with self-management technology [11]. An average duration of 20.6 years of diabetes diagnosis reflects extensive experience with diabetes self-management, which may limit the perceived value of diabetes apps by our participants.

The most commonly used functions cited by participants (blood glucose tracking, carbohydrate counting, and activity tracking) all relate to logging and tracking data, while more sophisticated functions such as education, feedback, and social networking were relatively underutilized. Further analysis of the specific apps preferred by participants revealed that the functions performed by these apps align with the most commonly used functions. This finding may suggest that the nature of participant app use is primarily based on what functions are included in currently available apps, and does not necessarily reflect patient preferences. Previous authors have illustrated that many patients feel that existing apps are missing important functions [9]. From a patient perspective, education has been specifically identified as an area in need of further development for diabetes apps [7]. Importantly, perceived lack of additional benefit from apps for diabetes management has been shown to be a barrier to app use [9]. Development of apps that take patients' desires and preferences into consideration, and offer novel tools for self-management, is therefore necessary to improve patient engagement.

Interestingly, despite the ubiquitous use of smartphones and high acceptance of mHealth by patients, only a small proportion of patients are currently utilizing smartphone technology to manage their diabetes [7]. One factor potentially contributing to this trend is that most currently available apps are not capable of synchronization with a glucometer or insulin pump.

One insulin pump user specifically commented that carrying both an insulin pump and a smartphone while doing more intense physical activity was unappealing. Lack of interoperability of apps with other devices has been identified as an area of concern from a patient perspective [9]. Redundant data tracking and entry into a smartphone app, in addition to an insulin pump or glucometer, could therefore be an important barrier to utilization of diabetes apps by patients, representing a potential implication for future development in mHealth technology.

Finally, while the vast majority of participants had never paid for an app, an equal proportion expressed a willingness to do so. Although the overall results of this study reflect general dissatisfaction with the currently available technology, these findings suggest that there is desire and interest for using diabetes apps from a patient perspective. To ensure that these tools are fully harnessed, existing technology must be adapted to better meet the needs of this patient population.

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Conflicts of Interest

None declared.

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Abbreviations

CGM: continuous glucose monitor
mHealth: mobile health

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Original Paper

Mixed-Methods Research in Diabetes Management via Mobile Health Technologies: A Scoping Review

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Abstract

Background: Considering the increasing incidence and prevalence of diabetes worldwide and the high level of patient involvement it requires, diabetes self-management is a serious issue. The use of mobile health (mHealth) in diabetes self-management has increased, but so far research has not provided sufficient information about the uses and effectiveness of mHealth-based interventions. Alternative study designs and more rigorous methodologies are needed. Mixed-methods designs may be particularly useful because both diabetes self-management and mHealth studies require integrating theoretical and methodological approaches.

Objective: This scoping review aimed to examine the extent of the use of mixed-methods research in mHealth-based diabetes management studies. The methodological approaches used to conduct mixed-methods studies were analyzed, and implications for future research are provided.

Methods: Guided by Arksey and O'Malley's framework, this scoping review implemented a comprehensive search strategy including reviewing electronic databases, key journal searches, Web-based research and knowledge centers, websites, and handsearching reference lists of the studies. The studies focusing on mHealth technologies and diabetes management were included in the review if they were primary research papers published in academic journals and reported using a combination of qualitative and quantitative methods. The key data extracted from the reviewed studies include purpose of mixing, design type, stage of integration, methods of legitimation, and data collection techniques.

Results: The final sample (N=14) included studies focused on the feasibility and usability of mHealth diabetes apps (n=7), behavioral measures related to the mHealth apps (n=6), and challenges of intervention delivery in the mHealth context (n=1). Reviewed studies used advanced forms of mixed-methods designs where integration occurred at multiple points and data were collected using multiple techniques. However, the majority of studies did not identify a specific mixed-methods design or use accepted terminology; nor did they justify using this approach.

Conclusions: This review provided important insights into the use of mixed methods in studies focused on diabetes management via mHealth technologies. The prominent role of qualitative methods and tailored measures in diabetes self-management studies was confirmed, and the importance of using multiple techniques and approaches in this field was emphasized. This review suggests defining specific mixed-methods questions, using specific legitimation methods, and developing research designs that overcome sampling and other methodological problems in future studies.

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KEYWORDS

mHealth; self-management; methods; review

Introduction

The Increasing Need for mHealth and Mixed-Methods Research in Diabetes Management

Increases in diabetes incidence and prevalence are a major concern in today's health care system. There are nearly 385 million diabetic patients in the world, and almost 90% of them have type 2 diabetes, which can be treated with appropriate lifestyle and nutrition changes. Diabetes is a complicated disease and requires a high level of patient involvement; 95% of its management is patient initiated. Considering the additional 235 million patients with type 2 diabetes expected worldwide by the year 2035, the development of diabetic patients' self-management skills is critical [1].

Mobile health (mHealth) apps that offer personalized, fast, cost-effective, and engaging services to patients have been used increasingly in diabetes self-management [2,3]. The "disease and treatment" apps category currently includes more than 2250 diabetes apps (iOS and Android systems in total). The number of mobile apps for diabetes is growing rapidly and market penetration is expected to grow to 7.8% by 2018, reaching 24 million diabetic patients [4].

Despite the increase in the diabetes cases and rapid growth in the mobile app market, research does not yet provide sufficient information about the factors fostering or hindering the adoption of these apps, patients' attitudes toward using them, or their effectiveness in terms of health behavior change [2,5,6,7,8]. Therefore, the controversy over whether research methodologies or mHealth-based interventions are ineffective [9,10] still remains. Alternative study designs and more rigorous methodologies to advance mHealth research, especially in diabetes management, are strongly suggested [2,11].

There is a growing interest in using mixed-methods research in mHealth-based diabetes management studies because both diabetes self-management and mHealth studies require using different approaches, techniques, and measures cooperatively within an integrated perspective [7,12,13]. This scoping review examined the extent of mixed-methods research used in mHealth-based diabetes management studies. The methodological approaches used to conduct mixed-methods studies were also investigated, and implications for future mHealth and diabetes management research are provided.

A Brief Review of Mixed-Methods Research

Mixed-methods research grew out of the "paradigm" controversy between positivist (quantitative) and constructivist (qualitative) research traditions in the 1980s and 1990s [14]. Mixed-methods research relies on both theory and practice to integrate knowledge from multiple approaches, perspectives, tools, positions, and opinions. The term "method" is used to cover a broad range of methodological (data collection techniques, design types, research methods, and so on) and related philosophical issues (eg, ontology, epistemology, axiology) [15].

The main goal of mixed-methods research is to use both quantitative and qualitative approaches to provide a better understanding of the research phenomena [16]. Because of the complementary strengths of different research paradigms, methodologies, and methods, mixed-methods research may provide new and different perspectives about an issue, expanding study findings beyond those produced by only one approach. Mixed-methods research increases the credibility of results when different approaches suggest the same conclusion, so it's a value-added methodology [17,18].

Mixed-methods research is generally used for (1) triangulation of different approaches and methodologies to explain a single phenomenon; (2) complementarity of the research methods where one method is used to elaborate, illustrate, enhance, or clarify the results from another method; (3) sequential development of a study in which the results of one method are used to inform the other; (4) initiation of a study by using one method to find contradictions and paradoxes in findings from another method; and (5) expansion of a research study by using different methods to gain new perspectives or insights about a research problem [19].

Selecting an appropriate research design is a crucial step in a mixed-methods research. The purpose of a study and the nature of the research question help shape the design used in a mixed-methods study. In addition, using either concurrent or sequential time orientation affects study design, sampling, and data collection.

In a concurrent time orientation, data collection is completed for quantitative and qualitative phases of the study at approximately the same time to answer the same question. Both datasets are processed during data analysis and interpretation stages.

In a sequential time orientation, data can be obtained in stages, so the data from the first stage are used to shape the selection of data in the second stage (exploratory or explanatory sequential design). On the basis of their study purposes, questions, designs, and resources, researchers might place equal emphasis on both methods or use one of them primarily [16,20].

Integration is the central issue of mixed-methods research because it enables researchers to examine both types of data intensively [20]. Integration can be achieved at the method level or at the interpretation and reporting level. Bryman [21] reported that 57% of social science studies using mixed methods collected qualitative and quantitative data separately, while in approximately 27% both quantitative and qualitative data were derived from a single data source (eg, survey questionnaires including closed and open-ended questions). A growing scholarly interest has advanced mixed-methods research in various areas. Especially in health sciences, several important applications of mixed-methods research have been reported [22,23]. However, the majority of these studies failed to provide a detailed description of their data collection techniques, methods of analysis, stages of integration, and justifications for the use of mixed methods [24].

Methods

The 5-stage scoping review framework developed by Arksey and O'Malley [25] was used to identify and examine the related

literature in this review. This framework allows researchers to clearly describe the methods used at each stage to increase the transparency and replicability of the studies.

Framework Stage 1: Identifying the Research Question

The research questions addressed in this review are as follows: (1) what is the extent and nature of mixed-methods research in mHealth-based diabetes management studies and (2) what are the current methodological approaches for designing and conducting mixed methods in these studies?

As a scoping review, this study did not intend to evaluate the scientific rigor of the selected studies as seen in systematic reviews [25]. It aimed to present the different ways in which researchers have used mixed methods.

Framework Stage 2: Identifying Relevant Studies

Because the key purpose of the study was scoping the area of research, a comprehensive search strategy using multiple sources was used to identify all the relevant studies. Content-specific electronic databases, key journals, Web-based research and knowledge centers, websites, and handsearches of reference lists from studies and reviews were included in the search. The search was run between May 15, 2016, and June 30, 2016, and included all articles published by July 1, 2016. Table 1 presents the literature sources used for this review.

Table 1. Sources used to search the literature in this scoping review.

Source type	Literature sources used
Electronic databases	PubMed, CINAHL[a], Web of Science, PsycINFO, Google Scholar
Key journal search	Journal of Medical Internet Research, The Journal of mHealth, The Diabetes Educator, The Journal of Mixed Methods Research, Journal of Diabetes, Journal of Diabetes Research, Journal of Telemedicine and Telecare, Telemedicine and e-Health
Research and knowledge networks	mHealth Evidence
	US NIDDK[b] Diabetes Research Center, ResearchGate
Reference lists search	Systematic reviews, meta-analyses, narrative reviews, and similar article searches of the Web-based publishers

[a]CINAHL: Cumulative Index to Nursing and Allied Health Literature.

[b]NIDDK: National Institute of Diabetes and Digestive and Kidney Diseases.

Three sets of search term combinations were used in the search, and they were entered and combined using Boolean operators where applicable. Combination 1 was the most detailed and was used in each electronic database and on the mHealth Evidence website. It included “mobile health,” “mHealth,” “m-Health,” “mobile,” “mobile phone,” “smartphone,” “cellular phone,” “texting,” “text messaging,” “SMS,” “telemedicine,” “telehealth,” “telecare,” “telemonitoring,” “diabetes,” “diabetes mellitus,” “diabetic,” “mixed method,” “multi-method,” and “mix methodology.”

Because some studies do not explicitly indicate their methodologies as mixed methods, mix methodology, or multimethod, combination 2 was applied without using the methodology terms (mixed methods, multimethod, mix methodology). Because of the excessive number of records that resulted in the search with combination 2 in Google Scholar, PubMed, and Web of Science, this search was only completed in CINAHL (Cumulative Index to Nursing and Allied Health Literature) and PsycINFO databases.

Combination 3 used the terms most relevant to our research question. “Mobile health,” “diabetes,” and “mixed methods” search terms were used in US NIDDK (National Institute of Diabetes and Digestive and Kidney Diseases) Diabetes Research Center and in Google Scholar. Wide search options were used in terms of text availability, publication dates, and document formats, and only the English-language and academic journal filters were applied in electronic sources. ResearchGate was only used to search for the authors’ personal files and to obtain full-text articles. Table 2 summarizes the search term combinations used in each electronic source.

Table 2. Search combinations used in electronic sources.

Search terms	Web of Science	CINAHL[a]	PubMed	PsycINFO	Google Scholar	mHealth Evidence	US NIDDK[b] Diabetes Research Center
Combination 1	✓	✓	✓	✓	✓	✓	
Combination 2	✓	✓	✓	✓	✓		
Combination 3					✓		✓

[a]CINAHL: Cumulative Index to Nursing and Allied Health Literature.

[b]NIDDK: National Institute of Diabetes and Digestive and Kidney Diseases.

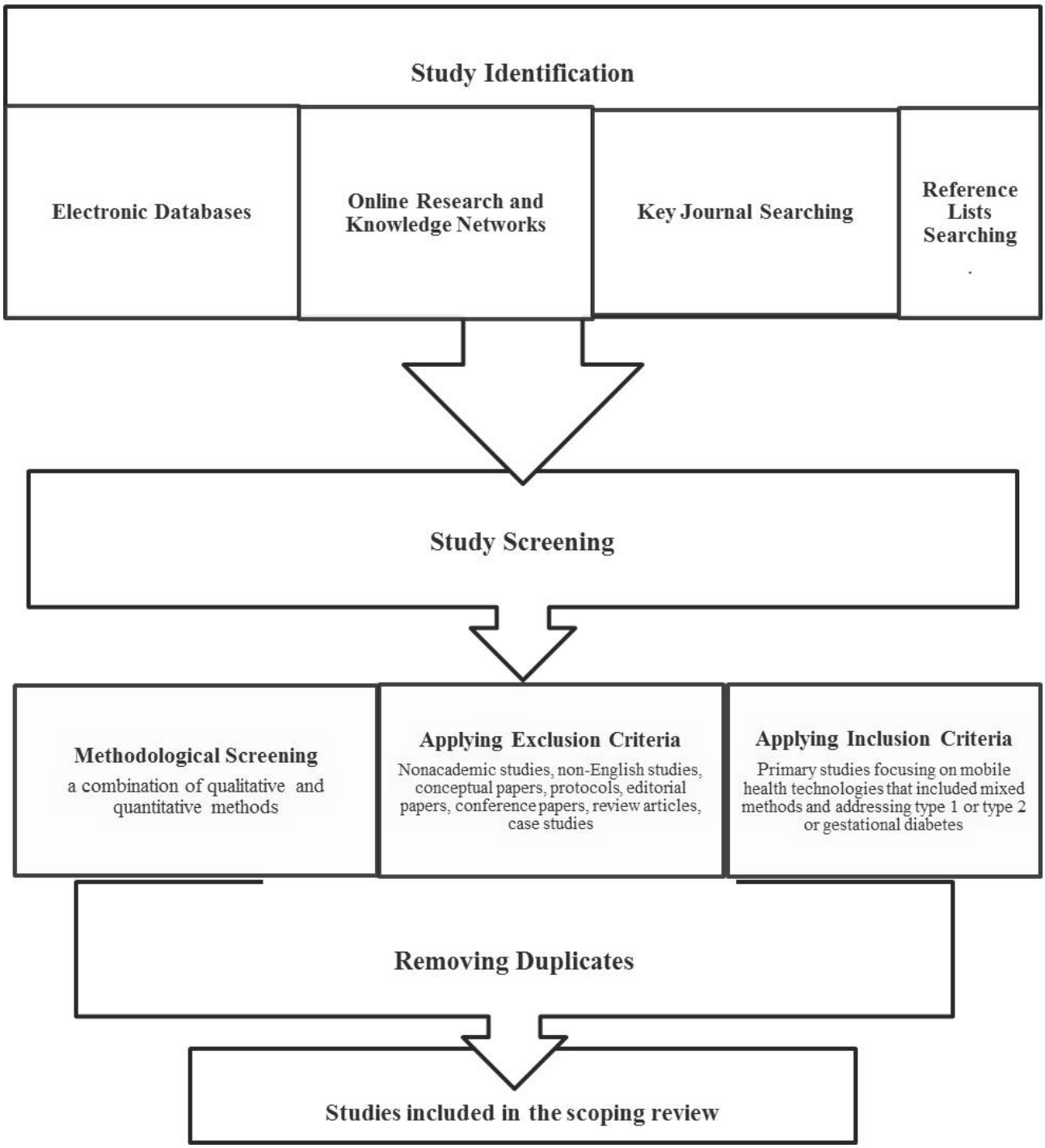
Framework Stage 3: Study Selection

Several inclusion and exclusion criteria were applied to the identified studies. The review included the primary research studies published in English-language academic journals that focused on using mHealth technologies in the context of type

1, type 2, or gestational diabetes management and included a combination of qualitative and quantitative methods.

In this review, the term “mobile health technologies” was used to cover mobile phones, portable monitoring devices (ie, accelerometer), and wireless devices used in medical care (ie, cell phones). Studies whose focus was Internet (computer)-based, telephone (landline)-based, or home-based monitoring were excluded. Examples of such studies include a mixed-methods diabetes telemonitoring study [26], using a Web-enabled glucometer for self-monitoring blood glucose, and a home-based monitoring study [27] including a randomized controlled trial and a series of interviews that used a transmission device to be attached to an analog telephone line or via USB to a computer to upload blood glucose and blood pressure measurements to a server. In addition, there were telephone coaching and counseling studies (ie, [28,29]) that did not match the inclusion criteria. The studies related to diabetic retinography were also excluded. Figure 1 presents the article selection process in this review.

Figure 1. Study selection process.



Framework Stage 4: Charting the Data

The descriptive-analytical method [25] was followed in order to standardize and chart key items of information acquired from the reviewed articles. The information collected and charted included the following elements:

- Authors, year of publication
- Main purpose of the study
- Recognition of mixed methods (mixed-methods terminology used or not)
- Purpose of mixing
- Formal mixed-methods research question formulated (yes or no)
- Prioritized method
- Design type
- Stage of integration
- Legitimation methods used
- Sources of qualitative data
- Sources of quantitative data
- Limitations described

Tables 3-5 present the definitions used to analyze the design types (Table 3), integration strategies (Table 4), and legitimation methods (Table 5) in this review.

Table 3. Common design types used in mixed-methods research.

Designs[a]		Objectives
Concurrent		This design aims to compare and contrast the results of both quantitative and qualitative findings, or to validate or expand quantitative results with qualitative data. This design is also labeled as parallel or convergent design. The researchers use different methods complementarily to investigate the same topic.
Sequential		
	Exploratory	If a study has one dataset built on the results from the other, it is classified as a sequential design. It is a 2-phase mixed-methods design that collects only one type of data at a time. This design aims to explore first by placing a qualitative phase before a quantitative phase, and the data from the first phase are used to develop the second phase.
	Explanatory	This design aims to clarify or interpret unexpected or confusing results from the quantitative phase with a follow-up qualitative phase. It can also be used to form groups based on quantitative results and monitor the groups through follow-up qualitative research.
Embedded		This includes the combination of both quantitative and qualitative data, but one data type has a supportive, secondary role within the overall design. One type of data is embedded within a methodology adapted by the other data type. It can be either a 1- or a 2-phase study. Unlike the conventional mixed-methods researchers, who think both methods should answer the same question in the research, some researchers have different questions requiring different types of data. Some complex interventions and experimental studies need embedded designs because this design is more manageable in terms of time and resources.
Multiphase		This design includes multiple qualitative, quantitative, or mixed measurement phases conducted over time and linked together so that one phase builds on another with a common overall objective. They usually include convergent and sequential elements.

[a]Developed based on the frameworks presented in Creswell [20], Creswell and Plano Clark [30], and Creswell et al [22].

Table 4. Integration through methods.

Approach[a]	Description
Connecting	One dataset links to the other through sampling.
Building	One dataset informs the data collection approach of the other.
Merging	The two datasets are brought together for analysis.
Multiple integration	Data collection and analysis are linked at multiple points.

[a]Adapted from Fetters et al [31].

Table 5. Methods of legitimation.

Approach[a]	Description
Inside-outside legitimation	Insider (emic) viewpoint refers to viewpoint of a group member while outsider (etic) viewpoint refers to an objective viewpoint gathered from an external source. Peer reviews, expert reviews, participant views, and team members' views are used for legitimation.
Paradigmatic or philosophical validity	Successful integration of philosophical and methodological beliefs, defining the paradigm assumptions explicitly, and conducting research accordingly are the main indicators of legitimation.
Commensurability legitimation	This type of validity is obtained when researchers develop a third, mixed view, which helps them make broader and richer explanations about their study conclusions.
Weakness minimization	This type of validity is related to the integration of the research; researchers must continuously work to have nonoverlapping weaknesses while planning and designing their study.
Sequential legitimation	This type of validity is used to understand whether the sequential order of qualitative and quantitative phases in a study influences the results.
Conversion legitimation	By quantifying the narrative descriptions and creating a narrative profile for quantitative results (qualitizing), researchers can interpret their data in a broader perspective.
Sample integration	This type of validity refers to making appropriate generalizations from mixed samples. The relationship between the sampling designs in quantitative and qualitative phases is an important indicator of validity.
Sociopolitical legitimation	In order to achieve this type of legitimation, mixed-methods researchers should advocate pluralism of perspectives and try to build a practical theory or result that research consumers will find valuable.
Multiple legitimation	This type of validity indicates the extent to which all the pertinent validities (quantitative, qualitative, and mixed) are addressed and resolved successfully.

[a]Adapted from Onwuegbuzie and Johnson [32].

Results

Framework Stage 5: Collating, Summarizing, and Reporting the Results

Collating and Summarizing the Results

The database search revealed 8 articles; with handsearches of reference lists and key journals, a total of 14 articles were identified. The final sample included studies focusing on feasibility and usability of mHealth diabetes technologies (n=7), behavioral measures related to mHealth apps (n=6), and challenges in patient recruitment, fidelity, and intervention delivery in the context of mHealth (n=1).

For this scoping review, the first author derived the data from the articles and completed the initial coding, which was verified by the second author. In addition, an independent researcher (an experienced researcher and doctoral student in social sciences) separately coded the articles based on the study design framework used in this review. Comparing the results revealed an interrater reliability level of more than 90%.

The characteristics of mixed-methods research used in the reviewed studies and the summary of the findings are presented in Tables 6 and 7. Table 6 presents the data gathered on formal recognition of mixed methods and purpose of using mixed methodology, indicating a formal mixed-methods question, priority of the methods used, stages of integration, and the design type used in the studies. Table 7 lists the data gathered on legitimation methods, qualitative and quantitative sources of data, and limitations as described in the studies.

Table 6. The characteristics of mixed-methods research in mHealth-based diabetes management studies examined in this review (part 1).

Author, year	Main purpose of the study	Recognition of MM[a]	Purpose of mixing	Formal MM research question	Prioritized method	Stage of integration	Design type
Allen et al, 2009 [33]	To assess feasibility and acceptability of continuous glucose monitoring and accelerometer technology in exercising type 2 diabetic patients	Yes, as multimethod	Complementarity	No	Equal	Sampling and interpretation	Explanatory sequential
Baron et al, 2015 [34]	To identify the challenges related to recruitment, fidelity, implementation, and context of mobile telehealth interventions targeting diabetic patients	Yes	Complementarity: different measures for different parts of the research phenomenon	No	QUAN[b]	Sampling, data collection, data analysis, and interpretation	Embedded
Baron et al, 2016 [35]	To examine the behavioral effects of a mobile phone–based home telehealth intervention in diabetic patients	No	Triangulation	No	QUAN	Sampling and interpretation	Embedded
Burner et al, 2013 [36]	To explore the attitudes of inner-city Latino patients toward TExT-MED[d] program and other health information sources	Yes	Initiation: the qualitative study was conducted to understand the contradictory findings of the quantitative method	No	Equal	Sampling and interpretation	Explanatory sequential
Carroll et al, 2007 [37]	To evaluate user satisfaction with an mHealth diabetes monitoring system	Yes	Sequential development	No	QUAN	Discussion or interpretation	Exploratory sequential
Franklin et al, 2008 [38]	To explore the interactions of type 1 patients with SMS text messaging support	Yes	Triangulation	No	Equal	Sampling, data analysis, and interpretation	Concurrent
Froisland et al, 2012 [39]	To explore ways mobile apps can be used to monitor adolescents with type 1 diabetes	Yes	Triangulation	No	QUAL[c]	Sampling, data collection, and interpretation	Embedded
Georgsson and Staggers, 2016 [40]	To test the feasibility of a multimethod approach for patients' experienced usability of a diabetes mHealth system	Yes, as multimethod	Triangulation	No	Equal	Sampling, data analyses, and interpretation	Concurrent
Grindrod et al, 2014 [41]	To examine the usability and usefulness of mobile medication apps with older adults	Yes	Triangulation	No	Equal	Sampling, interpretation, and data analysis	Concurrent
Jones et al, 2015 [42]	To evaluate the attitudes of American Indian women toward postpartum intervention approaches (including mHealth) and risk factors for developing gestational diabetes	Yes	Complementarity: different measures for different parts of the research phenomenon	No	QUAL	Sampling and interpretation	Embedded

Author, year	Main purpose of the study	Recognition of MM[a]	Purpose of mixing	Formal MM research question	Prioritized method	Stage of integration	Design type
Nundy et al, 2014 [43]	To investigate the behavioral effects of a theory-driven mobile phone–based intervention using an automated, interactive SMS text messaging system	Yes	Triangulation	No	QUAN	Sampling and interpretation	Embedded design
Osborn and Mulvaney, 2013 [44]	To examine the capability of an SMS text messaging and interactive voice response intervention for low-income adults with type 2 diabetes mellitus	Yes	Sequential development	No	Equal	Sampling, data analysis, and interpretation	Embedded
Verwey et al, 2016 [45]	To examine the reach, implementation, and satisfaction with a counseling tool combining an accelerometer, a mobile phone, and a Web application	Yes	Triangulation	No	Equal	Sampling, interpretation, and data analysis	Embedded
van der Weegen et al, 2014 [46]	To test the usability of a monitoring and feedback tool targeting diabetic patients	Yes	Sequential development	No	Equal	Sampling, data collection, data analysis, and interpretation	Multiphase study

[a]MM: mixed methods.

[b]QUAN: quantitative.

[c]QUAL: qualitative.

[d]TExT-MED: Trial to Examine Text Message–Based mHealth in Emergency Department Patients With Diabetes.

Table 7. The characteristics of mixed-methods research in mHealth-based diabetes management studies examined in this review (part 2).

Author, year	Legitimation methods described	Sources of qualitative data	Sources of quantitative data	Limitations described
Allen et al, 2009 [33]	Inside-outside legitimation	A 1-hour, structured, focus group interview (n=7) following the completion of the quantitative phase. Field notes were also taken on key discussion points and observations (eg, body language and group mood).	Descriptive measures of the sample (n=9). Wearable Continuous Glucose Monitoring System, activity monitor data, and activity counts reviewed for each participant.	Small sample size and lack of control group setting in quantitative phase were reported.
Baron et al, 2015 [34]	Inside-outside legitimation	Interviews, meetings, field notes, and communications between team members.	A 9-month randomized controlled trial (n=81) to assess intervention delivery and fidelity (patients and nurses).	A possible sample selection bias was indicated.
Baron et al, 2016 [35]	Inside-outside legitimation and conversion legitimation (quantizing the qualitative data)	Semistructured interviews (n=26) on perceived effects of mobile telehealth system on diabetes self-management.	A randomized controlled trial (n=81) with intervention and control groups was conducted. Self-report measures of self-efficacy, illness beliefs, and self-care were taken at baseline and 3- and 9-month points.	Sample size was indicated as insufficient to make generalizations.
Burner et al, 2013 [36]	Inside-outside legitimation	Two focus groups of 90-minute duration, one in English, one in Spanish (n=8), were conducted with a structured guide.	A 1-month bilingual diabetes SMS text messaging intervention (n=23). Quantitative data included demographic, clinical, and biometric data of patients, and measures of health behaviors, knowledge, and beliefs were taken.	Small sample size was indicated as a limitation to the generalizability of the results.
Carroll et al, 2007 [37]	Weakness minimization legitimation: large focus groups to support small-scale usability test	A series of focus groups (10; n=59) was conducted before testing a prototype cell phone with a glucose monitoring system.	A pilot usability test to evaluate satisfaction with the new system (n=10). A 15-item questionnaire is used.	Sample size and sample selection, intervention duration, and incentives to the participants were seen as barriers to generalizability of findings.
Franklin et al, 2008 [38]	Inside-outside legitimation and conversion legitimation	Content analysis of text messages and messaging patterns of a 12-month Sweet Talk intervention period.	A 12-month 3-armed randomized controlled trial of a text messaging support system, Sweet Talk (n=64), was conducted. Observational data on messaging patterns were triangulated with patient clinical and demographic data. Post hoc analyses combining qualitative data and demographic variables were made.	Small sample size was indicated as a limitation to generalizability of the results.
Froisland et al, 2012 [39]	Inside-outside legitimation	Semistructured in-depth interviews lasting between 45 and 90 minutes (n=12) were conducted at the end of the quantitative phase.	A pilot test of 2 mobile apps (n=12), after a 3-month trial.	Possible sampling bias, small sample size, and short intervention period were indicated.
Georgsson and Staggers, 2016 [40]	Inside-outside legitimation, conversion legitimation	Think aloud protocol and open-ended interviews (15-20 minutes) were conducted (n=20).	First, a brief demographic questionnaire, and, at the end of the intervention, a posttest questionnaire measuring the usability of an interactive SMS[a]- text messaging system for a randomly selected sample of patients with diabetes (n=10) were conducted.	Using a convenient sample frame and the novelty of the system to patients were indicated as a limitation to the generalizability of the findings.
Grindrod et al, 2014 [41]	Outside legitimation, sequential legitimation, sample integration legitimation	A 10-minute group discussion of what medication management meant before each usability evaluation and 30-minute focus group discussion after each session (n=35).	A 2-hour usability testing (n=35) of different mobile apps using a 10-item system usability scale and a visual analog scale was used.	Short intervention period was indicated as a limitation of the study.
Jones et al, 2015 [42]	Inside legitimation	Four focus groups consisting of 2-5 participants (n=11 in total) were conducted, maximum duration of 60 minutes. Individual interviews (n=15) ranged from 25-45 minutes.	A cross-sectional study (n=26) was conducted with eligible group of patients. The questionnaire included measures for personal and family health history and technology feasibility and acceptability.	The purposive sampling and small sample size were seen as barriers to the generalizability of the results.

Author, year	Legitimation methods described	Sources of qualitative data	Sources of quantitative data	Limitations described
Nundy et al, 2014 [43]	Inside-outside legitimation	Approximately 1-hour, semistructured, in-depth interviews (n=14) based on topic guides and open-ended questions after the intervention.	A longitudinal observational cohort study (n=74) was conducted and data were collected at baseline, 3 months (mid-intervention), and 6 months (end of intervention). Diabetes self-care, medication adherence, self-efficacy, health beliefs, and social support measures were used.	The limitations were described as the lack of control group measure and sole use of SMS text messaging intervention, which may create a causality problem. Sample size was small to make proper generalizations.
Osborn and Mulvaney, 2013 [44]	Inside-outside legitimation	Motivational interviewing, face-to-face interviews (n=20) before and after trial, at baseline, and after week 3.	Secondary research: previous descriptive data on target population obtained, and self-administered daily text messages and interactive voice response calls are collected for analysis (n=20).	Sampling size was indicated as small to generalize results.
Verwey et al, 2016 [45]	Inside and outside legitimation, conversion legitimation, sample integration	30-Minute semistructured telephone interviews with the nurses about the receipt of intervention and the evaluation forms regarding consultations were used.	A longitudinal 3-armed cluster randomized controlled trial in a total of 24 family practice locations; evaluation questionnaire after intervention with practice nurses (n=20) and patients (n=131; 71 with type 2 diabetes and 42 with chronic obstructive pulmonary disease).	A possible sample bias was indicated as a limitation of the study.
van der Weegen et al, 2014 [46]	Multiple legitimation: weakness minimization, conversion legitimation, inside-outside legitimation	Heuristic evaluation with 6 experts, thinking aloud procedure and video recordings of 5 patients at two different stages, a series of interviews with patients in the pilot test.	A usability test with 5 patients, a pilot test in real-life settings with 20 patients, and a poststudy system usability test were conducted.	The small sample size was indicated as a limitation to the generalizability of the findings.

[a]SMS: short message service.

Reporting the Results

Recognizing Mixed Methods and Purpose of Using Mixed Methods

According to Creswell and Plano Clark [47], mixed-methods studies should have a properly defined methodology and a formal terminology. This review shows that almost all the studies (13/14, 93%) defined their methodologies explicitly as either mixed methods or multimethod.

Only a few studies (4/14, 29%; Verwey et al [45], Georgsson and Staggers [40], Froisland et al [39], and Franklin et al [38]) used mixed-methods terminology or explained its purpose explicitly. For example, Franklin et al [38] stated that their purpose was to triangulate the messaging patterns and contents of an automated, scheduled SMS text messaging with diabetic patients' clinical and demographic data, and Froisland et al [39] reported that they triangulated the usability assessments of a picture-based diabetes diary app and an SMS (short message service) text messaging with semistructured, in-depth interviews and field notes.

In other studies, information about the purpose of mixing methods had to be extracted from the methodology and discussion sections of the studies. Particularly for the embedded design studies, a decision rule was used based on the phases of a study because they could signify the purpose of mixing the methods in a study [30]. If different measurements using different types of data were addressing different parts of the research phenomena, it was evaluated as complementarity [30]. For example, in an embedded design study, the attitudes of a group of American Indian women toward potential Internet or mHealth interventions were examined using qualitative interviews and focus groups that were complementary to a cross-sectional study assessing their risk perceptions of diabetes [42]. If one method was embedded into the other method and used to compare and validate its results, it was evaluated as triangulation. For example, Nundy et al [43] conducted a longitudinal cohort study and compared and validated the results with in-depth interviews. In addition, if one type of data was used to inform the other type during the sequential development of a study, its mixing purpose was evaluated as sequential development. For example, motivational interviews before the intervention and follow-up phone interviews during the testing period were used in a study focusing on the development and feasibility of a text messaging and interactive voice response intervention [44].

In total, the purpose of mixing methods was triangulation in 7 studies [35,38,39,40,41,43,45], complementarity in 3 studies [33,34,42], sequential development in 3 studies [37,44,46], and initiation in 1 study [36].

Design Types

Because the studies did not use a formal mixed-methods terminology when describing their design types, stages of integration, and priority of the methods they used, information on these categories was extracted from the methodology sections of the studies.

The most common design used by the studies was embedded design (n=7). These studies (ie, [34,39,42,43,45]) were designed to mix different datasets at the design level. For example, Vervey et al [45] conducted a 3-armed cluster randomized controlled trial with nurses and patients to evaluate the physical activity counseling process with and without the use of mobile technology. During the intervention, data were gathered from nurses who interviewed the patients periodically, collected evaluation forms, and logged data. They conducted in-depth interviews with nurses after the trial to compare and cross-validate their findings.

There were 3 concurrent design studies in the review [38,40,41]. In their text messaging intervention, Franklin et al [38] conducted a content analysis and derived qualitative themes from the messaging patterns, which were also analyzed by quantitative methods. In addition, 3 sequential design studies were identified: 1 exploratory [37] and 2 explanatory design studies [33,36]. After completing the qualitative phase and establishing the framework of the research, Carroll et al [37] implemented a usability test of a diabetes monitoring system. On the contrary, Burner et al [36] conducted a focus group study to clarify the results of their quantitative study, measuring behavioral effects of an mHealth intervention in Latino diabetic patients.

The only multiphase design study in this review was the study by van der Weegen et al [46], which measured the usability of a monitoring tool targeting diabetic patients. They conducted different qualitative and quantitative measurements focusing on different aspects of a study including 4 phases.

Stages of Integration

All the studies enabled integration by connecting samples. The studies used either identical or nested sampling methods. On the basis of their designs and time orientation, they used samples sequentially or concurrently. Some studies (ie, [35,38,45,46]) made the integration at multiple points throughout their studies. They largely connected their samples, analyzed the data, merged their datasets, and interpreted their findings with an integrated view.

Some studies also enabled integration through the merging of both datasets in the data analysis stage. In an explanatory sequential design study on diabetes self-management [36], the themes from the qualitative analysis were merged with the demographic variables. In another study [33], descriptive measures of physical activity patterns and glucose levels of patients with type 2 diabetes were merged with the focus group data on the feasibility and acceptability of a new glucose monitoring and accelerometer technology.

The studies also presented various forms of data integration at the stage of interpretation or discussion. They identified themes or concepts and integrated their qualitative and quantitative findings into these themes [35,39,40,42,44,45]. In addition, the findings of a multiphase design study were reported in a series. After each stage was completed, its findings were written separately [46]. In some studies, specific findings were written in the separate parts of their reports and then an overall interpretation of the findings was made [34,38,43].

Prioritized Methods

More than half the studies evaluated their quantitative and qualitative methods equally; neither method was prioritized (8/14, 57%). Some studies with randomized controlled trial data [38,40,45] highlighted their comprehensive qualitative methodologies and their contributions to the results. For example, in order to completely measure young diabetic patients' engagement with a new text messaging support system, a comprehensive content analysis of messages and message patterns of patients was performed [38]. Interestingly, in an explanatory design study [36], focus group results led researchers to reanalyze their quantitative data.

In another study [44], face-to-face interviews conducted before and after a text messaging trial provided important insights about the intervention's technical features, tailored text messaging content, and motivational messaging. Researchers were guided to develop a better design for their apps. Three studies [34,35,43] primarily highlighted quantitative methods (QUAN + qual) and used qualitative methods to support quantitative data.

Data Collection Techniques

The most frequently used qualitative method in the studies was in-depth interviews (n=9). The studies conducted semistructured interviews [35,39,42,43,45,46], open-ended interviews [40], and motivational interviews [44]. Several studies conducted focus group meetings to collect data [33,36,37,41,42]. The interview or discussion duration varied from approximately 30 minutes to 90 minutes in these studies. In addition, 2 think aloud protocols [40,46], a content analysis [38], and a video-recording technique [46] were used to generate qualitative data.

Surveys were the most common quantitative data collection method (n=10), such as pre- and posttest questionnaires used to measure the usability of an interactive SMS text messaging intervention developed for patients with diabetes [40]. Perceptions of a group of American Indian women about gestational diabetes risk and related Internet and mHealth interventions were surveyed in a cross-sectional study [42]. In addition, there was a longitudinal cohort study [43] that collected survey data at multiple periods.

Quantitative data were also generated from descriptive measures, such as glucose and exercise levels of patients after a 72-hour trial of a continuous glucose monitoring system [33], usage data of patients after a 12-month trial of a text messaging support system [38], and interactive voice response calls and previous descriptive data [36,44].

The Methods of Legitimation and the Limitations Described

Although the studies in this review explicitly mentioned their procedures and strategies to increase the objectivity and credibility of their research, they did not use formal mixed-methods terminology. Therefore, the information on legitimation methods was extrapolated from the methodology and discussion sections of the studies.

Almost all the studies in this review applied an "inside and outside" legitimation method (13/14, 93%). For example, Nundy et al [43] assigned a team of 5 experienced research investigators

to make an initial transcript coding and then randomly assigned 2 reviewers to code each transcript independently. In addition to peer reviews, team members' views were important means for legitimation. For instance, conducting separate analyses helped the researchers compare their coding results and increased the validity of their study [39].

In addition to inside-outside legitimation, different methods of legitimation were identified in the studies. For instance, the qualitative and quantitative methods were used to complement each other and to minimize weaknesses (weakness minimization method) in a small-scale usability test study [37]. A small number of questionnaires were supported by conducting 10 different focus groups to increase the legitimacy of the results. The use of conversion legitimation was observed in 4 studies [35,43,45,46]. In 1 study [41], sequential legitimation was applied to minimize possible sequential order effects on the results.

Because the studies used either identical or nested sampling methods, sample integration legitimation was another frequently observed method of legitimation. Using similar samples in each phase minimizes lack of representativeness in qualitative findings and increases overall generalizability of the study [32]. For example, Grindrod et al [41] used identical samples in their qualitative and quantitative phases and performed multiple measurements to increase the validity of their small-scale intervention design, which lacked control group measurements.

Although various legitimation methods were used, they were also the source of study limitations. Many of the limitations were related to insufficient sample sizes and possible generalizability problems associated with them (ie, [35,36,38,44,46]). Sample selection problems and possible sample biases were also pointed out [33,39,40,42,43,45]. The duration of intervention [37,39,41], fidelity to the study [42], and other interventional issues, such as incentives (ie, lending cell phones, paying call charges) [37], and technical problems [39] were further limitations.

Discussion

Principal Findings

This scoping review identified comprehensive mixed-methods applications in the growing field of mHealth-based diabetes management. Mixed methods research can be effectively used if there is a strong and appropriate design dictated by research questions [48,49]. Creswell and Tashakkori [50] suggest using at least one clearly defined mixed methods question. Although none of the studies defined a separate mixed-methods research question and a very few studies (4/14, 29%) used formal mixed-methods terminology, the studies showed promise in their uses of multiple approaches and techniques. In addition to the common uses of mixed methods (triangulation and complementarity), studies with advanced designs presented various forms of combining different methods and techniques in sequential development of their studies. These studies are good examples for the field of diabetes management via mHealth technologies in which complicated interventions and multiple measurements are often required.

This study confirms the prominent role of qualitative methods in mixed-methods research. Qualitative measures were very important for the evolution of the majority of the papers reviewed, and they strongly influenced study findings. Because of the growing need for interpreting complex longitudinal studies and interventions [51] and big and sophisticated data coming from Web-based and mobile technology usage statistics, the importance of qualitative methods seems to be increasing.

The studies in this review presented various forms of integration at the method level. Some studies enabled integration at multiple points, linking their data collection and analysis at each point in the research. This is also noteworthy for mixed-methods studies in which integration is generally made at the level of data interpretation or discussion [52].

In terms of validity or legitimation strategies, little variation existed among the studies. In addition to inside-outside legitimation, these advanced designs should have also used weakness minimization and conversion legitimation methods because they are very specific to mixed-methods research.

The major limitations of the studies included in this review were related to data collection processes. Surveys were the most common data collection method used in the studies, but (as opposed to experimental studies) descriptive studies do not show causality, as they have poor control over external factors and external validity problems due to standardized question types. In addition, almost all studies acknowledged sampling problems (13/14, 93%). Small sample sizes, sampling bias, and use of convenient sampling are important barriers to the generalizability of findings in any type of study.

When various data collection techniques are used together, researchers are able to provide rich analysis and interpretations. This study shows that in addition to the common qualitative data collection techniques (focus group discussions and semistructured interviews), multiple data collection techniques (including think aloud protocols, interviews, field notes, content analysis, and evaluation forms) are used.

It is also noteworthy that these studies failed to discuss the advantages gained by using mixed-methods approaches. The majority of the studies (13/14, 93%) failed to provide a methodological discussion concerning the inconsistency or consistency between quantitative and qualitative data. Thus, this study supports Brown et al [24], who indicated that mixed-methods studies still lack justifications for using this approach.

Study Strengths and Limitations

This study is an early exploration into the scope of mixed-methods studies in the field of mHealth-based diabetes management. This paper itself provides a demonstration of how to classify, analyze, and evaluate mixed-methods research. Regardless of field of interest, we believe many researchers could benefit from the guidelines, criteria, and examples provided in this review.

Although the database search was quite comprehensive, it was limited to the papers published in scientific journals and written in English. To increase the consistency of the coding, some

established frameworks were used to identify design types [20], integration methods [31], and legitimation methods [32]. Because related information was not always clearly reported in the studies, some decision rules were applied and the most relevant choices presented in the frameworks were adopted. Another limitation is related to the coding process. Although the design types were classified by 2 coders, and a high level of agreement between them was established, the rest of the coding was done by the first author. However, to increase the confirmability of our analysis, she took the role of a "devil's advocate" with respect to the results, checking and rechecking each coding and analysis throughout the study.

Conclusions and Future Recommendations

This review provided important insights into the evaluation of mixed-methods studies focusing on diabetes management via mHealth technologies. The prominent role of qualitative methods in mixed-methods research and tailored measures in diabetes self-management studies was confirmed, and the importance of using multiple methods and techniques in this field was emphasized. Future studies could continue to use different qualitative approaches and try to integrate new tools and approaches that seem to be effective in health care settings, such as participatory video, photovoice, online communities, and chat and discussion groups [3].

Considering the opportunities provided by mixed methods, it is surprising to see such a small number of studies in this field. The lack of systematic approaches in establishing rigor in mixed-methods studies seems to be a major barrier to the adoption and recognition of this research by a large group of social researchers [20]. However, in the field of mHealth-based diabetes management both usability studies and behavioral change interventions require complex measurements, so researchers could utilize the advantages of mixed methods more frequently. Future research should focus on the ways to improve precision in measurements by incorporating experimental designs with properly selected, adequate number of participants and new and creative data collection techniques.

In the future, researchers should incorporate formal mixed-methods terminology, starting with defining a mixed-methods question separately at the beginning, aiming to answer this question, and discussing the value of using the methodology at the end. In this growing field of diabetes management, future reviews should systematically analyze rigor in mixed-methods studies and compare the results with those of single-method studies.

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Conflicts of Interest

None declared.

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Abbreviations

CINAHL: Cumulative Index to Nursing and Allied Health Literature
mHealth: mobile health
NIDDK: National Institute of Diabetes and Digestive and Kidney Diseases
SMS: short message service
TExT-MED: Trial to Examine Text Message–Based mHealth in Emergency Department Patients with Diabetes

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Original Paper

A Novel Intervention Including Individualized Nutritional Recommendations Reduces Hemoglobin A1c Level, Medication Use, and Weight in Type 2 Diabetes

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Abstract

Background: Type 2 diabetes (T2D) is typically managed with a reduced fat diet plus glucose-lowering medications, the latter often promoting weight gain.

Objective: We evaluated whether individuals with T2D could be taught by either on-site group or remote means to sustain adequate carbohydrate restriction to achieve nutritional ketosis as part of a comprehensive intervention, thereby improving glycemic control, decreasing medication use, and allowing clinically relevant weight loss.

Methods: This study was a nonrandomized, parallel arm, outpatient intervention. Adults with T2D (N=262; mean age 54, SD 8, years; mean body mass index 41, SD 8, $kg \cdot m^{-2}$; 66.8% (175/262) women) were enrolled in an outpatient protocol providing intensive nutrition and behavioral counseling, digital coaching and education platform, and physician-guided medication management. A total of 238 participants completed the first 10 weeks. Body weight, capillary blood glucose, and beta-hydroxybutyrate (BOHB) levels were recorded daily using a mobile interface. Hemoglobin A_{1c} (HbA_{1c}) and related biomarkers of T2D were evaluated at baseline and 10-week follow-up.

Results: Baseline HbA_{1c} level was 7.6% (SD 1.5%) and only 52/262 (19.8%) participants had an HbA_{1c} level of <6.5%. After 10 weeks, HbA_{1c} level was reduced by 1.0% (SD 1.1%; 95% CI 0.9% to 1.1%, P<.001), and the percentage of individuals with an HbA_{1c} level of <6.5% increased to 56.1% (147/262). The majority of participants (234/262, 89.3%) were taking at least one diabetes medication at baseline. By 10 weeks, 133/234 (56.8%) individuals had one or more diabetes medications reduced or eliminated. At follow-up, 47.7% of participants (125/262) achieved an HbA_{1c} level of <6.5% while taking metformin only (n=86) or no diabetes medications (n=39). Mean body mass reduction was 7.2% (SD 3.7%; 95% CI 5.8% to 7.7%, P<.001) from baseline (117, SD 26, kg). Mean BOHB over 10 weeks was 0.6 (SD 0.6) $mmol \cdot L^{-1}$ indicating consistent carbohydrate restriction. Post hoc comparison of the remote versus on-site means of education revealed no effect of delivery method on change in HbA_{1c} ($F_{1,260}$=1.503, P=.22).

Conclusions: These initial results indicate that an individualized program delivered and supported remotely that incorporates nutritional ketosis can be highly effective in improving glycemic control and weight loss in adults with T2D while significantly decreasing medication use.

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KEYWORDS

type 2 diabetes; ketosis; Hb A1c; weight loss; mobile health

Introduction

Type 2 diabetes is generally regarded as a chronic, progressive disease that can be slowed by the vigorous use of lifestyle changes and medications but eventually results in vascular damage and end-organ failure [1,2]. Current medical treatment interventions result in virtually no disease remission, as seen in a study within the Kaiser health care population where the spontaneous remission rate is 0.5% [3]. As the disease progresses, it has been shown that glucose-lowering medication use, health care costs, and complications all rise. At 9 years, less than 25% of patients are able to control their blood glucose level with only one medication [4], and 10-15 years after the diagnosis of type 2 diabetes, more than 50% of patients will require insulin [5].

Despite the overall paucity of type 2 diabetes remission data, there exist three notable treatment exceptions. Bariatric surgery, such as gastric bypass, is effective at reversing type 2 diabetes, with 40%-60% of surgical patients demonstrating remission 1 year after the surgery. The most comprehensive study of surgical intervention to prevent or reverse type 2 diabetes is the Swedish Obese Subjects Trial [6], demonstrating an 8-fold reduction in the incidence of the disease at 2 years. However, further out into the postoperative experience, many of these patients regain weight and relapse into diabetes, and they are at risk of developing nutritional deficiencies as well [7].

There have been many reports of short-term improvement in glycemic control with very low-calorie diets (VLCDs) consisting of either common foods or chemically defined formulas, ranging in energy from 400-800 kcal·day^{-1}. Bistrian et al [8] administered a common-food 600-800 kcal·day^{-1} VLCD to 7 insulin-using subjects with type 2 diabetes for inpatient and outpatient durations of 2-12 months. All 7 subjects achieved rapid improvement in glycemic control despite the cessation of insulin therapy, and 6 of 7 subjects experienced substantial weight loss. Bauman et al [9] hospitalized 64 patients with type 2 diabetes, including 42 patients taking insulin, and administered a VLCD for a mean of 23 days. After 19 months, 10 patients remained in remission. Wing et al [10] randomized 93 obese individuals with type 2 diabetes to either a low-calorie diet or an intermittent formula VLCD for 1 year. The VLCD group achieved greater initial weight loss and greater hemoglobin A_{1c} (HbA_{1c}) reductions, but these differences between the 2 diet arms were not sustained over the duration of the study. In a recent study by Steven et al [11], 13 of 30 individuals with type 2 diabetes but not using insulin achieved normal blood glucose values after 8 months of lifestyle intervention. In this case, a chemically defined, liquid, low-carbohydrate VLCD was prescribed for 8 weeks, followed by 6 months of an unspecified energy maintenance diet.

These 4 studies [8-11] used VLCDs to control blood glucose level while stopping or reducing diabetes medications. The limitation of using a VLCD to manage a chronic disease is that this type of diet is necessarily temporary, given that it provides less than 800 kcal·day^{-1} and thus is unsustainable in the long term.

Alternatively, nutritional ketosis, defined as a dietary regimen resulting in serum beta-hydroxybutyrate (BOHB) levels between 0.5 and 3.0 mmol·L^{-1} [12], may yield similar or better results over longer periods of time by not explicitly prescribing caloric restriction. Nutritional ketosis is often achieved by reduced carbohydrate, moderate protein, and increased fat intake. In this setting, moderately reduced energy intake may occur in association with the proportionately high fat intake, reduced circulating insulin due to reduced carbohydrate consumption, and potential metabolic benefits of mild ketonemia. For example, Boden et al [13] reported that in patients with type 2 diabetes fed a ketogenic diet to satiety improved insulin sensitivity by 75% within 2 weeks. When given free access to a ketogenic buffet, daily energy intake dropped by about one-third, resulting in a total weight loss of 2 kg over 2 weeks. The authors concluded that this modest weight loss in and of itself could not explain the improved insulin sensitivity.

There have been a number of studies using low-carbohydrate, high-fat dietary strategies in the management of type 2 diabetes [14-20], but these group sizes have been small and often excluded subjects taking insulin. In addition, the dietary interventions used in these studies frequently were not sufficiently low in carbohydrate or protein to induce sustained nutritional ketosis. However, multiple studies of ketogenic diets prescribed without energy restriction have demonstrated both tolerability and effectiveness of this dietary approach to improve a broad range of cardiometabolic markers in prediabetic and dyslipidemic outpatients [21-23]. And finally, recent studies have identified BOHB in the nutritional ketosis range as a potent epigenetic signal that decreases oxidative stress [24], hepatic glucose output [25], and insulin resistance [26].

We therefore hypothesized that a comprehensive program with individualized nutritional recommendations that supports participants in achieving sustained nutritional ketosis while eating to satiety may have unique benefits in the management of type 2 diabetes. Specifically, this study was designed to assess the practical utility of an intensive digital intervention supported by medical management, continuous digital health coaching, nutrition education, behavioral support, biometric feedback, and peer support via an online community. We refer to this technology-enabled medical service as the Virta Clinic.

Methods

Subjects

Adults with type 2 diabetes between the ages of 21 and 65 years were recruited via clinical referrals, media advertising, and word of mouth in the greater Lafayette, Indiana, region. Exclusion criteria included advanced renal, cardiac, and hepatic dysfunction, history of ketoacidosis, dietary fat intolerance, or pregnancy or planned pregnancy.

The Virta Clinic

Virta utilizes a technology-enabled, full-service clinic model for metabolic recovery from type 2 diabetes including medical management by physicians, health coaching, nutrition and behavior change education, biometric feedback, and peer support. Physicians and health coaches were trained in the basic principles of achieving and maintaining nutritional ketosis based on previous published works [21,22,27]. In this study, educational content was delivered via either on-site weekly 90-minute group-based classes or Web-based recorded educational content, and participants self-selected their preferred mode of content delivery. The same educational content was provided by each delivery method. Educational content included discussion of the pathophysiology of diabetes, practical management of carbohydrate restriction while consuming protein in moderation and increasing fat intake, the utilization of ketones as a biofeedback mechanism, and appropriate utilization of behavior change techniques. No modifications to participants' physical activity were encouraged in the first 10 weeks of the intervention.

Remote support was provided to each subject through tracking of daily biometrics, the assignment of a personal health coach available daily via one-on-one texting for advice and problem solving, support via an online community of his or her peers, and physician supervision. Subjects were instructed to monitor and report glucose level via the Web to the care team 1-3 times per day, and a physician made medication changes as appropriate. Additionally, the medication status of each participant was reviewed by the care team and the principal investigator weekly.

Nutritional Ketosis

The Virta Clinic includes individualized nutritional recommendations to sustain nutritional ketosis by titrating carbohydrate and protein intake to the patient's individual tolerance [27]. With the insulin resistance characteristic of type 2 diabetes, subjects typically require total dietary carbohydrates to be restricted to <30 $g \cdot day^{-1}$. Daily protein intake was targeted to a level of 1.5 $g \cdot kg^{-1}$ of reference (ie, medium-frame "ideal") body weight and participants were coached to incorporate dietary fats to satiety. Other aspects of the diet were individually prescribed to ensure safety, effectiveness, and satisfaction, including consumption of 3-5 servings of nonstarchy vegetables and adequate mineral and fluid intake for the ketogenic state. BOHB was monitored routinely via finger-stick blood monitoring using a handheld device (Abbott Precision Xtra Blood Glucose and Ketone Monitoring System, Alameda, CA, USA) and participants were encouraged to obtain BOHB readings ≥0.5 $mmol \cdot L^{-1}$.

Outcome Measures and Testing Procedures

Type 2 diabetes status was determined by HbA_{1c} level at baseline and again at 10-11 weeks into the program. A value of 6.5% or greater, or HbA_{1c} level <6.5% but taking at least one hypoglycemic medication, was considered indicative of type 2 diabetes. Secondary outcome measures included assessment of (1) body weight determined daily on a cellular-connected scale (BodyTrace BT003 cellular-connected scale, New York, New York, USA); (2) medication use for control of diabetes; and (3) blood pressure obtained in the seated position. Fasting blood was analyzed for total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, triglycerides, C-reactive protein, total white blood cell count, and kidney and liver functions. All laboratory test results were analyzed by standard procedures. Hunger was assessed using a 4-point Likert scale from 1 (no) to 4 (always), representing the participant's subjective level of hunger over the previous 24-hours.

Statistical Analysis

Descriptive statistics were calculated for each variable as mean (SD). Baseline and 10- to 11-week follow-up measures were compared with paired-sample *t* tests to evaluate for significant differences in primary (HbA_{1c} level) and secondary outcome variables over time, following implementation of carbohydrate restriction per the Virta Clinic. Statistical significance was set a priori at $P<.05$; for secondary outcome variables, we applied a Bonferroni adjustment for multiple comparisons, setting $P<.003$ as the level of significance for those outcome measures. McNemar test with continuity correction and Bonferroni adjustment for multiple comparisons was utilized to assess for a difference in the proportion of participants who were prescribed each of the 7 medication classes at baseline compared with follow-up, setting $P<.007$ as the level of significance. We utilized an intention-to-treat analysis with the last observation carried forward for analyses of all participants; separate subanalyses were performed for participants who completed follow-up testing (completers). Given that 2 different modes were utilized for delivery of educational content, we performed a post hoc analysis on the primary outcome measure to determine if differences existed between groups.

Institutional Review Board Approval

The protocol was reviewed and approved by the Institutional Review Board at Franciscan Health Lafayette East, Lafayette, Indiana. Subjects were informed of the purpose and possible risks of the investigation before signing an informed consent document approved by the institutional review board.

Results

Characteristics of Subjects

A total of 262 subjects with diagnosis of type 2 diabetes were enrolled in this study. The mean age was 54 (SD 8) years and 66.8% (175/262) were female. Additional baseline data are provided in Table 1.

Table 1. Participant characteristics at baseline and follow-up.

Characteristics	n[a]	Baseline	Follow-up	Mean difference		t_{n-1}	P[b]
		Mean (SD)	Mean (SD)	Mean (SD)	95% CI		
Hemoglobin A_{1c} (%)							
All	262	7.6 (1.5)	6.6 (1.1)	−1.0 (1.1)	−1.1 to −0.9	14.9	<.001
Completers	238	7.6 (1.5)	6.5 (1.0)	−1.1 (1.1)	−1.2 to −1.0	15.6	<.001
Fasting glucose ($mg \cdot dL^{-1}$)							
All	259	162 (61)	131 (37)	−30 (56)	−37 to −25	8.68	<.001
Completers	236	163 (62)	129 (34)	−33 (58)	−41 to −26	8.8	<.001
Body mass index ($kg \cdot m^{-2}$)							
All	262	40.8 (8.9)	37.9 (8.5)	−2.9 (1.2)	−3.1 to −2.7	30	<.001
Completers	238	40.7 (8.5)	37.7 (8.0)	−3.1 (1.5)	−3.3 to −2.9	31.3	<.001
Weight (kg)							
All	262	117 (26.3)	109 (24.9)	−8 (4.6)	−9 to −8	29.1	<.001
Completers	238	117 (25.7)	109 (24.3)	−9 (4.5)	−9 to −8	30.7	<.001
Systolic blood pressure (mm Hg)							
All	260	132 (16)	126 (15)	−6 (19)	−8 to −4	5.29	<.001
Completers	236	132 (17)	125 (15)	−7 (20)	−9 to −4	5.32	<.001
Diastolic blood pressure (mm Hg)							
All	260	82 (10)	78 (10)	−4 (12)	−5 to −2	5.22	<.001
Completers	236	82 (10)	78 (9)	−4 (12)	−6 to −3	5.25	<.001
Total cholesterol ($mg \cdot dL^{-1}$)							
All	262	177 (41)	172 (41)	−5 (31)	−9 to −1	2.64	.009
Completers	238	177 (41)	172 (41)	−6 (33)	−10 to −1	2.64	.009
LDL-C[c] (calculated; $mg \cdot dL^{-1}$)							
All	245	97 (33)	99 (36)	2 (25)	−2 to 5	0.987	.32
Completers	223	98 (34)	99 (37)	2 (27)	−2 to 5	0.987	.32
HDL-C[d] ($mg \cdot dL^{-1}$)							
All	262	44 (13)	44 (13)	0.5 (8)	−0.5 to 1	0.966	.33
Completers	238	44 (14)	45 (13)	0.5 (8)	−0.5 to 1.5	0.966	.33
Triglycerides ($mg \cdot dL^{-1}$)							
All	262	185 (127)	147 (87)	−37 (107)	−50 to −24	5.61	<.001
Completers	238	185 (129)	145 (84)	−41 (112)	−55 to −27	5.64	<.001
Serum creatinine ($mg \cdot dL^{-1}$)							
All	259	0.88 (0.24)	0.85 (0.22)	−0.03 (0.12)	−0.04 to −0.01	3.61	<.001
Completers	236	0.88 (0.24)	0.85 (0.22)	−0.03 (0.13)	−0.05 to −0.01	3.61	<.001
ALT[e] ($units \cdot L^{-1}$)							
All	259	31 (23)	26 (16)	−4 (19)	−7 to −2	3.82	<.001
Completers	236	31 (24)	26 (16)	−5 (20)	−7 to −2	3.83	<.001
AST[f] ($units \cdot L^{-1}$)							
All	259	24 (15)	21 (9)	−3 (13)	−4 to −1	3.31	<.001
Completers	236	24 (16)	21 (9)	−3 (14)	−5 to −1	3.31	<.001

Characteristics	n[a]	Baseline	Follow-up	Mean difference		t_{n-1}	P[b]
		Mean (SD)	Mean (SD)	Mean (SD)	95% CI		
Alkaline phosphatase (units·L^{-1})							
All	259	74 (22)	68 (20)	−6 (11)	−8 to −5	9.78	<.001
Completers	236	75 (22)	67 (20)	−8 (11)	−9 to −6	9.96	<.001
C-reactive protein (mg·L^{-1})							
All	247	8.1 (8.2)	9.2 (11.5)	1.2 (7.5)	−0.2 to 2.1	2.45	.01
Completers	225	8.2 (8.1)	9.6 (12.1)	1.4 (8.1)	−0.3 to 2.1	2.6	.01
Total WBC[g] (x10^{9}·L^{-1})							
All	236	7.2 (1.9)	6.7 (1.9)	−0.5 (1.3)	−0.6 to −0.3	5.37	<.001
Completers	234	7.2 (1.8)	6.7 (1.9)	−0.5 (1.3)	−0.6 to −0.3	5.36	<.001

[a]Reductions in the number of participants (n) are due to missed laboratory orders, except in the case of LDL-C, where LDL-C was incalculable.

[b]We set P<.003 as the level of significance for multiple comparisons.

[c]LDL-C: low-density lipoprotein cholesterol.

[d]HDL-C: high-density lipoprotein cholesterol.

[e]ALT: alanine aminotransferase.

[f]AST: aspartate aminotransferase.

[g]WBC: white blood cell.

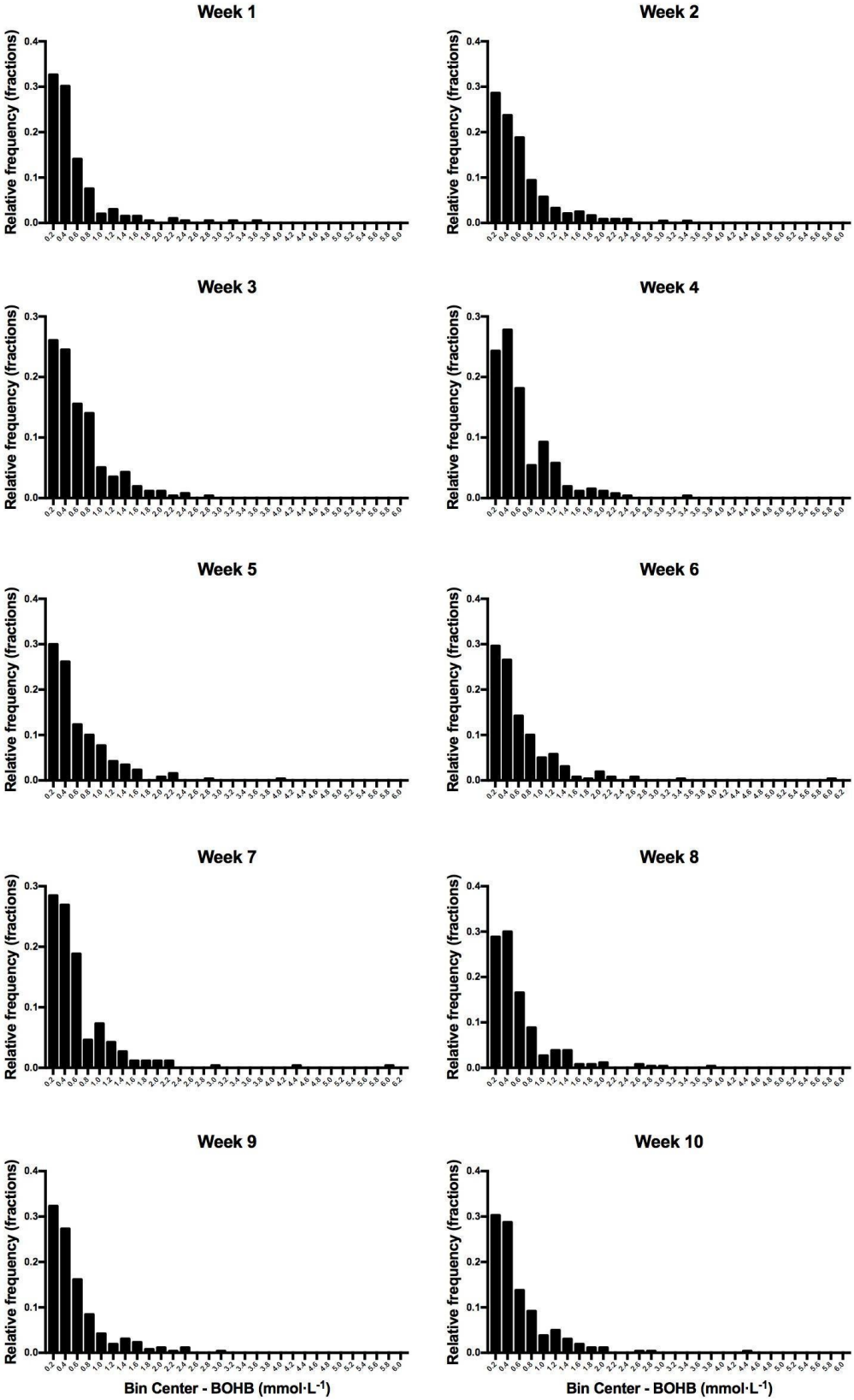
Retention

At 11 weeks, 21 of the 262 subjects had dropped out and 3 had not obtained the follow-up laboratory test results, yielding 238 or 90.8% retention for this phase of the study. Among the noncompleters, the most common reasons to leave the study were as follows: removed for noncompliance (n=6), unrelated health issue took priority (n=3), family illness or other issues (n=3), cost of medical appointments (n=2), and undisclosed personal choice (n=2). The age and sex distributions did not differ between noncompleters and completers.

Program Adherence

Daily BOHB level averaged over 10 weeks of the program was 0.6 (SD 0.6) mmol·L^{-1} (see Figure 1). This range is indicative of a modest state of nutritional ketosis in most of the subjects, with highest value similar to levels observed during fasting. There were no cases of diabetic ketoacidosis (ie, hyperglycemia concurrent with serum BOHB level >6 mmol·L^{-1}).

Figure 1. Relative frequency distribution of participant weekly average beta-hydroxybutyrate (BOHB) concentrations. An observed weekly average BOHB concentration on the border of 2 bins is placed in the bin holding the larger values. Evidence of carbohydrate restriction exhibited by elevated ketones was present in the first week in the majority of subjects and maintained for the duration of the study. All reported BOHB concentrations greater than 3.0 were in participants taking a sodium-glucose cotransporter-2 inhibitor, except for one (4.4 mmol•L−1) in which we suspect elevated BOHB due to increased exercise and another (6.0 mmol•L−1) in which we suspect participant data entry error. Excluding this 1 value, average BOHB concentrations for this participant ranged from 0.4 to 1.4 mmol•L^{-1}.

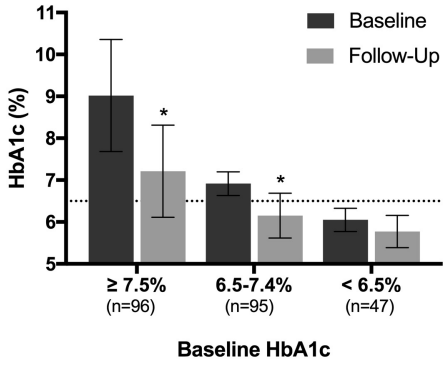


Hemoglobin A1c

Baseline HbA_{1c} level was 7.6% (SD 1.5%) and 210/262 (80.2%) participants had an HbA_{1c} level of ≥6.5%. After 10 weeks, HbA_{1c} level was reduced by 1.0% (SD 1.1%; 95% CI 0.9% to 1.1%, *P*<.001), and 56.1% (147/262) achieved an HbA_{1c} level of <6.5%. HbA_{1c} level for the 238 completers was similarly reduced from 7.6% (SD 1.5%) at baseline to 6.5% (SD 1.0%; 95% CI of mean difference −1.2% to −1.0%, *P*<.001) at 10-11 weeks into the Virta Clinic program. The varying responses of HbA_{1c} based upon starting level are shown in Figure 2. Of the 147 participants who achieved an HbA_{1c} level of less than 6.5%, 143 (97.3%) reached this goal without an increase in the number or dosage of diabetes medications. At follow-up, 47.7% of participants (125/262) achieved an HbA_{1c} level of less than 6.5% while taking metformin only (n=86) or no diabetes medications (n=39).

Post hoc analysis of method of educational content delivery revealed there was no significant interaction between delivery method and time for HbA_{1c} ($F_{1,260}$=0.18, *P*=.67), nor was there an effect of delivery method ($F_{1,260}$=1.503, *P*=.22). Baseline HbA_{1c} level was similar (on-site: mean 7.7%, SD 1.6%, digital: mean 7.5%, SD 1.4%; mean difference = 0.2%, 95% CI of mean difference: −0.2% to 0.5%; t_{520}=0.94, *P*=.69), and HbA_{1c} reductions of 1.0% (SD 1.1%) and 1.0% (SD 1.0%) for the on-site and digital content delivery methods, respectively, were achieved with no difference between delivery methods at follow-up (mean difference = 0.2%, 95% CI of mean difference: −0.2% to 0.6%; t_{520}=1.29, *P*=.39).

Figure 2. Hemoglobin A1c (HbA1c) changes by baseline level. Error bars represent SD; the dotted line represents the threshold for diagnosis of type 2 diabetes. Significant reductions in HbA1c level from baseline to follow-up were observed in subjects whose baseline HbA1c level was ≥7.5% (mean 9.0%, SD 1.3% to 7.2%, SD 1.1%, *P*<.001) and between 6.5% and 7.4% (mean 6.9%, SD 0.3% to 6.2%, SD 0.5%, *P*<.001). For those whose baseline HbA1c level was <6.5%, HbA1c level was improved but not significantly after correcting for multiple comparisons (mean 6.1%, SD 0.3% to 5.8%, SD 0.4%, *P*=.03). *Represents significant difference from baseline.



Hypoglycemic Medications

The majority of participants (234/262, 89.3%) were taking at least one diabetes medication at baseline. Both the number and dosage of most diabetes medications were reduced substantially in the first 10-11 weeks of the Virta Clinic program (Table 2, Figure 3). As shown in Table 2, of the initial 262 subjects, 112 (42.7%) experienced a decrease in their medications with another 21 (8.0%) having their medications eliminated. Only 13 (5.0%) of the 262 subjects were prescribed a new class or increased dose of medication. Of the 262 participants, 88 (33.6%) had no change in their medications and 28 (10.7%) were taking no hypoglycemic medications at entry into the study or at follow-up.

Table 2. Change in prescription of medication class or dose between baseline and follow-up.

Change in medication prescription or dose between baseline and follow-up	n	HbA_{1c}[a] <6.5% at follow-up, n (%)	Baseline HbA_{1c} (%), mean (SD)	Follow-up HbA_{1c} (%), mean (SD)
Increase	13	4 (31)	8.5 (2.0)	7.4 (1.4)
No change	88	57 (65)	7.2 (1.2)	6.5 (1.0)
Decrease	112	47 (42)	8 (1.6)	6.8 (1.1)
Complete elimination of medications	21	17 (81)	6.7 (0.9)	6.1 (0.5)
No medications prescribed	28	22 (79)	7.3 (1.3)	6.3 (1.1)

[a]HbA_{1c}: hemoglobin A_{1c}.

Figure 3 shows the changes in the 7 common classes of hypoglycemic medication prescribed to the subjects in this study. For sulfonylureas, sodium-glucose cotransporter-2 inhibitors, and thiazolidinediones, the vast majority of subjects discontinued these medications (90.3%, 86.2%, and 75.0%, respectively). To a lesser degree, this was also the case for dipeptidyl peptidase-4 inhibitors (56.7%), insulin (35.9%), and glucagon-like peptide-1 receptor agonists (27.9%). The exception to this trend was metformin. The proportion of participants who were prescribed insulin, sulfonylureas, and sodium-glucose cotransporter-2 inhibitors was significantly different at follow-up compared with baseline (all *P*<.007, see Figure 3). Given the reduced risk for hypoglycemia with the glucagon-like peptide-1 receptor agonists relative to insulin and sulfonylureas, the former was added in some cases in order to withdraw the latter two. In the case of metformin, given its modest but significant efficacy in the prevention of diabetes, its continued use in this cohort was encouraged (ie, 186 users at baseline and 181 at follow-up).

Figure 4 shows changes in HbA_{1c} level over 10-11 weeks in subjects whose insulin dosage was increased, unchanged,

reduced, or eliminated. Only 5% (4 of 78 initial users) had their dosage increased in order to manage their initial HbA_{1c} value of 8.3% (SD 0.4%). For the other 74 subjects who entered the study while taking insulin, the HbA_{1c} values declined significantly despite the same, reduced, or eliminated insulin dosages.

Figure 3. Frequency of medication dose changes by drug class. Bars represent total users of each drug with the type of dose change (increase, no change, decrease, or elimination) stacked within the bar and the relative frequency noted next to each section. The total number of users is noted at the top of each bar. The proportion of participants who were prescribed the drug was significantly different between baseline and follow-up for insulin ($\chi 2_1$=21.4, *P*<.001), sulfonylureas ($\chi 2_1$=54.0, *P*<.001), and sodium-glucose cotranporter-2 (SGLT-2) inhibitors ($\chi 2_1$=17.9, *P*<.001) but not for dipeptidyl peptidase-4 (DPP-4) inhibitors ($\chi 2_1$=6.9, *P*=.009), thiazolidinediones ($\chi 2_1$=1.3, *P*=.25), glucagon-like peptide-1 (GLP-1) receptor agonists ($\chi 2_1$=0.5, *P*=.50), or metformin ($\chi 2_1$=0.8, *P*=.36).

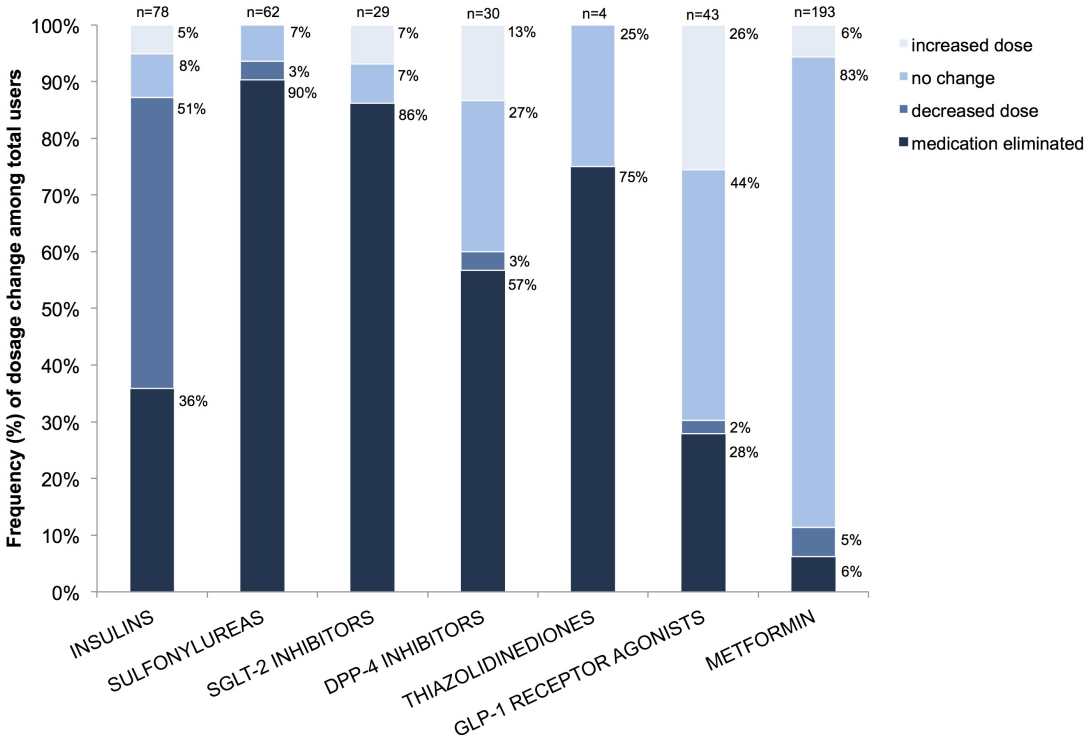
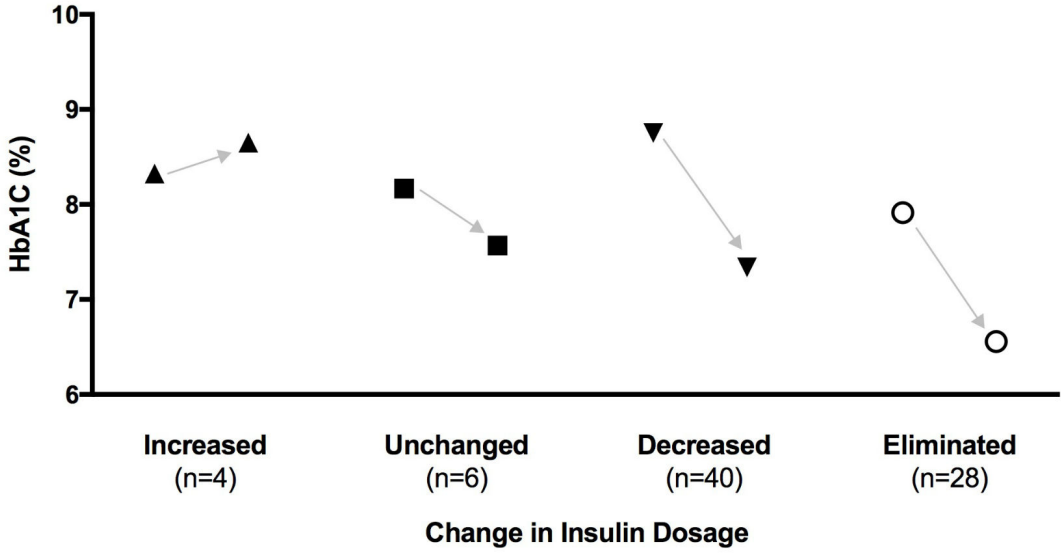


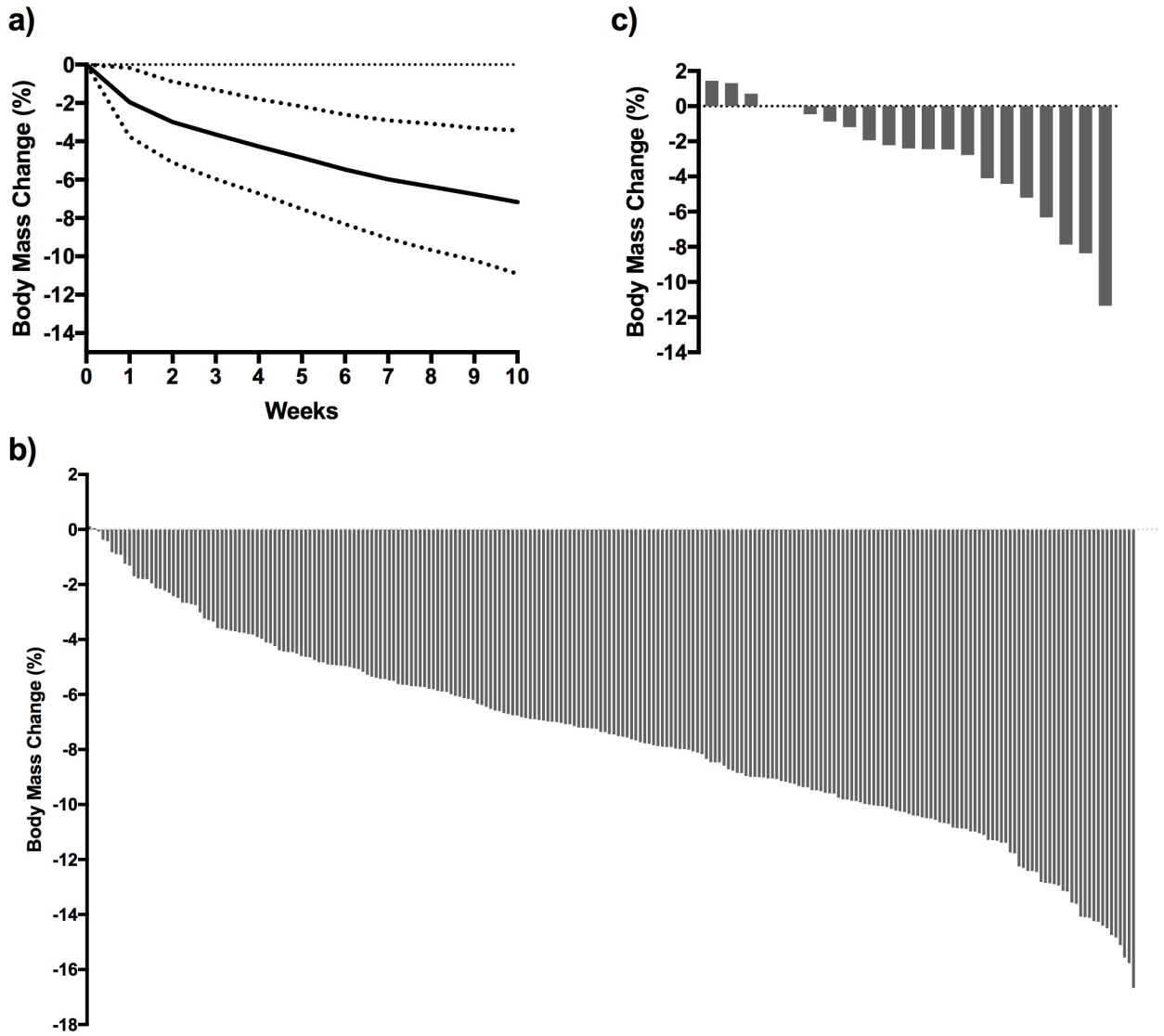
Figure 4. Hemoglobin A1c (HbA1c) level at baseline and 10-11 weeks per change in insulin dosage. Insulin users who were able to eliminate or reduce their use of the drug also significantly reduced their HbA1c level (7.9%, SD 1.5%, to 6.6%, SD 0.9%, P<.001 and 8.8%, SD 1.8%, to 7.4%, SD 1.2%, P<.001, respectively). Six users with no change in insulin dose achieved a reduction in HbA1c level, although it was not statistically significant (8.2%, SD 1.8%, to 7.6%, SD 1.2%, P=.25). Despite an increased insulin dosage in 4 users, HbA1c level increased but the difference was not significant (8.3%, SD 0.4%, to 8.7%, SD 0.8%, P=.61).



Body Weight

Weight and body mass index (BMI) changes from baseline to 10 weeks are presented in Table 1, and the mean weight change (as percentage of starting weight) over time is shown in Figure 5 (part “a”). Figure 5 (parts “b” and “c”) also shows individual subjects’ weight change over 10 weeks for completers and at the time of dropout for noncompleters. Mean weight loss at 10 weeks for completers was 7.2% (SD 3.7%) of initial body weight. Only 5 out of 262 subjects (2 completers, 3 noncompleters) registered a weight gain, and 75% of completers lost 5% or more of their initial body weight in this time period.

Figure 5. Participant weight loss over 10 weeks. Part “a”—weight change over 10 weeks for all participants. Solid line represents the mean; dotted lines represent one standard deviation from the mean. Part “b”—individual body weight changes as percentage of starting body weight at 10 weeks for completers (n=238). Part “c”—individual body weight changes as percentage of starting body weight for each noncompleter at the time of removal from study. For the 21 dropouts, time to drop out was 6 (SD 3) weeks (n=3 participants are still enrolled in the study but did not complete 10-week follow-up testing).



Laboratory Test Results and Measures

Consistent with the HbA_{1c} changes, the fasting glucose level (Table 1) declined markedly despite reduced hypoglycemic medication usage. There were no significant changes in total, low-density lipoprotein, or high-density lipoprotein cholesterol levels, nor were any changes made to statin prescriptions during this time. Triglycerides were significantly reduced by 20%. There were modest but significant reductions in both systolic and diastolic blood pressure. Although not elevated at baseline, the mean serum creatinine, alanine aminotransferase, aspartate aminotransferase, and alkaline phosphatase levels were all significantly reduced at 10-11 weeks. Biomarkers of inflammation were mixed. While C-reactive protein was unchanged, total white blood cell count decreased significantly after 10 weeks of the ketogenic diet.

Baseline hunger on a scale from 1 (no) to 4 (always) was 1.6 (SD 0.6). At 10 weeks, subjective hunger was 1.3 (SD 0.4; 95% CI of mean difference: −0.4 to −0.2, t_{134}=5.58, P<.001). Furthermore, 46/135 (34.1%) subjects at baseline reported no hunger, increasing to 78/135 (57.8%) at 10 weeks.

Side Effects

One subject withdrew from the study in the first 70 days because of a dietary side effect (diarrhea due to fat intolerance). There were no serious adverse events in this time period and, specifically, no serious symptomatic hypoglycemic events requiring medical intervention.

Discussion

Although the American Diabetes Association has recently relaxed its advocacy for severe dietary fat restriction, the current paradigm for the management of type 2 diabetes is to prescribe a diet containing about 40% of energy from carbohydrates (eg, a Mediterranean diet) and then adjust medications as necessary to maintain glycemic control [28]. The Virta Clinic manages

type 2 diabetes from the perspective that it is a disease of carbohydrate intolerance. Given that this investigation is a nonrandomized demonstration study without measurement against standard of care, no statistical comparisons are made. However, these data demonstrate that when participants were supported through a novel, individualized program including instruction for limiting dietary carbohydrates to <30 $g \cdot day^{-1}$, medications could be substantially reduced or eliminated in most subjects, overall glycemic control was improved, and clinically relevant weight loss (5% or greater) was achieved in a majority of participants.

Other group-based and digitally delivered programs have demonstrated improvements in HbA_{1c} level with modest or no reduction in weight and often without a reduction in medication. A recent in-person group-based intervention for weight loss in adults with type 2 diabetes reduced HbA_{1c} level by 0.7% and weight by 3.3% after 12-13 weeks [29], while our investigation reduced HbA_{1c} level by 1.0% and weight by 7.2% in 10-11 weeks. Digitally delivered programs have elicited a range of improvements in HbA_{1c} (from none to significant) [30]; however, these results were often achieved by increased medication use due to improved adherence and without a reduction in weight [31]. This study demonstrated that these results (reduced HbA_{1c} level, weight, and medication use) can be achieved concurrently. Specifically, 147 (56.1%) of the initial 262 subjects in this initial study of the Virta Clinic registered HbA_{1c} values <6.5% at 10- to 11-week follow-up. Of these, 39 participants were able to achieve these results without taking any diabetes medication and 86 participants were able to achieve these results taking only metformin. Considering the equilibration time for HbA_{1c} is approximately 120 days, the significant decrease after 70-77 days reported here is a conservative estimate of the true improvement in glucose metabolism.

Achieving an HbA_{1c} value under 6.5% is considered "tight control" for type 2 diabetes. There are two commonly reported side effects of tight control—weight gain [32,33] and symptomatic hypoglycemia [28,33,34]. Paradoxically, in this study, we observed very consistent weight loss while observing no severe symptomatic hypoglycemic events. In addition to the very close mobile communication between the participant, coach, and physician in the Virta Clinic, this absence of severe hypoglycemic episodes despite very tight glucose control may be due to the protection of central nervous system function by circulating levels of BOHB. Two studies of starvation-adapted humans have demonstrated full preservation of central nervous system function despite profound hypoglycemia induced by exogenous insulin administration [35,36].

As it pertains to weight loss, it is all the more interesting that the Virta Clinic instructs its participants to strictly limit carbohydrates and eat protein in moderation but to eat fat to satiety. In daily Web-based questionnaires, patients reported reduced hunger once adapted to the ketogenic diet. This subjective decrease in hunger, albeit modest in magnitude, may have allowed the majority of subjects to experience significant weight loss. This concurrent combination of weight loss and reduced hunger is particularly interesting given that significant weight loss by caloric restriction typically increases hunger [37]. However, in light of the recent reports of epigenetic effects of BOHB reducing oxidative stress [24,38] and improving insulin sensitivity [26], it is possible that these paradoxical results can be ascribed to a combination of the metabolic and epigenetic effects of mild nutritional ketosis.

Although we have not calculated the economic implications of improved glycemic control with reduced medications, the removal of diabetes medications combined with clinically significant weight loss [39] has been shown to generate health care cost savings. The timing of these cost savings is immediate in the case of the medication reductions and could accrue over time because of the effect of lowering BMI. As for the HbA_{1c} reduction observed in this study, when changes of this magnitude are attained with intensive medication use, this tends to increase both drug costs and adverse events [40]. However, given that a 0.5% reduction in HbA_{1c} level was associated with a 17% reduction in diabetic vascular complications following aggressive medication management [2], our 1.0% HbA_{1c} level reduction with less medication has the potential to yield even greater savings in the cost of complications over time.

In conclusion, we demonstrated for the first time that biomarkers of type 2 diabetes can be reversed in a substantial fraction of participants using a comprehensive digitally delivered intervention, including medical management by physicians, health coaching, nutrition education emphasizing individualized carbohydrate intake to induce nutritional ketosis, behavioral support, biometric feedback, and peer support. In contrast to current intensive pharmaceutical management strategies, the positive results were achieved with less use of medication and substantial weight loss. The brief duration of this initial study cannot predict the long-term outcomes or sustainability of the nutrition recommendations used by the Virta Clinic. Early results demonstrate markedly improved glycemic control with less medication and modest changes in blood pressure, total white blood cell count, and liver and kidney functions. Ongoing work will evaluate the efficacy and sustainability of this intervention over 2 years.

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Conflicts of Interest

Virta Health Corp. funded this study, and all authors have a financial relationship with the study sponsor. ALM, SJH, BCC, BMV, TML, MKA, RMG, JPM, and SJP are employed by Virta. JSV serves as a consultant to Virta. JSV and SDP are cofounders of Virta. All authors have stock options in Virta. The organization contributed to study design, the collection, analysis, and interpretation of data, and approval of the final manuscript. Potentially related conflicts of interest are as follows: SDP serves as a consultant to Atkins Nutritionals and has received royalties as an author of two science-based low-carbohydrate books published by Beyond Obesity LLC. JSV serves as a consultant to Atkins Nutritionals, Metagenics, and UCAN, has received grants from the National Dairy Council and Malaysian Palm Oil Board, and has received royalties as an author of two science-based low-carbohydrate books published by Beyond Obesity LLC. SJH serves as a consultant to Atkins Nutritionals.

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Abbreviations

BMI: body mass index
BOHB: beta-hydroxybutyrate
HbA1c: hemoglobin A1c
VLCD: very low-calorie diet

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Original Paper

How's Your Sugar? Evaluation of a Website for Aboriginal People With Diabetes

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Abstract

Background: Australia's Aboriginal and Torres Strait Islander peoples (hereafter referred to as "Aboriginal people") have the longest continuing culture in the world, living sustainably for at least 65,000 years on the Australian continent. In relatively recent times, colonization processes have resulted in Aboriginal people experiencing unacceptable health inequalities compared with other Australians. One disease introduced due to colonization is diabetes, the second leading cause of death for Aboriginal peoples.

Objectives: The objective of this study was to describe the construction and utilization of the website "How's Your Sugar, " a website for Aboriginal people with type 2 diabetes (herein after referred to as diabetes). The questions for the evaluation were as follows: how was the website constructed; did target groups utilize the website; and did engagement with the website improve diabetes management.

Methods: A mixed-method study design was employed. A content analysis of project documents provided information about the website construction. Data from Google analytics provided information about website utilization. To describe patterns of website sessions, percentages and numbers were calculated. A voluntary survey provided more information on website utilization and diabetes self-management. Percentage, numbers, and 95% CIs were calculated for each variable. A chi-square test was performed for Aboriginal status, age, gender, and Aboriginal diabetic status using Australian population estimates and Aboriginal diabetes rates.

Results: The website development drew on Aboriginal health, social marketing, interactive health promotion frameworks, as well as evidence for diabetes self-management. The website build involved a multidisciplinary team and participation of Aboriginal diabetics, Aboriginal diabetic family members, and Aboriginal health workers. This participation allowed for inclusion of Aboriginal ways of knowing and being. The highest number of website sessions came from Australia, 98.15% (47,717/48,617) and within Australia, Victoria 50.97% (24,323/47,717). There were 129 survey respondents, and the distribution had more female, 82.9% (107/129, 95% CI 76-88), Aboriginal, 21.7% (28/129, 95% CI 16-30), and Aboriginal diabetic, 48% (13/27, 95% CI 31-66) respondents than expected with $P<.001$ for these three groups. Most common reasons for visits were university assignment research, 40.6% (41/101), and health workers looking for information, 20.8% (21/101). The sample size was too small to calculate diabetes self-management change.

Conclusions: Inclusion of Aboriginal ways of knowing and being alongside other theoretical and evidence models in Web design is possible. Aboriginal people do utilize Web-based health promotion, and further understanding about reaching to this population would be of use. Provision of an education resource would likely have enhanced educational engagement. Web-based technologies are rapidly evolving, and these can potentially measure behavior change in engaging ways that also have benefits for the participant. A challenge for designers is inclusivity of cultural diversity for self-determination.

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KEYWORDS

Aboriginal and Torres Strait Islander peoples; type 2 diabetes mellitus; Indigenous populations; Internet

Introduction

Australia's Aboriginal and Torres Strait Islander peoples (hereafter referred to as "Aboriginal people") have the longest continuing culture in the world, living sustainably for at least 65,000 years on the Australian continent [1]. In relatively recent times (the last 230 years), the process of colonization has resulted in Aboriginal people experiencing unacceptable health inequalities compared with other Australians. Almost 10 years have passed since Australian governments agreed to closing the gap and improving Aboriginal health outcomes [2]. However, only minimal progress has been made. The median age at death for Aboriginal people is 24 years lower than that for non-Aboriginal Australians [3]. Despite this, there is a policy commitment to achieve equality in health status and life expectancy by 2031 [4].

One disease that colonization introduced to Aboriginal people is diabetes, the second leading cause of death among the Aboriginal population [5]. National surveys have estimated that approximately 1 in 10 Aboriginal people have diabetes, which is more than 3 times higher than that in the non-Aboriginal population [6,7]. In the 25- to 34-year age group, this prevalence is 5 times higher, indicating the earlier development of diabetes in the Aboriginal population [6]. Earlier onset of diabetes increases the chance of developing complications such as cardiovascular disease, renal failure, and retinopathy later in life [8]. Appropriate and effective diabetes management is essential for reducing morbidity and mortality among Aboriginal people.

Education and self-management are important components of diabetes care [9]. There is evidence that culturally appropriate self-management programs led by Aboriginal peers can be effective at improving participants' self-management practices, physical activity levels, and quality of life [10]. Professional- and nonprofessional-led Web-based programs for diabetics have been shown to provide improvement [11]. The recently released Australian National Diabetes Strategy [12], which includes a specific goal of reducing the impact of diabetes among Aboriginal people, calls for expansion of consumer engagement and self-management initiatives. One recommendation is that peer support programs (either face-to-face, telephonic, or Web-based) are accessible to all with diabetes [13].

Health promotion aimed at Aboriginal people is increasingly focusing on Web-based and digital environments [14]. These tools come in a range of formats with theory underpinning construction varied and often not described [14]. However, these tools do have potential to influence health behaviors. Web-based interventions for diabetes can improve general knowledge, and tracking and monitoring of diabetes, however, have not been shown to improve depression or anxiety. In addition, theory-based Web designs are more effective for behavior change [11]. The types of Web-based tools available for people living with diabetes are evolving rapidly and now combine elements of patient records, interactivity, feedback loops, and multiple hardware devices, such as phone, glucometer, tablet, and computer [15].

Many Aboriginal people access the Internet. In the 2011 Census, 63% of Aboriginal households reported having Internet connection, up from 40% in 2006. The quality of connection was high with 85% most frequently connected using broadband, 11% other types of connections (eg, mobile phones), and 4% dial-up connections. Younger Aboriginal people (aged 24 years and less) were more likely to have home Internet connection than those aged 55 years and more (63% and 42%, respectively) [16].

Sparse data exist about Aboriginal engagement in various websites [13]. Information about end user experiences with the technologies is also rare. One study in Victoria, Australia, explored young women's research recruitment from social networking sites with an Aboriginal participant rate consistent with Aboriginal population proportion [17]. Another study of Aboriginal people's Facebook use found that Aboriginal people were engaging with the platform to actively express identity and network with other Aboriginal people [18]. This study aimed to describe the construction and utilization of the website "How's Your Sugar," a website for Aboriginal people with type 2 diabetes (herein after referred to as diabetes). The questions for the evaluation were as follows: how was the website constructed; did target groups utilize the website; and did engagement with the website improve diabetes management.

Methods

Study Design

The How's Your Sugar website was developed during October 2009 to May 2010, and launched in June 2010. The website build was supported by a 12-month grant from the Australian Department of Health and Aging. Ethics approval for the evaluation was obtained from the Victoria University Human Research Ethics Committee. The evaluation included creation of a Logframe Matrix [19] (Table 1), and mixed methods were used to collate evaluation data including project document content analysis, website data collection, and survey.

Table 1. Logframe matrix.

Objectives	Indicator	Data source	Assumption
Goal: Develop a culturally relevant and evidence-based website to support Aboriginal people with type 2 diabetes to manage well-being.	Was an evidence and theory base used to develop the website? Was cultural relevance included in the website?	Program documents	Team has the skills required to build the website
Outcome: To support Aboriginal people with type 2 diabetes to manage well-being	Did the website focus on managing type 2 diabetes? Did the resource support Aboriginal people with type 2 diabetes?	Program documents Website content Web-based survey	A website can support people with type 2 diabetes to manage well-being
Outputs: Website supports Aboriginal people with type 2 diabetes to manage well-being	Was the website utilized by the target group? For instance, Aboriginal people with diabetes, friends and family members of Aboriginal people with diabetes, and health workers?	Website analytics Web-based Survey	Aboriginal people with type 2 diabetes will engage with the website Health professionals will access the website
Activities: Website is accessible, promoted, and utilized	Was the website accessed? Was the website promoted? Did engagement occur with the website?	Google analytics Web-based survey	Aboriginal people with type 2 diabetes engaging with the website will improve management of diabetes and well-being Health professionals will learn about Aboriginal people and staying well with diabetes

Website Build

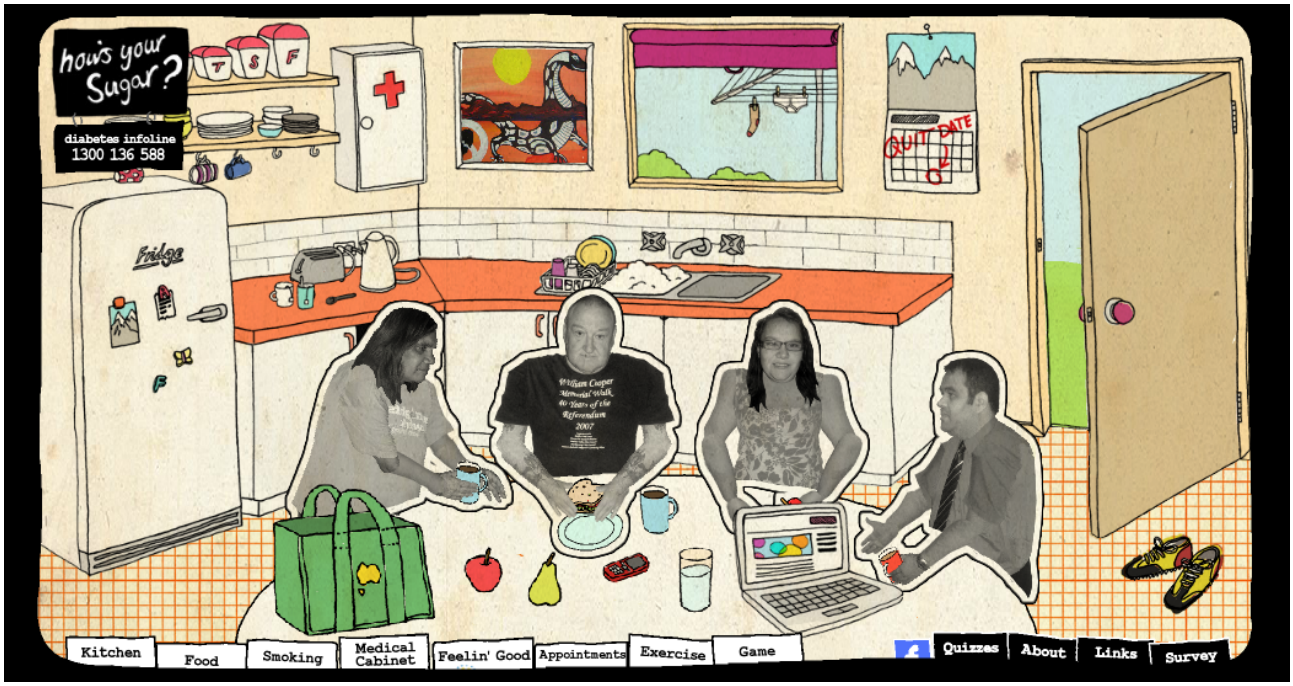
Data about the website build were extracted from documents generated by the project that described elements of the website build process. These project documents included minutes of project team meetings (6), reports to funding bodies (4), project planning session notes (8), communication strategy (1), conference presentations (2) and written notes taken at social marketing interviews (6), and a focus group (1). The documents were reviewed using content analysis with the aim to address the following logframe matrix indicators: was an evidence and theory base used, was cultural relevance included, did the website focus on diabetes management, and was the website promoted.

Website Utilization

To understand more about website access and usage, two sources of data were collected using Google Analytics [20] and SurveyMonkey (SurveyMonkey Inc) [21]. Google Analytics provided data on website sessions this data collection addressed the logframe matrix indicator questions: was the website accessed and did engagement occur with the website. To describe patterns of website sessions, percentages and numbers were calculated.

A voluntary survey was developed using SurveyMonkey with a link to this on the website front page (Figure 1). The survey allowed only 1 response per respondent through IP address tracking. The survey addressed the logframe matrix indicator questions: did the resource support Aboriginal people with type 2 diabetes, was the website used by the target group, and did engagement occur with the website. The survey included an explanatory statement, which then led to the survey questions. The first survey page asked for age, gender, reason for visit, and Aboriginal status. Those affirming Aboriginal status went to a second page that asked for diabetic status. Those indicating they were diabetic went to a fourth page asking questions about diabetes management with questions relating to the 10 steps for living well with diabetes. These respondents were invited to provide an email to be asked further questions in a 6-month time period. Further details on these variables can be found in Table 2. Percentage, numbers, and 95% CIs were calculated for each variable. A chi-square test was performed for Aboriginal status, age, gender, and Aboriginal diabetic status using Australian population [22] and Aboriginal diabetes estimates [6-7]. Calculations were conducted in the Microsoft Excel version 14.4.2 (Microsoft Corporation) [23].

Figure 1. Opening page of the website.



Results

Website Build

The How's Your Sugar project team was based at Victoria University in Melbourne and consisted of an Aboriginal nurse and two Aboriginal educators experienced in adult education. The project team also drew on expertise from the Victorian Aboriginal Community Controlled Health Organization and an Aboriginal worker from Diabetes Victoria. Initially the team reviewed websites aiming to provide information to Indigenous people with diabetes in Australia, New Zealand, Canada, and the United States. These commonly featured static materials, such as written text, images, and downloadable PDF information. Imagery accompanying the writing commonly included a mix of Indigenous iconography and clinical elements, such as a health professional in a white coat with a stethoscope. The materials provided didactic information on what a person should do to manage their diabetes, and were written in simple English from the perspective of a non-Aboriginal health professional as expert speaking to a client. One project team member stated during this review of websites, "Who do they think they are talking to? It's like they stuck some Aboriginal artwork on it and said 'that'll do', its patronizing." The project team recognized the potential for greater use of engaging and interactive website elements that could be inclusive of adult learning pedagogy and Aboriginal ways of knowing and being [24]. Aboriginal websites reflecting this type of inclusion, such as 12canoes [25] and Mission Voices [26] influenced the How's Your Sugar construction.

The team identified the 10 steps for living well with diabetes as a practical and evidence-based health education message for the website target groups. The 10 steps recommended 30 minutes of daily physical activity, taking prescribed medications, regularly checking blood sugar levels, visiting a general practitioner regularly, eating fruits and vegetables, having an annual foot and eye check, ceasing smoking, drinking alcohol in moderation, and living well [27]. Three frameworks informed the How's Your Sugar website construction, including interactive health communication [28], social marketing [29], and the definition of Aboriginal health [4]. Multimedia Appendix 1 provides further details about the application of the 3 frameworks.

The project team conducted interviews, and focus groups were the target groups of 4 Aboriginal people with diabetes (2 males and 2 females), 2 Aboriginal health workers (1 male and 1 female), 4 mature Aboriginal Victoria University students with family or friends with diabetes, and 4 employees at Victoria University with family or friends with diabetes. Travel to conduct broader consultation was not possible due to budget restriction. The 4 people with diabetes were individually asked about the types of information they had found helpful for managing their diabetes. These people described a common experience of health professionals providing information about what to do to manage diabetes and learning from peers with lived experiences of managing diabetes more about how to manage diabetes. For instance, 1 person described, "The doctor told me what I had to do and gave me the pamphlets but it wasn't until I was yarning up to someone like me that I really understood what I needed to do and how I could do it."

The cultural importance of managing diabetes in relation to social connection for Aboriginal people has been highlighted in other studies [30]. The peers described receiving this "how to" information in informal environments and liked being able to laugh and joke about their diabetes to relieve stress. For example, 1 person said "You feel like you need to be doing the right thing all the time, it's good to just have a laugh about it." Use of humor by Aboriginal people as a well-being mechanism to relieve stress and talk about uncomfortable areas has been described elsewhere [31]. When asked about Web-based interactions, people said they regularly accessed email, social

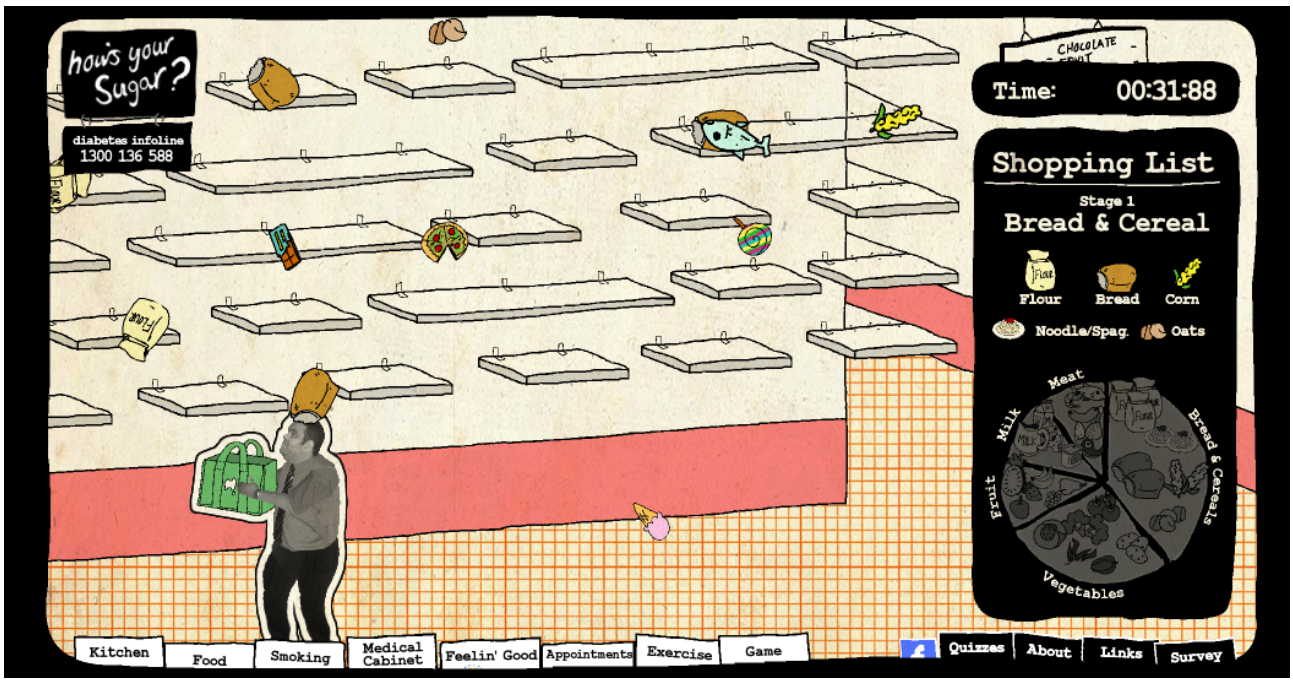
media, Web-based video and games. Based on this information, draft designs were made for further review. At this stage, the project team also began to investigate a suitable website designer to work with. Abilities to be flexible, to be transparent, and listen carefully to the project team needs were noted as desired qualities, which led to the engagement of a suited designer.

A set of draft designs were reviewed by the same 4 people with diabetes and the Aboriginal health workers. All were asked individually to reflect on what they liked, what they did not like, and what they would change. The focus group was asked the same questions. Participants collectively recommended the following: incorporation of more entertainment and humor, storytelling, cloud symbolism;, a barbecue in the backyard, inclusion of Koorie English [32], removing a no-smoking symbol from the website area with videos about tobacco cessation so smokers would not be repelled, providing something that welcomed people verbally to the site, inclusion of other fun health promotion activities aimed at Aboriginal people, inclusion of caring for country, and ensuring that men and women were represented in the site as peers and Aboriginal health workers. This advice was incorporated into the final design. During development, a non-Aboriginal health professional urged the project team to include a diabetes educator on the website to ensure that the messages conveyed were accurate. The project team thought that this could diminish the Aboriginal health worker and peer roles; however, a diabetes support and smoking cessation call line was included in case website visitors were seeking further information.

The name How's Your Sugar? was suggested by 1 of the Aboriginal health workers, as it is a common way for Aboriginal people to ask a person with diabetes how they are feeling or travelling with their diabetes. The final design of the website provided an opening page of a kitchen, a familiar informal space where people gather to yarn or talk replicating a generalized version of what it is like for an Aboriginal person to visit a family member or friend's home. Four peers gathered around the table inviting visitors to click on something. Visitors could navigate around the space and interact with various elements in the website, finding their own pathway through the material. Each peer featured in short videos about how they managed their diabetes in regard to the 10 steps for living well with diabetes. In addition, short videos of 4 Aboriginal health workers discussing self-care and 6 people reflecting on smoking cessation were included. All of the short videos were placed in a relevant space in the website. For instance, videos about diet were placed in the refrigerator and visitors clicked on the refrigerator door to view them. A nutrition game (Figure 2), quiz, and email reminder about recommended minimum appointments were also integrated into the website. Text message reminders were also considered; however, the cost of doing this was beyond the project budget. More details about the design can be viewed in Multimedia Appendix 1.

The project team developed a communication strategy to promote the website. This included posting packages of 50 to 100 fridge magnets to each of the Aboriginal Community Controlled Health Services listed as members of the National Aboriginal Community Controlled Health Organization. The project team wrote an article for the Aboriginal and Torres Strait Islander Health Worker Journal [33], and referral links were negotiated with the Indigenous Healthinfonet, the Victorian Aboriginal Community Controlled Health Organization, and Diabetes Victoria websites. An unexpected outcome was that the How's Your Sugar website was also promoted by other websites [34-37].

Figure 2. Nutrition game.



Website Utilization

Data from Google Analytics (Figure 3) revealed a total of 48,617 sessions from April 2010 to October 2016, with 30,852 out of 48,617 (64%) new sessions. Mean session duration and mean pages viewed per session suggested a pattern of engagement with the website. There was an annual pattern of increased sessions during the months April to May and August to September. In 2015 and 2016, there were spikes indicating increased site usage. The majority of sessions originated from Australia, 98.15% (47,717/48,617) with the highest number of sessions in Victoria 50.97% (24,323/47,717). Sources of website access included search engines and referring websites. Operating systems used per session indicated desktop preference.

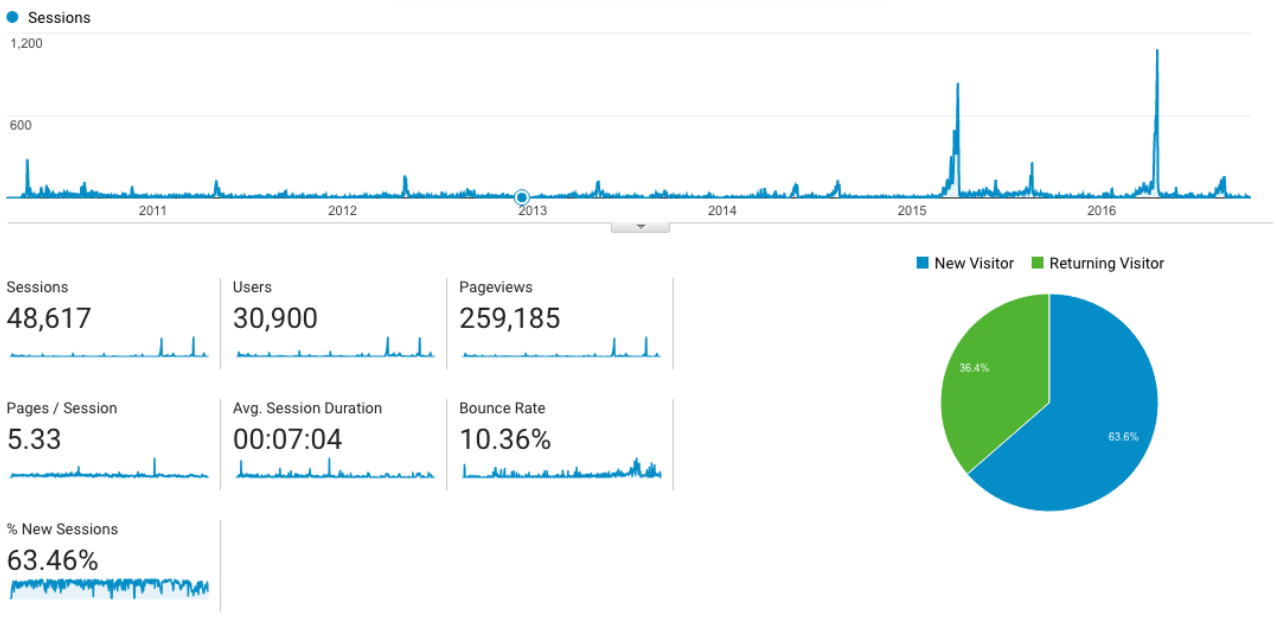
For the same time frame, there were 129 respondents to the survey (Table 2) with 30,700 individual users of the website. This indicated a less than 1% response rate, not unusual for voluntary Web-based surveys [38]. The survey respondent distribution had more females, Aboriginal people, and Aboriginal people with diabetes than expected with $P<.001$. Age group distribution of respondents differed from that of the Australian population, with the 26- to 35-year age group highest, followed by the 46- to 55-year age group. The most common reasons for visiting the site included research for a university assignment and health workers looking for information. Eleven Aboriginal respondents answered questions about self-assessed management of diabetes. This number was too small to calculate statistical significance lacking type II power; however, the data are provided in Table 2 for possible meta-analysis. Of the 11 respondents, 6 agreed to be resurveyed for diabetes self-management, with this number also too small to calculate statistical difference.

Table 2. Characteristics of survey respondents.

Characteristics		n (%)	95% CI	*P* value
Age group (n=127)				<.001
	18-25	29 (22.8)	14-27	
	26-35	44 (34.6)	23-38	
	36-45	23 (18.1)	11-23	
	46-55	30 (23.6)	15-28	
	56-65	8 (6.3)	3-10	
	66+	3 (2.4)	0.7-6	
Gender (n=129)	Female	107 (82.9)	76-88	<.001
	Male	22 (17.1)	12-25	
Reason for site visit (n=101)				
	Research for university assignment	41 (40.6)	32-50	
	Health worker looking for information	21 (20.8)	14-30	
	Curiosity	18 (17.8)	12-26	
	Diabetic looking for information	12 (11.8)	7-20	
	Research	8 (7.9)	4-15	
	Person with diabetic family member looking for information	1 (9.9)	0.2-5	
Aboriginal status (n=129)				<.001
	Aboriginal	28 (21.7)	16-30	
	Non-Aboriginal	101 (78.3)	70-85	
Aboriginal diabetic status (n=27)				<.001
	Diabetic	13 (48)	31-66	
	Non-Diabetic	14 (52)	34-69	
Aboriginal diabetic self-management (n=11)				
Regularly monitors blood sugar				
	Never	2 (18)	5-48	
	Rarely	2 (18)	5-48	
	Sometimes	3 (27)	10-57	
	Mostly	1 (27)	2-37	
	Always	3 (27)	10-57	
Takes medication regularly				
	Never	2 (18)	5-48	
	Rarely	0 (0)	-	
	Sometimes	2 (18)	5-48	
	Mostly	5 (46)	21-72	
	Always	2 (18)	5-48	
Recommended diabetic diet				

Characteristics		n (%)	95% CI	*P* value
	Never	2 (18)	5-48	
	Rarely	3 (27)	10-57	
	Sometimes	0 (0)	-	
	Mostly	5 (46)	21-72	
	Always	1 (9)	2-37	
Recommended exercise				
	Never	2 (18)	5-48	
	Rarely	3 (27)	10-57	
	Sometimes	2 (18)	5-48	
	Mostly	0 (0)	-	
	Always	4 (36)	16-65	
Checks feet daily				
	No	6 (55)	28-79	
	Yes	5 (46)	21-72	
Visit general practitioner at least twice a year				
	No	5 (46)	21-72	
	Yes	6 (55)	28-79	
Eyes checked in last 2 years				
	No	6 (55)	28-79	
	Yes	5 (46)	21-72	

Figure 3. Website session data.



Discussion

Principal Findings

The How's Your Sugar website development drew on Aboriginal health, social marketing, and interactive health promotion frameworks. An evidence base for diabetes self-management also informed the website content. The website build involved a multidisciplinary team and participation of Aboriginal diabetics, Aboriginal diabetic family members, and Aboriginal health workers. This participation allowed for inclusion of Aboriginal ways of knowing and being [27] through soundscape, imagery, and interaction. This was important, as approaches to dealing with Aboriginal health often omit

Aboriginal knowledge and focus instead on the illness and pathology that has arisen from cultural dispossession. This can effectively reduce self-determination of Aboriginal people by imposing a western cultural model not inclusive of Aboriginal well-being modalities, contributing further to identity loss and dislocation [39]. Rather than simply considering that Aboriginal people have a right to diabetes education, How's Your Sugar embedded this in Aboriginal ways of knowing and being. This is part of a global political movement in self-determination that aims to include indigenous knowledge and cultural practices in the everyday life [40]. To some extent this positioning is consistent with the self-determining component of the Chronic Care Model, whereby those experiencing chronic conditions ideally should feel empowered to maintain well-being [41]. Other authors have also called for those working in health to question how this locus of control relates to Aboriginal peoples [42].

The highest number of website sessions came from Victoria, the geographic region where the website was created. This might indicate increased relevancy for people living in this area. Varying promotion of How's Your Sugar in different states and territories might have also influenced this pattern. The How's Your Sugar website was successful in attracting visitors via referring websites, and this type of promotion could be considered by others. Desktop access was preferred. However, How's Your Sugar was constructed at a time when mobile and tablet Internet use was emerging and so the content does not translate well to these, thus likely impacting on findings. Since inception of the website, there has been much technology change [15] and if How's Your Sugar were made today, different Web-based tools would be available.

The study survey respondent distribution had more Aboriginal and Aboriginal people with diabetes than expected. It is possible that these people were more motivated to respond; however, it does indicate that this target group was accessing the website. Survey respondent distribution had more females than expected, and it is unclear why. Reasons for visiting the website varied, including personal diabetes education, university assignments, research, and health workers seeking information. This indicates that the target group of health workers were also accessing the website. The spikes in annual website sessions are indicative of Australian teaching semesters, and this may explain these spikes, particularly as the survey data indicate that university students were accessing the site and that the website was promoted by tertiary education institutions. The increased spikes in usage may indicate that more students were using the site over the past 2 years. Development of an associated education resource may have enhanced engagement with this group.

Limitations

The survey was unable to describe diabetes management behavior change due to limited numbers of respondents. In Aboriginal research, gaining enough numbers of people for statistical analysis is often a challenge [43]. We suggest to others attempting this type of research to consider other means of measuring change, and technology developed since the inception of this website could facilitate this. The survey is also limited to a small response rate, and the data represent those willing to undertake the survey and so is not representative of all visitors to the website.

Conclusions

This study identifies that Aboriginal ways of knowing and being can be included in website designs alongside other theoretical and evidence models. It also highlights that Aboriginal people do engage with Web-based health promotion and further understanding about reaching to this population would be of use. The website was also being utilized for education purposes, and provision of an education resource would likely have enhanced this engagement. Web-based technologies are rapidly evolving, and these can potentially measure behavior change in engaging ways that have benefits for the participant. A challenge for designers is inclusivity of cultural diversity for self-determination.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Application of frameworks.

[PDF File (Adobe PDF File), 2MB - diabetes_v2i1e6_app1.pdf]

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Original Paper

Machine or Human? Evaluating the Quality of a Language Translation Mobile App for Diabetes Education Material

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Abstract

Background: Diabetes is a major health crisis for Hispanics and Asian Americans. Moreover, Spanish and Chinese speakers are more likely to have limited English proficiency in the United States. One potential tool for facilitating language communication between diabetes patients and health care providers is technology, specifically mobile phones.

Objective: Previous studies have assessed machine translation quality using only writing inputs. To bridge such a research gap, we conducted a pilot study to evaluate the quality of a mobile language translation app (iTranslate) with a voice recognition feature for translating diabetes patient education material.

Methods: The pamphlet, "You are the heart of your family…take care of it," is a health education sheet for diabetes patients that outlines three recommended questions for patients to ask their clinicians. Two professional translators translated the original English sentences into Spanish and Chinese. We recruited six certified medical translators (three Spanish and three Chinese) to conduct blinded evaluations of the following versions: (1) sentences interpreted by iTranslate, and (2) sentences interpreted by the professional human translators. Evaluators rated the sentences (ranging from 1-5) on four scales: Fluency, Adequacy, Meaning, and Severity. We performed descriptive analyses to examine the differences between these two versions.

Results: Cronbach alpha values exhibited high degrees of agreement on the rating outcomes of both evaluator groups: .920 for the Spanish raters and .971 for the Chinese raters. The readability scores generated using MS Word's Flesch-Kincaid Grade Level for these sentences were 0.0, 1.0, and 7.1. We found iTranslate generally provided translation accuracy comparable to human translators on simple sentences. However, iTranslate made more errors when translating difficult sentences.

Conclusions: Although the evidence from our study supports iTranslate's potential for supplementing professional human translators, further evidence is needed. For this reason, mobile language translation apps should be used with caution.

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KEYWORDS

health literacy; health education; health communication; language translation; diabetes; machine translation; mobile translation app; human interpreter; translator

Introduction

Diabetes is a major health crisis for Hispanics and Asian Americans. According to the Centers for Disease Control and Prevention (CDC), 29.1 million people (9.3% of the US population) have diabetes; 12.8% Hispanics and 9% Asian Americans above 20 years old were diagnosed with diabetes, compared to 7.6% non-Hispanic whites [1]. From 1997-2014, diabetes rates increased 103% for Asian Americans and 60% for Hispanics [2].

Compared to other ethnic groups, Hispanics and Chinese Americans are also more likely to have low English proficiency. Over 21% of the US population speaks a language other than English at home. Further, the highest percentages of individuals who speak no English are Hispanics and Chinese Americans [3]. Approximately 43.7% Hispanics and 55.7% Chinese Americans speak English less than "very well" [3] and would be considered having limited English proficiency (LEP). LEP refers to any person age 5 or older who self-reported speaking English less than "very well" [3]. In brief, because Hispanic and Chinese Americans are more likely to have LEP, communication challenges arising from language barriers might impact the quality of the health services and information they receive.

Populations with LEP encounter numerous health communication challenges due to barriers related to language proficiency. These language barriers, as many studies have pointed out, might lead to health disparities and poor health outcomes. For instance, individuals with LEP are more likely to take inaccurate medication dosages [4], have poor health status [5], spend additional money and time utilizing health care services [6], experience unsatisfactory events with health care providers, make improper health choices [7], and have limited access and use of preventive health care services [8]. For diabetes patients who have LEP, negative health outcomes include poor glycemic control [9] and diabetic retinopathy [10].

One potential tool for facilitating language communication between patients and health care providers is technology, specifically mobile phones. In the United States, smartphone ownership increased from 35% of the population in 2011 to 72% in 2016 [11]. These smartphone owners can access various apps including machine language translation apps. For instance, iTranslate is a mobile app available for mobile phones with Apple, Android, and Windows systems that instantly translates text or voice inputs and converts them into text and voice outputs. Such voice recognition features were developed from computerized systems.

There are no significant differences in smartphone ownership among different racial/ethnic groups [12]. Further, about three-quarters (73%) of the Hispanic smartphone owners have used their phones to search for health-related information, compared to 58% white and 67% black [13]. Smartphones with machine translation apps are efficient tools for helping populations with LEP overcome language barriers [14,15]. For instance, translation mobile apps might improve their understanding of health information and access to health resources.

However, translation inaccuracy has the potential to adversely impact information's meaning and lead to negative health consequences. For example, language translation errors lead to misunderstandings about medical prescriptions [16] as well as misdiagnoses and mistreatments [17,18].

Previous studies have examined the usability of mobile language translation apps among clinicians and patients. In a study conducted by Abreu and Adriatico [19], the researchers investigated the experience of using the Google Translation App among a group of US audiologists and Spanish speaking patients/parents/guardians when they were communicating with each other. Abreu and Adriatico reported positive reactions from both the audiologists and the Spanish-speaking clients. Based on their findings, the authors concluded that the Google Translation App might be a viable tool for addressing language barriers and improving health communication when human interpreters were not available [19]. Similarly, Albrecht et al [20] examined the usage experience of a mobile translation app (xprompt) among nursing staff in Germany. The authors found that the participants perceived the xprompt app as useful for basic communication with non-German speaking patients [20]. Here, machine translation refers to automated computer translations powered by algorithms.

Besides usability, accuracy is another important criterion for evaluating machine language translation tools. With regard to the machine translation accuracy, previous studies assessed the translation product provided by Babel Fish and Google Translate websites using only writing inputs [21-24]. They noted that machine translation tools made errors when translating medical information [21-24]. Khanna et al [22] suggested that machine translation tools with a voice recognition feature might increase translation errors. Given the absence of research on voice recognition features and translations errors, we investigated the quality of a machine language translation mobile app with a voice recognition feature (iTranslate). Because diabetes is a major health crisis for Hispanics and Asian Americans [2], we selected diabetes patient education material. To the best of our knowledge, no study to date has investigated the quality of a mobile translation app interpreting spoken sentences.

The purpose of this pilot study is to evaluate the quality of iTranslate when interpreting spoken sentences from English to Spanish and Chinese. Our overarching research question is: Can iTranslate be an accurate and practical translation tool for patients-clinicians using diabetes education materials? To provide insights into this question, we posed the following research questions:

1. What is the quality of iTranslate when interpreting spoken sentences from English to Spanish, as compared to professional human interpreters?
2. What is the quality of iTranslate when interpreting spoken sentences from English to Chinese, as compared to professional human translators?

Methods

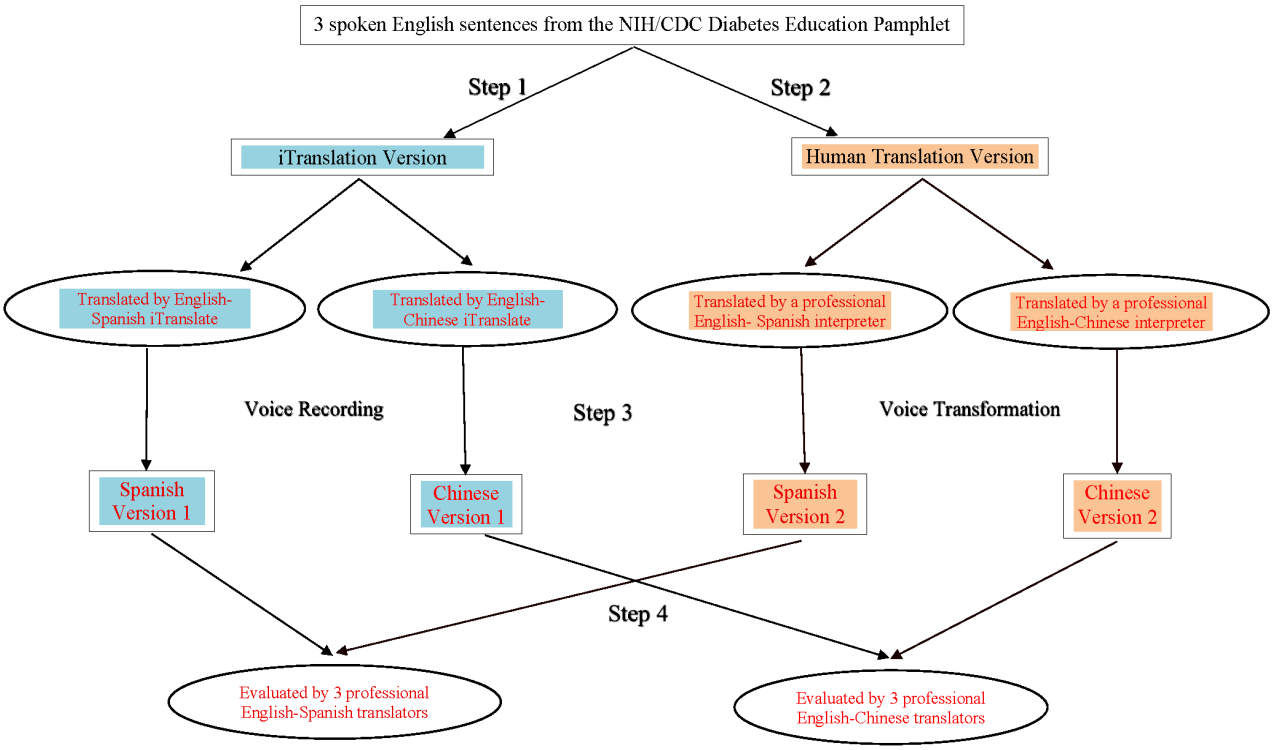
Materials to be Translated

We chose a publicly available diabetes patient education pamphlet as a heuristic example for this pilot study. The pamphlet, "You are the heart of your family…take care of it" (see Multimedia Appendix 1), is published by the National Institutes of Health and the CDC and distributed by the National Diabetes Education Program. This pamphlet contains two parts: Part A, six written sentences as behavior change suggestions for managing diabetes and Part B, three recommended questions for patients to ask their clinicians. Our study examined the quality of iTranslate when translating Part B. The study and results of Part A were reported by Chen et al [21].

Procedures

This study was approved by the appropriate institutional review board. Figure 1 outlines the procedures employed throughout this study, which comprise four steps: Step 1. iTranslate mobile app translation process; Step 2. Human translation process; Step 3. Voice transformation; Step 4. Evaluation.

Figure 1. Four-step procedures.



Step 1. Mobile Language Translation App

We used iTranslate app to translate three spoken questions from English into both Spanish and Chinese (Mandarin). We recorded these voice outputs into audio files.

Step 2. Human Translator

Two professional medical interpreters translated the three original English questions into Spanish and Chinese respectively. Both were American Translators Association (ATA) certified translators (one certified in English to Spanish and the other in English to Chinese). The ATA website lists all the certified translators' contact information. We approached the translators as regular customers seeking and paying for translation services. We did not inform them that their translations would be evaluated. We emailed the original English questions to the translators, and they returned the translated sentences in audio files by email as well. We also asked them to provide transcriptions of their voice translations in a separate MS Word file.

Step 3. Voice Transformation

Since the evaluators might distinguish the machine from the human translation because of the potentially recognizable characteristics of the mechanical voice, we converted all the human voice translations into a machine voice. First, we copied and pasted the transcription on a voice transformation website and clicked the voice button for the three questions translated by the human interpreters to be converted to the machine voice function. Second, we reviewed the transcriptions and compared the machine voice to the original human voice (translators' audio files) to ensure equivalency. Third, we recorded the three sentences, now in the machine voice, into audio files, and emailed these audio files to the evaluators. Table 1 lists the original English sentences and the translated Spanish and Chinese transcriptions.

Table 1. The original English and translated Chinese and Spanish versions of the sentences.

Original	iTranslate		Human	
English	Spanish	Chinese	Spanish	Chinese
What are my blood sugar, blood pressure, and cholesterol numbers?	¿Cuáles son mis azúcar en la sangre, presión arterial y colesterol?	我的血糖、血压和胆固醇是什么？	¿Cuáles son mis números de azúcar en la sangre, presión arterial y colesterol?	我的血糖、血压和胆固醇的值是多少？
What should they be?	¿Qué deberían ser?	他们应该是什么？	¿Cuáles deben de ser mis números?	正常值应该是多少？
What actions should I take to reach these goals?	¿Qué medidas debo tomar para alcanzar estas metas?	应该采取何种行动来达到这些目标？	¿Qué debo de hacer para alcanzar esas metas?	我应该怎么做来达到正常值？

Step 4. Evaluation

We sent invitation emails to the first 12 English-Spanish translators and 12 English-Chinese ATA certified translators listed on the ATA website. We emailed the survey package to the first six translators (three Spanish and three Chinese respectively) who accepted our study invitation. We asked them to evaluate the two versions of the voice translations (one by iTranslate app and the other one by the professional translator). Each evaluator received a US $15 check after submitting the evaluation survey package via email. The two interpreters who provided the human translation versions did not serve as evaluators, nor were they aware that their translations would be evaluated by other translators.

Survey Package

To minimize rater bias and blind the evaluation process, the audio files were marked as version 1 (sentences translated by iTranslate) and version 2 (sentences translated by a human). The survey package contained one evaluation rubric in an MS Word file and two audio files (versions 1 and 2). We asked the evaluators to score each of the translated sentences using the evaluation rubric (see Table 2).

Evaluation Rubric

We adapted the evaluation rubric from Khana et al [22], instructed the raters to evaluate the translated sentences based on four criteria—Fluency, Adequacy, Meaning, and Severity—on a 5-point scale (1 indicates the lowest quality and 5 indicates the highest quality). The Fluency and Adequacy criteria are standard domains for assessing machine translation quality [25]. Fluency assesses readability, grammar, and understandability. Adequacy assesses the amount of original information preserved. Meaning assesses the equivalency of the translation and the original sentence and detects misleading information [26]. Severity assesses the degree of the negative impact on a patient's health outcome. Table 2 presents the four criteria and the description for each criterion.

Table 2. Rubric for evaluating translation quality.

	Fluency	Adequacy	Meaning	Severity
1	No fluency; no appreciable grammar, not understandable	0% of information conveyed from the original	Totally different meaning from the original	Dangerous to patient
2	Marginal fluency; several grammatical errors	25% of information conveyed from the original	Misleading information added/omitted compared to the original	Impairs care in some way
3	Good fluency; several grammatical errors, understandable	50% of information conveyed from the original	Partially the same meaning as the original	Delays necessary care
4	Excellent fluency; few grammatical errors	75% of information conveyed from the original	Almost the same meaning as the original	Unclear effect on patient care
5	Perfect fluency; like reading a newspaper	100% of information conveyed from the original	Same meaning as the original	No effect on patient care

Data Analysis

We performed the Cronbach alpha test to assess the degree of rater agreement. Two sets of mean scores were calculated for each of the four domains (Fluency, Adequacy, Meaning, and Severity) on each sentence from the Chinese and Spanish rater groups. We also presented the readability statistics for each original English sentences. Readability statistics were generated using MS Word's Flesch-Kincaid Grade Level, which assesses the degree of difficulty for readers to understand a sentence or paragraph [27]. For ease of comparison, two sets of graphs shown in Figures 2 and 3 visually depict the translation quality between iTranslate app and the human interpreters starting from the easiest to the most difficult sentence based on the readability statistics.

Figure 2. Scatterplots comparing Spanish iTranslate with the human translator scores.

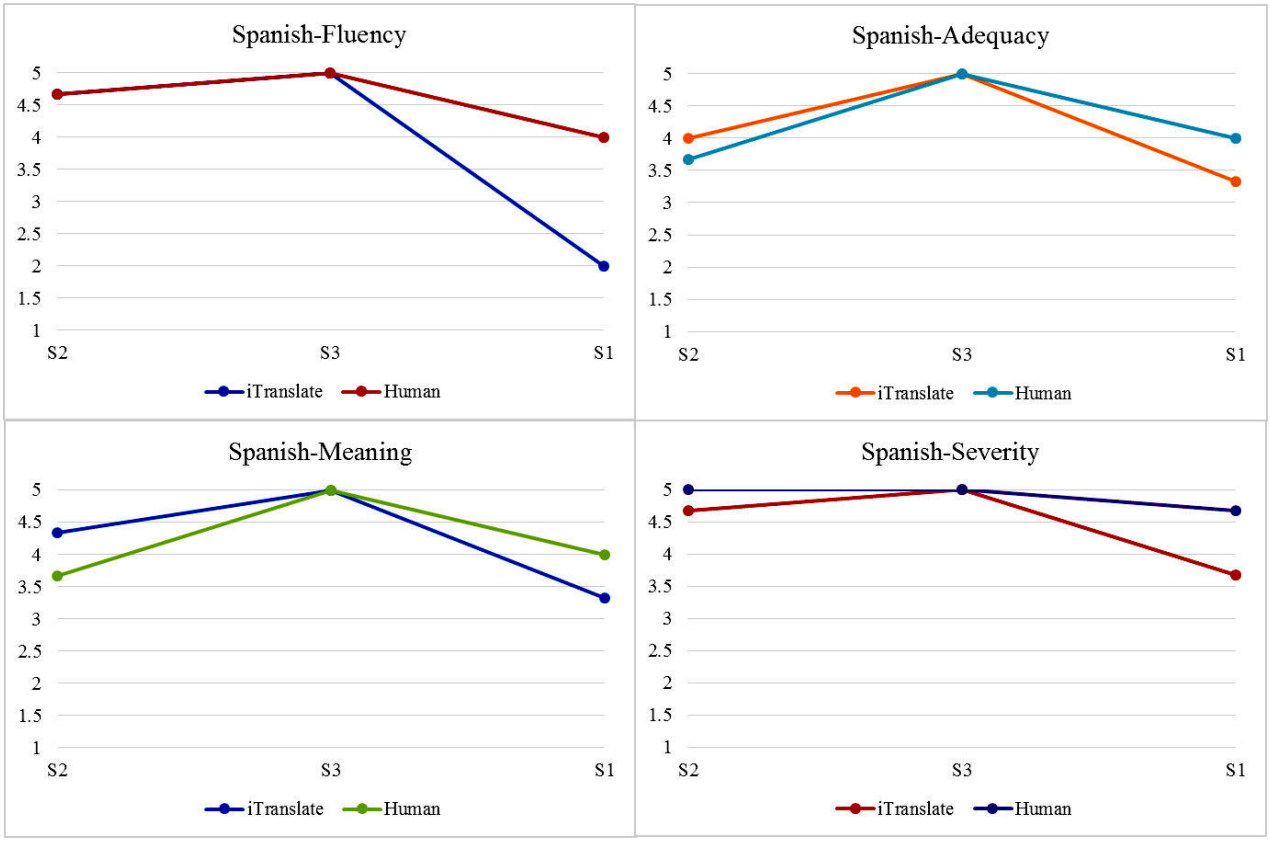
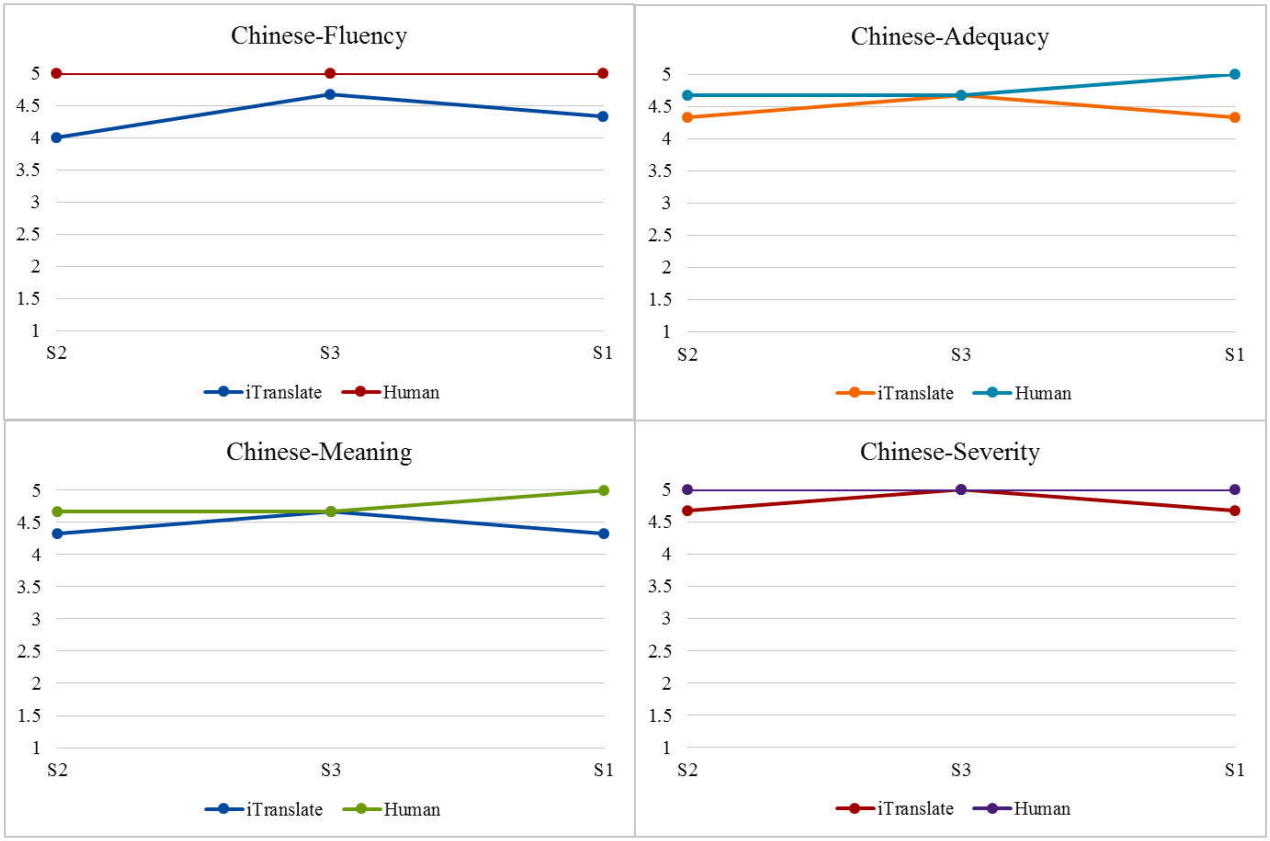


Figure 3. Scatterplots comparing Chinese iTranslate with the human translator scores.



Results

Interrater Reliability

Cronbach alpha was used to assess the rating reliability across each evaluator. The Cronbach alpha values exhibited high degrees of agreement on the rating outcomes of both rater groups: .920 for the Spanish raters and .971 for the Chinese raters.

Spanish Translation: iTranslate Versus Human

We ranked the sentences based on their readability scores and presented the results with the easiest sentence first, followed by the medium, and put the most difficult sentence last (Table 3). Within the Fluency domain for iTranslate, the two relatively simple sentences (S2 and S3) had almost perfect fluency; however, the most difficult sentence (S1) had marginal fluency with several grammatical errors (Fluency=2). All the sentences translated by the Spanish human translator received excellent or perfect fluency scores (Fluency≥4). Within the Adequacy domain for iTranslate, S2 conveyed about 75% of the original information, S3 conveyed 100% of the original information, but S1 conveyed about half of the original information. All the sentences translated by the Spanish human translator conveyed most of the original information. Within the Meaning domain for iTranslate, S2 and S3 had almost the same meaning as the original, but S1 had practically the same meaning as the original. All the sentences translated by the Spanish human translator had almost the same meaning as the original. Within the Severity domain for iTranslate, S2 and S3 had almost no effect on patient care, but S1 had unclear effect on patient care. All the sentences translated by the Spanish human translator had (almost) no effect on patient care.

Table 3. Mean scores for Spanish iTranslate and the human Spanish translator.

Original sentences	Flesch-Kincaid grade level	iTranslate				Human			
		Fluency	Adequacy	Meaning	Severity	Fluency	Adequacy	Meaning	Severity
S2. What should they be?	0.0	4.67	4	4.33	4.67	4.67	3.67	3.67	5
S3. What actions should I take to reach these goals?	1.0	5	5	5	5	5	5	5	5
S1. What are my blood sugar, blood pressure, and cholesterol numbers?	7.1	2	3.33	3.33	3.67	4	4	4	4.67

Chinese Translation: iTranslate Versus Human

As shown in Table 4, within the Fluency domain, all the sentences translated by both iTranslate and the Chinese human translator had excellent or perfect fluency. Within the Adequacy domain, all the sentences conveyed more than 75% to 100% of the original information. Within the Meaning domain, all the sentences had (almost) the same meaning as the original. Within the Severity domain, all the sentences had almost no effect on patient care.

Table 4. Mean scores for Chinese iTranslate and the human Chinese translator.

Original sentences	Flesch-Kincaid Grade Level	iTranslate				Human			
		Fluency	Adequacy	Meaning	Severity	Fluency	Adequacy	Meaning	Severity
S2. What should they be?	0.0	4	4.33	4.33	4.67	5	4.67	4.67	5
S3. What actions should I take to reach these goals?	1.0	4.67	4.67	4.67	5	5	4.67	4.67	5
S1. What are my blood sugar, blood pressure, and cholesterol numbers?	7.1	4.33	4.33	4.33	4.67	5	5	5	5

Visually Comparing iTranslate and Human Versions

To better compare and capture the trends among sentences with regard to the quality scores on four domains, we created two graphs, presenting the findings of the easiest sentence (S2) first and the most difficult sentence (S1) last.

When sentences were translated from English to Spanish (Figure 2), for the easiest sentence (S2), there was a slight difference between iTranslate and the Spanish human translator, where iTranslate received slightly higher scores in the Adequacy (4 vs 3.67) and Meaning domains (4.33 vs 3.67), but slightly lower scores in the Severity domain (4.67 vs 5). There was no difference between iTranslate app and the Spanish human

translator on S3 (the medium difficult sentence) in any of the four domains (5). For the most difficult sentence (S1), there was a slight difference between iTranslate and the Spanish human in the Adequacy and Meaning domains, where iTranslate received slightly lower scores (3.33 vs 4). We also noticed some gaps for S1 in the Fluency and Severity domains, where iTranslate received lower scores (2 vs 4 and 3.67 vs 4.67).

As shown in Figure 3, when sentences were translated from English to Chinese, there was almost no difference between the ratings of iTranslate app and the Chinese human translator on S3 (the medium difficult sentence) in any of the four domains. This funding is similar to the Spanish language. For the easiest sentence (S2) and the most difficult sentence (S1), there was a slight difference between iTranslate and the Chinese human translator, where iTranslate received slightly lower scores in all the four domains.

Discussion

Principal Findings

This pilot study compared the translation quality of iTranslate and professional human translators using three questions drawn from a diabetes patient education pamphlet. Materials were translated from English to Spanish and Chinese (Mandarin). We found iTranslate generally provided translation quality comparable to human translators on simple and medium difficulty sentences. The voice recognition feature and voice outputs employed by iTranslate produced text quality, clarity, and auditory richness (voice quality: native accent, tone, inflection, and delivery), which benefits individuals who cannot read in their native languages. However, iTranslate tends to make more errors when translating difficult sentences.

When translating the easiest sentence (ie, S2 “What should they be?”, Flesch-Kincaid Grade Level=0.0) from English to Spanish, the voice employed by iTranslate softened and deadened the [n] when pronouncing [deberían] so that the [n] almost sounds omitted. On the other hand, the Spanish human translator added the antecedent noun for the pronoun “they”. Therefore, even though the professional translator received slightly lower scores on the Adequacy and Meaning compared to iTranslate, the Spanish human translator received a slightly higher score on the Severity compared to iTranslate. One of the Spanish raters believed that S2 translated by iTranslate from English to Spanish had an unclear effect on patient care. When translating it from English to Chinese, iTranslate made no errors. Compared to the literal translation by iTranslate, the Chinese human interpreter added some extra information to clarify the word “they”, which translated the sentence into [正常值应该是多少？] (What should the normal range be?). Although iTranslate did not make any errors, the Chinese human version contained more specific and meaningful information. We believe this was the reason why iTranslate received slightly lower scores on all the four criteria compared to the Chinese human translator. Also, one of the Chinese raters believed that it had an unclear effect on patient care.

When translating the relatively easy sentence (ie, S3 “What actions should I take to reach these goals?”, Flesch-Kincaid Grade Level=1.0) from English to Spanish, the Spanish raters agreed that both versions had no effect on patient care even though the Spanish human interpreter substituted those [“esas”] for these [estas”]. Both iTranslate and the Spanish human interpreter received full scores on every criterion. When translating it from English to Chinese, iTranslate omitted the word “I” and translated this sentence into (“What actions should be taken to reach these goals?”). In comparison, the Chinese human interpreter substituted the phrase “take actions” into “do” and specified “these goals” into “normal numbers.” Therefore, the Chinese human interpreter translated S3 into [我应该怎么做来达到正常值？] (“What should I do to reach normal numbers?”). Neither iTranslate nor the human interpreter correctly translated S3 word for word; however, the general meaning of the original sentence has not been changed. Thus, all the raters agreed that S3 translated by either iTranslate or the Chinese human interpreter had no effect on patient care.

When translating the most difficult sentence (ie, S1 “What are my blood sugar, blood pressure, and cholesterol numbers?, Flesch-Kincaid Grade Level=7.1) from English to Spanish, iTranslate omitted the word “number.” Therefore, the Spanish evaluators believed it had marginal fluency with several grammatical errors, conveyed about half of the original information, had practically the same meaning as the original, and had an unclear effect on patient care or delays necessary care. On the other hand, the Spanish human interpreter did not make any errors when translating S1. When translating it from English to Chinese, iTranslate made the exactly same error as translating it from English to Spanish—it omitted the word “number” as well. Therefore, this sentence did not received full scores on Fluency, Adequacy, and Meaning, which led to one of the Chinese evaluators’ believing that such an error had an unclear effect on patient care. On the other hand, the Chinese human interpreter did not make any errors when translating S1. Interestingly, even though iTranslate made the exactly the same error on S1 for the Spanish and Chinese translations, the Spanish raters gave it lower scores on all the criteria than the Chinese raters did.

To minimize rater bias, we blinded the audio version of the translated question so that the raters could not identify the two audio versions (iTranslate and the human translations). However, rater bias might still exist because each rater had their interpretation of the evaluation rubric. Variability in the rating scores may result from bias (systematic error) or random error (unpredictable). For example, S1 translated by iTranslate from English to Spanish received lower scores on all the criteria than the same sentence translated by iTranslate from English to Chinese even though the Chinese and Spanish translations made the exact same error—omitting the head noun “numbers” in the nominal phrase “my blood sugar, blood pressure, and cholesterol numbers.” Usually there are number of ways to correctly translate a sentence; however, individuals might have different preferences on evaluating translation quality. Another example is Fluency. According to the rubric, 4 represents “excellent fluency” and 5 represents “perfect fluency.” We made no attempt to standardize the domain descriptors or train the raters; therefore, each evaluator might have a slightly different interpretation of “excellent” and “perfect.” Therefore, although

we can make broad statements about the comparability and adequacy based on the scoring rubric of the human and machine translation in each language, we cannot conclude that iTranslate produces more accurate translations from English to Chinese than from English to Spanish.

Our findings appear to support iTranslate as producing competent, understandable translations for simple sentences. However, once the sentences get more complicated, iTranslate tends to make more errors. Previous studies documented high rate of errors in machine translations when translating written sentences. For instance, Sharif and Tse [28] identified half of the medicine labels translated by computer programs from English to Spanish as being incorrect. In another study, Khanna et al [22] found that Google Translate made more errors compared to human translators when translating patient education texts from English to Spanish. Chen et al [21] evaluated the accuracy of Google Translate when translating diabetes patient education materials from English to multiple languages (Spanish and Chinese). The authors reported that Google produced more accurate translations from English to Spanish than English to Chinese [21]. Turner et al [23] also reported a high error rate when Google translated health websites from English to Chinese. One explanation for the difference between our findings and the evidence noted above might result from sentence difficulty. Interestingly, our findings indicated that iTranslate was a relatively comparable tool when translating simple spoken sentences from English to Spanish and Chinese. We propose that the machine translation quality was comparable to the human translations only when the sentence was easier to understand due to the simplicity of the grammatical constructions. Hence, our results support the findings of Zeng-Treitler et al [24] who found that machine translation tools appear to be less likely to provide accurate translation for longer and more difficult sentences.

Guidelines are available for health professionals to work with human interpreters in clinical encounters [29-32]; however, to date and to the best of our knowledge, there are no recommendations or guidelines about using mobile translation apps. Randhawa et al [33] pointed out that machine translation devices have several potential benefits in clinical settings such as helping clarify patient histories, reviewing a clinical diagnosis, restating the recommended treatment plan, and encouraging patients to ask questions. Based on previous machine translation commentary studies [33,34] and our pilot data, we recommend that clinicians consider the following when interacting with LEP patients using mobile language translation apps as communication assistance tools: (1) use the mobile translation apps to supplement but not supplant human translators, and (2) provide information in clients' and caregivers' mother tongue about the mobile translation apps and how to use them, along with appropriate precautions.

Limitations

This pilot study has several limitations. First, this study assessed the quality of the iTranslate mobile language translation app using only three spoken sentences from a diabetes patient education pamphlet. To compensate for the small number of sentence units, we investigated translations of these sentences from English into two languages (Spanish and Chinese). Second, we assessed only Spanish and Chinese translations so that the findings should not be applied to other languages. Future studies should investigate multiple machine translation tools with a larger sentence sample drawn from other public health materials as well as conversations from real clinical encounters. It is necessary to further investigate the relationship between machine translation error patterns and sentence complexity levels. Also, more studies should explore the app using experience from patients with LEP in various languages.

Conclusions

To the best of our knowledge, this is the first study to evaluate and compare the quality of a mobile language translation app with a voice recognition feature and professional human translators. We found iTranslate could produce competent, understandable translations for simple sentences. However, once sentences became more complicated, iTranslate seemed to make more errors.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

You are the heart of your family…take care of it.

[PDF File (Adobe PDF File), 132KB - diabetes_v2i1e13_app1.pdf]

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Abbreviations

ATA: American Translators Association
CDC: Centers for Disease Control and Prevention
LEP: limited English proficiency

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Original Paper

Telemonitoring and Health Counseling for Self-Management Support of Patients With Type 2 Diabetes: A Randomized Controlled Trial

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Abstract

Background: The prevalence of diabetes is increasing among adults globally, and there is a need for new models of health care delivery. Research has shown that self-management approaches encourage persons with chronic conditions to take a primary role in managing their daily care.

Objective: The objective of this study was to investigate whether the introduction of a health technology-supported self-management program involving telemonitoring and health counseling had beneficial effects on glycated hemoglobin (HbA_{1c}), other clinical variables (height, weight, body mass index, blood pressure, blood lipid profile), and health-related quality of life (HRQoL), as measured using the Short Form Health Survey (SF-36) version 2 in patients with type 2 diabetes.

Methods: This was a pragmatic randomized controlled trial of patients with type 2 diabetes. Both the control and intervention groups received usual care. The intervention group also participated in additional health promotion activities with the use of the Prescribed Healthcare Web application for self-monitoring of blood glucose and blood pressure. About every second month or when needed, the general practitioner or the diabetes nurse reviewed the results and the health care activity plan.

Results: A total of 166 patients with type 2 diabetes were randomly assigned to the intervention (n=87) or control (n=79) groups. From the baseline to follow-up, 36 patients in the intervention group and 5 patients in the control group were lost to follow-up, and 2 patients died. Additionally, HbA_{1c} was not available at baseline in one patient in the intervention group. A total of 122 patients were included in the final analysis after 19 months. There were no significant differences between the groups in the primary outcome HbA_{1c} level (P=.33), and in the secondary outcome HRQoL as measured using SF-36. A total of 80% (67/87) of the patients in the intervention group at the baseline, and 98% (47/50) of the responders after 19-month intervention were familiar with using a personal computer (P=.001). After 19 months, nonresponders (ie, data from baseline) reported significantly poorer mental health in social functioning and role emotional subscales on the SF-36 (P=.03, and P=.01, respectively).

Conclusions: The primary outcome HbA_{1c} level and the secondary outcome HRQoL did not differ between groups after the 19-month follow-up. Those lost to follow-up reported significantly poorer mental health than did the responders in the intervention group.

Trial Registration: Clinicaltrials.gov NCT01478672; https://clinicaltrials.gov/ct2/show/NCT01478672 (Archived by WebCite at http://www.webcitation.org/6r4eILeyu)

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KEYWORDS

self-management; clinical trial; telemonitoring; type 2 diabetes; health-related quality of life

Introduction

Research shows that self-management approaches encourage persons with a chronic condition globally to take a primary role in managing the daily care of their illness [1]. Through self-management interventions, patients with type 2 diabetes are equipped with essential skills to participate actively in self-management behavior and to manage their condition successfully [2]. The world prevalence of diabetes among adults (aged 20-79) was estimated at 415 million in 2015 (8.8%) and is expected to reach 642 million by 2040 (10.4%). Persons with type 2 diabetes constitute 95% of all cases. It is estimated that more than 59.8 million persons in the European region have diabetes, and that this number will rise to 71.1 million by 2040 [3]. In Sweden alone, there were 446,900 cases of diabetes in adults in 2015 (6.3%), with an estimated 168,700 undiagnosed cases [4].

In light of the increasing incidence of diabetes, preventive measures and lifestyle modifications are undeniably of utmost importance. Keeping blood glucose levels under control can reduce the complications of diabetes [5,6]. The prevention of complications is important and includes lifestyle management such as changing diet and participating in regular physical activity [7-9]. Studies show that persons with diabetes fear long-term complications that may influence their quality of life [10,11].

Self-management is recognized as a key component in the clinical treatment of diabetes, but patients often lack the knowledge and skills needed to manage their condition on a daily basis. The inability to understand the fundamental influences of diabetes-management activities on overall glycemic control leads to low levels of participation in self-care behaviors [12].

Systematic reviews [13-16]have provided evidence that telehealth interventions have a positive effect on the control of blood glucose levels in persons with diabetes. Home telehealth interventions reduce the number of patients hospitalized and the number of bed days of care, and are similar or favorable to the usual care in terms of quality of life, patient satisfaction, and adherence to treatment for persons with diabetes and chronic conditions [15]. Studies [14-18] indicate that home telehealth interventions are similar or favorable to the usual care in terms of quality of life, patient satisfaction, and adherence to treatment for people with diabetes and chronic conditions. Furthermore, Ciemins et al [19] reported that telehealth is an effective mode for providing diabetes care to rural patients when compared with face-to-face visits.

Despite these positive research results, home telemonitoring has also produced contradictory results, and the addition of technology alone does not improve the outcome of glycated hemoglobin (HbA_{1c}) for persons with type 2 diabetes [20-22]. One study has argued that health practices need to be selective in the use of telemonitoring, by limiting it to patients who have the motivation or a significant change in care such as starting insulin [20]. Earlier research also indicates that many patients who voluntarily participate in a telemedicine study are actually in a pre-action stage for behavioral change in the start-up phase, but they may not be ready to make changes in diet and physical activity [23].

A high dropout rate in telemedicine studies is not unusual; thus, it is important to report the discontinuation rate and/or being lost to follow-up in these studies [24]. Therefore, practices need to understand both the capabilities and limitations of the technology, as well as the involvement of the patients and stakeholders, and their willingness to use the tools. Telemedicine interventions in diabetes care have earlier evaluated the use of different telemedicine tools, the interaction between the technology and users [14], and the use of telemedicine with or without support from health care provider [25-29]; however, more research is needed.

Evaluating the clinical effectiveness of telemedicine is another important area [30]. Health-related quality of life (HRQoL) is a crucial outcome for persons living with a chronic condition, because it measures the impact of the condition on daily life. Therefore, evaluating the success of self-management interventions in terms of improvements in HRQoL seems appropriate from the perspective of persons with a chronic condition [31]. Quality of life for persons with diabetes is thought to be affected primarily by vascular complications such as peripheral vascular disease, cardiovascular disease, or associated comorbidities [32]. However, research indicates that functional impairments and physical disability affect the HRQoL of older persons with diabetes most significantly [32-34]. Therefore, the focus of diabetes management should be on the overall well-being rather than on the biological control of diabetes alone [35].

Thus, the objective of this study was to investigate whether the introduction of a Web application “Prescribed Healthcare” for self-monitoring of parameters such as blood glucose level and blood pressure, together with health counseling, produced benefits in terms of HbA_{1c} level; other clinical variables such as height, weight, body mass index (BMI), blood pressure, and blood lipid profile; and HRQoL in patients with type 2 diabetes.

Methods

Design and Setting

This study was a pragmatic parallel-group, unblinded, randomized controlled trial [36] with 1 intervention group and 1 control group. The study had a longitudinal design with 2 assessment points: at baseline and at the end of the trial (after 19 months). This is a Swedish study as part of the European Union collaborative project called Renewing Health (RH). The overall aim of the RH project was to evaluate innovative

telemedicine tools [30]. The Swedish part of the project was conducted in 4 health care centers situated in the northern part of Sweden during the years 2011-2013. This northern part covers 25% of Sweden's land area and has a population of 250,000 inhabitants.

Sample

A sample of 166 patients with type 2 diabetes was included in the study. The inclusion criteria were: having type 2 diabetes diagnosed >3 months before enrollment, HbA_{1c} level >6.5%, age ≥18 years, the capability to complete the questionnaires and to use the devices provided, and being cognitively able to participate. The patients who met the inclusion criteria were recruited from their health care center and approached through an information letter sent from their health care center in May 2011.

For sample size calculations, we needed 63 individuals in each group to maintain a statistical power of 80% and a significance level of 5%, and a standard deviation (SD) of the outcome variable of 0.5. Assuming a dropout rate of 20%, our aim was to enroll 95 individuals in each group to ensure that we had sufficient statistical power to reveal a significant difference of ≥.1 or in the primary outcome HbA_{1c} level to be statistically significant.

Usual Care

The control group received usual care. Care for patients with type 2 diabetes was regulated by the Swedish national guidelines for the treatment of diabetes mellitus and included methods for implementing lifestyle change, medical treatment, and follow-up [37]. Foot inspection was also recommended. In accordance with the guidelines, an ophthalmologist was responsible for eye examinations. All patients with type 2 diabetes were given a glucose meter, test strips, and lancets at no charge from the County Council. A multidisciplinary health counseling team comprising a general practitioner (GP), physiotherapist, dietitian, and diabetes nurse support the patients in performing physical activities and adopting a healthy diet. Patients with type 2 diabetes self-monitor their blood glucose level and report the results to their diabetes nurse.

The Intervention

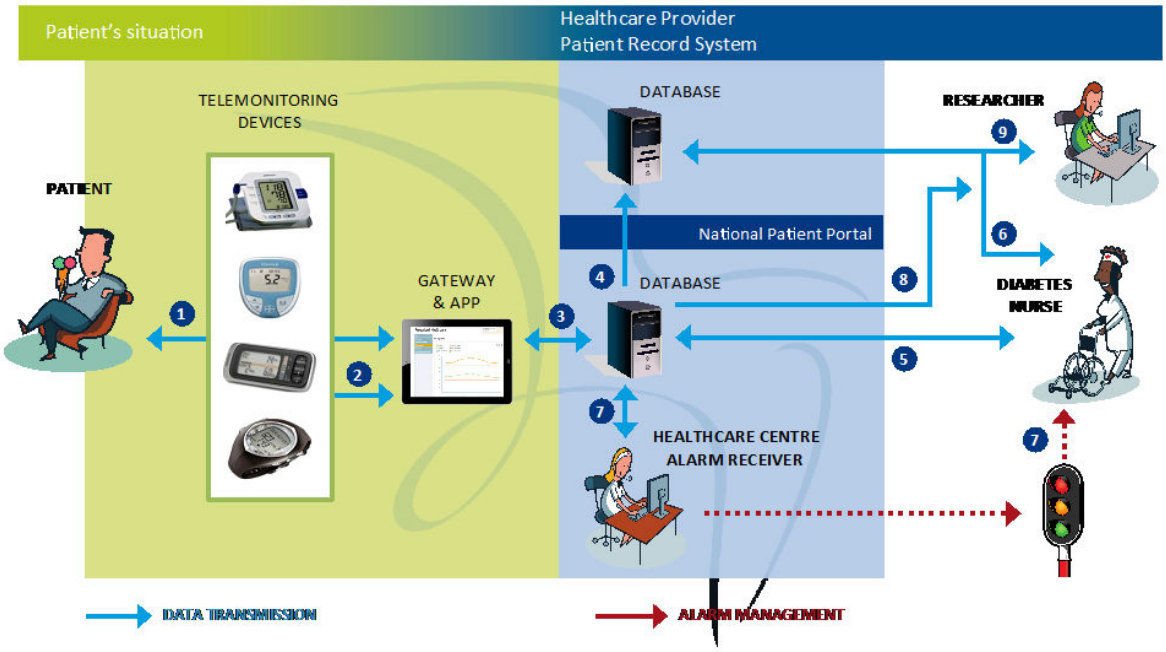
The intervention group received usual care in addition to the intervention, using a method that combined health counseling with the National Patient Portal. The idea was that the patients became more actively involved by self-monitoring their health by this Web-based management application. Measurement equipment, such as a blood glucose meter, was provided to the patients, and they used their own personal computers (PCs) to communicate. The few patients with no access to a computer were provided a tablet computer (see Figure 1).

Figure 1 shows how the patient is authenticated through electronic identification (1) to obtain access to the National Patient Portal. The connection between the patient and the National Patient Portal is encrypted (2). When the patient selects the Web application "Prescribed Healthcare," a connection is established to the servers at the County Council of Norrbotten. This connection (3) is made through a secure computer network connecting all health care providers in Sweden (Sjunet), and the connection is established with the Prescribed Healthcare server through configured firewalls (4). The caregivers are authenticated through SITHS, which is a smartcard-based secure authentication for caregivers employed by Swedish health care providers (6), and routed to the caregivers' intranet for the County Council of Norrbotten (7). The caregivers can obtain access to the electronic medical record system (8), connect to the National Patient Portal (3), and be rerouted to the Prescribed Healthcare server (4). Each health care center has an alarm receiver. If the health care provider who prescribed the measurement equipment does not manage the alarm on time, it is sent to another health care provider who can manage the alarm on time.

A patient entering the intervention, started with group sessions at the health care center that aimed to educate and motivate the patient to perform lifestyle modifications such as increasing physical activity, adopting a healthy diet, stopping smoking, and reducing alcohol consumption. The patient was trained to use the technology, to manage his or her health information, and to interact with health care professionals via email or video through the Prescribed Healthcare. An individualized activity plan was developed for each patient in the intervention group. During the project period, the patients performed health promotion activities and self-registered their parameters, such as duration of physical activity, into the application. The health care professionals provided reference values, and when applicable, the alarm levels.

The patients measured and manually entered medical parameters such as blood glucose level and blood pressure, which could be viewed through intuitive diagrams in each patient registration. The reference values made it easier for patients and caregivers to evaluate the outcome. If an alarm level was reached, the health care professional was notified. About every second month, or when needed according to the patient's initiative, the GP and/or diabetes nurse reviewed the results and revised the health care activity plan as needed. The patients then received feedback, such as any changes in medication or supporting comments about the performance of physical activities, from the health care professional via email or video. Furthermore, GPs, diabetes nurses (Figure 1), physiotherapists, and nutritionists worked cooperatively to interact with and manage each patient.

Figure 1. Telemonitoring devices and information flow during the field trial.



Randomization

In May 2011, eligible patients who met the inclusion criteria were approached with an information letter sent from their health care center. After the patient signed an informed consent form and completed the questionnaires, single-blind randomization was performed following standard procedures with a PC-based generation of random sequences, and an allocation based on consecutive assignment. A statistician performed the randomization; he or she had no access to the participants' personal code numbers. The researchers handling the database had no access to the participants' personal code numbers, when they analyzed the data.

Sociodemographic Measures

Demographic characteristics were collected from the health care centers before randomization through self-reported questionnaires. These included date of birth, gender, education, marital status, smoking habits, and level of computer and mobile phone skills.

Clinical Measures

Clinical baseline measures were collected at the health care centers before randomization. The participants' HbA_{1c} level, blood lipid profile, height, weight, and blood pressure were measured.

Primary Outcome

The primary outcome HbA_{1c} level was measured in the control and intervention groups at the baseline and after the intervention at 19 months. The rationale for the 19-month time frame was the desire for a long follow-up intervention, and for practical reasons, to allow the data collection to finish at the same time point as the other RH trials.

Secondary Outcome

The secondary outcome HRQoL was measured using the Short Form Health Survey (SF-36) version 2, which comprises 36 questions that measure 8 conceptual domains within physical functioning and mental health [38]. In addition to the 8 subscales, SF-36 is also analyzed as a 2-factor model, with physical and mental component summary scales. In this study, both the subscale scores and the summary scores of the SF-36 were presented. The SF-36 is internationally recognized as a reliable and valid tool [39].

Statistical Methods

Baseline characteristics were recorded for all randomized patients and between responders and nonresponders (ie, those missing) at 19 months. All analyses were based on the intention-to-treat principle. Categorical data were reported as counts and percentages. Associations between pairs of categorical variables were analyzed using the chi square test; continuous data were described as mean and SD (when normally distributed), or as median, minimum, and maximum (when not normally distributed). Group differences were identified using the Mann-Whitney *U* test. An independent sample *t* test was used to compare the change in the primary outcome between the intervention and control groups from the baseline to the follow-up at 19 months. All tests were two-sided. *P* values of ≥.05 were considered to be significant. SPSS Statistics version 22 (IBM Corp) was used for all analyses.

Ethics and Safety

The study was conducted according to the Ethical Review Act [40] and was approved by the Regional Ethical Review Board, Umeå, Sweden (Dnr 2010/386-31M). The portal provides secure access to their health information for all Swedish citizens and supports electronic interactions with health care professionals.

Results

Of 1048 eligible patients, 121 (11.55%) did not meet the inclusion criteria, and 761 (72.61%) chose not to participate in the study. A total of 166 patients (15.84%) were included for randomization; 87 patients were randomly assigned to the intervention group and 79 patients to the control group (Figure 2). One patient randomized into the intervention group was removed from the analysis because of a missing HbA_{1c} value. The percentages of dropouts differed between the groups; the reasons for dropping out included: being too ill, changing health care centers, or feeling that the technology was too difficult to handle. From the baseline to the follow-up, 36/86 patients (42%) in the intervention group and 5/79 patients (6%) in the control group were lost to follow-up; 2/79 patients (9%) died (Figure 2).

Of the 166 patients included in this study, 122 were included in the final analysis after 19 months. Their mean age was 67.5 years (SD 9.3), 48 (29.1 %) of the patients were female, and 63 (38.2 %) had >12 years of education. The mean HbA_{1c} was 64.6 mmol/mol (SD 11.0)/8.1% (SD 1.0), and the mean BMI was 30.7 kg/m^2 (SD 5.0). Twenty patients (12.1%) reported 2 or more comorbidities. The baseline data are presented for all patients in Table 1. This table also presents the data for the responders in both groups at 19 months. The baseline clinical and demographic characteristics did not differ significantly between the intervention and control groups (Table 1). Because of the high attrition rate and the large number of nonresponders in the intervention group (Figure 2), we investigated possible differences between responders and nonresponders in the intervention group, by comparing the values after 19 months with the baseline data (Table 1).

Primary Outcome

Only patients, who responded at 19 months, and for whom the HbA_{1c} level was measured and available, were included in the analysis of the primary and secondary outcomes. The numbers analyzed were 50 patients in the intervention group and 72 patients in the control group (Figure 1).

Figure 2. Flow diagram depicting the phases of the parallel randomized trial of the two groups (intervention and control group).

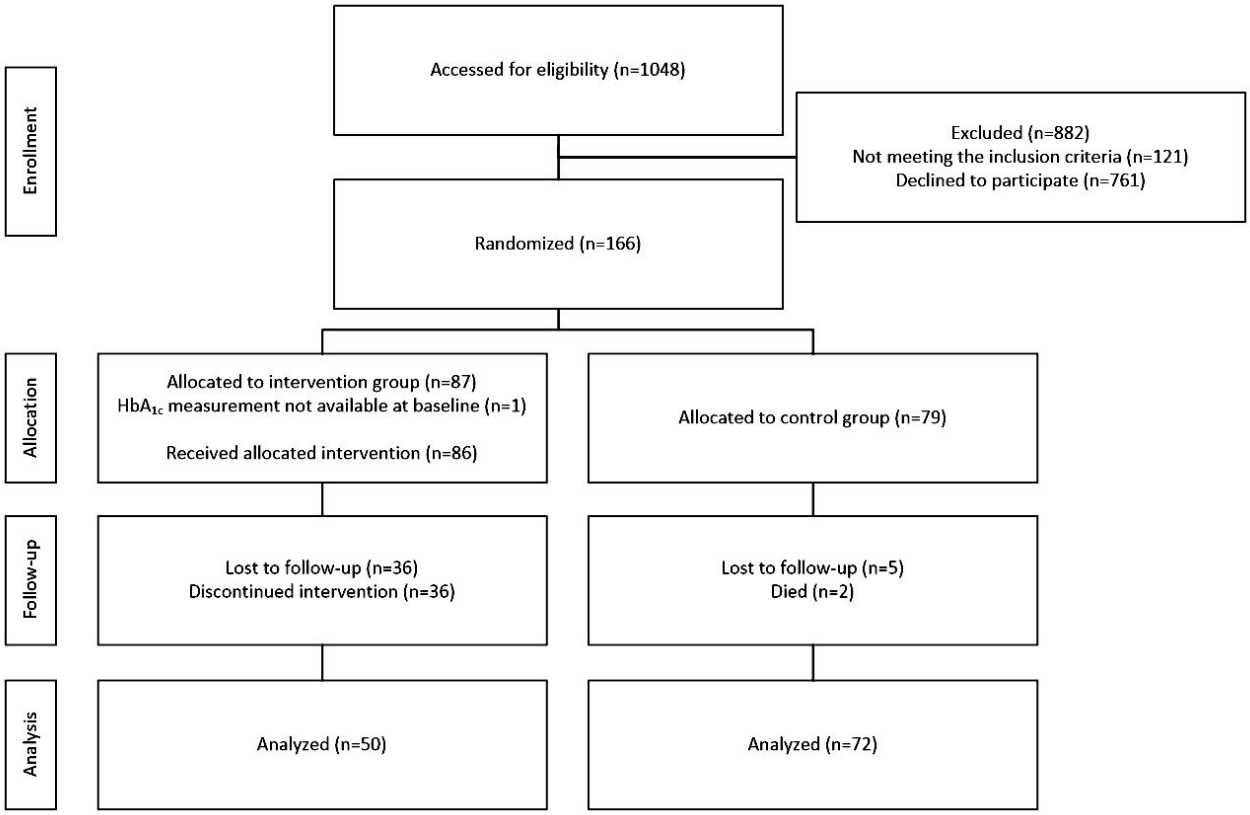


Table 1. Participants' characteristics at the baseline, and at 19 months for HbA_{1c} responders.

Characteristics	All randomized at baseline		Responders at the 19-month follow-up	
	Intervention (n=86)	Control (n=79)	Intervention (n=50)	Control (n=72)
Age in years				
Mean (SD)[a]	66.8 (8.8)	68.3 (9.9)	64.8 (8.5)	68.8 (9.8)
Median	67	69	66	70
Range	(39-91)	(37-89)	(39-91)	(37-89)
Missing	2	0	2	0
Gender: female				
n (%)	24 (29)	24 (30)	10 (21)	21 (29)
Missing	2	0	2	0
Education: >12 years				
n (%)	31 (37)	33 (43)	21 (45)	28 (41)
Missing	3	4	3	3
Marital status: married				
n (%)	47 (56)	49 (61)	30 (63)	45 (63)
Missing	2	1	2	0
Height in cm				
Mean (SD)	170.5 (9.6)	171.3 (8.2)	171.7 (8.2)	171.4 (8.1)
Median	171	171.5	172	171.8
Range	(151.5-190.5)	(153-192)	(156-189)	(153-192)
Missing	1	0	0	0
Weight in kg				
Mean (SD)	90.3 (16.3)	89.3 (16.9)	93.0 (17.8)	88.7 (14.6)
Median	88.0	90.8	92.1	91
Range	(55.0-124.8)	(58.7-156.0)	(55-124.8)	(58.7-131.4)
Missing	1	0	0	0
BMI[b] in kg/m^2				
Mean (SD)	31.0 (4.8)	30.4 (5.2)	31.4 (4.9)	30.2 (4.4)
Median	30.3	30.0	31.3	30.1
Range	(17.8,-40.7)	(20.8,54.0)	(17.8,40.7)	(20.8,43.3)
Missing	1	0	0	0
HbA_{1c}[c] in mmol/mol				
Mean (SD)	65.3 (11.7)	63.9 (10.2)		
Mean (SD)	65.3 (11.7)	63.9 (10.2)	65.8 (11.8)	63.6 (10.0)
Median	62.5	61.0	63	61.5
Range	(53.0-108.0)	(53.0-96.0)	(53-108)	(53-96)
Missing	0	0	0	0
HbA_{1c} in %				
Mean (SD)	8.1 (1.1)	8.0 (0.9)	8.2 (1.1)	8.0 (0.9)
Median	7.9	7.7	7.9	7.8
Range	(7.0-12.0)	(7.0-10.9)	(7.0,12.0)	(7.0,10.9)

Characteristics	All randomized at baseline		Responders at the 19-month follow-up	
	Intervention (n=86)	Control (n=79)	Intervention (n=50)	Control (n=72)
Missing	0	0	0	0
Comorbidities: 2 or more				
n (%)	8 (9)	12 (15)	3 (6)	10 (14)
Missing	0	0	0	0
Smoking: yes				
n (%)	14 (17)	12 (16)	9 (18)	11 (16)
Missing	3	2	2	1
Use of PC[d]: yes				
n (%)	67 (80)[e]	57 (72)	47 (98)[e]	52 (72)
Missing	2	0	2	0
Use of cell phone: yes				
n (%)	79 (94)	72 (92)	47 (98)	66 (92)
Missing	2	1	2	0

[a]SD: standard deviation.

[b]BMI: body mass index.

[c]HBA_{1c}: glycated hemoglobin.

[d]PC: personal computer.

[e]The difference between randomized participants and responders due to use of PC are statistically significant with *P*=.001 (chi-square test).

Table 2. HbA_{1c} responders: clinical characteristics.

Measures	All randomized at baseline		Responders at the 19-month follow-up	
	Intervention mean (SD)[a]	Control mean (SD)	Intervention mean (SD)	Control mean (SD)
HbA_{1c}[b] in mmol/mol	65.8 (11.8)	63.6 (10.0)	64.5 (15.8)	64.6 (14.8)
Missing	0	0	0	0
HbA_{1c} in %	8.2 (11)	8.0 (0.9)	8.0 (1.4)	8.1 (1.4)
Missing	0	0	0	0
BMI[c] in kg/m^2	31.4 (4.9)	30.2 (4.4)	31.1 (4.6)	29.8 (4.6)
Missing	0	0	0	1
Blood pressure in mm Hg				
Diastolic	146 (19)	145 (17)	143 (24)	144 (18)
Systolic	83 (10)	81 (11)	85 (12)	82 (8)
Missing	0	0	0	0
Lipids				
S-cholesterol[d]	5.29 (1.04)	5.35 (1.38)	5.18 (1.11)	5.21 (1.14)
Missing	0	0	0	0
Triglycerides	2.09 (1.23)	2.35 (1.75)	1.99 (0.98)	2.13 (1.25)
Missing	0	0	0	0
HDL[e]	1.23 (0.27)	1.26 (0.32)	1.22 (0.24)	1.29 (0.31)
Missing	0	0	0	0
LDL[f]	3.15 (0.86)	3.05 (1.19)	3.04 (0.84)	3.02 (1.01)
Missing	4	8	3	7

[a]SD: standard deviation.

[b]HBA_{1c}: glycated hemoglobin.

[c]BMI: body mass index.

[d]S-cholesterol: serum cholesterol.

[e]HDL: high-density lipoprotein.

[f]LDL: low-density lipoprotein.

We found no significant differences between the intervention and control groups in the change in HbA_{1c} level between the baseline and the 19-month follow-up (P=.33, 95% CI [−0.65 to 0.22]; Tables 2 and 3).

Secondary Outcome

The changes in the domains of SF-36 from the baseline to the 19-month follow-up did not differ significantly between the intervention and control groups. Similarly, there were no significant differences in clinical variables such as blood pressure, lipid levels, and BMI (data not shown). However, within the control group BMI decreased significantly during the study (Table 3), and the domains of bodily pain and role emotional functioning measured by the SF-36 also decreased (data not shown). In addition, the domain of physical functioning as measured by the SF-36 decreased significantly in the intervention group (data not shown). These findings might be accidental and with no obvious explications.

Other Clinical Outcomes

At the baseline, 80% (67/86) of the patients randomized to the intervention group were familiar with using a PC; after the 19-month intervention, this percentage was 98% (47/50) among the patients in the intervention group (Table 1). This difference from the baseline to the follow-up was significant (P=.001, chi square test; Table 1).

Table 3. HbA_{1c} responders: Change from baseline to 19 months.

Measures	Intervention		Control	
	Mean	95% CI	Mean	95% CI
HbA $_{1c}$ [a] in mmol/mol	−1.36	−4.81 to 2.09	0.97	−2.20 to 4.15
Missing	0		0	
HbA $_{1c}$ in %	−0.12	−0.44 to 0.19	0.09	−0.20 to 0.38
Missing	0		0	
BMI[b] in kg/m^2	−0.35	−0.72 to 0.03	−0.36	−0.60 to −0.11
Missing	0		1	
Blood pressure in mm Hg				
Diastolic	−2.78	−8.30 to 2.74	−1.13	−4.83 to 2.58
Systolic	2.70	−0.96 to 6.36	0.83	−1.73 to 3.39
Missing	0		0	
Lipids				
S-cholesterol[c]	−0.11	−0.34 to 0.12	−0.13	−0.40 to 0.13
Missing	0		0	
Triglycerides	−0.11	−0.35 to 0.13	−0.22	−0.50 to 0.05
Missing	0		0	
HDL[d]	−0.02	−0.08 to 0.04	0.03	−0.01 to 0.07
Missing	0		0	
LDL[e]	−0.11	−0.31 to 0.10	−0.09	−0.33 to 0.15
Missing	4		9	

[a]HBA_{1c}: glycated hemoglobin.

[b]BMI: body mass index.

[c]S-cholesterol: serum cholesterol.

[d]HDL: high-density lipoprotein.

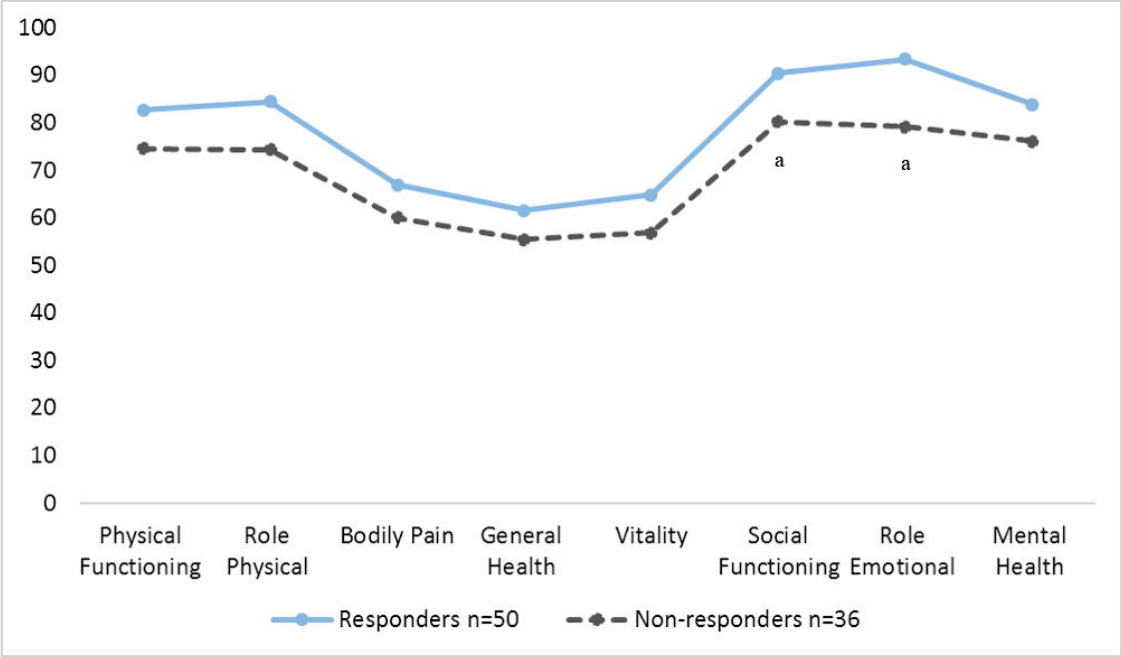
[e]LDL: low-density lipoprotein.

We also found significant differences in some SF-36 scores between the responders and the nonresponders in the intervention group after the 19 months (with baseline data). The responders reporting higher mental health in social functioning and in role emotional functioning than nonresponders (P=.03 and P=.01, respectively; Figure 3). There was also a trend for responders to report a higher HRQoL in all SF-36 domains as compared with the nonresponders. The nonresponders had significantly higher serum cholesterol levels than the responders (P=.04). However, given the limited sample size, this finding might be accidental.

Harm

No adverse events were reported during the study. Two deaths were reported in the study, both in the control group, but they were not related to the study or a lack of the intervention.

Figure 3. Intervention group: differences in HRQoL on the SF-36 between responders and nonresponders at 19 months (with baseline data). Significant differences were found between responders and nonresponders in social functioning and role emotional functioning (both P< .03).



Discussion

Principal Findings

The results of this study show no significant changes in the primary outcome of HbA_{1c} level from the baseline to the 19-month follow-up for the patients included in the study. We found no differences in the changes in the secondary outcomes between the intervention and control groups. This is inconsistent with studies conducted in parallel with ours in the RH project [27-29,41]. One possible reason for these similarities is that the inclusion criteria and the primary outcome, Hb_{A1c} level was low (>6.5%); therefore there was little chance for improvement, which was also noted by other studies in the RH project [27-29]. However, patients whose HbA_{1c} is around 6.5% are often in need of lifestyle interventions in addition to taking medication, and such lifestyle and behavioral changes may reduce the need for or dose of medication.

When using HRQoL measures as variables, as in this study, one can expect smaller changes over time and a larger variation between the persons, which means that more patients must be included. A larger sample is often desired, but it is often difficult to recruit a sufficient sample [42]. In our study, the inclusion of participants was time-consuming. Whether the use of the SF-36 was suitable for the aim of this study can be questioned. Using disease-specific instruments to assess the special conditions and concerns of diagnostic groups could be more sensitive for detecting small changes [10] than using generic measures such as the SF-36. We discussed previously whether these primary and secondary outcome measures were suitable for measuring behavior changes and the degree of self-management, and whether primary outcomes other than HbA_{1c} could have been better suited [29].

Of importance is that this randomized controlled trial showed no significant differences between patients in the intervention and control groups at baseline, which shows that the groups were balanced at the onset. The duration of the follow-up in this study might have increased the power, although the sample size was small.

Of interest was the trend for responders to report a higher HRQoL in all SF-36 domains compared with the nonresponders (Figure 2). Nonresponders reported lower HRQoL, and had significantly lower scores on social functioning, role emotional functioning, and all HRQoL domains. HRQoL was used to evaluate the effect of a telemedicine intervention with a self-management tool and health counseling, but HRQoL can also be used to identify patients who may be in need of more support. These findings identify a nonresponder population, with more health problems, who may need greater support and follow-up than do responders, and, as such, may need greater care and may impose a larger burden on the health care system. The patients in this study were older, but with few comorbidities, although many had a high BMI and incidence of obesity. The findings indicate that nonresponders had poorer mental health at inclusion than the responders of the intervention. Earlier research has noted that psychosocial problems are common among persons with diabetes, and that these problems represent barriers for self-management [11]. eHealth is a tool that could help to reduce costs and provide a more efficient delivery of care [30]; however, this group of patients was less familiar with computers and did not respond to the intervention provided.

As previously mentioned, high dropout rates is a typical problem in self-help applications. Others have commented on the importance of addressing this phenomenon because it poses a challenge to the evaluation of eHealth applications [24]. More research designed to investigate this problem is warranted. The development phase of a complex intervention such as ours is

considered to be important [43], and involves investigating both the existing evidence and the targeted group. For example, further knowledge about the targeted group may be obtained by conducting qualitative in-depth interviews in the preplanning stage of a complex intervention; this would help the investigators to learn more about user experiences and to identify both positive and negative user interactions [14]. The incorporation of user involvement (ie, patients, health care personnel, and stakeholders) is recommended at all levels in the design of telemedicine studies, as in this study [30]. This is also important to facilitate limplementation in health care organizations[43].

Of interest, we found significant differences between responders and nonresponders in the intervention group; the latter were less familiar with the use of PCs (P<.001; Table 2). This finding may indicate that those not accustomed to using a PC withdrew their participation in the study, and that the intervention was less likely to be accepted by patients with little experience in the use of a PC; however, if correct, the reason for this is not clear. It has been speculated that the lack of data and knowledge about withdrawal and/or dropout rates reflects a lack of investigation of this phenomenon, or that the reasons may be known but have not been published or were beyond the scope of reported trials [14]. Findings from the Whole System Demonstrator telehealth program in the United Kingdom have indicated that active rejection and patients' lack of acceptance of the telemedicine intervention are the most frequent reasons for withdrawal. The presence of diabetes was a factor leading to greater rejection of an intervention than were other chronic diseases [44]. This could reflect that many persons with diabetes are well trained in the recording of their clinical data and that the introduction of a new system for self-monitoring is perceived as a disruption to a well-practiced regime and is therefore not acceptable. However, the reasons for withdrawing from a trial are multifaceted [44].

Research has also investigated whether there is a literacy divide between responders and nonresponders of telemedicine interventions. The effect of health literacy has been considered by earlier studies using different telehealth applications [45,46]. Health literacy can be referred to 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" [47]. Our findings confirm the importance of recognizing that there is no "one size fits all" approach, meaning that when developing and initiating interventions such as ours, health care staff needs to consider carefully the patients' health literacy; for example, being old should not be a criterion for exclusion [48]. Earlier research has emphasized the importance of developing digital interventions that are designed to be accessible, and engaging persons with a wide range of health literacy levels [49]. Improvements in health literacy outcomes after a digital health intervention depend more on a clear design and person-based intervention to establish an in-depth understanding of the views and perspectives of the targeted group, rather than on interactivity and audiovisual presentation [50]. The interactive and audiovisual elements of the intervention are especially important for motivating the participants. It has also been shown that participants without adequate education or with a low health literacy level have a lower compliance, and that active participation with support from a health care service provider can reinforce a recommended behavior [51].

The use of telehealth and eHealth applications on the Web, as in this study, is therefore not appropriate for all persons with a chronic condition. This should be taken into consideration when developing a complex intervention such as ours. Self-management interventions with innovative treatments, such as the use of health technology devices at home and in close cooperation with community health centers, could be a more suited intervention for patients who self-manage better than some of those included in this study. Therefore, it is necessary to assess the targeted group and their characteristics before developing an intervention, because they may differ significantly in needs and health status, or be in need of more intensive interventions with more advanced and tailored support from health care providers than what was offered in this study. Earlier research also indicated a need for tighter self-management support of less motivated groups among patients with type 2 diabetes participating in telemedicine research [20], and of those not yet ready to change their behavior [23].

More research is needed to identify those not responding to telemedicine intervention to understand how to design different telemedicine applications that are suitable for specific groups and to identify the kinds of support needed by particular groups.

Conclusions

This technology-supported self-management telemonitoring and health counseling intervention did not improve the quality of life or clinical condition for patients with type 2 diabetes. There were significant differences between responders and nonresponders in the intervention group. Nonresponders reported being less familiar with the use of PCs, which suggests that those not accustomed to using computers had stopped participating in the study. More research is needed to target those not responding to telemedicine intervention and to understand how to design different telemedicine applications for different patient groups.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-EHEALTH checklist.

[PDF File (Adobe PDF File), 703KB - diabetes_v2i1e10_app1.pdf]

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Abbreviations

BMI: body mass index
GP: general practitioner
HbA1c: glycated hemoglobin
HDL: high-density lipoprotein
HRQoL: health-related quality of life
LDL: low-density lipoprotein
PC: personal computer
RH: renewing health
S-cholesterol: serum cholesterol
SD: standard deviation
SF-36: Short Form Health Survey

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Original Paper

The Use of Mobile Health to Deliver Self-Management Support to Young People With Type 1 Diabetes: A Cross-Sectional Survey

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Abstract

Background: Young people living with type 1 diabetes face not only the challenges typical of adolescence, but also the challenges of daily management of their health and evolving understanding of the impact of their diagnosis on their future. Adolescence is a critical time for diabetes self-management, with a typical decline in glycemic control increasing risk for microvascular diabetes complications. To improve glycemic control, there is a need for evidence-based self-management support interventions that address the issues pertinent to this population, utilizing platforms that engage them. Increasingly, mobile health (mHealth) interventions are being developed and evaluated for this purpose with some evidence supporting improved glycemic control. A necessary step to enhance effectiveness of such approaches is to understand young people's preferences for this mode of delivery.

Objective: A cross-sectional survey was conducted to investigate the current and perceived roles of mHealth in supporting young people to manage their diabetes.

Methods: Young adults (16-24 years) with type 1 diabetes in Auckland, New Zealand, were invited to take part in a survey via letter from their diabetes specialist.

Results: A total of 115 young adults completed the survey (mean age 19.5 years; male 52/115, 45%; European 89/115, 77%), with all reporting they owned a mobile phone and 96% (110/115) of those were smartphones. However, smartphone apps for diabetes management had been used by only 33% (38/115) of respondents. The most commonly reported reason for not using apps was a lack of awareness that they existed. Although the majority felt they managed their diabetes well, 63% (72/115) reported wanting to learn more about diabetes and how to manage it. A total of 64% (74/115) respondents reported that they would be interested in receiving diabetes self-management support via text message (short message service, SMS).

Conclusions: Current engagement with mHealth in this population appears low, although the findings from this study provide support for the use of mHealth in this group because of the ubiquity and convenience of mobile devices. mHealth has potential to provide information and support to this population, utilizing mediums commonplace for this group and with greater reach than traditional methods.

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KEYWORDS

mHealth; diabetes mellitus; mobile phone; mobile applications; text messages

Introduction

Rates of type 1 diabetes are increasing both in New Zealand and internationally [1-4]. Good diabetes control at an early age is integral in delaying the onset and slowing the progression of long-term complications of the disease such as renal failure, blindness, and lower limb microvascular disease [5-8]. Type 1 diabetes is one of the most demanding chronic conditions, both psychologically and behaviorally, requiring considerable daily management throughout the individual's life for optimal outcome. Successful diabetes management involves managing medical responsibilities (including blood glucose monitoring and insulin administration) alongside behaviors around diet and physical activity [9]. There is evidence of a positive relationship between diabetes self-management behaviors and metabolic control, particularly in adolescence [10-15]. Poor engagement with diabetes self-management in adolescence is likely to continue to poor self-management behaviors in adulthood [16], making this a vital period for the establishment of good self-management and prevention of debilitating long-term complications.

There is a wide range of interventions designed to support young people to self-manage their diabetes that tend to involve providing encouragement, information, and motivation to obtain greater control of their condition. This may be done by increasing their understanding of diabetes, encouraging them to be active participants in decision making around their condition, and motivating them to engage in healthy behaviors [17]. The importance of a combination of approaches for self-management support in individuals with type 1 diabetes is clear, including psychosocial support, education, diabetes monitoring and insulin-specific information and support, and multidisciplinary clinician support [18]. In particular, there is a need for interventions to actively demonstrate the link between diabetes management behaviors and the young people's daily life [19] and interventions that utilize platforms that engage young people.

Mobile health (mHealth) is the use of mobile devices, such as mobile phones, to deliver health services and information [20]. There is increasing evidence for the effectiveness of mHealth in health behavior change and disease management, including diabetes [21,22]. Mobile phones offer potential to reach all populations and provide access to an individual at opportune times regardless of location [23]. They also provide a tool for support outside of the hospital or clinic and in turn support increased independence. They provide a nonconfrontational method for support around sensitive issues such as contraception, alcohol and drugs, and sexual health, which can have considerable impact on a young person's diabetes control [24]. In addition, mHealth interventions capitalize on existing communication behavior in young people, who are more likely to bring their mobile phones than their glucose meters to clinic appointments [25].

There is growing evidence that mHealth interventions can successfully engage young people with diabetes, which has traditionally been difficult to do [25-38]. Research indicates strong patient interest in mHealth tools to support diabetes management [39] and a preference for smartphone apps in the young adult population [39]. However, with increasing availability of diabetes-related apps there is concern regarding the accuracy and evidence base of many of these [40]. It is essential to ensure that patients have access to tools that are safe, evidence-based, and known to be effective. In addition, these tools need to attend to the issues relevant to the young person rather than purely focusing on those considered relevant by the clinician [27]. To accommodate the preferences and priorities of the population, and thereby enhance the chances of success, it is crucial to engage the target population in the design and development of the intervention through obtaining feedback during intervention design [41,42] and linking of diabetes management with individual goals and priorities [19,43].

This study aimed to investigate the current and perceived roles of mHealth in supporting young people to manage their diabetes. This will inform the development of a self-management support intervention for this population.

Methods

Study Design

A descriptive cross-sectional survey was conducted with young adults with type 1 diabetes from March to September 2014. The survey incorporated both closed and open-ended questions to gain more in-depth information and to allow participants to elaborate further. The survey was designed in paper format and then uploaded into an electronic format using LimeSurvey (LimeSurvey Project), an Open Source survey tool. The survey was then pretested by researchers, members of the study advisory group, and young people. The survey is described according to the CHERRIES (Checklist for Reporting Results of Internet E-Surveys) checklist [44].

Ethics Approval

Ethical approval for this trial was obtained from the New Zealand Health and Disability Ethics Committee (14/CEN/24). Research approval from each district health board was also obtained.

Inclusion Criteria

Inclusion criteria were young adults aged 16-24 years (inclusive), diagnosis of type 1 diabetes, registered as a patient under one of the 3 Auckland regional diabetes services, able to read and understand English, and able to provide informed consent.

Procedures

All patients who met the inclusion criteria were sent a letter from their clinician inviting them to take part in the closed survey. Those wishing to participate could complete the survey

via 1 of 3 methods: (1) by going directly to the study website and completing it online, (2) over the phone, or (3) by completing a paper copy of the survey. Participants had 3 months from the letter date to complete the survey.

Before commencing the survey, participants provided informed consent (electronic consent if completing the survey online, verbal consent if completing over the phone, or written consent if completing on paper) to participate. Participants had to enter a unique code from their letter to ensure only those eligible completed the survey. Participants only had access to the survey once their unique code was entered and verified. Upon completion of the survey, participants had the option to enter their contact details to receive a NZ $20 voucher reimbursing them for their time. This personal information was stored separately to the main data file and password protected.

The survey was identical for all participants (no randomized items), and participants were able to go back and change their responses before submission. Adaptive questioning was used to minimize response burden and reduce complexity of questions.

Survey Design

The survey consisted of 3 parts, with each part of the survey presented on a separate page:

1. Demographic information and technology access: including age, sex, ethnicity, occupation, age at diabetes diagnosis, and mobile phone ownership and use.
2. Using technology to manage diabetes and health: use and perceived usefulness of currently available apps, interest in text message (short message service, SMS)–based diabetes support, and preferences for mHealth content.
3. Your diabetes and how you manage it: perceptions of own diabetes management, confidence in diabetes management, diabetes self-management tasks they find most difficult, and whether they would like to learn more about diabetes and its management.

Statistical Analysis

Survey data were analyzed and summarized using descriptive quantitative analyses including means, standard deviation, and proportions. Qualitative comments were analyzed using a simple, general inductive thematic approach to identify common themes and meanings from the data. Only completed surveys, with correct unique codes, were included in the analysis and no time limit was imposed. Prioritized ethnicity was used as recommended by the New Zealand Ministry of Health for the reporting of ethnicity data; only one of the ethnic categories nominated by the participant was used according to a predetermined hierarchy (Māori, Pacific Islander, Asian, European, and other ethnic groups, in order of prioritization) [45].

Results

Survey Response

There were 141 entries to the survey website; of these, 115 completed the survey, giving a completion rate of 82%. All participants chose to complete the survey online.

Part 1: Demographic Information and Technology Access

A total of 115 young adults completed the survey, giving a response rate of 29% (see Table 1 for a breakdown of respondents) of the invited population (N=402). There was no significant difference between those invited to complete the survey and those who responded in terms of ethnicity or age. There was a significant difference (*P*=.02) for sex, with the participant sample having a higher proportion of females. The mean age of diagnosis as reported by participants was 11.12 years (SD 5.15, range 1-23).

Table 1. Demographics of invited population and survey respondents.

Characteristic	Total eligible (n=402), n (%)	Respondents (n=115), n (%)
Sex: male	229 (56.9)	52 (45.2)
Ethnicity		
European	301 (74.9)	89 (77.4)
Māori	27 (6.7)	10 (8.7)
Pacific Islander	41 (10.2)	7 (6.1)
Asian	22 (5.5)	6 (5.2)
Other	9 (2.2)	3 (2.6)
Not stated	2 (0.5)	0 (0.0)
Age in years, mean (SD)	19.94 (2.47)	19.51 (2.53)

All of those who completed the survey reported they owned a mobile phone, with 110/115 (96%) reporting they owned a smartphone (a mobile phone with the addition of a computer operating system). Of those who owned a smartphone, only 71/110 (65%) reported having access to data (Internet) on their phone all the time, 36/110 (33%) sometimes, and 3/110 (3%) reported never accessing the Internet on their phone. The majority of respondents reported that their mobile phone was “pay-as-you-go” (84/115, 73%) as opposed to 30/115 (26%) who were on a monthly contract, and 1 respondent did not know. Most participants (76/115, 66%) reported that they never turn their phone off.

Part 2: Using Technology to Manage Diabetes and Health

Apps for Diabetes Management

A total of 38 (33%) of the 115 respondents reported they use or have used apps to help them manage their diabetes. Rates of app usage differed by ethnicity, with Māori and Pacific Islander respondents having lower rates of app use (10% and 0%, respectively) compared with Europeans (38%), Asians (33%), or the other ethnicities (33%). A total of 43% of females who completed the survey reported they use or have used apps to help them manage their diabetes compared with 21% of males.

Of those who reported having used apps (n=38), they reported having used a mean of 1.87 different apps (SD 1.33, range 1-7). The most commonly reported apps were Carbs & Cals (n=10), Glucose Buddy (n=9), MyFitnessPal (n=6), and DAFNE Online (n=5). Of the 38 respondents who had used apps, 10 (26%) reported finding them "extremely useful" in helping them manage their diabetes, 20 (53%) reported finding them "a little useful," and 8 (21%) "not very useful." Common reasons included that they were useful for tracking diabetes data, for carbohydrate counting and insulin calculations, and that they were accessible and convenient for managing diabetes on the go. Participants reported that a key benefit of the apps was that they provided an easy and convenient way to track their diabetes and store data. They also reported that they provided an easy way to see patterns through graphs of their capillary glucose data.

> *Helps me keep a record of what I'm eating my levels and my insulin intake along with the other medications I'm on and shows a pattern of when I go lower or higher*
>
> *They graph patterns of blood sugar levels, and are a great place to store data related to your diabetes*

They reported that, because their phones are always with them, they provided a great way to manage their diabetes on the go. They mentioned having access to information when out as being a benefit and providing a replacement for pen and paper methods of keeping track of their diabetes.

> *Because I always have my phone and it makes it easier to log in my blood sugars on something that I always have access too*
>
> *I find them useful because I'm always on the go and I always have my smartphone on me so if I ever need to check the carb content of something I can do so immediately*

A number of participants also reported that apps are useful for carbohydrate counting, particularly for less common foods or meals, and for calculating insulin dosage:

> *It [the app] gives me an idea of how many carbs are in foods I don't normally consume on a day to day basis. Takeaway foods in particular are harder to count carbs in.*
>
> *It makes the maths easier- calculating how much insulin I need when taking into account how many carbs I'm eating and what my current blood glucose is.*

The most common reason for why they were not useful was the data entry being tedious and therefore not being bothered to use the app.

> *Too fiddly to mess around with and enter all the data. As well as when I test my blood, I just want to eat not mess around with my phone.*
>
> *Just another thing to remember to do so I can't be bothered sometimes.*

Technical issues were also identified as a reason for apps not being perceived as useful, and the need for Wi-Fi or data connection meant they could not always use them.

> *Sometimes I can find out how many carbs my food I'm eating has but I have trouble using it sometimes because it doesn't load and it requires internet access and if I haven't got good reception I can't see the portion sizes*

Others reported that because they forget to use the app or do not enter their data regularly the app was not useful.

> *I fail to enter in my readings from my testing machine. So therefore I have no data in the app at all.*

Only 1 participant identified not being able to trust the app and another identified cost as a barrier.

> *I didn't really trust them, I was too scared to use them in case they were wrong*

The majority (33/38, 87%) of the participants who had used apps reported that they would recommend diabetes-related apps to other young people with diabetes. Those who had never used apps to manage their diabetes were asked to provide the reasons. The most common reasons for not having used apps to help manage their diabetes included that they did not know of any apps or that they existed at all, that they did not feel they would be of any help or use to them, or that they did not feel that they needed them.

Text Messages for Diabetes Management

A total of 74 (64%) of the 115 respondents reported that they would like to receive SMS text messages designed to support them to manage their diabetes. Those who were interested were asked how often they would want to receive messages, with 21% of the 74 wanting messages more than once per day, 17% once per day, 15% only once every few days, and 12% once a week or less. They were also asked to identify topics they would want the SMS text messages to be about (see Table 2), with tips on how to manage diabetes being the most preferred topic.

Table 2. Topics for text messages (n=74).

Topics	Count[a]	Percentage of sample, %
Tips on how to manage my diabetes	57	77
Motivational messages	50	68
Reminders to test my blood glucose	45	61
Information about diabetes	38	51
Other[b]	7	10

[a]Participants could identify multiple topics.

[b]Other topics identified by participants included recreational drugs, interesting diabetes facts, and research updates.

The 41 participants who reported that they would not be interested in receiving SMS text messages to support them were asked to provide their reasons. Key responses included they did not think that they needed them and concern that they would be annoying. There were 19 participants who identified that they did not feel they needed SMS text message–based diabetes support as they felt they were already managing their diabetes well.

> *Because I feel I'm perfectly capable of managing my diabetes myself, I know what i have to do and know what I face if i am neglectful. Someone texting me with things I already know is unnecessary.*
>
> *I think it's unnecessary and have done fine on my own for the most part.*

In addition, 19 of the 41 participants reported they would not sign up as they felt that it would be annoying and would just remind them that they had diabetes when they did not want to think about it.

> *I think I manage my diabetes quite well, I don't really need to read motivational messages and I check my blood glucose regularly on my own. I personally can find texts like that can become annoying. I may consider using the option only if there was an unsubscribe option available if I didn't want to receive them anymore.*
>
> *Will become irritating. Sometimes it is nice to forget, [believe] that you aren't diabetic - having constant reminders will continuously remind you that you are different from everyone else*

There were 2 participants who felt that this type of support would not be personal enough and 2 participants who reported they would prefer apps to SMS text messages.

Part 3: Diabetes and How It Is Managed

A majority (66/115, 57%) of the respondents reported that they felt they managed their diabetes "extremely" or "very" well. There were 44/115 (38%) who reported that they managed their diabetes "not so well" and only 5/115 (4%) "not well at all." On a scale from 0 "Not at all confident that I can manage my diabetes" to 10 "Completely sure I can manage my diabetes," participants reported a mean rating of 7.23 (SD 2.091, range 1-10). Significantly lower ratings of confidence were seen in those who reported interest in receiving SMS text messages designed to support them to manage their diabetes (mean 6.89, SD 2.10) than those who did not (mean 7.85, SD 1.94; *P*=.02). Although more than half the participants reported that they felt that they managed their diabetes well, 72/115 (63%) reported that they would like to learn more about diabetes and how to manage it. Participants were also asked about the 3 specific areas of diabetes management that they find most difficult; results are presented in Table 3. The most common areas identified were "Remembering to check my blood glucose" (55/115, 48%) and "Eating well" (40/115, 35%).

Table 3. Diabetes self-management tasks participants find most difficult (n=115).

Diabetes self-management tasks	Count	Percentage of sample, %
Checking my blood glucose	35	30.4
Remembering to check my blood glucose	55	47.9
Eating well	40	34.8
Managing insulin	27	23.5
Problem solving (especially around blood glucose, highs and lows, sick days)	29	25.2
Being psychically active	31	27.0
Attending my medical appointments	21	18.3
Other[a]	10	8.7

[a]Other responses included remembering to administer insulin, needles, carbohydrate counting, being in unexpected situations unprepared, correcting highs, managing alcohol, recording blood glucose levels, and the social effects.

Discussion

Principal Findings

This study aimed to investigate the perceived role mHealth can play in supporting young people to manage their diabetes and to inform the development of a self-management support intervention for this population. Overall, results indicated interest in mHealth for supporting diabetes self-management and provides further support for mobile phones to deliver self-management support in this population group because of high access. In addition, the survey highlighted that although young adults were confident in their ability to manage their diabetes, there was strong interest in learning more about aspects of diabetes management.

As expected, mobile phone, and in particular smartphone, ownership in this population was high, although more than one-third of the respondents did not have consistent access to Internet or data on their device. Because of the demanding and continuous nature of diabetes self-management, tools to support this group need to take data access into consideration. A downside of many of the currently available apps is the need for the user to have ongoing Internet or data to access many of the apps' functionalities. Apps designed to be used offline, therefore avoiding the need for ongoing data or Internet access, can require greater storage capacity on the phone to download the app and this can be a barrier for those with lower-level devices that typically have smaller storage capacity.

Contrary to expectations, use of currently available apps was low in this group, particularly in Māori and Pacific Islander respondents. The lack of awareness of available apps as well as a perception that these would not be of use contribute to the low utilization of the most accessible mHealth tools for this population. The use of apps by participants for insulin calculations is of concern in light of research showing that most insulin calculation apps could be putting patients at risk of harm by providing no protection for incorrect insulin dosage recommendations [40]. A common use of apps in this study was for the collection and tracking of data, which, owing to the members of this population commonly having their phone with them and turned on at all times, is ideal. The privacy of this information was highlighted in a recent letter in the *Journal of the American Medical Association* on the lack of privacy policies in diabetes apps [46]. They reported that 81% of the diabetes apps investigated did not have privacy policies and, of those that did, many of the provisions did not actually protect the user's privacy. Health care professionals have the potential to play a key role in increasing the awareness of apps and recommending that patients choose guideline-based and secure apps to increase safety.

A strong interest in the use of SMS text messaging for diabetes self-management support was observed, particularly among those with lower confidence to manage their condition. Previous research has shown that as beliefs in the ability to maintain a healthy lifestyle increased, the need for support through SMS text messaging decreased [47]. Therefore, designing SMS text messaging interventions for those with lower confidence in their ability to manage their condition may be of greater pertinence and more positively received than for those already confident in their ability to manage their diabetes.

Of particular interest to participants was the use of SMS text messaging for providing motivation, reminders, and diabetes self-management tips. Nearly half the respondents reported that remembering to test their blood glucose was the part of their diabetes management that they found most difficult. Although the use of continuous glucose sensors, which have the option of setting high and low alerts, provides a solution, cost is currently a major barrier to widespread use of this technology [48]. Therefore, SMS text messaging is an attractive option to provide testing reminders because of the instant delivery as well as the low patient cost and high accessibility and reach of this type of mHealth tool [49].

This study highlights key factors that need to be considered when designing SMS text messaging–based diabetes self-management support, including the potential for messages to be annoying, to be unnecessary, or to not be personal enough. Therefore, future development of tools for this group needs to be tailored and personalized, rather than a "one size fits all" approach. Although it has been previously reported that young adults with diabetes have differing priorities from their health care team, our results indicate that nearly two-thirds were interested in learning more about diabetes. mHealth could provide the ideal medium for supporting learning as it can be personalized, nonconfrontational, and delivered at the time and place that it is needed and wanted.

Several limitations of the study should be noted. The response rate, although largely reflective of the wider population, was low, limiting the generalizability of the results. It is likely that those who did respond may have more interest in mHealth and therefore actual engagement with this type of tool may be even lower in the wider population. All respondents to the survey completed it online with none requesting to complete it by paper or phone. Although the alternatives were offered, it may be that those without Internet access were less likely to take part, biasing the sample to a more technological group. In addition, the self-report and cross-sectional design of the study are key limitations, as is the sex distribution of the sample differing from the target population. Although this study investigated the use of apps in this population, it did not assess how the population was using them and for how long. It is important that research into mHealth tools for this population assesses the degree of engagement, including intensity and duration, to ensure tools are designed to meet their needs and improve outcomes.

Conclusions

This study provides valuable insight into the engagement of young adults with type 1 diabetes with currently available mHealth tools, as well as providing insight into how future mHealth interventions can be designed to meet their need. The input of the end users regarding their use and preferences for mHealth tools provided by this survey will allow for the development of a more relevant and a potentially more efficacious intervention.

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Authors' Contributions

All authors contributed to the study concept, design, and procedures. RD obtained ethical approval, collected the data, analyzed the results, and drafted the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CHERRIES: Checklist for Reporting Results of Internet E-Surveys
mHealth: mobile health
SMS: short message service

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Original Paper

Phone Messaging to Prompt Physical Activity and Social Support Among Low-Income Latino Patients With Type 2 Diabetes: A Randomized Pilot Study

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Abstract

Background: Given disparities in diabetes prevalence, receipt of diabetes education, diabetes knowledge, and self-management behaviors among Latinos, there is a need to provide education and ongoing support to this population. Phone-based interventions have the potential to reach and engage both patients and their family members and friends.

Objective: The aim of this study was to investigate the feasibility, perceived usefulness, and potential effectiveness of a short text or voice message (STVM) intervention to activate (1) physical activity (PA) behavior change among urban, low-income Latino adults with type 2 diabetes and (2) supportive behaviors by their family members and friends.

Methods: A 12-week pilot study randomized 42 participants recruited in person from a safety-net ambulatory care clinic in Los Angeles into one of the 3 study arms: control, phone messaging (PM), and phone messaging plus social support from family members and friends (PM+FF). All participants were prompted to set PA goals and to self-monitor PA behavior using pedometers and walking logs. PM and PM+FF participants received STVMs with reminders to review goals and self-monitor, PA behavior change education, and feedback on performance. Participants in the PM+FF arm also had their family members and friends receiving STVMs with suggestions for how they could support the participant's PA behavior change efforts. Participants completed semistructured assessments in person at baseline, 6 weeks, and 12 weeks. Outcomes were PA (steps/day) and perceived social support from family members and friends.

Results: Among PM and PM+FF participants, those who opted to receive text messages (short message service, SMS) responded to 62.7% (128/204) of SMS text messages requiring a response while those who opted to receive voice messages responded 30% (12/40) of the time. Participants perceived guidance in self-regulation as useful, particularly self-monitoring, goal setting, self-instruction, feedback, and social support. All participants increased PA at 6 weeks, but only the PM and PM+FF arms increased PA at 12 weeks. All study arms experienced an increase in perceived social support from family members and friends at 6 weeks, but only those in the PM+FF arm had an increase in the perception of social support at 12 weeks.

Conclusion: Designing an STVM intervention based on self-regulation techniques is feasible and perceived as useful by participants. The STVM intervention has the potential to improve PA in terms of daily steps and perceived social support from family members and friends.

Trial Registration: Clinicaltrials.gov NCT02850770; https://clinicaltrials.gov/ct2/show/NCT02850770 (Archived by WebCite at http://www.webcitation.org/query?id=1495567756845570)

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KEYWORDS

short message service; reminder system; pilot project; exercise; Hispanic Americans; type 2 diabetes mellitus; self-care; social support

Introduction

Latinos in the United States have a 66% higher risk of developing diabetes and are 1.5 times more likely to die from the disease compared with non-Latino whites [1]. Education can effectively prepare individuals with knowledge, skills, and abilities necessary to perform the diabetes self-care behaviors that will improve glycemic control and reduce the risk of complications [2-5], but Latinos are less likely to receive education compared with non-Latino whites [6]. Deficiencies in knowledge about diabetes have been observed among low-income, predominantly Latino patients in a safety-net health care setting [7]. Additionally, compared with non-Latino whites, Latinos report worse engagement in diabetes self-care behaviors [6]. For example, a significantly lower proportion of Mexican Americans than whites with type 2 diabetes (T2D) report getting the recommended levels of physical activity (PA) (28% vs 32%, respectively) [8].

Given the aforementioned disparities among Latinos with diabetes, there is a need to provide education and ongoing support to this population. Automated text and voice messaging has enormous potential to target all aspects of diabetes self-management and lifestyle behavior modification and reach many people at a relatively low cost [9]. In theory, these tools can promote effective self-care behaviors, assist with monitoring changes in health and health behaviors, and enhance communication between patients and potential supports for their diabetes self-management [10]. A systematic review of reviews found that SMS text-messaging (short message service, SMS) interventions significantly improve health outcomes and health behaviors of individuals with diabetes [9]. The interventions targeted multiple aspects of diabetes self-management at once, but tended to focus on blood glucose monitoring. Lifestyle behavior modification, such as engagement in PA, which Latinos perceive as one of the most difficult aspects of diabetes self-care [11], perhaps because of a lack of behavioral activation or knowledge about its importance [7], were generally not emphasized. Extensive evidence shows that PA plays an important role in risk reduction and control of T2D [12-18]. In addition, only 1 of 16 reviewed interventions for individuals with diabetes included Latinos. The only study, led by Arora et al, found that a unidirectional text-messaging intervention targeting Latinos with poorly controlled diabetes in an emergency department did not produce significant improvements in blood glucose [19,20]. Perhaps these findings were observed because of the study population (emergency department patients with poorly controlled diabetes represent a high-risk group [21]) or because of the intervention design (it did not incorporate interactive elements such as assessments and feedback [22]). Overall, there is limited evidence for the feasibility, acceptance, and effectiveness of interactive text and voice messaging interventions to promote PA among Latino adults with T2D in order to improve their diabetes outcomes.

In addition to text and voice messaging, another potential source of education and ongoing support are family members and friends. A qualitative study found that Latino adults with diabetes desired an increase in support from family members, and that family members were eager to provide support, but did not know how [11]. Family members of low-income, predominantly Latino patients with diabetes in a safety-net health care setting have demonstrated poor knowledge about diabetes [7]. Text and voice messaging interventions may leverage on the willingness of family members and friends to learn about the disease and how to provide support. In an intervention to support diabetes self-management among Spanish-speaking patients, family members and friends were called and emailed to get notified of patients' health status and receive instructions for how to provide support [23,24], but the impact of their support on health outcomes or health behaviors was not reported. In general, it is unknown whether it is feasible to reach and engage family members and friends through technology-based interventions and what is the impact on patient outcomes.

Furthermore, few text-messaging interventions to promote healthy behaviors are designed with reference to behavior change theory [9]. Theoretically informed interventions are expected to be more effective than those that are not as they target causal determinants of behavior and behavior change [25]. In this study, we designed a short text or voice message (STVM) intervention targeting both Latino adults with T2D and their family members and friends. The intervention was based self-regulation techniques derived from the Social Cognitive Theory (SCT) [26] and patient preferences for how to operationalize these techniques [27]. The techniques were as follows: prompting goal setting, prompting self-monitoring, providing feedback on performance, and prompting social support. SCT posits that a person can achieve self-regulation by observing the behavior, identifying attainable short- and long-term behavior change goals, receiving information about the recorded behavior, and receiving encouraging support from another person. Meta-regression analyses of interventions to promote PA and healthy eating indicate these self-regulation techniques are associated with positive outcomes [28,29].

Given the potential of phone-based interventions to reach and engage both patients and family members and friends [9,10,23,24], the objective of this study was to investigate the feasibility, perceived usefulness, and potential effectiveness of the STVM intervention that was designed based on

self-regulation techniques and patient preferences to activate (1) PA behavior change (steps/day) among urban, low-income Latino adults with T2D and (2) supportive behaviors by family members and friends.

Methods

Ethical Considerations

The Health Sciences Institutional Review Board at the University of Southern California approved all study procedures. Eligible participants provided written informed consent.

Study Design

We conducted a pilot study (ClinicalTrials.gov NCT02850770) that randomized participants into one of three study arms: control, phone messaging (PM), and phone messaging plus social support from family members and friends (PM+FF). The PM versus control comparison was intended to provide insight into the potential effectiveness of the STVM intervention for improving PA behavior change. The PM+FF versus PM comparison was intended to provide insight into the potential effectiveness of the STVM intervention for improving supportive behaviors by family members and friends. The study consisted of a 7-day baseline period, followed by a 12-week intervention period. In-person assessments were conducted after the baseline period, at 6 weeks, and at 12 weeks. Participants received a US $10 gift card for each completed assessment. Family members and friends received a US $10 gift card at the end of the study.

Setting and Recruitment of Participants

Participants were recruited from a diabetes management program (DMP) at an ambulatory care clinic of the Los Angeles County Department of Health Services, a public safety-net health care system. After routine clinic visits, DMP clinicians referred patients to a research assistant (RA) who was hired by the study and was not affiliated with the clinic. The RA explained the study to patients, screened for eligibility, and consented interested patients. Patients eligible to participate were of age 18 years or older, had a diagnosis of T2D, did not have a medical condition restricting participation in a walking program (judged by DMP clinicians before referral), preferred to speak English or Spanish, self-identified as Latino, had the ability to walk without the use of assistive devices, were available to attend 3 interviews at the clinic, did not have plans to move away from the region or be out of the country during the subsequent 3 months, and possessed a phone that could receive regular STVMs for 3 months.

Eligible participants received an OMRON HJ-321 Tri-Axis Pedometer (OMRON HEALTHCARE Co., Ltd., Japan) and were instructed to identify a family member or friend willing to participate in the study if need be. After the 7-day baseline period, participants were dismissed from the study if there were fewer than 3 consecutive days of data stored in the pedometer with at least 10 hours of self-reported pedometer use per day [30], the average daily steps exceeded 8800 (indicating sufficient PA) [31], or if they were unable to identify a family member or friend willing to participate in the study. Only participants who were continuing the study after the baseline period were assigned to a study arm.

Intervention Procedures

Findings from our study of patient preferences were used to inform intervention components [27], which are summarized in Table 1. Participants in all study arms were encouraged to use the pedometers and walking logs to self-monitor daily steps. The walking logs contained instructions to set goals for gradually increasing daily steps during the course of 12 weeks until reaching 10,000 steps per day.

Participants in the PM and PM+FF arms received support via STVMs (at least 4 per week). On Sundays, participants received an STVM reminding them to review daily step goals and self-monitor using pedometers and walking logs. On Tuesdays and Thursdays, participants received a unique STVM with educational content largely adapted from public material available on the websites of the American Diabetes Association, National Institute of Diabetes and Digestive and Kidney Diseases, and Healthy People 2020. On Saturdays, participants received an STVM asking them to report on their perceived PA performance. If participants replied, they received another STVM providing tailored feedback. Participants in the PM+FF arm had a family member or friend receiving 2 unique STVMs per week (on Tuesdays and Thursdays) that suggested things they could do or say to support the participant's PA behavior change efforts [32]. Unless there was a scheduling conflict, all STVMs were delivered at 9:00 AM on the aforementioned days of the week. Table 2 contains an example of each type of STVM delivered to participants and family members and friends.

Table 1. Intervention components for each study arm.

Intervention components	Control	PM[a]	PM+FF[b]
Self-monitoring (pedometers and walking logs)	✓	✓	✓
Goal setting (recommended 10,000 steps/day)	✓	✓	✓
Support via STVM[c]		✓	✓
Reminder to review goals and self-monitor (1 STVM/week)			
PA[d] behavior change education (2 STVMs/week)			
Reporting on PA performance (1 STVM/week)			
Feedback on PA performance (1 STVM/week)[e]			
Support from a family member or friend (2 STVMs/week)			✓

[a]PM: phone messaging.

[b]PM+FF: phone messaging plus social support from family members and friends.

[c]STVM: short text or voice message.

[d]PA: physical activity.

[e]Delivered only if participant reported on PA performance.

Table 2. Examples of short text or voice messages.

Recipient	STVM[a] type	Example
Participants in PM[b] and PM+FF[c] arms	Reminder to review goals and self-monitor PA[d]	Remember to review your daily step goals, wear your pedometer, and fill out your walking log.
	PA behavior change education	Brisk walking can lower your blood sugar and improve your A1C. Your doctor may instruct you to take fewer diabetes pills or less insulin.
		Brisk walking will leave you feeling better so you can do activities you enjoy, such as spending quality time with family and friends.
		Walk first thing in the morning before your day gets too busy. If you don't have 30 minutes, look for three 10-minute periods.
	Reporting on PA performance	How well did you do with your daily step goals in the past 7 days? Reply with a number from 1 (not well at all) to 5 (excellent).
	Feedback on PA performance	If response was 1, 2, or 3: Walking needs to be a regular habit to produce benefits. Make an effort to improve your walking in the next 7 days.
		If response was 4 or 5: Great! Keep up your hard work, and you will see that it will pay off. Increase your daily goal by 1000 steps.
Family members and friends of participants in PM+FF arm	Supportive behaviors	Brisk walking can help lower the patient's blood sugar to keep diabetes under control. Offer your support by joining them on a brisk walk as often as you can.

[a]STVM: short text or voice message.

[b]PM: phone messaging.

[c]PM+FF: phone messaging plus social support from family members and friends.

[d]PA: physical activity.

Each person receiving STVMs indicated preference for message type (voice or text) and language (English or Spanish). All messages were written in English, translated to Spanish by a native Spanish speaker, and reviewed by a second Spanish speaker for accuracy. All voice messages were voice recorded in English and Spanish by a bilingual Spanish-English speaking woman who did not otherwise have contact with participants.

Study Measures

This study assessed technical feasibility, perceived usefulness, and potential effectiveness of the STVM intervention. Baseline, 6-week, and 12-week assessment questions are available in Multimedia Appendix 1.

Technical Feasibility

Technical feasibility was assessed by examining receipt of STVMs, engagement with STVMs requiring a response, barriers to receipt of and engagement with STVMs, and pedometer usability. For receipt of STVMs, data on the receipt of voice messages was obtained from the service provider that delivered the voice messages. An individual receiving voice messages was considered to have received an STVM if there was a live answer or if the message was left in a voicemail. Data on the

receipt of text messages were obtained from participants' self-report during the 6- and 12-week assessments. For engagement with STVMs, participants were considered engaged if they replied to STVMs requiring a response. For barriers to receipt of and engagement with STVMs and perceived pedometer usability, participants were asked during the 6- and 12-week assessments to explain any problems they had with receiving STVMs, replying to STVMs, or using pedometers.

Perceived Usefulness

Perceived usefulness was assessed by asking participants during the 6- and 12-week assessments to what extent they perceived the program to enhance their ability to make PA behavior changes. More specifically, the assessment questions inquired about participants' perceptions of setting PA goals, self-monitoring and reporting on PA performance, receiving educational and feedback STVMs, and the idea of using STVMs to communicate with patients about PA behavior change. For participants in the PM+FF arm, the questions also inquired about supportive behaviors exhibited by family members and friends since the start of the program as well as participants' perceptions of the idea of using STVMs to communicate with family members and friends about their PA behavior change efforts.

Potential Effectiveness

Potential effectiveness was assessed by measuring PA and perceived social support from family members and friends at baseline, 6 weeks, and 12 weeks. PA was used to assess the potential effectiveness of the STVM intervention for improving PA behavior change. To measure PA, average steps per day in the past 7 days were obtained from the pedometer 7-day data storage. Steps per day were considered an appropriate measure of PA in this study because the intervention specifically promoted walking. Perceived social support from family members and friends was used to assess the potential effectiveness of the STVM intervention for improving supportive behaviors by these individuals. To measure perceived social support from family members and friends, a modified version of the Social Support and Exercise Survey [32] was used. Participants were asked to evaluate how often they perceived supportive behaviors from either family members or friends. Participants responded on a Likert scale from 1 (none) to 5 (very often), with higher numbers indicating higher perceived support.

Sample Size

The sample size was 42 total participants, 14 per study arm. It was based on a rule of thumb, which is an accepted method for setting sample sizes in pilot studies [33]. We used the rule of thumb of 12 participants per group put forth by Julious et al [34], but we increased the sample size to 14 per group to anticipate having about 12 participants per group complete the study. Our experience in conducting studies at the DMP clinic led us to expect about a 16% dropout rate.

Randomization and Blinding

Participants were randomized with equal probability into one of the 3 study groups. A Web-based statistical computing program was used to generate a simple randomization schedule. The RA assigned participants to a study arm via opaque sealed envelopes marked according to the randomization schedule. Participants, the RA who administered all assessments, and the data analysts were not blinded.

Analysis

To analyze participants' qualitative responses to technical feasibility questions, the authors used the following a priori codes that directly reflected the technical feasibility measures: barriers to receipt of STVMs, barriers to engagement with STVMs, and pedometer usability. Excerpts in each code were then sorted to identify themes. The most salient themes are presented in the findings. To analyze participants' qualitative responses to perceived usefulness questions, the authors used the following a priori codes that were derived largely from self-regulation techniques [35]: ongoing behavior change support, self-monitoring, goal setting, self-instruction, reporting on PA performance, receiving feedback, and social support. Social support was further divided into subcodes representing broad types of supportive behaviors: instrumental, emotional, and informational. Excerpts in each code were then sorted to identify themes. The most salient themes are presented in the findings. The first author coded the data independently and then discussed the coding with the second author to reach consensus for final coding. Dedoose version 7.1.3 was used to manage and code the qualitative data. Descriptive statistics are provided for receipt of and engagement with STVMs requiring a response.

To analyze potential effectiveness, participants' average steps per day were computed for consecutive days (at least 3) wherein participants wore the pedometer for at least 10 hours per day; otherwise, their daily step counts were not included in the analysis. Participants' perceived social support from family members and friends was computed by averaging the Likert-scale points across items in the scale. Means and standard deviations for the 3 study arms were calculated for each outcome measure. Analysis of variance was used to assess differences in means among study arms. Paired *t* tests were used to assess differences in means within study arms. *T* tests were used to assess differences in the difference in means between study arms. All analyses were conducted at the .05 significance level using STATA version 14.2.

Results

Participants were recruited from April to August 2015, and follow-up assessments were conducted until November 2015. Figure 1 displays the participant flow diagram. Table 3 presents participant characteristics; there were no statistically significant differences in participant characteristics among the three study arms.

Figure 1. Participant flow diagram.

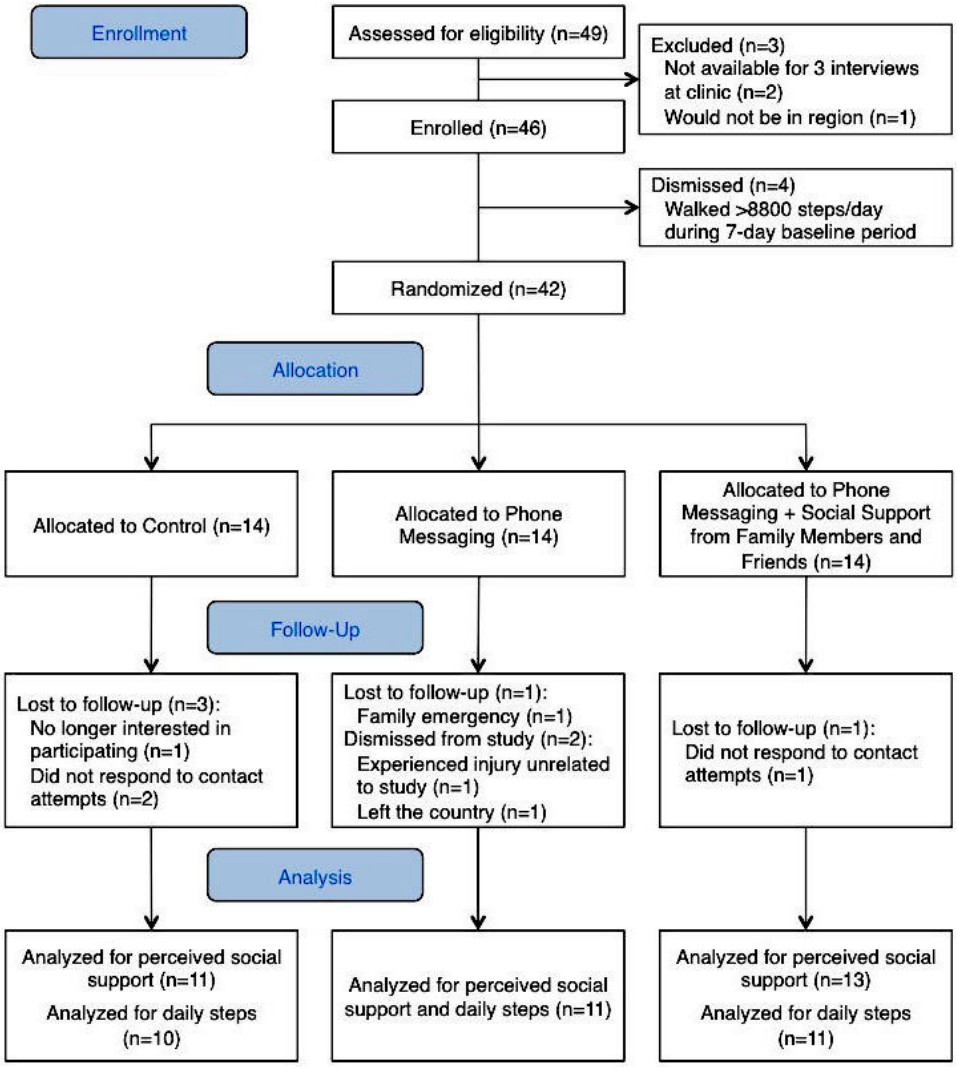


Table 3. Participant characteristics. There were no statistically significant differences among study arms at the .05 level of significance.

Characteristics	Total (N=42)	Control (N=14)	PM[a] (N=14)	PM+FF[b] (N=14)
Gender (female), n (%)	28 (67)	9 (64)	7 (50)	12 (86)
Age in years, mean (SD)[c]	52 (9)	53 (8)	53 (9)	50 (9)
Spanish as preferred language, n (%)	32 (76)	10 (71)	12 (86)	10 (71)
Educational attainment, n (%)				
Less than high school	22 (52)	8 (57)	5 (36)	9 (64)
High school graduate	4 (10)	1 (7)	2 (14)	1 (7)
More than high school	16 (38)	5 (36)	7 (50)	4 (29)
Years since T2D[d] diagnosis, mean (SD)	12 (9)	12 (7)	11 (11)	12 (8)
Phone with text-messaging capability, n (%)	36 (86)	12 (86)	11 (79)	13 (93)
Prefer voice instead of text messages, n (%)	11 (39)		6 (43)	5 (36)

[a]PM: phone messaging.

[b]PM+FF: phone messaging plus social support from family members and friends.

[c]SD: standard deviation.

[d]T2D: type 2 diabetes.

Technical Feasibility

In terms of receipt of STVMs and engagement with STVMs requiring a response, all participants reported receiving STVMs throughout the 12-week study. Participants receiving text messages reported receiving an average of 4 or 5 messages per week and responded to 62.7% (128/204) of messages requiring a response. Participants receiving voice messages were reached on 91.6% (308/336) of calls and provided a response during 30% (12/40) of calls that were answered and required a response.

In terms of barriers to receipt of and engagement with STVMs, 18% (3/17) of participants receiving text messages reported that they did not respond to messages asking about their PA performance because they either did not understand the instructions or because they did not know how to send text messages. Similarly, since they did not understand the instructions, 29% (2/7) of participants receiving voice messages stated that they did not respond. Participants receiving voice messages also said that they were too busy to respond (2/7, 29%), were not given enough time to respond before the call ended (1/7, 14%), or were confused after hearing an English voice on the call (default, non-customizable message giving instructions for how to opt out of calls; 3/7, 43%).

In terms of pedometer usability, 13% (3/24) of participants stated that they did not wear the pedometers consistently because the pedometers would fall off the clips; 17% (4/24) reported having difficulty reading the text on the pedometer screen and navigating the various screen display options; 13% (3/24) admitted at the end of the study that although they wore the pedometer each day, they never learned to read their steps; and 25% (6/24) stated that they were afraid of accidentally pushing the "wrong" button on the pedometer.

Perceived Usefulness

Participants described how the program enhanced their ability to make PA behavior changes, which we categorized as providing convenient and ongoing behavior change support; prompting self-monitoring, goal setting, and self-instruction; reporting on PA performance and receiving feedback; and instrumental, emotional, and informational support. Direct quotations from participants can be found in Table 4.

Providing Convenient and Ongoing Behavior Change Support

Several participants in the PM and PM+FF arms explained that receiving STVMs was a better alternative than a clinic-based program because restrictive work hours and transportation issues would make it difficult for them to participate in the latter. In addition, according to participants, receiving regular STVMs was a good way of being reminded to stay active in between visits to the DMP clinic. Many participants stated that they preferred receiving text messages to talking to a real person because it was more convenient and because they felt more comfortable texting than speaking to a real person. However, an individual suggested that participants periodically receive a call from a real person.

Prompting Self-Monitoring

In terms of using pedometers as a self-monitoring tool, most participants in the PM and PM+FF arms viewed the devices favorably and recognized that wearing them enabled objective tracking of PA. Several participants also explained that writing their daily steps in a log allowed them to have a longer record of how much they walked because the pedometers only stored 7 days of data. According to these participants, viewing their daily steps prompted them to assess whether they were making progress toward the long-term goal of 10,000 steps per day and allowed them to discover patterns in their PA behavior.

Prompting Goal Setting

Most participants in the PM and PM+FF arms reported that having a daily step goal motivated them to walk more throughout the day. One participant, on the other hand, disliked goal setting because it was "traumatizing" not to meet the goal. Participants had mixed perceptions about the recommended long-term goal. Some were satisfied with the 10,000 daily step goal, others challenged themselves by setting an even greater goal, and other participants felt that the goal was too ambitious.

Prompting Self-Instruction

According to participants in the PM and PM+FF arms, having information about their actual PA behavior prompted them to self-instruct. After reviewing their progress, participants explained how they would reflect on how they needed to keep walking until they reached a certain step count, walk more steps the next day, or think about how walking was going to benefit their health. Participants said this type of self-instruction served as a motivation to walk more.

Reporting and Receiving Feedback

Participants in the PM and PM+FF arms stated that the STVMs asking them to report their PA performance prompted them to self-reflect and motivated them to improve their PA behavior in order to provide a more favorable response the next time. Participants enjoyed receiving positive feedback when they replied with a high number. Although 1 participant reported being indifferent about the feedback messages, several others reported that these messages motivated them to continue their behavior change efforts and increase their daily steps. In terms of the reporting mechanism, 1 participant liked that it was quick and easy to reply with a single number. Another participant, however, perceived this as a limitation because of the inability to explain the reason for the given response.

Table 4. Exemplar quotations from participants describing how they perceived the program to be useful.

Category	Exemplar
Convenient and ongoing behavior change support	"I like that I don't have to go to the clinic to get help for physical activity because I live far."[a]
	"The doctor will tell me (during a clinic visit) to walk, but then we won't discuss it again until the next visit. I like that the messages constantly remind me."[a]
	"If you are not home or you cannot pick up the call, the text message is saved and you can read it any time."[a]
Self-monitoring	"Having a pedometer keeps you from lying to yourself that you did walk enough."[a]
	"I found out that on Saturdays, I walk the most—that is because I go to parties and dance a lot."[a]
	"I try to see which days I had the most steps. I want to see what kinds of things I did that day that made me get a lot of steps. I noticed that on the weekends, I don't walk that much."[b]
Goal setting	"(Setting a goal) is a good idea because it tells me what I need to work towards."[b]
	"I like having goals because they motivate me to walk more. Without goals, I don't think I would walk as much as I do now."[a]
	"The 10,000 steps goal is too much. I have to go walk, then rest, then walk, then rest. My back and my legs hurt because of the arthritis."[a]
Self-instruction	"When I don't have enough steps, I tell myself that I need to keep walking more."[a]
	"When I don't walk enough that day, I tell myself that I need to walk more the next day."[a]
	"I ask myself, 'Do I want to walk more or do I want to take insulin?'"[b]
Reporting and feedback	"I like reporting because it helps me to keep track of how I am doing. Each week, I try to improve so that I will give a higher number the next time."[a]
	"It's like someone grading you, like you did good on your test."[b]
	"I liked that it was so simple to reply, just one number. I didn't have to type out a long response. Even if you don't have time, you can quickly type one number."[a]
Instrumental support	"(My husband) constantly asks me, 'Did you walk already? If you haven't, let's eat dinner and then go.' He walks with me, and I forget that I am exercising because we begin talking."[a]
	"(My husband) helps me around the house so that I have time to exercise… He tells me that he will watch our baby so that I could go walk with my sister… I feel like our relationship has improved."[a]
	"(My husband) parks his car very far so that we can walk more. He takes me to go walking because he says the text messages told him to."[a]
Emotional support	"I like that someone is concerned and cares and takes the time to check on me. It gives me more motivation."[b]
	"I am thankful that someone was interested in my health. I have put more effort into walking more."[a]
	"The messages motivate me. I don't have family so knowing that someone cares about me makes me feel special."[b]
Informational support	"I didn't exactly know why I had to exercise. I didn't know it was beneficial for my health."[b]
	"Before (participating in this program), I didn't know how many steps I needed to walk each day."[b]
	"My mom says, 'You know the drill. I am going to call later to see how much you walked. Even if you don't feel like it, just get up and go around the school a few times. Just do something, and then you feel like doing more.'"[a]

[a]Quotation from a participant in the phone messaging + social support from family members and friends (PM+FF) arm.

[b]Quotation from a participant in the phone messaging (PM) arm.

Instrumental Support

Most participants in the PM and PM+FF arms felt that the STVMs motivated and reminded them to be active. One person described STVMs as "an alarm to go out and walk." The majority of PM+FF participants reported that family members and friends regularly reminded them to walk, offered encouraging words, inquired about how much they had been walking, or walked with them. Another common form of instrumental support from family members and friends was creating opportunities for participants to be more active; for example, by parking vehicles farther away from destinations or by helping with household responsibilities in order to free up time for the participant.

Emotional Support

Only one PM+FF participant stated that their family member or friend was a source of emotional support—that is, the family member or friend was perceived as caring about the participant's PA behavior. On the other hand, numerous PM and PM+FF participants perceived emotional support from the receipt of STVMs from the program. They used words such as "care,"

"concerned," and "interested" to describe how the STVM messaging system "felt" about the participants' behavior change efforts and well-being.

Informational Support

Several participants from both intervention arms stated that they learned from the STVMs, for the first time, about the benefits of PA for individuals with diabetes. Many participants in the PM+FF arm also reported having received this type of information from family members and friends. Additionally, these participants described how family members and friends regularly offered ideas of where and how to be active.

Potential Effectiveness

PA (steps/day) and perceived social support from family members and friends for each study arm at Weeks 0, 6, and 12 are presented in Table 5 and Figure 2. There were no significant differences in outcomes among study arms at Week 0. The following sections describe differences within study arms during the 6- and 12-week follow-up assessments. Unless otherwise stated, these within study arm differences were not statistically significant. In addition, differences in differences for each outcome were not statistically significant at Week 6 or Week 12.

Daily Steps

Participants in all study arms increased their PA (steps/day) from Weeks 0 to 6. The increases within the control and PM arms were statistically significant. The control arm had the greatest increase, followed by the PM arm and then the PM+FF arm; however, the PM and PM+FF arms started with higher levels of PA than the control arm at baseline. Only participants in the PM and PM+FF arms continued to increase their PA from Weeks 6 to 12. The increase in PA was highest within the PM arm.

Table 5. Physical activity and perceived social support from family members and friends at baseline and change from the previous assessment. Values are mean (standard deviations). There were no significant differences among groups at Weeks 0, 6, and 12.

Outcome	n	Control			n	PM[a]			n	PM+FF[b]		
		Week 0	Week 6	Week 12		Week 0	Week 6	Week 12		Week 0	Week 6	Week 12
		M (SD)[c]	MΔ[d] (SD)	MΔ (SD)		M (SD)	MΔ (SD)	MΔ (SD)		M (SD)	MΔ (SD)	MΔ (SD)
Physical activity (steps/day)	10	3691 (892)	1915 (2308) (*P*=.03)	−454 (1733)	11	3829 (1205)	1584 (1858) (*P*=.02)	439 (2069)	11	4680 (2731)	597 (2039)	233 (2538)
Perceived social support from family members and friends	11	2.4 (0.9)	0.2 (0.6)	-0.1 (0.6)	11	2.9 (0.9)	0.1 (0.8)	−0.1 (0.4)	13	2.9 (0.7)	0.4 (0.8)	0.1 (0.5)

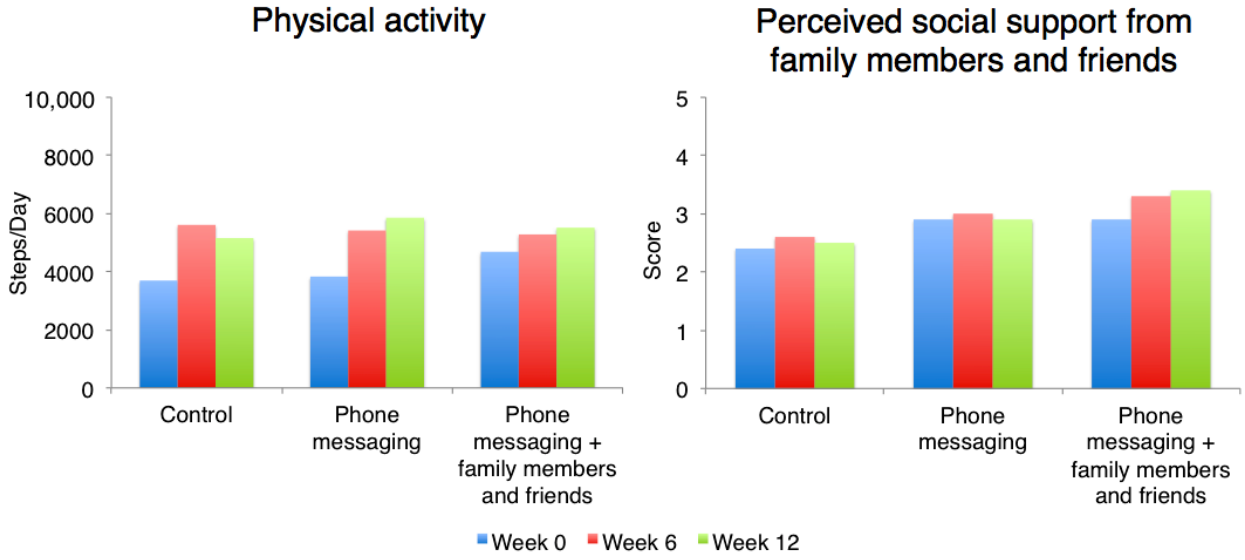
[a]PM: phone messaging.

[b]PM+FF: phone messaging plus social support from family members and friends.

[c]SD: standard deviation.

[d]Δ: (current assessment value−previous assessment value).

Figure 2. Changes over time in physical activity and perceived social support from family members and friends. Perceived social support is based on the Social Support and Exercise Survey, with higher numbers indicating higher perceived support.



Perceived Social Support from Family Members and Friends

Participants in all study arms had an increase in their perception of social support from family members and friends from Weeks 0 to 6. The PM+FF arm had the greatest increase, followed by the control arm and then the PM arm. Only participants in the PM+FF arm continued to have an increase in the perception of social support from family members and friends from Weeks 6 to 12.

Discussion

Principal Findings

This study found that it was feasible to reach and engage urban, low-income Latino adults with T2D and their family members and friends using an STVM intervention. However, receipt of and engagement with STVMs varied by mode of message delivery; participants who opted to receive text messages were reached more and were more engaged than those who opted to receive voice messages. The majority of participants complied with wearing pedometers as instructed, although several encountered barriers with wearing and using pedometers. In addition, this study found that guidance in self-regulation was a useful mechanism for supporting PA behavior change via STVMs. Specifically, participants generally perceived as useful the prompting of self-monitoring, goal setting, self-instruction, reporting and feedback, and social support. Finally, participants in all study arms improved their PA (steps/day) in the first half of the study, but only intervention participants continued to improve their PA in the second half of the study. Similarly, the perception of social support from family members and friends improved for participants in all study arms in the first half of the study. In the second half of the study, however, perceived social support improved only for participants that had a family member or friend receiving STVMs as part of the intervention.

There is evidence that Spanish-speaking adults with diabetes can be successfully engaged in a self-management intervention delivered using interactive voice response phone calls [23,24]. Participants in our study who received voice messages were willing to reply to messages requiring a response, but the platform used to deliver voice messages created barriers, which could have been prevented if the platform could be customized in terms of language and time given to respond. If using a platform with similar limitations, the results of this study suggest that text messages are superior to voice messages for ensuring patient engagement. Given that most participants reported having a phone with text-messaging capability, a larger study could restrict the mode of delivery to text messages and teach participants how to send and receive them.

Our study demonstrates that self-regulation techniques can be successfully applied in an STVM intervention to support PA behavior change and that patients perceive these techniques as useful. A recent systematic review examining the impact of information technology on behavior change for various health conditions found that less than a third of interventions delivered via phones explicitly reported using a behavior change theory as a guide for intervention design [36]. Among those that did report using behavior change theory, none used self-regulation theory even though self-regulation techniques (ie, goal setting, self-monitoring, and feedback) are associated with positive outcomes in interventions that promote PA and healthy eating [28,29]. Future studies may use our intervention components, which are aligned with self-regulation theory and patient preferences, to inform the design of phone-based interventions.

There is evidence that using a pedometer to self-monitor daily steps is associated with increases in PA [37]. Given that improvements in PA within the control arm were observed only in the first half of the study, it appears that being prompted to use a pedometer and walking log to self-monitor and being prompted to set goals was a sufficient short-term intervention. However, ongoing support via STVMs and family members and friends appeared to be a promising approach for continued improvements in PA. This finding is consistent with evidence indicating that individuals require ongoing self-management support in order to maintain initial gains achieved through intervention [5]. Furthermore, there are limited published studies examining technology-based chronic disease self-management interventions that also incorporate a component of support from family members and friends [23,24]. These studies have not examined the additional benefit, if any, on patient outcomes. Our results indicate that using STVMs to prompt supportive behaviors from family members and friends has the potential to improve perceived social support. Future research is needed to investigate how improvements in perceived social support resulting from an STVM intervention impact PA behavior.

Limitations

The first limitation is the small sample size. The small sample size made it hard to check whether the distributional assumptions of the hypotheses tests were met. However, we re-did the analysis using nonparametric tests (not presented) and the conclusions did not change. The second limitation is that the randomization process resulted in the PM+FF arm having participants with more daily steps at baseline compared with the other arms. The results of this imbalance may explain the observation of a significant increase in daily steps in the control and PM arms, but not the PM+FF arm. Another limitation is that the majority of participants' perceptions about the usefulness of the program were positive, which may be an indication of social desirability bias. However, only 1 participant was lost to follow-up due to not responding to our contact attempts (compared with 3 in the control arm), making us confident that our results indeed represent participants' perceptions. A final limitation is that we measured perceived social support instead of actual social support. Participants in the PM+FF arm could have perceived higher levels of social support from family members and friends—whether or not this was actually the case—because they knew that their family members and friends were being prompted to provide support. However, in qualitative interviews, PM+FF participants provided specific examples of how the supportive behaviors of their family members and friends had changed since the start of the study, which helps to validate our quantitative results.

Conclusions

This study demonstrated the potential of using STVMs to support PA behavior change among urban, low-income Latino adults with T2D and to prompt social support from family members and friends. Text messaging may be a better mode of message delivery than voice messaging for ensuring participant receipt of and engagement with messages. Pedometers can successfully be used by investigators for data collection purposes and by participants for self-monitoring, although adjustments to instructions are needed so that participants feel more comfortable using this tool without fear. Moreover, designing an STVM intervention based on self-regulation techniques (ie, self-monitoring, goal setting, self-instruction, feedback, and social support) is feasible and perceived as useful by participants. Finally, such an intervention may improve PA in terms of daily steps and perceived social support from family members and friends who participate in the intervention.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Assessment questions.

[PDF File (Adobe PDF File), 247KB - diabetes_v2i1e8_app1.pdf]

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Abbreviations

DMP: diabetes management program
PA: physical activity
PM: phone messaging
PM+FF: phone messaging plus social support from FF
RA: research assistant
SCT: Social Cognitive Theory
STVM: short text or voice message
T2D: type 2 diabetes

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Original Paper

Situation of Diabetes and Related Factors Among Qatari Adults: Findings From a Community-Based Survey

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Abstract

Background: Diabetes mellitus (DM) is a prominent public health problem in Qatar with one of the highest prevalence in the Gulf Cooperation Council region. Obesity continues to be a challenging public health problem in Qatar along with other social determinants contributing to the high DM prevalence.

Objective: This paper examines the data from Qatar National STEPS survey (2012) to determine diabetes prevalence among Qatari adults and identify the effect of both generalized and central obesity on it. The article also describes the contribution of selected social and demographic factors on diabetes prevalence in Qatar.

Methods: Secondary data analysis of 1471 Qatari adults (18-64 years) from STEP 3 component of the 2012 STEPS Survey was executed. Multivariate binary logistic regression analysis was carried out to assess the role of social and biomedical factors in the prevalence of DM.

Results: Among participants, 18.97% (279/1471) of the study population had DM. Both generalized (OR 1.8, P=.005) and central obesity (OR 1.9, P<.001) were significantly associated with DM when adjusted for various respondent characteristics. Older age (P<.001), marital status of ever married (P<.001), and lower educational status (P=.01) were associated with DM. Hypertension (OR 1.5, P=.003 total cholesterol level ≥190 mg/dL (OR 2.2, P<.001) and triglyceride level ≥150 mg/dL (OR 3.6, P<.001) were significantly associated with DM among the study participants. Although family history of DM was significantly associated with development of DM (OR 1.7, P=.01), parental consanguinity was not associated with DM (OR 0.96, P=.80).

Conclusions: The DM prevalence in Qatar seems to be highly associated with obesity; however, various additional population characteristics and comorbidity factors should also require attention and should be incorporated while developing intervention strategies.

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KEYWORDS

diabetes mellitus; obesity; public health; Qatar

Introduction

Diabetes mellitus (DM) is one of the most costly preventable public health condition causing mortality and morbidity in millions of people globally [1]. It is diagnosed by a series of blood tests based on the raised blood glucose levels and is caused by either insufficient insulin production from pancreas (type 1 DM) or decreased ability of the body to use insulin (type 2 DM) [1]. Majority of DM cases are type 2 compared with type 1 and comprise 90% of people with DM around the world [1]. DM is known to increase the risks of cardiac, cerebrovascular, and kidney diseases and also contribute to complications associated with nerve damage such as diabetic retinopathy, foot ulcer, skin infections, and so on [2]. DM also doubles the risk of mortality among people with the disease than those without the disease [3].

According to the World Health Organization (WHO) estimates, in 2014 the global prevalence of DM in adults was 8.5%, and in 2012, mortality due to DM was 1.5 million worldwide [1]. Similarly, the prevalence of DM is also high in Arab region and has been identified to be a major disease burden in the Eastern Mediterranean Region countries where its prevalence ranges from 3.5% to 30% [4]. Increased body weight raises the risk of type 2 DM and other chronic conditions such as cardiovascular disease, musculoskeletal disorder, and cancers [1,5]. Since 1980, the obesity prevalence has doubled globally with over 600 million people estimated to be suffering from obesity [5]. Obesity is one of the contributory factors in developing insulin resistance which is the inability of the body to respond to insulin [6]. Body mass index (BMI) is considered a reliable parameter to assess the body weight and defined as weight (in kilograms) divided by the square of height (meters) of a person. The BMI ≥30 kg/m^2 is classified as obesity [5]. Central obesity or wide waist circumference (WC) also increases the risk of developing type 2 DM sometimes even among individuals with normal or low BMI [7]. This is due to the fact that the increased degree and the duration of abdominal or body fat is associated with higher levels of insulin impairing hormones and chemicals in the body [7-9]. These excessive fat cells act like endocrine glands and therefore could eventually lead to DM if obesity is not controlled [7-9]. Lifestyle and cultural norms such as eating and exercise habits that may impact on body weight or fat content also influence the occurrence of DM in families [10].

The World Health Survey (WHS) in 2006 revealed that about 8% of Qatar population was diabetic which was higher than the worldwide diabetes prevalence of 5.1% [11]. Furthermore, the prevalence of diabetes among Qatari adults was higher (11.6%) compared with non-Qatari adult residents (6.6%) [12]. In 2011, the country's estimated comparative diabetes prevalence for adults (aged between 20 and 79 years) was 20.1% ranking Qatar in top 5 among Arabic and non-Arabic speaking countries [3,4]. In 2012, 6% of deaths were related to DM in Qatar with higher proportion among Qatari nationals (9.9%) versus non-Qataris (4%) [12]. Type 2 DM is considered to be one of the leading causes of mortality due to non-communicable diseases (NCDs) in Qatar along with the cardiovascular disease and neoplasm [13]. Socioeconomic development in past decades has influenced the lifestyle of Qatari population which could be the reason that Qatar has one of the highest obesity prevalence in the Gulf Cooperation Council region [14,15]. As indicated in WHS 2006, a large proportion of population in Qatar was overweight (39%) and obese (32%). It was noted that obesity proportion was higher among Qatari nationals (40%) versus non-Qataris (28%) [11]. WHS 2006 report also showed that the likelihood of having DM was 1.5 times higher when BMI was greater than 30 [11].

This study examines the data from Qatar National STEPwise Survey (2012) to determine DM prevalence among Qatari adults and identify the effect of both generalized and central obesity on it. The STEPS survey is a standardized approach to collect population level data pertaining to the NCD including DM and the related risk factors [16,17]. The aim of this study is to also describe the contribution of selected social and demographic factors on DM prevalence in Qatar. This area has not been extensively explored and published before; hence, the findings from this study could help in designing effective public health techniques and interventions to reduce DM-related mortality and morbidity in the county.

Methods

Sampling

The secondary data from WHO-based Qatar National STEPwise Survey for chronic diseases and risk factors were utilized for this particular study [16]. The STEPS was implemented between March and May of 2012 in which 2496 Qatari nationals aged 18-64 years were randomly selected with a response rate of 88%. A multistage cluster sampling design was used for the survey. Using a two-stage sampling design, a total of 96 primary sampling units (PSUs) were selected at the first stage. In the second stage, 30 households were selected from each selected PSU by simple systematic sampling.

The DM status by obesity and sociodemographic factors was examined among 1471 Qatari adults aged 18-64 years and who participated in the STEP 3 survey tool. The response rate for STEP 3 component was about 60% [16]. STEPwise consists of three survey tools: STEP 1 is for gathering demographic and behavioral risk factors information; STEP 2 is for collecting physical measurements such as weight, height, WC and blood pressure (BP); and STEP 3 is for taking blood samples for biochemical measurements: fasting blood glucose level (FBG), and lipid profile, respectively [16,17]. The STEPS methodology provided a sample which was representative of all Qatari nationals. The sampling design took into account the WHO STEPS formula for calculating the sample size, as specified in the STEPS guidelines for participating countries and considered as multistage, systemic random sampling [16,17].

Data to assess obesity in STEP 3 participants were analyzed using the STEPS methodology [16,17]. BMI and WC cutoff values were determined as per WHO recommendations, that is, BMI ≥30 kg/m^2 denoted generalized obesity and WC ≥102 in males and ≥88 in females represented central obesity [8,18]. Data for pregnant women were removed from the analysis while performing body weight and WC calculations.

Cutoff values for FBG, lipid profile, and BP were determined in accordance with the WHO STEPS Guidelines, that is ≥190 mg/dL of total cholesterol, ≥150 mg/dL triglyceride level, <40 mg/dL and <50 mg/dL of high-density lipoproteins (HDL) in men and women, respectively, and ≥110 mg/dL of FBG were considered unfavorable [16,17]. The participants who had FBG levels ≥110 mg/dL and/or were taking insulin or other prescribed medications to control their DM (regardless of their FBG results) were considered diabetics. The participants with systolic BP of ≥140 mmHg and/or diastolic BP ≥90 mmHg or who were currently on medications for raised BP were considered hypertensive [16].

Data Analysis

Statistical analysis was performed using IBM SPSS statistics version 20.0 for Windows. All categorical variables were presented as frequencies and percentages. Study outcomes were assessed using Fisher exact test or chi-square test with Yates

correction for discrete variables appropriately. The Kolmogorov-Smirnov test was used for checking normality. Continuous variable such as FBG, BMI, WC were presented as geometric mean and 95% CI. Independent sample *t* test was used to compare means across two different groups. Odds ratio (OR) and 95% CI was computed using multivariate logistic regression, which identifies the degree of the association between DM and various factors. In the crude model, no adjustments were made, whereas age and gender were controlled in the first model. Second model was adjusted for age, gender, and sociodemographic indicators such as marital status, education, and smoking status. In addition to the factors included in model 2, family history of DM (among parents, siblings, and/or children) and parental consanguinity variables were controlled in the final model 3. The sensitivity, specificity, positive predictive values, and negative predictive values were calculated using family history of DM, parental consanguinity and obesity variables and their impact on diabetic status of participants. This was used to test the ability of factors to correctly identify respondents with and without DM. The *P* value <.05 was considered statistically significant.

Results

Sample Characteristics

The female-to-male ratio among the total surveyed population (N=1471) was 1.7 (62.5% women and 37.5% men). The overall mean age of participants was 38.5 years with higher mean age (45.8 years) for diabetics (*P*<.001). Almost 80.35% (n=1182) of the study participants were currently or previously married. In relation to the level of education, the results showed that over one-third of the participants completed their college or university education (34.9%, n=513). Overall parental consanguinity was reported by 36% (n=528) of the respondents and 69.14% (n=1017) stated that they had a family history of DM. In accordance with the study criteria, 19% (n=279) of participants had DM with women comprising 60.2% (n=168) of diabetics. By gender, 20.1% (n=111) of male and 18.3% (n=168) of female participants had DM. About 34.1% (n=158) of the participants aged 45-64 years and 12% (n=121) of the participants aged 18-44 years had DM. Mean WC for males was 102 cm, higher among diabetics (108 cm) compared with nondiabetics (100.8 cm; *P*=.01). Mean BMI was also high among diabetics (*P*<.01). Mean HDL level was significantly lower among diabetic women compared with nondiabetic (*P*=.04). Mean total cholesterol (*P*=.002) and triglyceride levels (*P*<.01) were higher among diabetic participants. Both, mean systolic and diastolic BP readings were higher among diabetics (*P*<.01). The characteristics of participants are shown in Table 1.

Table 1. Study participants' characteristics by diabetes status. Geometric means are presented with 95% CI. Age is presented with SD. Pregnant women are excluded from the BMI and WC calculations.

Parameters	Categories	Total, N (%)	Diabetic, n (%)	Normal, n (%)	*P*
Overall sample	N	1471 (100.0)	279 (19.0)	1192 (81.0)	
	Mean (SD)	38.5 (12.2)	45.8 (11.7)	36.7 (11.7)	<.001
Age	18-44 years	1008 (68.5)	121 (43.4)	887 (74.4)	<.001
	45-64 years	463 (31.5)	158 (56.6)	305 (25.6)	
Gender	Male	552 (37.5)	111 (39.8)	441 (37.0)	.38
	Female	919 (62.5)	168 (60.2)	751 (63.0)	
BMI (kg/m^2)	Mean (95% CI)	29.4 (29.0-29.8)	31.8 (30.9-32.7)	28.8 (28.4-29.3)	<.001
	Lean	39 (2.7)	1 (0.4)	38 (3.3)	<.001
	Normal	315 (22.2)	34 (12.5)	281 (24.4)	
	Overweight	403 (28.3)	75 (27.6)	328 (28.5)	
	Obese	665 (46.8)	162 (59.6)	503 (43.7)	
Waist circumference (cm)					
Male	Mean (95% CI)	102.2 (100.0-104.5)	108.0 (103.1-113.2)	100.8 (98.3-103.3)	.01
	Central obesity (WC ≥102 cm)	268 (49.3)	71 (64.5)	197 (45.4)	<.001
	Normal (WC <102 cm)	276 (50.7)	39 (35.5)	237 (54.6)	
Female	Mean (95% CI)	97.8 (94.7-100.8)	102.1 (98.1-106.1)	96.8 (93.3-100.5)	.20
	Central obesity (WC ≥88 cm)	509 (60.0)	127 (79.9)	382 (55.4)	<.001
	Normal (WC <88 cm)	340 (40.0)	32 (20.1)	308 (44.6)	
Education level	Secondary or less/no formal education	957 (65.1)	200 (71.7)	757 (63.6)	.01
	College/university/PG	513 (34.9)	79 (28.3)	434 (36.4)	
Marital status	Ever married	1182 (80.4)	256 (91.8)	926 (77.7)	<.001
	Never married	289 (19.6)	23 (8.2)	266 (22.3)	
Parental consanguinity	Yes	528 (35.9)	97 (34.8)	431 (36.2)	.66
	No	943 (64.1)	182 (65.2)	761 (63.8)	
Family history of DM	Yes	1017 (69.1)	208 (74.6)	809 (67.9)	.03
	No	454 (30.9)	71 (25.4)	383 (32.1)	
Mean fasting blood glucose (95% CI)	Overall	90.3 (88.8-92.0)	149.2 (143.5-155.1)	80.3 (79.6-81.0)	<.001
	Men	90.2 (87.8-92.7)	148.8 (140.1-158.2)	79.6 (78.3-80.8)	<.001
	Women	90.3 (88.5-92.1)	149.4 (142.0-157.1)	80.7 (79.8-81.6)	<.001
Current smoker	Yes	197 (13.4)	35 (12.5)	162 (13.6)	.64
	No	1274 (86.6)	244 (87.5)	1030 (86.4)	
Smoking status	Daily	179 (12.2)	31 (11.1)	148 (12.4)	.82
	Nondaily	18 (1.2)	4 (1.4)	14 (1.2)	
	Past smoker	53 (3.6)	12 (4.3)	41 (3.4)	
	Never smoker	1221 (83.0)	232 (83.2)	989 (83.0)	
Hypertension	Mean systolic blood pressure (SBP), mmHg (95% CI)	118.3 (117.4-119.2)	127.4 (125.1-129.8)	116.2 (115.3-117.1)	<.001
	Mean diastolic blood pressure (DBP), mmHg	79.0 (78.4-79.5)	83.0 (81.8-84.2)	78.0 (77.4-78.6)	<.001

Parameters	Categories	Total, N (%)	Diabetic, n (%)	Normal, n (%)	*P*
	SBP ≥140/DBP ≥90 mmHg or on medication	540 (37.0)	150 (54.0)	390 (33.1)	<.001
	Normal	918 (63.0)	128 (46.0)	790 (66.9)	
Total cholesterol (mg/dL)	Mean (95% CI)	160.4 (158.6-162.2)	166.6 (161.8-171.4)	159.0 (157.0-160.9)	<.01
	≥190 mg/dL	381 (26.0)	124 (44.6)	257 (21.7)	<.001
	<190 mg/dL	1083 (74.0)	154 (55.4)	929 (78.3)	
HDL (mg/dL)					
Male	Mean (95% CI)	39.7 (38.5-40.9)	38.8 (36.4-41.4)	39.9 (38.5-41.3)	.47
	<40 (mg/dL)	264 (47.8)	59 (53.2)	205 (46.5)	.21
	≥40 (mg/dL)	288 (52.2)	52 (46.8)	236 (53.5)	
Female	Mean (95% CI)	54.5 (53.4-55.6)	52.0 (49.4-54.8)	55.1 (53.8-56.4)	.04
	<50 (mg/dL)	341 (37.4)	73 (43.7)	268 (36.0)	.06
	≥50 (mg/dL)	571 (62.6)	94 (56.3)	477 (64.0)	
Triglyceride (mg/dL)	Mean (95% CI)	96.1 (93.8-98.5)	122.9 (115.7-130.7)	90.7 (88.4-93.1)	<.001
	≥150 (mg/dL)	257 (17.7)	103 (37.2)	154 (13.1)	<.001
	<150 (mg/dL)	1197 (82.3)	174 (62.8)	1023 (86.9)	
LDL (mg/dL)	Mean (95% CI)	89.1 (87.6-90.5)	89.5 (86.1-93.1)	88.9 (87.3-90.5)	.75
	≥130 (mg/dL)	144 (10.8)	34 (12.8)	110 (10.3)	.24
	<130 (mg/dL)	1188 (89.2)	232 (87.2)	956 (89.7)	

Crude Analysis

Crude analysis showed that the older age group (45-64) had 3.8 time odds of having DM compared with younger age (18-44) group (95% CI 2.9-4.9, *P*<.01). By gender, male participants showed 1.1 time odds of having DM compared with females, but this relationship was not statistically significant (95% CI 0.86-1.5, *P*=.38). Secondary or lower educational status was found to be associated with development of DM among study participants (OR 1.45, 95% CI 1.1-1.9, *P*=.01). Participants who were currently or previously married also had higher odds of having DM compared to the ones who were never married (OR 3.2, 95% CI 2.0-5.0, *P*<.01). The detailed crude associations of predictors and participant categories are shown in Table 2.

Table 2. Relationship (crude) of diabetes between participant parameters and categories. Odds ratios (OR) and 95% CI were estimated using logistic regression models. Model 0: crude odds ratio.

Parameters	Categories	Crude OR (95% CI)	
Predictors		OR (95% CI)	*P*
Age	18-44	Reference	
	45-64	3.8 (2.9-4.9)	<.001
Gender	Male	1.1 (0.86-1.5)	.38
	Female	Reference	
Marital status	Ever married	3.2 (2.0-5.0)	<.001
	Never married	Reference	
Highest level of education	Secondary or less/no formal education	1.45 (1.09-1.9)	.01
	College/University/PG	Reference	
Parental consanguinity	Yes	0.94 (0.72-1.2)	.66
	No	Reference	
Family history of DM	Yes	1.4 (1.03-1.8)	.03
	No	Reference	
Smoking status	Daily	0.89 (0.59-1.3)	.59
	Nondaily	1.22 (0.39-3.7)	.73
	Past smoker	1.24 (0.64-2.4)	.51
	Never smoker	Reference	
BMI (kg/m^2)	Lean	0.21 (0.03-1.6)	.14
	Normal	Reference	
	Overweight	1.9 (1.2-2.9)	.004
	Obese	2.6 (1.8-3.9)	<.001
Waist circumference (cm)			
Male	≥102 cm	2.2 (1.4-3.4)	<.001
	<102 cm	Reference	
Female	≥88 cm	3.2 (2.1-4.8)	<.001
	<88 cm	Reference	
Blood pressure (BP, mmHg)	Raised BP or currently on medication	2.3 (1.8-3.1)	<.001
	Normal	Reference	
Total cholesterol (mg/dL)	≥190 mg/dL	2.9 (2.2-3.8)	<.001
	<190 mg/dL	Reference	
HDL (mg/dL)			
Male	<40 (mg/dL)	1.3 (0.86-1.9)	.21
	≥40 (mg/dL)	Reference	
Female	<50 (mg/dL)	1.4 (0.98-1.9)	.06
	≥50 (mg/dL)	Reference	
Triglyceride (mg/dL)	≥150 (mg/dL)	3.9 (2.9-5.3)	<.001
	<150 (mg/dL)	Reference	
LDL (mg/dL)	≥130 (mg/dL)	1.3 (0.84-1.9)	.25
	<130 (mg/dL)	Reference	

Multivariate Analysis

Multivariate logistic regression analysis revealed that generalized obesity was significantly associated with DM (OR 1.8, 95% CI 1.2-2.8, *P*=.005); however by gender, this relationship was only significant among females (OR 2.2, 95% CI 1.2-4.0, *P*=.009) versus males (OR 1.4, 95% CI 0.78-2.7, *P*=.23). Central obesity was found to also be associated with DM in overall sample (OR 1.9, 95% CI 1.4-2.6, *P*<.01), among males (OR 1.8, 95% CI 1.1-2.9, *P*=.007) and as well as among females (OR 2.0, 95% CI 1.2-3.1, *P*=.003; Table 3). Hypertension (OR 1.5, 95% CI 1.1-2.0, *P*=.003), total cholesterol level ≥190 mg/dL (OR 2.2, 95% CI 1.6-3.0, *P*<.01) and triglyceride level ≥150 mg/dL (OR 3.6, 95% CI 2.6-4.9, *P*<.01) were significantly associated with DM among study participants (Table 3). HDL and LDL levels did not show a significant relationship in DM causation (Table 3).

Family history of DM was significantly associated with DM (OR 1.7, 95% CI 1.2-2.3, *P*=.001; Table 3). Parental consanguinity did not have any impact on diabetic status (OR 0.96, 95% CI 0.72-1.3, *P*=.77; Table 3).

Including obesity parameters in the relationship between consanguinity and family history with obesity, respectively (not shown in the table), showed that the family history of DM in presence of generalized obesity was not statistically significant (OR 1.3, 95% CI 0.95-1.7, *P*=.09) in having diabetic status; however, it was slightly significant for central obesity (OR 1.4, 95% CI 1.0-1.8, *P*=.05). Parental consanguinity had no influence on development of DM among participants with generalized (OR 0.97, 95% CI 0.73-1.3, *P*=.86) as well as central obesity (OR 1.02, 95% CI 0.77-1.4, *P*=.85).

Table 3. Relationship of diabetes between participant parameters and categories, multivariate logistics regression models. Odds ratios (95% CI) were estimated using multivariate logistic regression models.

Parameters	Categories	Multivariate models					
		Model 1[a]		Model 2[b]		Model 3[c]	
Predictors		OR (95% CI)	*P*	OR (95% CI)	*P*	OR (95% CI)	*P*
BMI (kg/m^2)	Lean	0.29 (0.04-2.2)	.23	0.35 (0.04-2.6)	.31	0.36 (0.04-2.7)	.33
excluding pregnant	Normal	Reference		Reference		Reference	
	Over weight	1.5 (0.97-2.4)	.06	1.4 (0.92-2.3)	.1	1.4 (0.91-2.3)	.12
	Obese	2.1 (1.4-3.2)	<.001	1.9 (1.2-2.9)	.002	1.8 (1.2-2.8)	.005
Waist circumference (cm)							
(no gender, no pregnant)							
Male	≥102 cm	2.0 (1.3-3.2)	.002	1.9 (1.2-2.9)	.006	1.8 (1.1-2.9)	.007
	<102 cm	Reference		Reference		Reference	
Female	≥88 cm	2.3 (1.5-3.5)	<.001	2.1 (1.3-3.2)	.002	2.0 (1.2-3.1)	.003
	<88 cm	Reference		Reference		Reference	
Blood pressure (BP, mmHg)	Raised BP or currently on medication	1.7 (1.3-2.2)	<.001	1.6 (1.2-2.1)	.001	1.5 (1.1-2.0)	.003
	Normal	Reference		Reference		Reference	
Total cholesterol (mg/dL)	≥190 mg/dL	2.3 (1.8-3.2)	<.001	2.3 (1.7-3.1)	<.001	2.2 (1.6-3.0)	<.001
	<190 mg/dL	Reference		Reference		Reference	
HDL (mg/dL)							
Male	<40 (mg/dL)	1.3 (0.87-2.1)	.18	1.32 (0.85-2.1)	.21	1.28 (0.82-2.0)	.27
	≥40 (mg/dL)	Reference		Reference		Reference	
Female	<50 (mg/dL)	1.3 (0.93-1.9)	.11	1.29 (0.91-1.8)	.15	1.3 (0.89-1.8)	.16
	≥50 (mg/dL)	Reference		Reference		Reference	
Triglyceride (mg/dL)	≥150 (mg/dL)	3.9 (2.8-5.3)	<.01	3.7 (2.7-5.1)	<.01	3.6 (2.6-4.9)	<.001
	<150 (mg/dL)	Reference		Reference		Reference	
LDL (mg/dL)	≥130 (mg/dL)	1.1 (0.75-1.7)	.54	1.1 (0.73-1.7)	.6	1.1 (0.71-1.7)	.66
	<130 (mg/dL)	Reference		Reference		Reference	
Family history of DM	Yes	1.6 (1.1-2.1)	.004	1.7 (1.2-2.3)	.001		
	No	Reference		Reference			
Parental consanguinity	Yes	0.97 (0.73-1.3)	.86	0.96 (0.72-1.3)	.77		
	No	Reference		Reference			

[a]Model 1: adjusted for age and gender.

[b]Model 2: adjusted for age, gender, sociodemographic indicators (marital status, education, smoking status).

[c]Model 3: adjusted for age, gender, sociodemographic indicators, family history, and consanguinity.

Family History, Consanguinity, and Obesity as a Screening Tool

Using family history as a screening tool, the family history of DM identified 74.6% of participants who had DM. For obesity (generalized), 59.6% of participants were identified to have DM. Family history and obesity together identified 46% diabetics. This means that family history is a better indicator of DM among participants compared with obesity or other combinations including consanguinity (Table 4). Positive predictive value which identify the participants who truly had disease during screening, showed that the family history of DM predicted DM among 20.4% of participants, while obesity predicted DM among 24.4% of participants. Obesity and family history together increased the prediction of DM to 25.7 %. Consanguinity alone increased the prediction of DM to 18.3%, but consanguinity with obesity increased it to 23.7% and with family history and obesity to 25.1% (Table 4).

Table 4. Sensitivity, specificity, positive and negative predictive values of family history of diabetes, consanguinity, obesity and all their possible combinations.

Selected social characteristics	Sensitivity % (95% CI)	Specificity % (95% CI)	Positive predictive value % (95% CI)	Negative predictive value % (95% CI)
Family history of DM	74.6 (69.0-79.6)	32.1 (29.5-34.9)	20.4 (19.2-21.7)	84.4 (81.3-87.0)
Consanguinity	34.8 (29.2-40.7)	63.8 (61.0-66.6)	18.3 (15.8-21.2)	80.7 (79.2-82.1)
Obesity	59.6 (53.5-65.4)	56.3 (53.4-59.1)	24.4 (22.2-26.6)	85.5 (83.6-87.3)
Family history of DM with obesity	46.0 (39.9-52.1)	68.6 (65.8-71.3)	25.7 (22.9-28.8)	84.3 (82.7-85.8)
Consanguinity with obesity	20.2 (15.6-25.5)	84.6 (82.4-86.6)	23.7 (19.1-28.9)	81.8 (80.8-82.7)
Consanguinity with family history of DM	26.5 (21.4-32.1)	75.1 (72.5-77.5)	19.9 (16.7-23.7)	81.4 (80.2-82.5)
Consanguinity and family history of DM with Obesity.	16.2 (12.0-21.1)	88.6 (86.6-90.4)	25.1 (19.7-31.5)	81.7 (80.9-82.5)

Discussion

Principal Findings

In summary, the results of this study support the fact that the family history of DM, older age, high WC, high BMI, hypertension, dyslipidemia, lower educational status, and marital status (ever married) have significant relationship with DM and are consistent with the findings from other studies [19-22]. The individuals with higher educational status tend to avoid unhealthy behaviors such as physical inactivity, alcohol abuse, smoking, and so on. [23]. This is usually coupled with the knowledge and circumstances favoring better understanding of health needs and easier access to the health care services [23,24]. Even though family history of DM is a reasonable indicator of DM in this study and supports the fact that the genetics may have a strong influence on burden of disease among participants; however, the impact of other social, environmental, and health factors cannot be ignored

DM prevalence is a result of complex interaction between personal, social, economic, and environmental factors in a geographical region. This study demonstrates DM as an important public health challenge in Qatar somewhat similar to the other countries in the region [11,14,15]. Overall, 19% of sample had DM with a higher frequency among women compared with men (Table 1). Furthermore, the STEPwise data shows that Qatar has a higher prevalence of obesity especially among women [16,25]. This gender distribution is similar to a study conducted in the Saudi Arabia (2012) in which female participants had higher obesity compared with men [26]. The overall DM prevalence was also similar in the Saudi Arabia study (21.5%); however, a higher percentage of DM was observed among males compared with females [26]. Even though 60.2% of participants among diabetics group were females, it is important to mention that the percentage of having DM among male participants (out of all male participants) was slightly higher than females.

While examining the impact of obesity on DM, both generalized and central types obesity were found to be significantly associated with DM in this study. Central obesity among females had slightly higher odds (OR 2.0) of having DM versus males (OR 1.8; Table.3). According to the 2001 Korea National Health and Nutrition Examination Survey (KNHANES), WC and BMI both were identified as a risk factor for DM in females and WC was also associated with DM in males [27]. A meta-analysis based on 18 prospective cohort studies showed that the obese and overweight individuals were at 7 and 3 times higher risk of developing DM, respectively, when compared with those with normal weight [28]. The same study also showed that females with obesity were relatively at higher risk of developing DM compared with males [28].

In this study, the family history of DM was found among about 70% of STEP 3 survey participants. The data also showed that around 20% of survey participants who had family history of DM also had DM which constitutes 74.6% of identified 279 diabetics in the sample of this study (Table 1). The high prevalence of DM with family history coincides with the findings from other studies [19,29-31]. The study also revealed that hypertension was a risk factor in the development of DM among participants which is consistent with the findings from a study based on UK Clinical Practice Research Datalink [32].

Strengths and Limitations

In this study, using data from a national population based survey was a main strength [16]. The survey is based on the WHO-STEPS protocol and considered a standardized tool [17]. The STEPS survey methodology provides a representative sample from a target population [16,17]. Furthermore, the DM status was determined by using subjective as well as objective (bio-chemical) responses/outcomes from the survey data to avoid any missing individuals with DM, for example, the ones who were previously diagnosed to have DM and had FBG levels less than cut off point. Like any other cross-sectional study, STEPS survey in Qatar also faced issues pertaining to the response rates, recall bias and associated misclassification. One of the study limitation is that the findings may not be directly comparable with other studies from different geographical regions, mainly due to the differences in methodology; however, it can be compared with the findings that were obtained using STEPS or similar methodology.

Conclusions

According to this study, the central and generalized obesity both have an impact on the DM prevalence among Qatari adults.

Furthermore, social and behavioral factors seem to have an influence on DM prevalence. In general, DM and obesity together are a major problem in the State of Qatar that requires evidence-based strategies to reduce associated morbidity and premature death. The results of this study might help public health and medical professionals in planning and implementing effective and sustainable interventions.

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Conflicts of Interest

None declared.

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Abbreviations

BMI: Body mass index
BP: Blood pressure
DM: Diabetes mellitus
FBG: Fasting blood glucose
NCDs: Noncommunicable diseases
PSUs: Primary sampling units
STEPS: STEPwise survey
WC: Waist circumference
WHO: World Health Organization
WHS: World health survey

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Viewpoint

The Case for Jointly Targeting Diabetes and Depression Among Vulnerable Patients Using Digital Technology

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Abstract

It is well publicized that mobile and digital technologies hold great promise to improve health outcomes among patients with chronic illnesses such as diabetes. However, there is growing concern that digital health investments (both from federal research dollars and private venture investments) have not yet resulted in tangible health improvements. We see three major reasons for this limited real-world impact on health outcomes: (1) lack of solutions relevant for patients with multiple comorbidities or conditions, (2) lack of diverse patient populations involved in the design and early testing of products, and (3) inability to leverage existing clinical workflows to improve both patient enrollment and engagement in technology use. We discuss each of these in depth, followed by new research directions to increase effectiveness in this field.

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KEYWORDS

diabetes; depression; chronic illness; digital health; vulnerable populations

Introduction

Targeting Conditions Like Diabetes and Depression Simultaneously

Depression and diabetes are highly comorbid disorders that are of major public health concern, particularly among low-income populations [1]. Having diabetes doubles the risk of depression [2]. Comorbidity of the 2 disorders is associated with increased mortality [3] and worse clinical outcomes, including increased diabetes symptoms, poorer glycemic control, poorer self-management, and higher likelihood of complications [4]. There is a growing body of literature that suggests that physical activity is strongly linked to both depressive symptoms and glycemic control [5-10], making self-management strategies with an emphasis on initiating and maintaining physical activity levels a high priority [11]. In fact, targeting depression by increasing physical and social activity, also known as behavioral activation, may be more palatable to patients and as effective as approaches focused on thoughts and emotions alone [12]. Stress management, healthy coping strategies, and problem solving are also key elements of behavioral interventions for both diabetes and depression [13]. However, interventions have tended to focus on *either* depression or diabetes alone, despite their co-occurrence and similar behavioral treatment strategies. The siloed approach to addressing conditions individually is often criticized, yet it remains the standard approach in both traditional health care and digital health.

Technology-based interventions like text messaging and smartphone applications have shown some efficacy in helping patients engage in the healthy behaviors but similarly remain siloed in their approaches. Thinking creatively about targeting common elements such as physical activity management to improve mood as well as blood sugar levels is one novel way to ensure that patients facing multiple chronic conditions do not

need to download or enroll in multiple programs to be able to work on improving their health. For example, there is evidence that 1-way educational content delivered via texting can improve diabetes outcomes for vulnerable patient populations [14], and this content could be combined with passive sensing technology on smartphones to provide even more personalized support on physical activity behaviors using accelerometers that could benefit patients with both diabetes and depression without significant tracking effort required for patients [15,16].

Lack of Design and Testing With Diverse Patients

Underserved and vulnerable patient populations from low-income and racial/ethnic minority backgrounds face the disproportionate burden of chronic disease like diabetes in the United States, and yet few digital health products are designed with these patients' needs and skills in mind. As of October 2015, smartphone ownership in the United States was at 68% with Latinos (64%) and African Americans (68%) very close to the overall ownership rate. Individuals with incomes under $30,000 (52%) and those whose highest level of education was less than high school (41%) or high school (56%) had lower rates of smartphone ownership rate [17]. Including diverse patient populations with complex health care conditions in user-centered design work would better reflect the general patient population and their competing needs and lived experiences in everyday life [18]. Diversity in participants also ensures a wide range of feedback, as opposed to only recruiting participants who have extensive prior experience using technology and give much different types of information about the digital solution. For example, we understand the importance of designing within safety net populations to ensure that the content is easy to understand and available in the appropriate format and languages. Also, digital health interventions may be experienced differently based on one's cultural and social context. For example, during a text messaging intervention for depression, Spanish speakers tended to report feeling cared for and supported while English speakers reported that the intervention helped them be more self aware [19]. In the end, it is more likely that mobile interventions will be accessible and easy to use for all patient populations if they are designed and tested with diverse patients from the outset, which has direct implications for widespread dissemination and implementation [20].

Thoughtfully Linking Digital Programs to Clinical Processes to Increase Patient Engagement

We see a role for mobile technology to extend existing care processes to provide support for patients in between office visits to reduce the burden on providers and to make integrated treatment more personalized, efficient, and available [21]. It is clear from the growing body of literature that mobile interventions result in even larger effect sizes when the messages are integrated into existing clinical care structures [18,21-25]. For example, patients are more likely to sign up for technology programs when they have an established relationship with a provider or health care system that will be sponsoring the program, and digital health interventions are most effective when they are combined with real or perceived connections to health care providers [26]. In many instances, patients state that they feel that their provider is directly communicating with them via technologies like texting, even if the content is mostly automated on the back-end [19].

In addition, clinical practitioners recognize the importance of increasing holistic support for patients with both depression and diabetes [27-29] but acknowledge that providing intensive, in-person comanagement cannot be ramped up without improved clinic capacity and/or efficiency. In this realistic understanding of time constraints, technology can then serve as a means to reach a larger group of patients with personalized educational or motivational content. For example, there is evidence that self-reported patient data such as mood ratings collected via technology can be a proxy for more intensive gold standard measures [30]. Without much additional effort, the same clinic-embedded technology platform could also be used to subsequently identify nonresponsive individuals as the program progresses. Clinic staff members could use the nonresponse data to target intensive in-person support to nonengaged patients who need it most. This is particularly salient because one of the primary barriers to the widespread implementation of technology-enabled interventions is the ability to keep patients engaged in using the programs over time. Several real-world examples have shown that uptake of many digital interventions is high at the onset but wanes quickly over time [31]. Particularly for vulnerable patient populations, there are higher levels of competing life demands that make long-term participation in disease self-management programs challenging [32]. Therefore, targeting and planning for some level of human support from the clinic is essential in maintaining use with digital interventions.

Future Research Directions

Codesign of Technology Among Diverse Patients With Multiple Chronic Conditions

As the first steps in creating technology relevant for diverse patients with both diabetes and depression, we have ensured that our research team (1) reflects both behavioral health and physical health expertise and (2) is situated within outpatient clinics that serve predominantly low-income patients who bring a wide variety of life experiences to this work. We will use this environment to ensure that our user-centered design and technology usability testing represents a diversity of people so that the final products can be applied more broadly. Sampling directly from patient populations served in public health care systems and community health centers can ensure that the future uptake of the technology will not be hindered by fundamental challenges of digital literacy, health literacy, and/or language accessibility.

Integrated Focus on Primary Care Integration and Leveraging Technology to Improve Patient Engagement

Moving forward, we will also continue to aim for clinic integration whenever possible. The roles of technology and in-person clinic relationships are likely cyclical and reinforcing. For example, the perceived connection with a provider may be a powerful component that increases enrollment into technology

programs offered within a clinic setting. In turn, the technology might provide engagement/usage data that can then allow clinics to know to whom and when to reach out to solve barriers and improve sustained participation in the program. In other words, rather than offering one-on-one support to all participants, technology can help triage one-on-one intensification *only* to those not responding to the initial automated messaging. Our goal also includes answering important research questions about how much human support and when is ideal to reach the highest number of people.

Considerations of Low-Cost Technology Solutions for Widespread Impact

Finally, our team will continue to investigate technologies that are widely accessible for low-income and diverse populations rather than designing for the newest devices or services. For example, the widespread use, low cost, and highly scalable nature of text and other messaging technologies (eg, WhatsApp, Facebook Messenger) makes them potential tools in reducing disparities. While the digital divide is wide for use of broadband Internet and for smartphone use, mobile technologies are pervasive across the socioeconomic spectrum, making messaging an ideal tool to increase the reach, adoption, and implementation of efficacious interventions for chronic illness. Furthermore, text messaging is a powerful common denominator technology that can be powerful when combined with back-end programming and machine learning that can take data that are received and act upon them in a personalized manner. When these data are analyzed and visualized by a clinician, they can also inform provider decision making. For example, clinicians could be alerted when individuals have had long periods of lower than average activity or mood to intervene and problem solve at indicated times. The bottom line is that technologies continue to change, but our research program will focus on key functions like messaging that will continue to be a core tool of digital health for many years to come.

Conclusions and Implications

In order for digital health technologies to achieve their promise, they must address health in a more holistic way that helps prevent and treat the various health conditions that people manage without having to engage in various interventions. In this essay, we have presented the example of diabetes and depression as 2 interventions that can be addressed simultaneously by a broader vision of supporting key health behaviors like physical activity and stress management. It is also important to create and test these technologies with populations most impacted by health problems, in particular, vulnerable and underserved populations. Last, in order to reach scale, digital health technologies should be integrated into clinical care so that data can be integrated and used to improve quality and efficiency. If these steps are taken, we believe that digital health can maximize its positive impact on improving population health.

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Conflicts of Interest

None declared.

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Original Paper

Impact of Facebook on Glucose Control in Type 1 Diabetes: A Three-Year Cohort Study

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Abstract

Background: As the world is changing, traditional health care services should be adapted for the new era of technology and the Internet. One of the possible ways for communication between health care providers and patients is social media. There are several benefits of social media in health: increased interactions with others; more available and shared information; increased accessibility; social or emotional support.

Objective: The aim of this study was to evaluate the results of Facebook and CareLink software as a possible Internet tool to improve diabetes control in type 1 diabetes patients using a sensor augmented pump.

Methods: A total of 67 adolescents with type 1 diabetes and in the age range of 14-23 years were randomized in 2 groups: (1) Traditional group and (2) Internet group. In the traditional group, 34 patients were treated using standard medical protocol with regular clinic visits, where data were uploaded at the clinic and interventions (pump settings-basal bolus insulin and education) were delivered to the patient. In the Internet group, 33 patients were treated using Facebook and CareLink software (Medtronic Diabetes) on a monthly basis, where the data were uploaded by the patient at home and interventions (same as traditional group) were delivered via Facebook (written reports and chats). Both the traditional and Internet group had regular visits every 3 months with standard medical protocol. Glycosylated hemoglobin (HbA1c) was obtained before and every 3 months during the study for a 3-year-period.

Results: The improvement in glucose control was found in both groups: 7.9% (SD 1.4) [62.8 mmol/mol (SD 12.9)] to 6.9% (SD 1.2) [51.9 mmol/mol (SD 10.8)] in the traditional group, and 7.8% (SD 1.8) [61.7 mmol/mol (SD 17.2)] to 6.7% (SD 1.8) [49.7 mmol/mol (SD 17.3)] in the Internet group). Significant improvement of HbA1c (P<.05) was found in favor of the Internet group.

Conclusions: Social media such as Facebook as a tool can assist in standard medical care to improve glucose control in a long term period in adolescents with type 1 diabetes using insulin pump therapy.

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KEYWORDS

social media; type 1 diabetes; insulin pump; Facebook

Introduction

Diabetes is a public health problem of increasing magnitude. The prevalence of diagnosed diabetes increased by 49% from 1990 to 2002 and is expected to increase by 165% from 2000 to 2050 [1]. Health care providers are faced with an increased need of services with enormous number of patients and visits.

As the world is changing, traditional health care services should adapt to the new era of technology and the Internet.

Patients use the Internet to seek, meet, and interact with a community of patients with similar problems to share clinical information and to provide and receive support [2-4]. This is a new type of dynamic online communication in contrast to earlier health-related websites. It offers patients an opportunity to benefit from a social media to learn about their illness and to gain support from others with similar experiences.

Patients are becoming increasingly active on the Web [5]. One study reports that searching for health care information was the third most common Web-based activity [6], whereas the other study reports that 72% of adult Internet users search for support and medical information on the Web [7]. Other studies demonstrate that 67% of Internet users were using social media for whichever purpose, whereas 26% were using it for health-related issues [8].

One of the possible ways to deliver Internet care is social media, which can be defined as a group of Web-based applications that allow for the creation and exchange of user-generated content [9].

There are several benefits [10] of using social media in health: increased interactions with others, increased availability and sharing of information; increased accessibility; and peer, social, or emotional support. But there are also some limitations: lack of reliability, quality concerns, lack of confidentiality and privacy, risks of disclosing personal information on the Web, and harmful or incorrect advice.

Social media is sometimes viewed as manipulative and often perceived as a contradiction in terms because it is often interpreted as the business of selling goods and services. On the other hand, it can be used as a social purpose for behavior change and improved health [11].

There are different types of social media and they can overlap among the various services. With over 1.78 billion active monthly users worldwide in 2016 [12], Facebook is an important Web-based meeting place for social networking. Many specific groups for disease management have arisen on Facebook, representing important sources of information, support, and engagement for patients with chronic disease. However, relatively little research has been conducted for disease management. Facebook and Facebook groups serve as promotional spaces, support patients and their families [13], are repositories of recruitable research subjects, and serve as venues for the solicitation and provision of forms of disease management knowledge not necessarily available through more formal channels of professional consultation [14]. Recent studies evaluate the data of Facebook groups, where the mothers of children with type 1 diabetes seek and provide information to better manage the disease's daily demands [15] with 5 dominant thematic clusters ("*food and correction,*" "*diabetes and life,*" "*hi group,*" "*bureaucracy,*" and "*needle*"). The data from discussion boards with use of computer technology can assist health care providers to address these problems and improve glucose control and quality of life [16]. Facebook group "Diabetes Macedonia" was formed by patients' needs in 2008. Its first task was to share diabetes information among patients. It is a closed group that helps patients to communicate and share their experience with other patients. The enormous growth of new users (1840 patients, family members, etc, by September 2012) led to the creation of a structured platform by health care providers (doctors and nurses) to adjust and correct the information posted by patients, if needed.

The aim of the study was to evaluate results of Facebook and CareLink software as a possible Internet tool to improve diabetes control in adolescents with type 1 diabetes on sensor augmented pump. To our knowledge, this is the first long-term study where Facebook is used as a supplemental treatment to traditional clinic visits.

Methods

Study participants included adolescents with type 1 diabetes, aged 14-23 years, with diabetes duration of 6.1 (2.3) years, treated with an insulin pump and sensor for at least 6 months, and had at least two outpatient visits to our center in the past year with intention to return. We did not find significant difference of glycosylated hemoglobin (HbA_{1c}) level in the beginning of the study with 6 months before entering the study.

Patients were recruited at their regularly scheduled appointments, where the adolescent met with a trained research assistant who obtained written informed consent and assent, respectively. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2005. Eligible patients and families were sequentially approached until 70 agreed to participate (3 patients did not finish the study).

Patient's participation was on a voluntary basis, and the opportunity to join the Facebook group "Diabetes Macedonia" was promoted in our service with an appropriate information packet. Patients were randomized in 2 groups:

- Traditional group: A total of 34 type 1 diabetes patients were treated using standard medical protocol with regular visits at clinic, where the data were downloaded using CareLink professional software (Medtronic Diabetes) at the clinic, and intervention (education, pump settings, basal and bolus insulin) were delivered to the patient.
- Internet group: A total of 33 type 1 diabetes patients were treated using CareLink personal program (Medtronic Diabetes), where the data were uploaded by the patient at home, automatically transferred to CareLink Professional, and interventions (same as traditional group) were delivered via Facebook (written reports and chats).

Insulin pump therapy was performed using aspart, lispro, and glulisine in a Medtronic insulin pump (model 722 or Veo) with a Medtronic MiniLink sensor. En-lite sensors (Medtronic Diabetes) were used on a continuous basis during the study and patients were encouraged to use the sensor at least 80% of the time. A CareLink personal account was prepared for all the patients and linked to the CareLink Professional software, which was used to analyze diabetes control.

During the entire study, all the patients received a standardized protocol of education about correct diabetes control provided by diabetologist and diabetes nurse, including carbohydrate counting, balanced nutritional program, and regular physical activity (3 h a week).

Patients from both groups were members of the Facebook group, and all of them got an opportunity to share their experience. Health care providers followed the posts on Facebook and intervened if anyone needed further information and advice. This information was available for patients from both groups. The traditional and Internet group had the same intervention delivered by different methods retrospectively (in clinic visit vs Facebook visit).

The duration of visit was 22 min (SD 4.5) in the traditional group and 21 min (SD 3.2) in the Internet group. The communication in the Internet group was performed using Facebook messages and chats.

Internet visits were mostly performed by physicians, and changes in the pump (ICHR, ISF, basal rates, and bolus wizard) was done by patients, if needed. Advice from nurses was mainly on support and technical aspects (low and high blood sugar, regular SMBG, infusion rotation, tubing, etc).

The following characteristics were evaluated (self-reports and previous medical history): age, duration of diabetes, and body mass index. Severe hypoglycemic events (defined as glucose level <2.8 mmol/l and inability to self-treat, requiring treatment by another person, where glucagon or intravenous glucose was required to solve the situation), and diabetic ketoacidosis (DKA) episodes (defined as hospital admission due to ketoacidosis with positive ketonemia or ketonuria, hyperglycemia >11 mmol/L and pH <7.3, and clinical signs with episodes of hyperglycemia) were also evaluated during the study.

Hb_{A1c} (by high-performance liquid chromatography, reference value 4.6-5.8% [26.8 mmol/mol (SD 39.9)]) was measured every 3 months during the study in the 3-year-period. Mean blood glucose and insulin requirements were obtained from CareLink software every 3 months. Weight was measured at the beginning and at the end of the study.

Statistical analysis was performed with SAS version 8 for Windows (SAS Institute). Frequency distributions and appropriate summary statistics for central tendency and variability were used to describe possible differences between the two groups. The analyses included paired *t* tests to compare potential differences in Hb_{A1c} between two groups from baseline.

Results

Clinical characteristics are shown in Table 1. There was no significant difference of patient's characteristics.

All patients had Hb_{A1c} above 7.5% (58.5 mmol/mol) before enrolling in the study. Hb_{A1c} decreased in both groups: 7.9% (SD 1.4) [62.8 mmol/mol (SD 12.9)] to 6.9% (SD 1.2) [51.9 mmol/mol (SD 10.8)] in the traditional group, and 7.8% (SD 1.8) [61.7 mmol/mol (SD 17.2)] to 6.7% (SD 1.8) [49.7 mmol/mol (SD 17.3)] in the Internet group), with significant difference in the Internet group at the end of the study.

We did not find significant difference in TDD of insulin and weight change during the study. We noticed three DKA episodes in the Internet group (cannula occlusion and flu), in comparison with two DKA episodes in the traditional group (cannula occlusion), but there was no significant difference (Table 2). There were no severe hypoglycemia events in both groups.

Table 1. Clinical characteristics of patients enrolled in the study.

Patient characteristics	Traditional group	Internet group	*P* value
Number	29	27	
Age (years), mean (SD[a])	16.9 (2.7)	17.4 (2.4)	.54
Gender			
Male	13	12	
Female	16	15	
Diabetes duration (years), mean (SD)	5.6 (2.1)	5.4 (2.8)	.92
BMI[b], mean (SD)	22.4 (3.8)	21.7 (3.4)	.64

[a]SD: standard deviation.

[b]BMI: body mass index.

Table 2. Glucose control of patients before and at the end of study. Severe hypoglycemia and Diabetic Ketoacidosis (DKA) are calculated as total number of events during the study.

Glucose control	Baseline		After 3 years		
	Traditional group	Internet group	Traditional group	Internet group	*P* value
Hb_{A1c}[a] (%), mean (SD[b])	7.9 (1.4)	7.8 (1.8)	6.9 (1.2)	6.7 (1.8)	<.5
Hb_{A1c} (mmol/mol), mean (SD)	62.8 (12.9)	61.7 (17.2)	51.9 (10.8)	49.7 (17.3)	<.5
Mean blood glucose (mmol/l), mean (SD)	9.7 (3.2)	9.8 (2.9)	8.8 (2.4)	8.6 (2.8)	<.5
TDD[c] insulin (units), mean (SD)	48.6 (1.9)	45.4 (2.1)	51 (2.6)	49 (1.7)	NS[d]
Severe hypoglycemia			0	0	NS
DKA[e]			1	2	NS

[a]Hb_{A1c}: glycosylated hemoglobin.

[b]SD: standard deviation.

[c]TDD: total daily insulin.

[d]NS: not significant.

[e]DKA: Diabetic Ketoacidosis.

Discussion

This study evaluates Facebook as a tool for communication and treatment in type 1 diabetes patients on the insulin pump compared with traditional clinic visits.

Outside of the Internet, social media have been shown to improve disease management and health outcomes for patients [17,18]. The use of social media in health care has been widely advocated [19,20], but there is little evidence describing the current state of the science and whether or not these tools can be used to treat the patient and to evaluate the potential benefits [21]. A recent study shows that use of the CareLink system with regular upload and contact with a diabetes team is associated with significantly improved glycemic control in compliant patients on sensor augmented pump [22]. Our findings demonstrate that social media can be used as an Internet tool for treatment of type 1 diabetes patients on the insulin pump as a part of traditional clinic visits. The idea of a synergistic relationship between social media users is one of the main perceived advantages of using these platforms [23]. Some of the recent studies suggest that there is inappropriate substitution for in-person visits and can also potentially lead to harmful results [24]. CareLink analysis together with Facebook was used to advice the patients about their diabetes control and to make changes in basal rates, bolus wizard setting, adherence to therapy, approach for low and high blood sugar, and education. Personalization, presentation, and participation in social media and health care make them highly effective [25]. The content can be tailored to the priorities of the patients. Every Internet visit was personalized with the patient's need (appropriate time and date) and used active patient participation in the decision-making process of diabetes management.

Despite the advantages of social media use in health, criticisms have emerged. The availability of misinformation is a risk, as health care providers are unable to control the content that is posted or discussed [26]. Our study tried to overcome these disadvantages, where the posted comments can be used if only the doctors granted the comment with "like." Additionally, accepting new patients in the groups must pass several controls to be assured that they are real.

Several authors speculate and denounce the role of the Internet in diffusing the flow of disease-management information [27,28], which are reported in several studies with empirical data, where self-management and compliance to insulin pump therapy can be improved using telemedicine [29]. Our findings suggest that Facebook diabetes communities contain a plurality of participants, including patients, family members, and health care providers. Our patients share their personal experience about specific issues (eg, hypoglycemia treatment) from which others can gain information and knowledge. Facebook can be used as a motivational tool, where patients post their Hb_{A1c} levels, whereas others support them in the management of their diabetes. We can easily reach the patients with posting educational information on a Facebook group page. Acute complication (DKA and severe hypoglycemia events), TDD insulin, and weight change were not significant in both groups. Our study demonstrates a significant decrease (0.9%) in Hb_{A1c} in the Internet group after 3 years. One of the possible reasons for improved diabetes management can be addressed to Internet monthly visits.

The project was lead on a voluntary basis for both patients and doctors. We are trying to raise a new momentum in the possible treatment of type 1 diabetes using social media and understanding from health care decision makers to include this option in their services.

We found that by using social media, patients gain diabetes knowledge and information, can be closer to their health care providers, and interact in their daily adjustments and moreover, it could help patients cope better with their daily life. This trial suggests that patients with type 1 diabetes prefer to communicate with their health care providers using social media. Social media such as Facebook as a tool can assist in standard medical care to improve glucose control in a long-term period in adolescents with type 1 diabetes using an insulin pump therapy.

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Authors' Contributions

Dr Goran Petrovski had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. GP performed the study concept and design, data acquisition, statistical analysis and interpretation of data, drafting of the manuscript, and clinical revision of manuscript. MZ performed statistical analysis and interpretation of data, drafting of the manuscript, and clinical revision of manuscript.

Conflicts of Interest

None declared.

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