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Original Paper

A Website to Promote Physical Activity in People With Type 2 Diabetes Living in Remote or Rural Locations: Feasibility Pilot Randomized Controlled Trial

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Abstract

Background: Research supports the use of Web-based interventions to promote physical activity in diabetes management. However, previous interventions have found poor levels of engagement or have not included health professionals and people with diabetes in the design of the tool.

Objective: To develop and explore the feasibility and indicative effect of a Web-based physical activity promotion intervention in people diagnosed with type 2 diabetes living in remote or rural locations.

Methods: A qualitative approach using focus groups that included patients with diabetes and health professionals were run to identify key concepts, ideas, and features, which resulted in the design of a physical activity website. This site was tested using a quantitative approach with a qualitative 6-month pilot study that adopted a three-armed approach. Participants were randomized into three groups: a control group who received written diabetes-specific physical activity advice; an information Web group, a Web-based group who received the information online; and an intervention Web group, an interactive Web-based group who received online information plus interactive features, such as an activity log, personalized advice, and goal setting.

Results: A website was designed based on patient and health professional ideas for effective physical activity promotion. This website was tested with 31 participants, 61% (19/31) male, who were randomized into the groups. Website log-ins decreased over time: 4.5 times in month 1, falling to 3 times in month 6. Both the information Web group—mean 134.6 (SD 123.9) to mean 154.9 (SD 144.2) min—and the control group—mean 118.9 (SD 103.8) to mean 126.1 (SD 93.4) min, d=0.07—increased time spent in moderate-to-vigorous physical activity, but this decreased in the intervention Web group—mean 131.9 (SD 126.2) to mean 116.8 (SD 107.4) min.

Conclusions: Access to online diabetes-specific physical information was effective in promoting physical activity in people with type 2 diabetes; access to interactive features was not associated with increases in activity.

Trial Registration: International Standard Randomised Controlled Trial Number (ISRCTN): 96266587; http://www.isrctn.com/ISRCTN96266587 (Archived by WebCite at http://www.webcitation.org/6tzX6YesZ)

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KEYWORDS

blood glucose; diabetes; physical activity; rural; virtual trainer; Web based

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Introduction

Regular physical activity has been shown to be beneficial in the management of type 2 diabetes [1-4], with guidelines recommending that adults should accumulate 150 minutes of moderate physical activity a week [5,6]. Up to 80% of people with type 2 diabetes do not meet these recommendations [7], highlighting the need for the development of effective interventions.

Physical activity interventions have been delivered through face-to-face contact, telephone contact, print and mail materials, and group-based activities [8,9]. Although many interventions have been effective in stimulating physical activity behavior changes, implementation of these methods of delivery into current diabetes practice has often been restricted by lack of time and appropriate personnel for effective delivery. It is also important to identify and create channels of information delivery that can reach a large and broad range of the diabetes population, including those who may not or cannot access more traditional methods of delivery, for example, those living in remote or rural locations [10].

Innovations in technology and access to the Internet have led to an increased number of technology-based interventions. Using technology to deliver an intervention offers several advantages, including the potential reach, continuing availability, and cost containment of the intervention [11]. Web-based interventions have been successfully implemented in promoting physical activity in diabetes self-management [12]. However, these interventions often resulted in poor levels of user engagement [13] and frequently reported major decreases in usage over time [14,15]. There is therefore a need to develop a tool with specific features that aim to increase user engagement.

The primary aim of this study was to utilize coproduction methodology to develop a Web-based physical activity promotion intervention. The secondary aims were to evaluate the feasibility and indication of effectiveness of using this intervention to promote physical activity in people with type 2 diabetes living in remote and rural localities.

Methods

Study Design

This study utilized a mixed-methods research design to incorporate coproduction into the development of the intervention. Using a qualitative approach, focus groups were conducted with people living with type 2 diabetes to explore the key features of a Web-based physical activity promotion intervention. Quantitative data was collected on overall and individual component use of the intervention and an objective measure of physical activity and sedentary behavior was conducted. The full study was approved by the North of Scotland research ethics committee (12/NS/0115) and was conducted according to the principles of the Helsinki agreement. The trial was registered with the International Standard Randomised Controlled Trial Number (ISRCTN) Registry (ISRCTN96266587).

Research Design of Focus Groups

Recruitment

Participants were recruited through purposive sampling from diabetes clinics, diabetes volunteer lists, and posters put up in general practice surgeries. Inclusion criteria included the following: diagnosis of type 2 diabetes, over 18 years of age, and ability to communicate verbally in English.

A total of 30 participants (18 males, 12 females) with a mean age of 63 (SD 12) years participated in four patient focus groups—focus group 1 (n=8), focus group 2 (n=8), focus group 3 (n=7), and focus group 4 (n=7)—held over a 4-month period. One group was also run with health professionals (n=6). Participants who attended these groups lived in rural or remote locations in Scotland.

Data Collection and Analysis

NVivo (QSR International) and thematic analysis were used with initial codes generated in a systematic fashion across the dataset. Coding was carried out and collated into tables, which were separated by themes and subthemes. This was then reviewed to ensure the themes worked in terms of each individual code. Coding checks were conducted on a subset of three of the five transcripts by researchers external to the research team to ensure consistency within themes as recommended by Barbour [16].

Research Design for Website Testing

Overview

To test the effectiveness of the intervention, in addition to the active intervention group there were two comparator groups: one group had access to the website, but not interactive features to control for any effect of online information access, and a second was provided with written information only.

Recruitment and Randomization

A total of 31 participants, not previously involved in the focus groups, who were diagnosed with type 2 diabetes were recruited from primary and secondary care sites from three rural localities in Highland Region, Scotland. The aim was to recruit between 10 and 12 participants per group. The method of randomization for this pilot trial was to use opaque envelopes to conceal group allocation from the researcher, which the Cochrane Review reports as having a low risk of bias [17]. Envelopes were prepared by a researcher who was not involved in the study and allowed for equal numbers across the recruitment areas in each of the intervention groups.

Participants were included in the study if they met the following criteria: diagnosed with type 2 diabetes managed through lifestyle or oral medication; over 18 years old; resident in Inverness, Isle of Skye, and Sutherland areas; and had access to a computer with Internet access. Exclusion criteria included the following: treatment with insulin therapy, to reduce the potential for immediate effects on glycemic control and need for insulin adjustment; unable to understand study requirements or give informed consent; visual or hearing impairments or physical disability; or diabetes-related complication that precluded ability to increase physical activity.

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Participants met with the research nurse on three occasions: baseline, 3 months, and 6 months. During the first visit, demographic and medical details were collected and participants were randomized using opaque envelopes into one of the three groups: the interactive Web group (InterG) had online access to diabetes-specific physical activity information and interactive features; the information Web group (InfoG) were given online access to diabetes-specific physical activity information, but not interactive features; and the control group received leaflets based on the website material. Each of the three sites was inducted into the study in a stepped-wedge approach over 6 weeks.

Primary Outcome: Website Measures

To assess use of the website, log-on to the site was monitored with each participant given personalized log-on details, which were then used to measure contact over the 6 months. Access to the site without logging in was not measured. The use of interactive features on the site was recorded for each participant to assess frequency of use and thus determine those features most likely to be useful in future versions of the website.

Secondary Outcomes

Assessment of Physical Activity

To assess the effectiveness of the intervention, data on physical activity were collected. Data were also collected on standard anthropometric measurements and glycated hemoglobin (HbA1c), a measure of glycemic control, both of which may be impacted by change in physical activity. These data were collected from all groups at three intervals across the duration of the study. Participants wore an ActiGraph GT3X+ monitor (ActiGraph, LLC) around the waist for 7 days at baseline, 3 months, and 6 months. Accelerometer data were downloaded and analyzed using ActiLife data analysis software, version 6.10 (ActiGraph, LLC). A 60-second epoch was applied with a minimum wear time of 10 hours per day on at least 4 days, including one weekend day. A time of 60 minutes and over of consecutive zeroes was considered nonwear time and was excluded from analysis. The following Freedson adult cut-points were applied to categorize physical activity [18]: sedentary, 0-99 cpm; light, 100-759 cpm; lifestyle, 760-1951 cpm; moderate, 1952-5724 cpm; vigorous, 5725-9498 cpm; and very vigorous, ≥9499 cpm.

Anthropometric Measurements and Blood Sampling

All measures were carried out by a research nurse. Body mass index (BMI) was calculated as weight in kg over height in m^2(kg/m^2). Waist circumference was calculated in cm and was taken in the midpoint between the iliac crest and the lowest rib. A blood sample was drawn at baseline, 3 months, and 6 months and analyzed at the hospital clinical laboratory for HbA1c using a high performance liquid chromatography (HPLC) method (Tosoh Bioscience) on diabetes control and complications-aligned equipment.

Statistical Analysis

Data were analyzed using SPSS version 22 (IBM Corp). After normality-testing, repeated-measures analysis of variance (ANOVA) or the nonparametric Friedman k related-samples tests were used, Bonferroni corrections were applied. Data are presented as mean (SD). As this was a pilot study, a sample size calculation was not performed so, in addition to the arbitrary significance level of .05, the effect size is reported. Effect size was calculated using Cohen *d*, where 0.2 indicates a small effect, 0.5 indicates a medium effect, and 0.8 indicates a large effect. Outliers more than 3 standard deviations from the mean were removed per variable.

Results

Web Features Developed in Response to the Focus Groups

Overview

Excerpts from focus groups are displayed in Table 1 and Multimedia Appendix 1.

Virtual Coach

Groups highlighted a perceived need for support to increase their physical activity (Excerpt 1.0). To accomplish this, the website was centered on a virtual coach, Dave; all interface conversations with the site were between the user and Dave. This was to ensure that people felt that the website provided personal advice structured to each individual.

Ask the Expert

The need for support led to the creation of an *Ask the expert* section of the website to allow users the opportunity to speak to the physical activity expert. This allowed users the chance to ask physical activity-related questions related to their diabetes to a physical activity expert through the interface of Dave.

Physical Activity Tracker

A tool for users to evaluate the physical activity they had undertaken was suggested to enable users to make more active choices (Excerpt 2.0). A tracker diary to help monitor activity was built into the site. This tracker allowed users to enter type and duration of the activity displayed in a bar chart permitting users to see days they were active and days they were not active (Excerpt 2.1). A range of physical activity options were available on the drop-down list, based on the American College of Sports Medicine list of activities [19]. The website remembered the activities entered; if more than one activity was carried out in the one day, the activities were stacked.

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Table 1. Quotes from focus groups used to design key features of the website.

Subthemes from focus groups	Example excerpt highlighting subtheme meaning	Participant type	Excerpt number
Importance of support	"I need help in exactly what I need to do; it's not the advice of what to do it's the support of doing it."	Patient	1.0
Monitoring physical activity and diabetes			
	"...sitting down and thinking about what I've done, when I've done it and if I haven't done it I think it would make me think about why I'm not being active."	Patient	2.0
	"...by displaying your activity, say in graph form, it would give you some sort of target and to help you evaluate the days you weren't active."	Patient	2.1
Methods to increase user engagement	"... if you do lands' end and do it in bite-size chunks it doesn't matter how long it takes you to do it, you will still have done it at the end."	Health professional	3.0

Goals and Challenges

An online physical activity consultation based on the transtheoretical model [20] was developed allowing each user to set up realistic incremental goals based on current behavior. The consultation was conducted through a Web interface and gave personalized advice based on what was entered.

Any activity entered into the site was converted into walking using metabolic equivalent values [19] and the distance was added into a challenge (Excerpt 3.0). Users could pick a challenge to complete over a few weeks or months and in theory complete a hypothetical marathon through any number of activities emphasizing the spectrum of activity at a level to suit each individual.

Activities in Local Areas

A Google map was created of physical activity opportunities in Highland Region, pinpointed so users could zoom into their area and find out what was available. This was developed through contact with the Highland council and local groups to ensure opportunities on the map were current. All pinpoints on the map had contact details or Web links to the person or facility running the activity.

Online Intervention

Baseline characteristics of the groups are described in Table 2. Statistical tests—one-way ANOVA (continuous data), chi-square, or Fisher's exact tests (categorical data)—indicated a significant difference between groups for weight: $F_{2,28}$=3.6, P<.04. This was accounted for by the higher percentage of males (80%) in the InfoG; when looking at BMI there were no significant differences across the group. Mean duration of diabetes was highest in the InfoG and lowest in the InterG: 9.3 (SD 5.5) years versus 5.7 (SD 1.6) years.

Regarding study attrition, 5 participants out of 31 (16%) withdrew from the study: 3 out of 11 (27%) InterG, 1 out of 10 (10%) InfoG, and 1 out of 10 (10%) control group. Figure 1 shows the flow diagram of recruitment and attrition.

Changes in Primary Outcome: Website Measures

Total log-in counts for the website was 262. Over the first 3 months, each participant logged in an average of 12.5 (SD 15.7) times dropping to 11.3 (SD 37.1) times from 3- to 6-month follow-up. There was a large range in the number of log-ins, starting at zero and going up to 50 times in 1 month. In the last 2 months, only 1 person continued to use the website. Table 3 highlights log-in rates per month of study.

Out of the features, only *goal setting* and *log book* were used. The *log book* feature was used 142 times in the first 3 months and increased to 191 times in the second 3 months. The *goal setting* feature was used 108 times in the first 3 months and dropped to 61 times in the second 3 months. Usage broken down per month is highlighted in Figure 2. The most common goal was walking, with 41 goals set in the first 3 months and 83 goals set in the second 3 months. Other goals included swimming, stair climbing, cleaning, cycling, gardening, and circuit training.

Changes in Secondary Outcomes

Physical Activity

Table 4 reports the ActiGraph accelerometer-defined physical activity results broken down into groups at baseline, 3 months, and 6 months.

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Table 2. Baseline demographic characteristics of participants in the interactive Web, information Web, and control groups.

Characteristic	Interactive Web group (n=11)	Information Web group (n=10)	Control group (n=10)
Gender (male), n (%)	6 (55)	8 (80)	4 (40)
Age (years), mean (SD)	67.3 (10.4)	66.2 (8.4)	66.5 (6.0)
Duration of diabetes (years), mean (SD)	5.7 (1.6)	9.3 (5.5)	6.9 (4.1)
Weight (kg), mean (SD)	83.1 (11.6)	100.0 (15.9)	88.7 (16.1)
BMI[a](kg/m^2), mean (SD)	30.3 (4.2)	33.0 (5.5)	31.4 (5.8)
Metformin therapy, n (%)	9 (82)	5 (50)	6 (60)
Lifestyle only, n (%)	2 (18)	5 (50)	4 (40)

[a]BMI: body mass index.

Figure 1. Recruitment and attrition flow diagram for pilot randomized controlled trial.

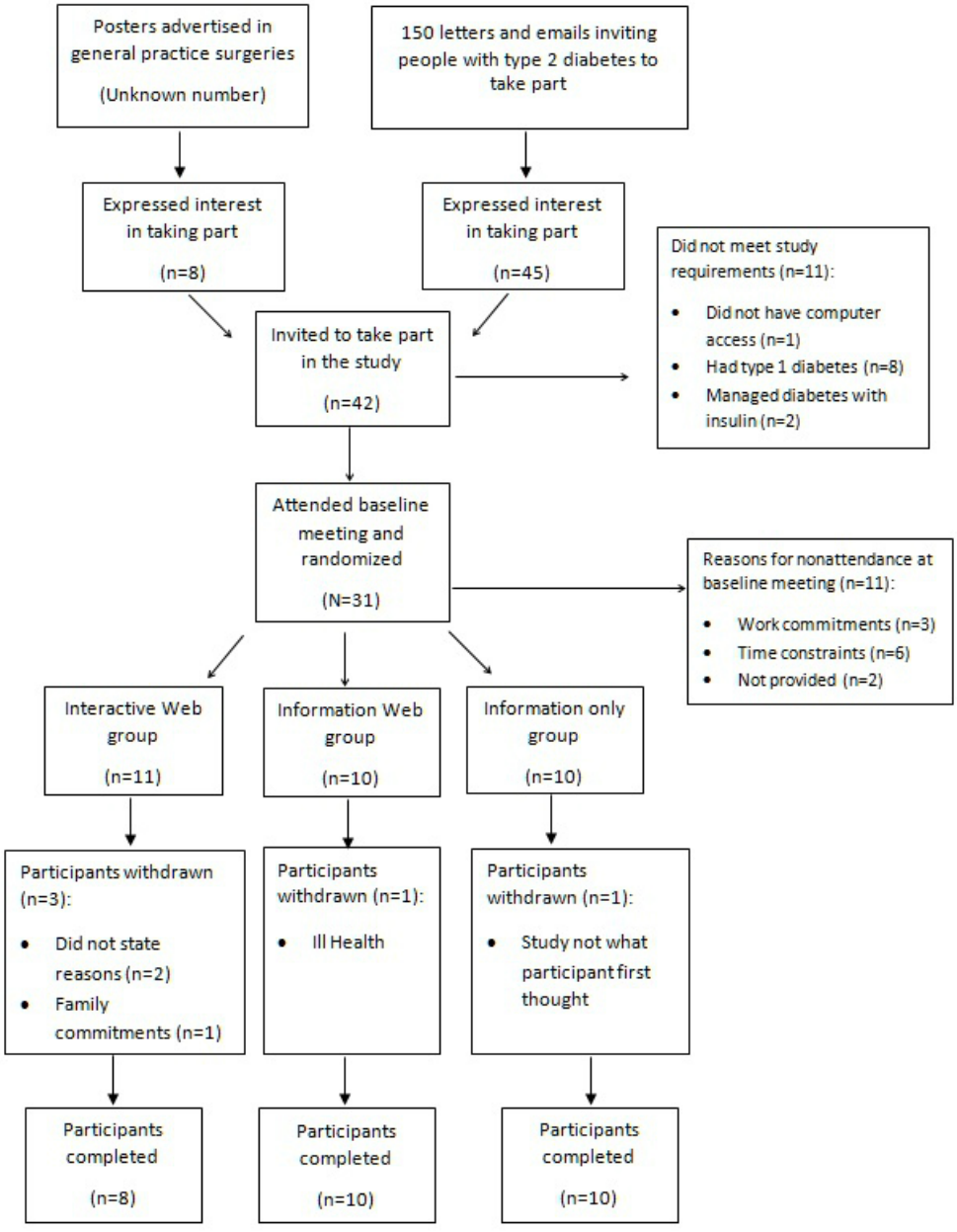

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Table 3. Log-in rates per month broken down into intervention months.

Month	Number of log-ins			
	Minimum, n	Maximum, n	Sum, n	Mean (SD)
1	0	14	48	4.4 (4.2)
2	0	27	55	5.0 (7.7)
3	0	16	34	3.1 (4.9)
4	0	39	40	3.6 (11.7)
5	0	50	50	4.5 (15.1)
6	0	34	34	3.1 (10.3)

Figure 2. Use of interactive features over time.

Table 4. Changes in ActiGraph accelerometer-defined physical activity data broken down into groups and collection dates.

Physical activity	Interactive Web group (n=11), mean (SD)			Information Web group (n=10), mean (SD)			Control group (n=10), mean (SD)		
	Month 0	Month 3	Month 6	Month 0	Month 3	Month 6	Month 0	Month 3	Month 6
Light (min/wk)	1136.8 (334.7)	896.8 (176.4)	1160.4 (302.2)	1169.9 (501.0)	1225.2 (422.0)	1211.6 (376.0)	1271.2 (288.3)	951.8 (280.8)	1249 (313.1)
Lifestyle (min/wk)	360.5 (182.9)	294.5 (145.7)	332.8 (302.2)	301.4 (191.2)	397.9 (188.9)	361.6 (188.9)	374.9 (174.3)	303.8 (56.3)	459.3 (149.8)
Moderate (min/wk)	127.1 (127.0)	72.2 (64.1)	108.4 (108.3)	127.5 (178.0)	134.0 (147.8)	140.1 (40.9)	112.9 (102.7)	83.4 (66.8)	121.7 (96.7)
Vigorous (min/wk)	4.8 (3.9)	2.0 (1.7)	8.4 (5.9)	7.1 (2.1)	8.5 (2.7)	14.8 (4.6)	5.7 (1.4)	2.5 (0.8)	9.6 (1.5)
Moderate-to-vigorous (min/wk)	131.9 (126.2)	74.2 (65.6)	116.8 (107.4)	134.6 (123.9)	142.5 (135.9)	154.9 (144.2)	118.9 (103.8)	86.5 (74.1)	126.1 (93.4)
Step count (steps/wk)	33,571 (20,134)	22,949 (10,398)	30,058 (16,116)	33,655 (24,684)	35,271 (20,679)	37,083 (25,387)	33,412 (20,845)	25,716 (10,414)	34,597 (17,675)
Sedentary time (total min/wk)	3275 (646)	2509 (756)	3004 (485)	3202 (759)	3129 (997)	3055 (807)	2993 (662)	2429 (776)	2833 (764)
Sedentary time (max bout in min)	72.5 (16.8)	41.4 (35.4)	37.7 (38.4)	69.5 (17.4)	78.8 (21.6)	55.4 (7.4)	68.2 (22.6)	47.4 (25.8)	47.6 (35.8)
Sedentary time (mean bout in min)	22.4 (1.2)	22.4 (2.3)	22.8 (3.9)	22.8 (3.0)	23.5 (2.6)	22.8 (4.1)	21.6 (2.8)	21.6 (2.9)	21.6 (2.6)

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Moderate-to-Vigorous Physical Activity

Regarding moderate-to-vigorous physical activity (MVPA), the InterG dropped from 131.9 (SD 126.2) to 74.2 (SD 65.6) min/week at 3 months, increasing to 116.8 (SD 107.4) min/week at 6 months: *d*=-0.12. The control group dropped from 118.9 (SD 103.8) to 86.5 (SD 74.1) min/week at 3 months, increasing to 126.1 (SD 93.4) min/week at 6 months: *d*=0.07. The InfoG increased from 134.6 (SD 123.9) to 142.5 (SD 135.9) min/week at 3 months, furthering increasing to 154.9 (SD 144.2) min/week at 6 months: *d*=0.15.

Total Sedentary Time

The InterG's sedentary time decreased from 3275 (SD 646) to 2509 (SD 756) min/week at 3 months, increasing to 3004 (SD 485) min/week at 6 months: *d*=0.5. In the InfoG, sedentary time decreased from 3202 (SD 759) to 3129 (SD 997) min/week at 3 months, further decreasing to 3055 (SD 807) min/week at 6 months: *d*=0.18. Within the control group, there was a decrease in total sedentary time from 2993 (SD 662) to 2429 (SD 776) min/week at 3 months, followed by an increase to 2833 (SD 764) min/week at 6 months: *d*=0.2. Table 5 reports the ActiGraph accelerometer-defined physical activity results broken down into groups at baseline, 3 months, and 6 months.

The InterG increased in light intensity percentage from 23.2 (SD 4.9) at baseline to 24.0 (SD 6.1) at 3 months: *d*=0.1. They also increased in lifestyle intensity percentage from 7.3 (SD 2.5) at baseline to 7.8 (SD 2.8) at 3 months: *d*=0.18. Sedentary behavior percentage decreased slightly in the InterG group from 66.7 (SD 7.6) at baseline to 66.5 (SD 6.1) at 3 months: *d*=0.02.

The control group increased their sedentary behavior percentage from 62.9 (SD 6.3) at baseline to 64.4 (SD 10.4) at 3 months: *d*=0.17.

Table 5. ActiGraph accelerometer-defined physical activity data broken down into wear-time percentage.

Physical activity	Interactive Web group (n=11), mean (SD)			Information Web group (n=10), mean (SD)			Control group (n=10), mean (SD)		
	Month 0	Month 3	Month 6	Month 0	Month 3	Month 6	Month 0	Month 3	Month 6
Light (%/wk)	23.2 (4.9)	24.0 (6.1)	25.0 (4.6)	24.3 (4.1)	25.0 (3.4)	25.0 (4.0)	26.7 (4.5)	25.2 (6.3)	26.7 (7.4)
Lifestyle (%/wk)	7.3 (2.5)	7.8 (2.8)	7.2 (2.3)	6.3 (3.0)	8.1 (3.6)	7.6 (3.0)	7.8 (3.5)	7.6 (3.3)	9.8 (5.1)
Moderate-to-vigorous (%/wk)	2.7 (2.2)	1.9 (2.3)	2.2 (3.0)	2.8 (3.0)	3.0 (1.9)	3.5 (2.8)	2.5 (1.9)	2.3 (2.5)	2.7 (2.3)
Sedentary time (total %/wk)	66.7 (7.6)	66.5 (6.1)	65.6 (6.1)	66.6 (7.5)	63.0 (6.4)	62.8 (7.2)	62.9 (6.3)	64.4 (10.4)	60.7 (11.9)

Table 6. Changes in physiological measures broken down into groups and collection dates.

Physiological measure	Interactive Web group (n=11)			Information Web group (n=10)			Control group (n=10)		
	Month 0	Month 3	Month 6	Month 0	Month 3	Month 6	Month 0	Month 3	Month 6
Weight (kg), mean (SD)	83.1 (11.6)	84.5 (13.1)	81.8 (12.8)	100.0 (15.9)	100.1 (14.4)	99.0 (15.8)	88.7 (16.1)	87.1 (15.7)	87.7 (5.6)
BMI[a](kg/m^2), mean (SD)	30.3 (4.2)	30.5 (4.0)	29.3 (4.1)	33.0 (5.5)	33.0 (5.1)	32.7 (5.6)	31.4 (5.8)	30.9 (5.8)	31.0 (5.6)
Waist circumference (cm), mean (SD)	104.0 (10.9)	106.0 (10.4)	102.8 (10.2)	118.3 (12.7)	113.6 (10.3)	114.2 (11.1)	108.3 (13.4)	107.2 (14.4)	101.0 (11.7)
HbA1c[b](mmol/mol), mean (SD)	57.7 (11.2)	56.7 (10.0)	54.1 (9.5)	51.8 (8.0)	55.7 (7.6)	57.5 (9.1)	55.3 (13.7)	54.4 (15.6)	50.5 (5.9)
HbA1c, %	7.5	7.4	7.1	6.9	7.3	7.5	7.2	7.1	6.8

[a]BMI: body mass index.

[b]HbA1c: glycated hemoglobin.

Changes in Physiological Measures

All changes in physiological data are displayed in Table 6. Waist circumference decreased in the InfoG from 118.3 (SD 12.7) to 113.6 (SD 10.3) cm at 3 months, then increased to 114.2 (SD 11.1) cm at 6 months: *d*=0.34. It decreased in the control group from 108.3 (SD 13.4) cm at baseline to 107.2 (SD 14.4) cm at 3 months, then further decreased to 101.0 (SD 11.7) cm at 6 months: χ^2_9= -2.1, *P*<.02, *d*=0.5.

The InterG HbA1c decreased from 57.7 (SD 11.2) to 56.7 (SD 10.0) mmol/mol at 3 months, further decreasing to 54.1 (SD 9.5) mmol/mol at 6 months: *d*=0.34. The InfoG increased from 52.4 (SD 8.2) to 55.8 (SD 8.0) mmol/mol at 3 months, then

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decreased to 55.0 (SD 4.7) mmol/mol at 6 months: *d*=-0.38. The control group dropped from 55.3 (SD 13.7) to 54.4 (SD 15.6) mmol/mol at 3 months, further decreasing to 50.5 (SD 5.9) mmol/mol at 6 months: *d*=0.45.

Discussion

Principal Findings

This composite study is unique in that it reports on patient-identified features of a Web-based physical activity promotion intervention, overall and individual component use of the online intervention, together with change in physical activity. Patient-identified features included a *physical activity tracker*, *user support*, *goal setting*, *ask the expert*, *what is on*, and *interactive challenges*. Of the identified and included features within the online intervention, only the *activity log book* and *goal setting* were used.

Overall access to the website was good, specifically in the first 3 months of the intervention. This reduced in the second half of the intervention, which is common in Web-based interventions [13,21]. However, when education was combined with interactive elements, it did not result in any significant changes in physical activity. The two interactive features that were consistently used were *goal setting* and the *physical activity log book*; of these, neither appeared to be particularly effective in increasing physical activity, in contrast to previous research where those who used goal setting and log books had greater increases in physical activity [11].

Including patients in the design was key in the development of the current intervention. Even though the International Organization for Standardization principles [22]—recognized to ensure quality management—were followed, with more time, user-design workshops would have been helpful. These workshops would allow those using the site to test the features they deemed to be useful in an iterative fashion in process evaluation to determine their role in promoting activity. Longer-term interventions should be conducted to assess sustainability and strategies to increase engagement with the site.

This study provides some support for the use of online diabetes education in the promotion of physical activity. Although no significant change was reported in physical activity levels, a trend toward increasing physical activity was recorded in the InfoG, with 50% (5/10) in the InfoG meeting the current guidelines for physical activity at the end of the study. Online, tailored, physical activity advice has been shown to be effective in the general population [23], with interactive emails resulting in greater increases in physical activity. These are encouraging findings and endorse access to specific Web-based information to increase time spent in physical activity. Access to diabetes-specific physical activity information should be considered in endeavors to support patients with type 2 diabetes in becoming more physically active.

Access to interactive features resulted in a nonsignificant drop in physical activity. The reason for this is unclear, but this pattern was mirrored in the control group and seasonal reasons described in other studies could be postulated to explain the pattern [24]. However, a stepped-wedge method was used for recruitment into the trial, with equal numbers of participants randomized into each group per site and each site starting the intervention at a separate time. Given that these results were not observed in the InfoG makes it less likely and raises the question of whether issues with the interactive part of the website may have been a factor.

There was no significant difference in wear time across all groups and time points and all participants met wear-time criteria defined in the methods section. There were discrepancies in the data for the InterG in terms of light physical activity, lifestyle physical activity, and sedentary time, as well as for the control group in sedentary time from baseline to 3 months. However, none of these were significant and had low effect sizes. The main ActiGraph secondary outcome was MVPA and there was no difference in weekly wear-time percentage compared to minutes.

The current intervention did not contain any specific information on decreasing sedentary behavior; however, there was a trend toward decreases in total time spent in sedentary behavior, which may have been at the expense of increasing physical activity, which concurrently decreased. Thereafter, as physical activity increased, total sedentary time subsequently also increased in parallel, possibly due to a compensatory increment in resting time as individuals became more active. The benefits of decreasing sedentary spells are becoming more widely studied, with improvements in metabolic health suggested [25] and an acknowledgment that decreasing sedentary time is just as important as increasing physical activity in terms of health outcomes [26]. Moreover, evidence has shown that even people who meet the current guidelines for physical activity suffer adverse effects from too much sitting time, irrespective of meeting physical activity guidelines [27].

Although the study was not powered to detect significant changes and the mean HbA1c level reflected reasonable control at baseline, for the majority of patients in the InterG there were nonsignificant decreases in HbA1c across the 6 months. This may reflect the shorter duration of diabetes and higher percentage of participants receiving oral antidiabetic therapy in this group. The explanation for the upward trend in HbA1c with increases in MVPA in the InfoG is not clear, although it has been reported in other studies [28]. Possible reasons may include changes in diet or medication associated with increased physical activity, a component that was not a measured outcome of this study.

Waist circumference was used as a surrogate marker for abdominal fat mass; significant reductions were observed in the InfoG despite a lack of change in weight. Studies have shown that even without weight loss, increased physical activity is associated with reductions in fat mass [29], which can improve insulin sensitivity and in turn lead to improvement in blood glucose levels.

Limitations

The study had a small sample size with only 31 participants in total. As this was a pilot intervention, no sample size calculation was undertaken and effect size was reported as an alternative.

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Future research should include in-depth follow-up, such as qualitative interviews, to explore the issues participants may or may not have had with the interactive features and so participants can provide feedback on what was useful and/or effective in promoting activity and engagement with the site.

All groups received new information on top of usual care procedures. The information received was diabetes-specific physical activity advice to aid in the promotion of physical activity. This new information, as well as increased patient contact, could influence outcomes.

Comparison With Prior Work

Unlike previous work, this paper reports on the development and feasibility testing of the codesigned tool. It reports on what health professionals and people with type 2 diabetes considered to be essential tools for engagement with the site and support to increase physical activity and compared this with what was actually used. This study supported the use of a Web-based physical activity promotional intervention to communicate personalized physical activity education, which resulted in increased physical activity behavior in people with type 2 diabetes.

Conclusions

Web-based physical activity information was associated with a trend toward increased physical activity across a 6-month intervention in people with type 2 diabetes. Interactive features were not effective in increasing physical activity participation.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Excerpts from focus groups that aided in the development of the website.

[PDF File (Adobe PDF File), 34KB - diabetes_v2i2e26_app1.pdf]

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Abbreviations

ANOVA: analysis of variance
BMI: body mass index
HbA1c: glycated hemoglobin
HPLC: high performance liquid chromatography
InfoG: information Web group
InterG: interactive Web group
ISRCTN: International Standard Randomised Controlled Trial Number
MVPA: moderate-to-vigorous physical activity

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Original Paper

Web-Based Weight Loss Intervention for Men With Type 2 Diabetes: Pilot Randomized Controlled Trial

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Abstract

Background: Rising obesity levels remain a major public health concern due to the clear link with several comorbidities such as diabetes. Diabetes now affects 6% of the UK population. Modest weight loss of 5% to 10% has been shown to be associated with significant reductions in blood sugar, lipid, and blood pressure levels. Men have been shown to be attracted to programs that do not require extensive face-to-face time commitments, illustrating the potential audience available for health behavior change via the Web.

Objective: The objective of our study was to evaluate the feasibility and acceptability of a Web-based weight loss intervention in men with type 2 diabetes.

Methods: We conducted a pilot, parallel 2-arm, individually randomized controlled trial with embedded process evaluation. Participants were randomly assigned in a one-to-one ratio to the usual care group or the 12-month Web-based weight loss intervention, including dietitian and exercise expert feedback. Face-to-face recruitment and assessment were performed by the researcher unblinded. Data collected included weight, height, body mass index (BMI), and waist circumference, together with an audit trail of eligibility, recruitment, retention, and adherence rates. A process evaluation (website use data and qualitative interviews) monitored adherence, acceptability, and feasibility of the intervention.

Results: General practice database searches achieved the recruitment target (n=61) for the population of men with type 2 diabetes, of whom 66% (40/61) completed 3-month follow-up measurements. By 12 months, the retention rate was 52% (32/61), with 12 of the 33 men allocated to the intervention group still active on the website. The intervention was seen as acceptable by the majority of participants. We gained insights about acceptability and use of the website from the parallel process evaluation.

Conclusions: Recruitment to the Web-based weight loss intervention was successful. Results are descriptive, but there were positive indications of increased weight loss (in kilograms and as a percentage), and reduced waist circumference and BMI for the intervention group from 3 to 12 months, in comparison with control. This research adds to the evidence base in relation to incorporating a Web-based weight loss intervention within the UK National Health Service (NHS). NHS weight loss services are struggling to provide sufficient referrals. Therefore, alternative modes of delivery, with the potential to reduce health professional input and time per patient while still enabling individual and tailored care, need to be investigated to identify whether they can be effective and thus benefit the NHS.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN): 48086713; http://www.isrctn.com/ISRCTN48086713 (Archived by WebCite at http://www.webcitation.org/6rO4xSlhI)

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KEYWORDS

weight loss; Web-based intervention; feasibility studies; pilot RCT; randomized controlled trial; pilot projects; type 2 diabetes; diabetes mellitus, type 2; men; men's health; process evaluation

Introduction

The direct cost of obesity in the United Kingdom is estimated at more than £5 billion per year [1] to the National Health Service (NHS). The prevalence of obese adults (body mass index [BMI] ≥30 kg/m^2) in England is 24.9% for men and 25.2% for women [2-4]. This is cause for concern, due to the clear link between obesity and several comorbidities such as diabetes [5,6]. The risk of developing type 2 diabetes is increased considerably for people categorized as obese compared with those who have a healthy weight [7,8], with 65% to 80% of new cases of diabetes being attributed to patients being overweight or obese [9].

Diabetes now affects 6% of the UK population, with around 90% of those having a diagnosis of diabetes found to have type 2 diabetes. Complications of diabetes affect the eyes (retinopathy), heart (cardiovascular disease), kidneys (nephropathy), and nerves and feet (neuropathy) [10]. Modest weight loss of 5% to 10% is associated with significant reductions in blood sugar, lipid, and blood pressure levels [11,12].

Recruiting men to weight loss programs is notoriously difficult, with men less likely to attend NHS or commercially run weight loss services [13-17]. Men were attracted to programs that did not require extensive face-to-face time commitments [17], suggesting the potential for men to favor or at least be accepting of Web-based interventions. A previously used individualized Web-based service was shown to be successful in decreasing glycated hemoglobin and 2-hour postprandial blood glucose test in obese patients with type 2 diabetes [18].

Evidence suggests that traditional primary care management (one-to-one dietitian or practice nurse consultations) can be costly and subject to high attrition rates [19,20]. Therefore, alternative methods for effective weight loss need to be investigated.

Using the Web for a weight loss intervention may provide a suitable alternative owing to the available audience already using the Internet. In 2016, 89% of households in Great Britain (23.7 million) had Internet access, an increase from 86% in 2015 and 57% in 2006, with 82% of adults accessing the Internet almost every day in 2016 [21]. The number of households in the United Kingdom with Web access is increasing annually in all age groups [22]. Over half (51%) of Web users actively used the Internet to investigate health issues, increasing from 18% in 2007 [21].

Internet-based interventions have the potential to minimize the stigma that may be experienced during face-to-face consultations, increase accessibility, privacy, and control for the user, and reduce the cost of an intervention [23,24].

Although the number of studies on Web-based weight loss interventions has increased, conclusions on their effectiveness still remain uncertain. Previous reviews have identified the potential of Web-based weight loss interventions to result in greater weight loss and engagement with physical activity and diet in comparison with a control group [25-27]. Intervention characteristics have been shown to be heterogeneous [26,28]. In a previous review, commonly incorporated active ingredients in Web-based weight loss interventions, identified using the Coventry, Aberdeen, and London-Refined (CALO-RE) taxonomy [29], included providing feedback on performance, planning social support or social change, prompting self-monitoring of behavior or behavioral outcome, and goal setting (behavior and outcome) [30]. The review also identified that incorporating personalized feedback within Web-based weight loss interventions led to greater weight loss in comparison with control groups providing no personalized feedback [30].

There is a range of modes of delivery that can be used when providing a Web-based weight loss intervention: websites or mobile app-based technology; automated or human feedback; and text messages, email, or Web-based messaging [30].

Web-based weight loss interventions have the potential to offer long-term programs at a low cost due to their potentially greater reach, in comparison with traditional face-to-face approaches [23,31]. Effectiveness remains unclear, and there are many uncertainties regarding feasibility and acceptability of the intervention and of trial processes. Therefore, a definitive trial, preceded by a randomized pilot trial, is needed.

The aim of this study was to evaluate the feasibility and acceptability of a Web-based weight loss intervention, and the trialing of that intervention, for men with type 2 diabetes.

Methods

We conducted a parallel-group 2-arm patient randomized rehearsal pilot randomized controlled trial (RCT) with embedded process evaluation. The pilot RCT was multicentered, consisting of patients registered with general practices within the catchment area of County Durham and Darlington in northeast England.

The aim was to recruit and randomly allocate 60 patients. A suggested sample size for pilot trials is 30 participants per arm, to enable estimation of parameters for a future trial [32,33].

Inclusion and Exclusion Criteria

We aimed to recruit men who had a diagnosis of type 2 diabetes and had a BMI of at least 30 kg/m^2 but less than 40 kg/m^2 at baseline measurement. The BMI inclusion criterion was 30 kg/m^2 or greater, as this is the inclusion criterion for the majority of NHS tier 2 (lifestyle interventions) or tier 3 (specialist services) weight management services in England [34]. As this

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study was examining the change in service delivery of weight management within the NHS, we followed the criterion used within the NHS. When a patient reaches a BMI of 40 kg/m^2, lifestyle modification may no longer be appropriate and bariatric surgery may be recommended [35]. Men had to be aged 18 years or older, with no upper age restrictions.

Participants were required to have access to the Web (at home, the workplace, or a public location) on any device (desktop computer, laptop, tablet, or mobile phone).

We excluded patients unable to give written informed consent or access the intervention in English (resource constraints precluded adaptation of the intervention for non-English speakers) or who were identified by their general practitioners (GPs) as having a contraindication to the weight loss intervention (such as previous eating disorders or other mental health problems).

Ethics

The study was accepted onto the UK National Institute for Health Research clinical research network portfolio and registered (October 26, 2012) on a clinical trial registry (ISRCTN: 48086713). We gained NHS ethical favorable opinion from National Research Ethics Service Committee East of England - Cambridge Central Proportionate Review Sub-committee on August 9, 2012 (Research Ethics Committee reference: 12/EE/0361).

Recruitment

We recruited participants through GP database searches; we identified participating practices through the UK Primary Care Research Network. In response to participant invitation letters, potential participants could state their intention by completing an attached reply slip and returning by reply-paid mail to the research team. Participants could also contact the research team directly via email or telephone. Those who did not want to take part in the research could return the slip and (optionally) provide a reason why. During baseline appointments in GP offices, participants provided written informed consent to the researcher (AH) prior to baseline measurements.

The researcher (AH) then randomly allocated each participant to 1 of the 2 arms using the Sealed Envelope Web-based system (Sealed Envelope Ltd). Randomization was by a one-to one allocation, to either usual care (control group) or the Web-based intervention group. We used stratification to ensure that the potential confounding variable of diabetes medication was balanced between the intervention and control arms, since this might affect outcomes. The strata were diet only, oral hypoglycemic agents, or insulin. Participants who were taking insulin and tablets were assigned to the insulin stratum. Participants were informed of allocation via postal letter by the researcher (AH). Blinding of intervention allocation was not possible for anyone involved in the pilot trial.

The control arm experienced usual care for weight loss, according to their general practice's normal processes. This was a pragmatic trial and we did not seek to influence what was offered to the patient, with no specific arrangements to review or refer participants.

Participants randomly allocated to the intervention group were sent log-in details and encouraged to log in to the intervention website [36] before their initial face-to-face consultation with their assigned dietitian.

We asked participants randomly allocated to the intervention to state whether they were engaged in any other weight loss services. None of the intervention group were using any other services.

Intervention Description

The website (My Dietitian) was created by PraksisCare (Odense, Denmark) based on a previous study that had identified successful weight loss via a Web-based intervention [37]. We worked together with PraksisCare to develop and adapt the My Dietitian intervention to make it relevant for use within the United Kingdom and the NHS. Table 1 describes the intervention based on the Template for Intervention Description and Replication checklist [38].

A key feature of the 12-month intervention was the Web-delivered consultations (embedded email-style messages sent within the website), which were delivered to participants by health care professionals (dietitians and exercise experts). Consultations were delivered in accordance with a scheduled protocol created prior to the start of the study (Table 1). The initial one-off face-to-face meeting with the dietitian was conducted in an hour-long appointment slot. Dietitians were expected to provide Web-based consultations on a maximum weekly basis for the first 3 months (n=12) and then monthly for the last 9 months (n=9; total planned dietitian contact n=21). Exercise experts provided Web-based consultations on a maximum monthly basis for the first 3 months (n=3) and then every 3 months for the last 9 months (n=3; total planned exercise expert contact n=6). There were thus 15 planned consultations (diet and activity) in total over the first 3 months and 27 by the end of the 12-month intervention.

Time taken to write the consultations varied across the participants based on the required advice. The content of the consultations was at the professional discretion of the dietitians and exercise experts. Every intervention participant received personalized Web-based consultations from their designated dietitian and exercise expert. This feedback was based on participant input on the website and was typically concerned with areas of improvement in relation to dietary intake and physical activity.

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Table 1. Template for Intervention Description and Replication (TIDieR) checklist[a] for the My Dietitian Web-based weight loss intervention.

TIDieR checklist item	Description
What	
Consultant feedback	The health care professionals received training on setting SMART[b] goals with the participants and putting together action and coping plans, addressing barrier identification, and problem solving. An initial one-off consultation with the dietitian face-to-face was then followed by a structure of scheduled Web-based consultations, with the patient also able to contact the professional in between if needed. The user received a notification that feedback was available for them to read. Consultations provided the user with information in relation to their weight status and recommendations on how to improve their behaviors. Example food diaries provided users with instructions on how to perform the behavior. (BCT[c]: provide feedback on performance; provide instruction on how to perform the behavior; provide information on consequences of behavior in general; provide information on consequences of behavior to the individual; action planning; relapse prevention and coping planning; barrier identification and problem solving; goal setting: behavior and outcome).
Daily food intake input	Type and amount of food and time consumed. Information could be converted into calories consumed and represented in a pie chart showing percentages for food types consumed. (BCT: prompt self-monitoring of behavior; provide feedback on performance).
Physical activity input	Type, time, and intensity of any completed physical activity, which could be translated into calories burned. (BCT: prompt self-monitoring of behavior; provide feedback on performance).
Diet budget	Daily outline of calories consumed, calories burned and the allowance they have remaining. (BCT: Prompt self-monitoring of behavior; Provide feedback on performance).
Body measurements	Participants had the option to record waist and weight measurements and amount of steps taken presented in a graph to display participant's progress as part of the intervention. (BCT: prompt self-monitoring of behavior and behavioral outcomes; provide feedback on performance).
My community	Users could interact through forums, diaries, and chat rooms. Recipes and relevant articles were available to users. (BCT: plan social support and social change).
Who provided	Registered dietitians and exercise experts (Health Improvement Specialists)
How	Individually delivered via the Web
Where	A one-off face-to-face meeting with the dietitian in the participants' homes. Then solely Web-based delivery.
When and how much	12-month intervention. The initial one-off face-to-face meeting with the dietitian was conducted in an hour-long appointment slot. Dietitians provided Web-based consultations on a maximum weekly basis for the first 3 months (n=12) and then monthly for the last 9 months (n=9, total maximum planned dietitian contact n=21). Exercise experts provided Web-based consultations on a monthly basis for the first 3 months (n=3) and then every 3 months for the last 9 months (n=3, total planned maximum exercise expert contact n=6). Total maximum consultations over the first 3 months n=15, total maximum consultations at the end of the 12-month intervention n=27. The content of the consultations was at the professional discretion of dietitians and exercise experts.
Tailoring	Every intervention participant received personalized Web-based consultations from their designated dietitian and exercise expert. This feedback was based on participant input on the website.
Modifications	No modifications were made during the study
Fidelity	
Planned	A protocol of Web-based consultation provision was created for the dietitians and exercise experts. Fidelity was assessed by monitoring website use and consultation provision by dietitians and exercise experts.
Actual	Website use data identified the number of delivered consultations in comparison with the number planned before the start of the intervention
Included BCTs from CALORE taxonomy[d]	Prompt self-monitoring of behavior Prompt self-monitoring of behavioral outcomes Provide instruction on how to perform the behavior Provide information on consequences of behavior in general Provide information on consequences of behavior to the individual Provide feedback on performance Action planning Relapse prevention and coping planning Barrier identification and problem solving Goal setting (behavior) Goal setting (outcome) Planning social support and social change

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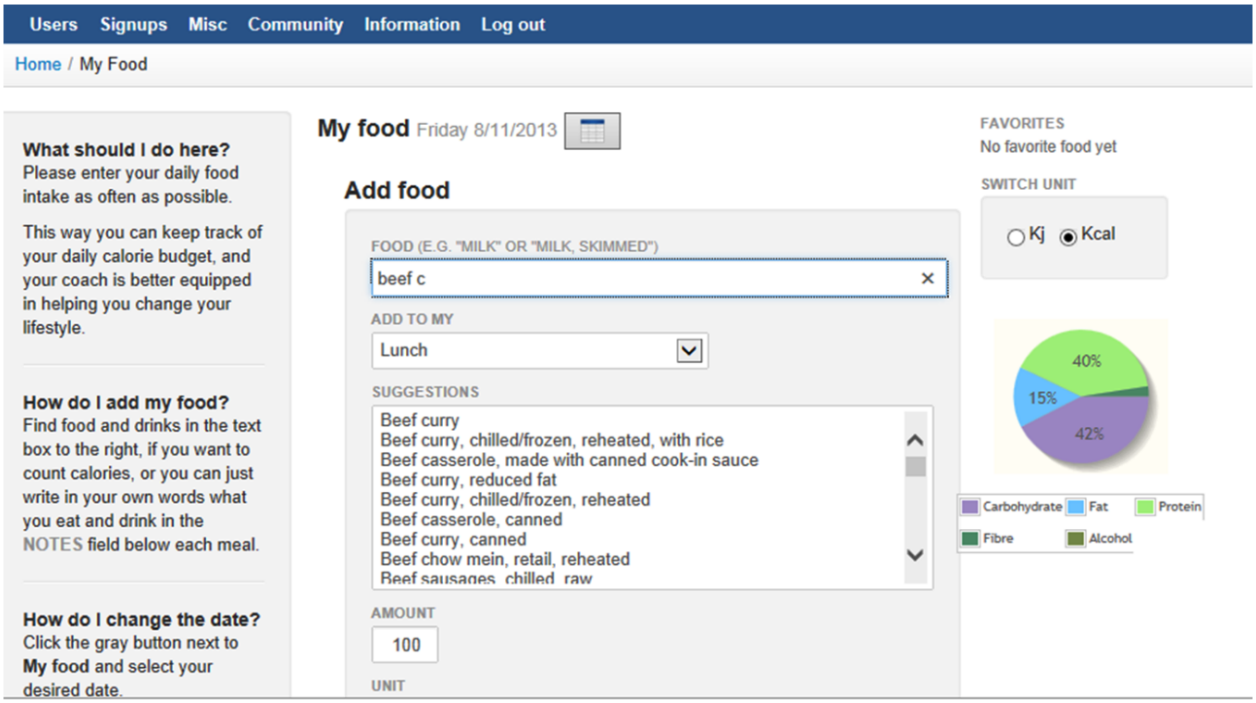
[a]Based on Hoffmann et al [38].

[b]SMART: specific, measurable, agreed upon, realistic, and time-based goals.

[c]BCT: behavior change technique.

[d]CALO-RE: Coventry, Aberdeen, and London-Refined taxonomy [29].

Figure 1. My Dietitian website screenshot of dietary intake entry page.



Website pages allowed participants to record their personal daily dietary intake (Figure 1), physical activity, or weight status, which was viewed by the health care professionals. Participants were advised to enter their dietary intake (all meals, snacks, and drinks) and physical activity on a daily basis. Using the website features was important so that the health care professionals were able to provide thorough consultations to the participants. Other features were less interactive but were provided to inform or encourage participants, such as a database of recipes, relevant articles on physical activity, diet and weight loss advice, and the ability to chat online with other participants.

We recruited and trained 2 NHS dietitians and 2 exercise experts to work on the study intervention, the My Dietitian website. The health care professionals provided quality assurance checks on the content of the website. Training consisted of 2 half-day sessions covering behavior change techniques relevant to weight loss, an overview of the Web-based intervention, and practical sessions to enable the health care professionals to become familiar with and competent at using the website.

Primary Outcomes

The primary outcomes were recruitment and retention in the trial, as measured by rates of eligibility, response to invitation, ineligibility, declines, consent, and retention for data collection at 3 and 12 months. Within the parallel process evaluation, we examined adherence to the intervention through collection of website use data. We examined acceptability of the intervention by conducting semistructured interviews with participants.

Secondary Outcomes

Secondary outcomes were comprehensiveness and feasibility of the measures proposed as primary or secondary outcomes in the future definitive RCT (anthropometric measures: body weight, height, BMI, and waist circumference). Losing 5% of one's initial body weight is a target recommended by UK National Institute for Health and Care Excellence guidelines to improve health [35]. Another secondary outcome was parameter estimates of the proposed primary and secondary outcomes measures for the future definitive RCT to inform sample size calculations.

Reporting of the rehearsal pilot RCT follows the Consolidated Standards of Reporting Trials (CONSORT) statement extension to randomized pilot and feasibility trials guidelines [39] (see Multimedia Appendix 1 for the study's CONSORT checklist [40]).

Data Collection

Data collection points were at baseline, 3 months, and 12 months and were completed in GP offices. Rates of eligibility, recruitment, randomization, retention, attrition, and adherence were logged from the initial invitation letters through intervention allocation (baseline) to follow-up (3 and 12 months), enabling an audit trail to be maintained [41].

We collected process evaluation data for adherence by tracking and monitoring website use. Website data were collected in relation to number of website log-ins for participants, self-monitoring diaries completed (food and dietary intake and

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exercise entries), number of consultations made by the health professionals to the participants, and Web-based messages sent to the health professionals by the participants. Any food and dietary intake that was entered on the website on a given day was classified as 1 entry, and the same also applied to exercise entries.

We examined acceptability and feasibility through semistructured interviews conducted once with participants, lasting between 15 and 60 minutes, at the end of the 12-month study.

Anthropometric measures were collected at baseline, 3 months, and 12 months. We recorded height using a Leicester height stadiometer (Marsden Weighing Group Ltd, Rotterham, England), with participants asked to stand as straight as possible with their shoes off. Body weight was measured using calibrated Shekel personal floor scales (H151-7, Class III; Shekel Scales Ltd, Lower Galilee, Israel), allowing capacity weight up to 250 kg. Each participant was required to produce 2 body weight readings to check for consistency (within 0.1 kg). If these were not consistent then a third reading was required, and the average of the 3 readings was used as the final body weight recording. Participants remained clothed but were asked to remove coats and shoes. The Shekel scales also allowed a participant's height to be entered along with body weight to calculate a BMI recording. Waist circumference was measured, midway between the lowest rib and the iliac crest, underneath clothing, using a tape measure.

Data Analysis

We examined the number of participants and percentages to identify rates of eligibility, response to invitation, ineligibility, declines, consent, and retention at baseline, 3 months, and 12 months.

The recorded website data were examined to identify average number of log-ins for participants, self-monitoring diaries completed (dietary intake and exercise inputs), consultations by health professionals to the participants in comparison with scheduled consultations, and diaries and messages sent to the consultants by participants. We also examined adherence to the intervention in terms of the number of users and nonusers of the website at each time point to identify adherence over time and by population group.

Interviews were recorded and transcribed. Qualitative data were imported into NVivo 10 software (QSR International) and analyzed using framework analysis, a 5-step process: familiarization, identification of a thematic framework, indexing, charting, and mapping (interpretation) [42,43].

We used descriptive statistics to characterize rates of completion for anthropometric measures, rates of implausible values, and 5-figure summaries (minimum, maximum, median, and lower and upper quartiles). We also calculated means and standard deviations to inform sample size calculations for a potential definitive trial. Quantitative data were analyzed using IBM SPSS Statistics version 21.0 software (IBM Corporation).

Results

Eligibility, Recruitment, Retention, and Attrition

A total of 8 general practices agreed to perform database searches to identify potential participants, but 1 did not complete the searches due to time pressures. Practice size ranged from 1663 to 19,976 patients and varied in terms of location: town centers (n=3), housing estates (n=2), and rural villages (n=2).

Figure 2 shows the CONSORT diagram. GP database searches achieved the recruitment target after a period of 5 months, with a total of 61 men providing consent and being randomly allocated. The first patient was recruited during November 2012 and March 2013, with the last 12-month follow-up appointment held in March 2014. Of the participants, 66% (40/61) completed 3-month follow-up measurements. By 12 months, retention rates had 32/61 (52%) of the men remaining.

Response Rates

Men with diabetes (n=968) were identified from database searches (Figure 2). The response rate, expressed as those who stated an interest in joining the study as a percentage of those contacted by their practice, was 85 of 968 (8.8%). Only a small proportion of these were found to be ineligible at the baseline appointment due to changes in BMI (5/968, 0.5%).

Of those invited to the study, 187 of 968 (19.3%) of the men with diabetes explicitly declined to the invitation letter, and 115 of 187 (61.5%) did not give a reason for nonparticipation. The most common reasons for declining participation were no Web access (29/187, 15.5%), work commitments (12/187, 6.4%), poor health (10/187, 5.4%), and age (8/187, 4.3%). Those who declined due to lack of Web access did so in response to the invitation letter. Although this meant they were not eligible for participation, as these patients declined the invitation letter before any contact with the research team, they were never seen at the baseline assessment and therefore were not formally excluded. The vast majority of invited participants did not respond to the letter (696/968, 71.9%).

Data completion rates and retention rates decreased over the study time period (baseline to 3 months to 12 months). For the control group, 12 of 28 (43%) participants had dropped out by 3 months, and 16 of 28 (57%) had dropped out by the end of the study (12 months). For the intervention group, attrition was lower, with 9 of 33 (27%) participants dropping out by 3 months and 13 of 33 (39%) dropping out by 12 months. The main reasons for participants leaving the study were being too busy or having family or work commitments, for both the intervention- and the control-arm participants (Figure 2).

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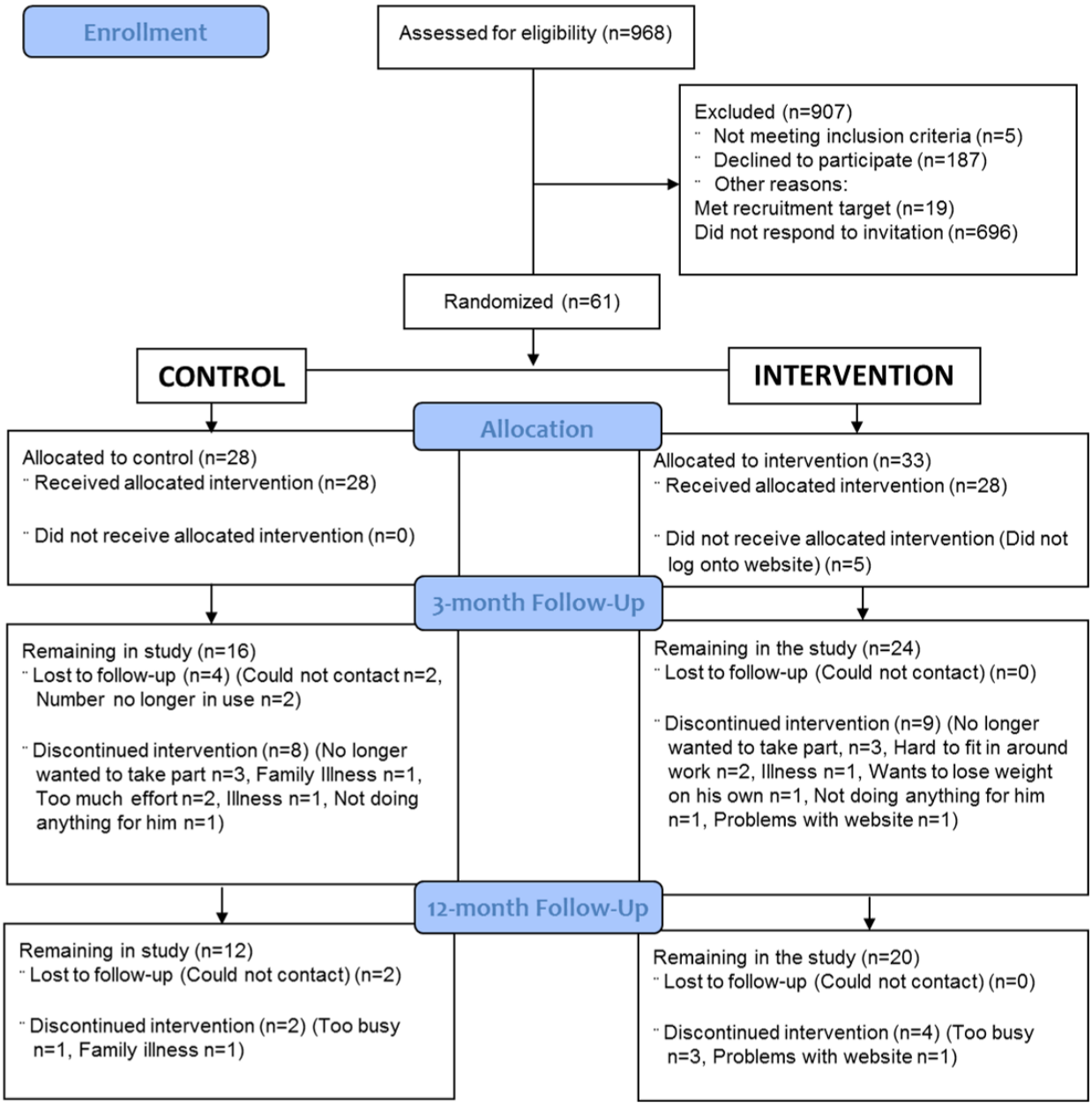
Figure 2. Consolidated Standards of Reporting Trials (CONSORT) recruitment flow diagram.



Anthropometric Measures

Table 2 shows baseline demographic and anthropometric descriptive statistics.

Change variables relate to change in measurements from baseline to 3 months and baseline to 12 months (Table 3). All changes, at both 3 and 12 months, were decreases (ie, positive changes). Of the remaining men in the intervention, 8 lost 5% of their initial body weight at 12 months in comparison with 4 of the control group. In terms of mean weight loss, intervention participants in our study lost on average 5.4 kg (Multimedia Appendix 2).

Process Evaluation (Adherence)

We examined adherence to the intervention in terms of users versus nonusers among those allocated to use the website (intervention group) (Table 4). “Users: relates to participants who entered information onto the website. “Nonusers” were those participants who never logged on to the website or only logged on to register on the website and did not enter any inputs.

At 3 months, the 9 intervention men who dropped out of the study had all been nonusers of the website from the outset (Figure 2).

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Table 2. Baseline demographic and anthropometric measures by intervention status.

Outcome measure	Control (n=28)	Intervention (n=33)
Age (years)		
Median (LQ-UQ)[a]	61 (54.5-66.8)	58 (50-67.5)
Range (min-max)[b]	39 (40-79)	41 (37-78)
White ethnicity, n (%)	28 (100)	33 (100)
Education (years)		
Median (LQ-UQ)	12 (11-12)	12 (10-14)
Range (min-max)	4 (12-16)	6 (12-18)
Employment status, n (%)		
Employed	11 (39)	9 (27)
Self-employed	1 (4)	2 (6)
Unemployed	3 (11)	6 (18)
Retired	11 (39)	14 (42)
Caregiver, sick leave, disabled	2 (7)	2 (6)
Marital status n (%)		
Married or in a relationship	25 (89)	24 (73)
Single	1 (4)	4 (12)
Divorced or separated	2 (7)	3 (9)
Widowed	0 (0)	2 (6)
Weight (kg)		
Median (LQ-UQ)	109.3 (96.9-119.0)	106.5 (100.1-115.4)
Range (min-max)	45.2 (87.2-132.3)	43.2 (86.6-129.8)
Body mass index (kg/m^2)		
Median (LQ-UQ)	34.4 (31.6-37.0)	33.3 (31.6-36.4)
Range (min-max)	9.1 (30.3-39.4)	8.2 (30.4-38.6)
Waist (cm)		
Median (LQ-UQ)	119.5 (114-126.8)	118.0 (112-124)
Range (min-max)	32 (103-135)	33 (100-133)

[a]LQ-UQ: lower quartile to upper quartile.

[b]min-max: minimum to maximum.

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Table 3. Anthropometric measures across assessment times by group (control vs intervention).

Outcome measure	3 months		12 months	
	Control (n=16)	Intervention (n=24)	Control (n=12)	Intervention (n=20)
Weight (kg)				
Median (LQ-UQ)[a]	105.7 (92.3-114.9)	102.2 (97.4-110.3)	100.7 (91.9-118.1)	99.2 (90.7-106.8)
Range (min-max)[b]	38.6 (85.5-124.1)	44.3 (84.4-128.7)	40.3 (86.1-126.4)	46.8 (81.2-128)
Weight change (kg)				
Median (LQ-UQ)	–2.2 (–3.7 to –0.9)	–2.35 (–4.5 to –0.9)	–2.5 (–5.0 to 0.2)	–4.3 (–7.8 to –1.0)
Range (min-max)	9.7 (–8.6 to 1.1)	10.3 (–8.4 to 1.9)	16.1 (–12.6 to 3.5)	21.4 (–18.5 to 2.9)
5% weight loss, n (%)	3 (19)	3 (13)	4 (33)	8 (40)
BMI[c] (kg/m^2)				
Median (LQ-UQ)	33.3 (30.8-36.1)	32.2 (31.1-34.5)	33.3 (29.9-36.8)	31.3 (29.8-33.2)
Range (min-max)	8.7 (28.7-37.4)	9.9 (28.4-38.3)	8.9 (29.3-38.2)	9.9 (27.5-37.4)
BMI change (kg/m^2)				
Median (LQ-UQ)	–0.7 (–1.1 to –0.2)	–0.9 (–1.4 to –0.2)	–0.8 (–1.6 to 0.8)	–1.7 (–2.7 to –0.3)
Range (min-max)	3.2 (–3.0 to 0.2)	3.4 (–2.8 to 0.6)	5 (–3.9 to 1.1)	7.8 (–6.5 to 1.3)
Waist circumference (cm)				
Median (LQ-UQ)	118.5 (109.8-124.8)	112.5 (108.5-122.8)	117 (112.3-126.8)	112 (107-121)
Range (min-max)	22 (106-128)	26 (102-128)	31 (103-134)	21 (103-124)
Waist circumference change (cm)				
Median (LQ-UQ)	–3.0 (–1.3 to –5.0)	–2.0 (–1 to –3)	–2.0 (–3.8 to –1)	–3.5 (–7 to –1.3)
Range (min-max)	11 (–9 to 2)	14 (–11 to 3)	12.5 (–11 to 2)	19 (–17 to 2)

[a]LQ-UQ: lower quartile to upper quartile.

[b]min-max: minimum to maximum.

[c]BMI: body mass index.

Table 4. Website use by intervention participants over the course of the study.

Participants	Baseline (n=33)	3 months (n=33)	12 months (n=33)
Users, n (%)	16 (48)	16 (48)	12 (36)
Nonusers, n (%)	17 (52)	17 (52)	21 (64)

We analyzed website use for those remaining in the intervention group (Table 5). We collected data from 28 men, as 5 intervention participants never registered on the website. Data were examined in relation to their website use between baseline (0 months) and the 3-month data collection point. Data were then examined for website use between 3 months and the end of the study (12 months): 9 intervention participants left the study at the 3-month data collection point and therefore we included 19 men in the analysis. We divided website activity to examine participant's use in relation to food intake and exercise levels, as well as interactions with allocated dietitians and exercise experts (Table 5). As outlined in Table 1 (intervention description), the proposed number of consultations within the intervention protocol over the first 3 months was 15, with the total number of consultations at the end of the 12-month intervention stated as 27. Table 5 shows that 13 of the 15 intended health professional (dietitian, exercise expert) consultations were delivered at 3 months, whereas at 12 months, 22 out of the 27 were delivered. At the end of the intervention, the number of dietitian-delivered consultations was 1 less than the number scheduled to occur (20 out of 21); however, exercise experts averaged up to 4 fewer than scheduled (2 out of 6). Consultations were delivered fewer times than expected due to nonresponsive participants and time pressures on the health care professionals due to competing demands (eg, full-time jobs). Food-related messages from participants to the health professionals were sent more often than exercise messages. The food intake entries were used more frequently than the exercise entries, with both demonstrating high levels of variability between participants (Table 5). No log-in data were obtained at 3 months, as the website hosts did not record this information, and therefore Table 5 shows only 12-month results. Participants did not use the social support features, interactive chat room, and discussion forums at all. We identified no unintended effects were identified from the pilot trial.

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Table 5. Website use data averages per intervention participant.

Type of use	0-3 months (n=28)	3-12 months (n=19)
Dietitian- and exercise expert-sent consultations		
Median (LQ-UQ)[a]	13 (12-15)	22 (20-25)
Range (min-max)[b]	11 (5-16)	15 (14-29)
Dietitian-sent consultations		
Median (LQ-UQ)	12 (10-12)	20 (18-22)
Range (min-max)	10 (4-14)	10 (13-23)
Exercise expert-sent consultations		
Median (LQ-UQ)	2 (1-2)	2 (1-3)
Range (min-max)	4 (0-4)	6 (0-6)
Participant-sent messages		
Median (LQ-UQ)	1 (0-8)	9 (0-32)
Range (min-max)	34 (0-34)	75 (0-75)
Food-related messages		
Median (LQ-UQ)	1 (0-7)	7 (0-29)
Range (min-max)	33 (0-33)	68 (0-68)
Exercise-related messages		
Median (LQ-UQ)	0 (0-1)	1 (0-2)
Range (min-max)	7 (0-7)	7 (0-7)
Food intake entries		
Median (LQ-UQ)	8 (1-59)	99 (3-246)
Range (min-max)	82 (0-82)	330 (0-330)
Exercise entries		
Median (LQ-UQ)	3 (0-26)	22 (2-124)
Range (min-max)	69 (0-69)	262 (0-262)
Log-ins		
Median (LQ-UQ)	N/A[c]	43 (12-167)
Range (min-max)	N/A	490 (1-491)

[a]LQ-UQ: lower quartile to upper quartile.

[b]min-max: minimum to maximum.

[c]N/A: not available.

Process Evaluation (Acceptability)

We conducted 13 semistructured interviews, which enabled us to explore participants' views in relation to the acceptability of the Web-based weight loss intervention. We classified 7 of the interviewees as active users, participants who logged on to the website and entered information until the end of the study, while 6 of the interviewees were nonusers and therefore were no longer using the website by the end of the study. Interviewees' ages ranged from 41 to 78 years.

The main themes identified from the interviews were (1) practicality, (2) interaction with the health care professional, and (3) future development of the Web-based intervention.

Practicality

This theme was discussed in relation to the participant's engagement with the intervention.

> *Rather than have appointments and have to trail wherever it is, I think they're quicker and they're more expedient at getting the message across.* [Participant 20, age 58, active user]

> *It's flexible, communication hasn't got to be restricted to clinic type hours…you can do it when they want…and you haven't got issues with them cancelling.* [Participant 17, age 57, active user]

The website was viewed as more accessible than conventional treatment, such as face-to-face meetings, overcoming the difficulty of fitting restricted clinic hours and appointment times

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into everyday life. Participants also referred to the website as "easy to use" once they had become accustomed to it.

Interaction With the Health Care Professional

Interaction between the health care professionals and the participants was referred to with regard to the relationship built up during the course of the study.

However, participants deemed having a one-off initial face-to-face meeting with the dietitian as important for their future Web-based interaction.

> *This is who I'm talking to and you're not just I don't know a nameless blob out there somewhere they know you're a real person.* [Participant 4, age 58, nonuser]
>
> *That would've helped me because it would have felt more like I knew who was watching. It felt a lot more distant with the exercise person. So it felt like it could've been that that message has gone across the board.* [Participant 60, age 53, nonuser]

There was no face-to-face meeting with the exercise experts, and many participants believed that having the opportunity to talk through expectations would possibly have avoided misconceptions that appeared to take place during the study; that is, that the ability level of the participants could have been witnessed and assessed by the exercise expert, and that the exercise experts would have been able to vocalize from the beginning that slow and gradual increase of physical activity was recommended, whereas participants often assumed that they were expected to do vigorous exercise and this was not suitable for them.

The interaction between the health care professionals and the participants was also referred to in relation to monitoring and receiving guidance on their progress.

Acknowledgment of the participants' self-monitoring appeared to be an essential aspect in the provision of guidance to ensure they knew it was a human and personal response rather than simply an automated message.

> *But it obviously is getting monitored and that gives me the confidence to carry on using it. It's a trust thing as much as anything else, and I'm more than trustful of it.* [Participant 17, age 57, active user]

Feedback consultations seemed to provide participants with the reassurance that they could be helped with any issues, comforted by the knowledge that professional guidance was available if needed.

Future Development of the Web-Based Intervention

Aspects that could be developed in future emerged through participants highlighting technical or practical issues and with participants suggesting potential changes that could be made to improve the Web-based intervention.

A suggested improvement of the website was for the food database to be in alphabetical order to save participants time.

> *I think the menus require some pretty solid attention. Obviously, they are trying to be helpful, but it is the way they are presented. It is labour-intensive. [Participant 50, age 78, nonuser]*

Participants also suggested that including healthy eating or exercise recommendations would allow them to compare their own performance against these set recommendations. Other comments emerged during the interviews with regard to the website needing more color to be more appealing.

> *Another observation I would make is that on the website, there is an awful lot of text. There are not many cheerful graphics.* [Participant 45, age 62, active user]

This suggests that, as well as functionality and professionalism, the website also needs to be visually attractive to make it interesting to users.

Suggestions were raised on ways to improve the website in order to aid productivity and ease of use for both health professionals and participants, with the overall objective being to create a website that could be less time consuming and more straightforward for users to operate while providing adequate support. Examples of these suggestions are organizing the food database alphabetically to make finding a meal or food choice quicker, adding the ability to enter free-text calorie information, making the website more colorful and appealing, adding healthy eating or exercise recommendations to compare against their own progress, and adding the ability to view a full week of food or exercise inputs rather than just daily reports.

Sample Size Calculations for a Main Trial

We calculated sample size, as issue 1 in Table 6 reports [44], using PS: Power and Sample Size Calculation version 3.1.2 [45] to identify the sample size needed for a main trial, while we based our other calculations on response and retention rates from this pilot study. Sample size was calculated based on the main trial being a superiority trial and for a target difference of 5% between the control and the intervention arms in terms of percentage weight change from participants' initial baseline weight to follow-up at 12 months (eg, 5% loss in the intervention group versus 0% in the control group, or 6% vs 1%), with 90% power, 5% significance level, one-to-one allocation, and analysis with independent-samples *t* test; a standard deviation of weight loss change of 5.6% was assumed.

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Table 6. Summary of findings against 14 methodological issues for feasibility research[a].

Methodological issues		Findings	Evidence	Suggested improvements for a full trial
1.	Did the feasibility/pilot study allow a sample size calculation for the main trial?	Measure of variability and retention rates was identified. Sample size for main trial was calculated.	Target of 60 was achieved.	Sample sizes were calculated to inform main trial requirements. Number of practices required: 12 (based on average of 138 eligible patients identified per practice). Number of participants needing to be identified and contacted: 1587 (based on consent rate of 6.3%). Number needing to be randomly allocated: 100 (based on retention rate of 52%). Number needed at 12 months to detect target difference: 54 (27 per arm).
2.	What factors influenced eligibility and what proportion of those approached were eligible?	High numbers of eligible men (968) were identified from GP[b]database searches.	5 out of 61 approached were ineligible.	Inaccurate body mass index records in GP databases led to 5 ineligible participants, a small number but an issue to consider when contacting general practices.
3.	Was recruitment successful?	Recruitment was successful.	Target of 60 was achieved. Response to study invitation was 9% of identified men.	Recruitment via GP database searches was effective. Invitation letters could be revised, to be based on behavior change principles, to potentially increase response rate and those recruited.
4.	Did eligible participants consent?	Conversion to consent was high.	Of the 61 eligible men, all were recruited.	The consent process was successful and could stay the same for a main trial.
5.	Were participants successfully randomized and did randomization yield equality in groups?	Randomization worked well.	Allocation was concealed. Groups were of fairly equal size and were well balanced on stratification variables.	Randomization and stratification worked well and could progress into a main trial.
6.	Were blinding procedures adequate?	Blinding was not possible and was not planned.	Blinding was not implemented.	Blinding would not be possible in a main trial.
7.	Did participants adhere to the intervention?	Fewer than half of the participants adhered to the intervention website.	16 out of 33 (48%) allocated intervention participants actively used the intervention website, with 12 out of 33 (36%) still engaged at 12 months.	The use of incentives could aid both adherence and retention. Improvements to the website, suggested in the process evaluation, were mentioned in relation to increasing adherence.
8.	Was the intervention acceptable to the participants?	The intervention appeared to be acceptable to participants.	All eligible participants consented once full study information was explained. The majority of participants interviewed believed the intervention to be feasible to implement within the UK National Health Service.	A Web-based weight loss intervention was identified as acceptable.
9.	Was it possible to calculate intervention costs and duration?	These were not assessed within this pilot trial.	No costs were calculated.	Cost analysis would be conducted in a main trial to assess the cost effectiveness of the intervention.
10.	Were outcome assessments completed?	Anthropometric measures were completed well.	Anthropometric measures were completed by all participants remaining in the study.	Face-to-face anthropometric measures could be used in a future trial.
11.	Were outcomes measured those that were the most appropriate outcomes?	Outcome measures used did assess main areas of interest.	Anthropometric measures allowed health outcomes to be measured.	Outcome measures would be suitable to measure in a full trial.

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Methodological issues	Findings	Evidence	Suggested improvements for a full trial
12. Was retention to the study good?	Attrition was substantial.	Remaining men: 3 months: 73% intervention, 57% control 12 months: 61% intervention, 45% control.	Incentives could be used, as in previous research, to aid both adherence and retention.
13. Were the logistics of running a multicenter trial assessed?	Logistics for running a multicenter trial identified no problems during the trial.	However, the number of participants recruited from each general practice was largely influenced by the number of eligible participants identified in the GP database search; 50 of the 61 (82%) recruited were from the 3 practices where the greatest number of eligible participants were identified.	The logistics for running a multicenter trial were effective and could be used in a main trial. Focusing on larger practices may be most effective.
14. Did all components of the protocol work together?	Components had strong synergy.	No difficulties were identified in the ability to implement any of the study processes. Participants were recruited, were randomly allocated, and progressed into the appropriate trial arm smoothly.	The protocol allowed all components to work well together.

[a]Based on Shanyinde et al [44].

[b]GP: general practitioner.

Methodological Issues and Possible Solutions for a Main Trial

The CONSORT guidelines recommend that pilot trials provide prespecified criteria to judge whether to proceed with a future trial [39]. A previous study identified 14 methodological issues for feasibility research to consider when making the decision to proceed with a future trial [44]. Therefore, Table 6 outlines this study's findings, evidence, and suggested improvements for a main trial. Findings detailed in Table 6, along with the overall findings of the study, have enabled the recommendation that a main trial of the intervention should not proceed without the modifications and improvements identified. The main challenges that arose within this study were the low response rates to express interest in joining the study and low retention rates. Table 6 outlines possible solutions to these problems. A potential solution to the low response rates to join the study is the use of incentives for participation to try to increase uptake and recruitment. However, we achieved the recruitment target of 60 participants; therefore, although a low number responded to the GP invitation letters, we were also able to reach a large audience. In relation to the challenge of retaining participants in the study, the interview findings identified that improvements to the website would have encouraged participants to use the website more frequently and would have upheld their interest to a greater degree. Participants viewed the website as acceptable. The conversion to consent, recruitment, and randomization protocols were all found to be effective.

Discussion

Principal Findings

We achieved the recruitment target. Participant interviews identified the Web-based intervention as an acceptable method of delivery for weight loss; however, improvements to the website were suggested in relation to ease of use and to maintain adherence. Participants' Web-based messages to health professionals tended to be directed to the dietitians rather than the exercise experts. However, it was also evident that the dietitians achieved more of their scheduled number of professional-initiated consultations than the exercise experts. Data completion rates at each time point were sufficient to inform sample size calculations for a future definitive trial.

Comparison With Prior Work

To address problems identified in pilot studies, solutions should relate to study context, trial design, the intervention, or all 3 of these, and whether these could be effective or feasible within trial or real-world settings [46]. This study has examined these feasibility issues noted in Table 6.

In agreement with this study, findings from previous research [47] identified Web-based weight loss interventions as acceptable and feasible, including Brandt et al [37], the Danish study that originated the My Dietitian website.

We used general practices in this study, as this is how patients would be referred to exercise experts or dietitians for weight loss within the NHS. Within this pilot trial, only 9% of those invited expressed an interest in the study, but we met the recruitment target of 60 participants. A previous study that contacted patients via GP mailouts achieved a 6.5% response rate [48]. A suggestion to improve research study recruitment strategies, such as GP mailouts, is the use of opt-out techniques. Although these are disliked by ethics committees, previous research suggested it can increase response rates by 12% and should be used in low-risk groups, as opt-in techniques can result in a biased sample [49].

Previous research has shown great variability in Web-based weight loss trial recruitment levels, ranging from 6% to 83%, and in terms of the recruitment techniques implemented. Previous methods for recruitment range from a wider audience approach, such as advertisement techniques [50-53], to a

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targeted approach through GP mailouts or referrals [47,54], with varied success. Many of the studies used several methods of recruitment rather than one single approach [50,51,55,56]. One difficultly when comparing against previous research is the reporting of response and recruitment numbers. Published work can often report on the number screened for eligibility assessment and not the actual numbers who viewed the invitation, with the reach of some recruitment strategies, such as advertisements, unknown [37,47].

Attrition levels from previous studies range from 17.4% to 51.4% for Web-based intervention arms and 15.2% to 35.5% for control arms [47,53,57] at 12 months. This study experienced higher rates of attrition for the control arm but rates similar to those in previous research for the intervention arm. However, the control group had higher attrition than in previous research. Control groups have been discussed by Morgan et al [58], with the suggestion that a minimal intervention is necessary due to some form of intervention being more acceptable to participants than no intervention, which therefore prevents attrition, with attrition rates identified as 29% by 12 months. Tate et al [47] had similar attrition rates for both included groups—an Internet-only group and an e-counselling group—with an overall attrition of 16%. Their study used incentives for appointment attendance, which could be a potential improvement for our study. Our study used usual care, which we discovered to be near nonexistent in terms of specific weight loss treatment, with only 1 participant being referred to exercise classes. For this study, it was deemed important, and was achieved, to identify what usual care constituted for this population within the NHS. However, an improvement may be the use of a minimal intervention as the control group. Further investigation into different modes of delivery would also be beneficial to identify whether delivering an intervention in person or via the Internet would affect the overall findings.

In terms of mean weight loss, intervention participants in our study lost on average 5.4 kg, which is greater than in previous studies, which had losses of 4.4 kg [47], 4.6 kg [54], and 5.3 kg [58], although lower than Brandt and colleagues' study, in which mean weight loss was 7 kg [37].

Strengths and Limitations

In addition to the pilot RCT, it was possible to conduct a process evaluation alongside the trial, which enabled us to investigate participants' views and to track website use. We attributed the nondelivery of over half of the exercise consultations to the change in job status of the exercise experts, as well as nonresponsive participants. However, these reasons emerged from the process evaluation interviews. The health care professionals were not required to provide reasons for nondelivered consultation, and this was not recorded in the website use data. Therefore, we do know how many consultations were not delivered due to nonresponsive participants and how many were due to the health care professionals. A potential improvement going forward would be to require the health care professionals to enter reasons for missed consultations. As the health care professionals did not meet the proposed number of consultations, we suggest that large-scale trials should employ health care professionals as research study staff. If this is not possible, at least providing health care professionals with dedicated time to work on the study would be beneficial to the fidelity of intervention delivery rather than having their involvement with the study being in addition to their other full-time employment.

Participants were sent details of their username and operational directions in a postal letter in advance of the face-to-face meeting. In hindsight, the face-to-face meeting could have been a potential opportunity to explain the functions and resources within the website and explore how to effectively interact with it. This identifies a potential improvement and refinement of the intervention procedures for future research.

The intervention is reliant on feedback from a health care professional and, unless provided through the NHS, this would not be possible in a standard weight loss website. However, this study demonstrates how a Web-based weight loss intervention may be used for a high-risk population. The study sample captured a wide age range of 41 to 79 years and contained a range of employment status (unemployed, employed, retired). A limitation of the study sample is the lack of ethnic diversity: the sample was all white British men. South Asian and Black African groups are known to be twice as likely to develop type 2 diabetes and therefore a future study should aim to recruit ethnic minority groups to identify whether a Web-based intervention is acceptable to people of different ethnicities.

It is important to acknowledge the conflict between conducting a rigorous RCT and the need to keep up with the fast progression of technologies. Evaluation research faces the reality of falling behind commercial companies with the ability to regularly update their websites or apps. Large companies may have the advantage of greater financial stability and flexibility of funding and resources in contrast to academic research, where budgets can be extremely constricted and individual costs and resources tend to be outlined in advance of receiving funding. However, RCT methodology remains the most robust way of determining the effectiveness of an intervention [59]. One way to keep up-to-date with technology and maybe another potential improvement for the study is the use of a mobile phone app, in replacement of or in addition to a computer-based website. Mobile phones have now overtaken laptops or desktops as the devices used to access the Internet [60]. Although the study website was accessible via a mobile phone, the creation of an app may make the format easier to access on a mobile phone and potentially improve engagement and adherence. Over 12 months, each participant had 3 visits by the researcher at either their home or general practice, with data collection typically ranging between 20 minutes and 1 hour per visit. This level of face-to-face assessment with participants could be feasible in a main trial. However, the use of electronic scales to measure and transmit weight status to the research team, as implemented within the NULevel study [61], may be a more efficient and feasible method of data collection in a definitive trial.

Implications for Policy, Practice, and Further Research

Research is lacking with regard to implementing a Web-based weight loss intervention within the NHS. Given the high number of obese patients and NHS resources being increasingly stretched, services are struggling to provide sufficient referrals.

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Therefore, alternative modes of delivery, with the potential to reduce health professional input and time per patient while still enabling individual and tailored care, need to be investigated to identify if they can be effective and thus benefit the NHS. Although not powered to assess changes in outcomes, the descriptive statistics show positive indications of increased weight loss (in kilograms and as a percentage), reduced waist circumference, and decreased BMI for the intervention group from 3 to 12 months, in comparison with the control group. This research provides preliminary findings that recruitment of men with type 2 diabetes is possible within a Web-based intervention. Suggested improvements to the website were valuably gained from the parallel process evaluation and could be incorporated to potentially improve adherence and retention in future research.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.1.

[PDF File (Adobe PDF File), 841KB - diabetes_v2i2e14_app1.pdf]

Multimedia Appendix 2

Anthropometric measures mean (SD).

[PDF File (Adobe PDF File), 91KB - diabetes_v2i2e14_app2.pdf]

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Abbreviations

BMI: body mass index
CALO-RE: Coventry, Aberdeen, and London-Refined
CONSORT: Consolidated Standards of Reporting Trials
GP: general practitioner
NHS: National Health Service
RCT: randomized controlled trial

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Original Paper

Improving Glycemic Control With a Standardized Text-Message and Phone-Based Intervention: A Community Implementation

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Abstract

Background: Type II diabetes mellitus (T2DM) presents a major disease burden in the United States. Outpatient glycemic control among patients with T2DM remains difficult. Telemedicine shows great potential as an adjunct therapy to aid in glycemic control in real-world settings.

Objective: We aimed to explore the effectiveness of EpxDiabetes, a novel digital health intervention, in improving hemoglobin A1c (HbA1c) and fasting blood glucose (FBG) among patients with uncontrolled diabetes.

Methods: We recruited 396 patients from a community clinic in St. Louis, Missouri, from a database of patients diagnosed with T2DM and with a most recent HbA1c >7% as part of a quality improvement project. An automated call or text-messaging system was used to monitor patient-reported FBG. If determined to be elevated, care managers were notified by email, text, or electronic medical record alert. Participants self-reported their FBG data by replying to EpxDiabetes automated phone calls or text messages. Data were subsequently analyzed, triaged, and shared with providers to enable appropriate follow-up and care plan adjustments. Absolute HbA1c reduction, patient engagement, and absolute patient-reported FBG reduction were examined at approximately 6 months post implementation.

Results: EpxDiabetes had an average 95.6% patient response rate to messages at least once per month and an average 71.1% response rate to messages at least once per week. Subsequent HbA1c drop with EpxDiabetes use over 4 months was -1.15% (95% CI -1.58 to -0.71) for patients with HbA1c >8% at baseline compared to the change in HbA1c over 4 months prior to the implementation of EpxDiabetes of only -0.005 points (95% CI -0.28 to 0.27), *P*=.0018.

Conclusions: EpxDiabetes may help reduce HbA1c in patients with high HbA1c baselines (>8%). The intervention demonstrates high patient engagement sustainable for at least 6 months.

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KEYWORDS

diabetes mellitus; glycemic control; telemedicine; electronic health (eHealth); mobile health (mHealth); telehealth; SMS; diabetes management

Introduction

Glycemic control among patients with type 2 diabetes mellitus (T2DM) remains a pressing problem ,. Poor glycemic control may be a factor of both poor access to care, poor health literacy, and poor return to follow-up and communication to providers of current glucose values. Current strategies to achieve glycated hemoglobin (HbA1c) control prove inadequate for a large proportion of patients ,. The standard of care for outpatient glycemic monitoring is a paper blood glucose log, but only 20%-52% of patients remain engaged with this tracking method, suggesting that there is a need to develop methodologies to improve patient follow-up and prevent complications [1-3].

Telemedicine interventions may facilitate remote glycemic monitoring, promote patient-provider communication, and reduce time to glycemic control. Most systems that monitor patients' fasting blood glucose (FBG) use mobile phone apps, Internet-linked glucose monitors, or other specialized equipment [1-5]. Significant obstacles hinder the widespread dissemination and adoption of these technologies, especially among the elderly, those with low socioeconomic status, and those with low technological literacy [6,7]. Drop-out rates of up to 50% are reported in some studies using these modalities [8-10]. In the United States, most current telemedicine interventions involve one-way communication from provider to patient, or bidirectional systems that do not align with physician workflow or are not scalable ,1. Community implementation of these services can often be difficult due to logistics in implementing device-based solutions and feasibly analyzing patient-reported data within busy primary care practices. Therefore, there is a need for an intervention that is not only successful at engaging patients with low income and high HbA1c but also facilitates provider follow-up by providing triaged FBG data to close the patient-provider loop with improved patient follow-up.

To this aim, we developed , a novel bidirectional communication system designed to both collect patient FBG data and facilitate provider feedback to patients using smartly triaged FBG data in an overall low overhead implementation. The system utilizes ubiquitous text messaging technology or phone calls to collect FBG data as self-reported by patients and to identify dysglycemic trends and events [1 1. Providers are subsequently able to access the triaged data to provide necessary feedback to patients. Using this bidirectional feedback loop of communication, EpxDiabetes ultimately aims to accelerate HbA1c and FBG reduction by allowing earlier detection and provider intervention during dysglycemic events and trends. EpxDiabetes creates a closed feedback loop between patient and providers to achieve successive, rapid improvements in glycemic control.

To investigate the feasibility and effectiveness of the EpxDiabetes intervention in reducing HbA1c among patients with poor glycemic control in a real-world clinical setting, we conducted a proof-of-concept community implementation of the system.

Methods

Intervention Design

The EpxDiabetes intervention is part of a broader telemedicine platform, Epharmix, which has been developed and applied for the management of other diseases. The EpxDiabetes intervention modifies the existing platform to incorporate questions exclusive and specific to diabetic care. Similar to other Epharmix interventions, EpxDiabetes creates a two-way communication modality to enable providers to more quickly titrate and address problems [11]. In the focus with diabetes, the platform was able to generate a custom tool for glycemic control demonstrating the ability to actually modulate biometrics. Because populations with limited health literacy require interventions with simple, easy-to-read instructions , all EpxDiabetes messages read at a 4th grade level as determined by the Flesch-Kincaid Grade Level formula and calculated on the Readable.io website. Text messages and phone calls were provided free of charge (excluding standard messaging rates) to patients on any network to further promote accessibility among low socioeconomic populations.

EpxDiabetes consists of either automated phone calls or short-message service (SMS) messages sent to the patient's preferred phone number, requesting patients to self-report their FBG values. The EpxDiabetes software algorithm remotely and automatically monitors patient-reported FBG values for hypoglycemic or hyperglycemic trends (FBG>160) or acute events (FBG<70 or >400). The frequency of messages for each patient varies based on their self-reported FBG to minimize message fatigue. Patients reporting dysglycemia receive messages more frequently than patients with euglycemia. In accordance with the definition in the 2013 report from the Workgroup on Hypoglycemia assembled by the American Diabetes Association and the Endocrine Society, hypoglycemia is defined in the EpxDiabetes system as a blood glucose value 70 mg/dL [12].

If the patient reports an FBG value beyond set thresholds, the designated provider receives an actionable "alert" notification via phone, SMS, or email requesting them to follow up with the patient. Any patient reporting hyperglycemia or hypoglycemia is provided the option to voluntarily contact their provider or to call 911 in the case of an emergency to minimize provider liability. When calling in, a patient hears the standard message, "If this is an emergency, please hang up and call 911" before being connected to their provider. The bidirectional patient-reporting and provider feedback loop represents a novel framework designed to achieve successive, rapid improvements in glycemic control.

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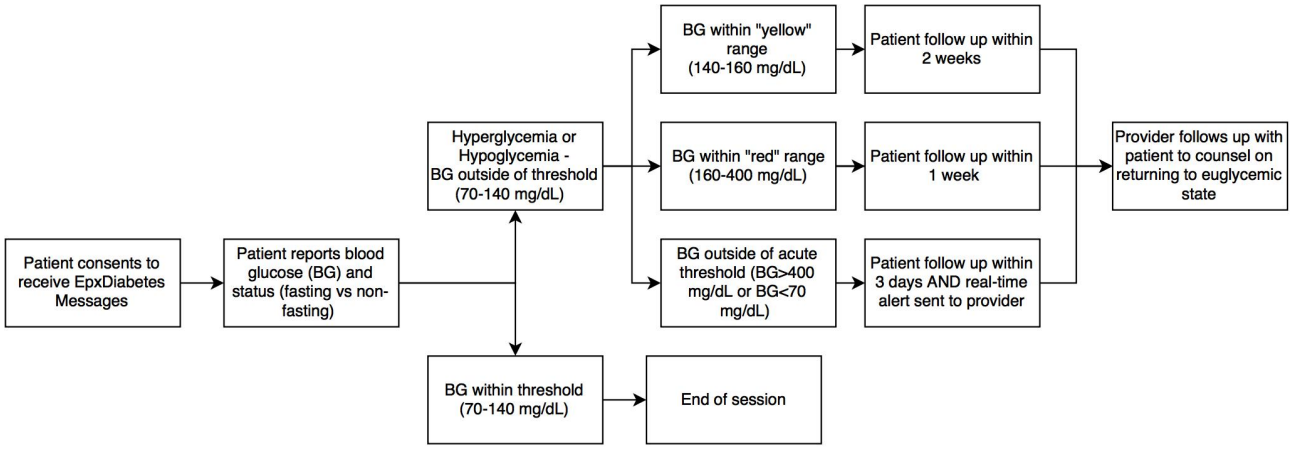
Figure 1. EpxDiabetes intervention flow diagram.



In addition to alert notifications, providers also receive a triaged bimonthly report prioritized by each patient's average FBG values for longitudinal monitoring. The goal of the triaging system is to allow efficient review of overall population and individual patients and to facilitate selective attention to patients with dysglycemia (Figure 1).

Patient Recruitment

The study was implemented as a prospective single-arm quality improvement project at community clinics across the St. Louis, Missouri, region. Patients consented to use the service under standard of care guidelines. Data were aggregated and de-identified per best practices for analysis under the permission of the community health center. A list of eligible participants was obtained by querying the clinic's electronic medical record (EMR) using International Statistical Classification of Diseases and Related Health Problems (ICD)-9 and ICD-10 codes for T2DM. All eligible patients were offered the EpxDiabetes service as part of their standard care under institutional policy and consented to receiving SMS messages/calls for health care communication. Patient recruitment and enrollment continues on a rolling basis, and at the time these data were collected, patient enrollment had taken place from August 2015 to February 2017. The population extended to adults >18 years old in the greater St. Louis Metropolitan area consisting of St. Louis City and St. Louis County. Both populations' demographics are listed in Table 1.

Aggregate de-identified data on patient engagement, HbA1c, and FBG were provided by Epharmix, Inc, and their clinical partners for analyzing outcomes with permission by the community health care institution. To be eligible for HbA1c analysis, patients needed a pretrial or baseline HbA1c value obtained within 6 months prior to receiving the first EpxDiabetes message. Participants also needed to obtain a posttrial HbA1c value between 2 and 5 months after receiving their first EpxDiabetes message. Patients who did not respond to a single intervention message were excluded from analysis.

Statistical Analysis

Patient HbA1c deltas were calculated as the difference between pre-intervention baseline HbA1c and most recent HbA1c since enrollment in EpxDiabetes. These values were averaged per individual patient to determine the overall population's aggregate delta. Historical, pre-EpxDiabetes HbA1c deltas were calculated by subtracting the two most recent HbA1c values before receipt of EpxDiabetes messages. Statistical significance was defined as $P<.05$ by one-sample t test with a theoretical mean delta HbA1c of 0.0%, and a two sample t test comparison of historical change in HbA1c versus postimplementation change in HbA1c. Standard error of the mean (SEM) and 95% confidence intervals (CI) were calculated as well. Identical HbA1c analysis was also performed for a subgroup of patients with a pretrial baseline HbA1c >8%.

Patient-reported FBG data were obtained by querying the Epharmix server. Baseline FBG for each patient was calculated as the median of the first 3 patient-reported FBG values. To account for the variable weekly message frequency between individual patients, monthly FBG was determined for each patient by averaging four consecutive weekly FBG averages. Monthly FBG deltas were calculated by subtracting the patient's baseline and monthly FBG values. Individual patient monthly FBG deltas were averaged together to calculate the average monthly FBG delta of the population. We compared the average fasting blood glucose pre- and post-EpxDiabetes using a two-tailed one-sample t test, with significance set at $P=.05$. We calculated the SEM for each monthly FBG deltas.

We defined weekly patient engagement rate as the proportion of total patients responding at least once per week to EpxDiabetes messages. Monthly patient engagement rate was determined by averaging four consecutive weekly engagement rates. Cumulative monthly patient engagement was calculated by averaging the monthly patient engagement. Gross response rate was defined by the number of messages responded to out of the total number of messages sent. Patients who did not respond to the initial consent message were excluded from engagement analysis.

We performed data analysis on Microsoft Excel 2016 and PRISM (GraphPad Software, 2016). Because of overtitration concerns, we found clinic providers aimed for optimizing FBG equivalent to an HbA1c cutoff of 8%. Therefore, analysis was performed for all patients and for the subset of patients with a baseline HbA1c >8%.

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Table 1. St. Louis City and County residents' demographic and income data from which the Epharmix population was recruited.

Characteristics	St. Louis City	St. Louis County
Population estimates, n	315,685	1,003,362
Age in years, %		
18-65	61.2	55.2
>65	11	16.8
Gender, %		
Male	48.3	47.7
Female	51.7	52.3
Ethnicity, %		
Caucasian	43.9	69.5
African American	49.2	24.1
Median household income 2011-2015, USD	$35,599	$59,755

Results

Patient Demographics

In total, 396 patients were consented and enrolled at a large St. Louis area health care institution who were already receiving standard of care treatment and education regarding their diabetes. In total, 79.3% (314/396) of patients in the community implementation consented to EpxDiabetes. The increased receptiveness of patients to use the service is perhaps due to EpxDiabetes being offered as part of their standard of care. Individual socioeconomic data were not able to be collected or analyzed for this particular implementation project. The majority of patients were adults from St. Louis City and County, and census data for socioeconomic status are reported as a corollary in Table 1 (US Census) [13].

HbA1c Analysis

For analysis of the effect of EpxDiabetes on the population, immediate pre-implementation HbA1c values were obtained, on average, 2.0 months (60.0 days) before implementing EpxDiabetes. Just under half (45.4%, 166/366) had pre-implementation HbA1c values available. Patients obtained their posttrial HbA1c values, on average, 4.0 months after intervention start (63.9%, 106/166). Not all patients had HbA1c values measured during their routine standard of care pre- and post-EpxDiabetes usage, so analysis was limited to all HbA1c values available. Because EpxDiabetes was implemented in a community population, patients were at various stages of getting HbA1c measured, which often fell outside of the 4-month window. As such, during analysis we looked only at patients who had both a pre- and post-HbA1c value during the 4-month analysis period (33.3%, 106/318). This snapshot is as a result a random sampling of HbA1c across the entire population.

Prior to receiving the EpxDiabetes intervention, patients with HbA1c >5% demonstrated nonsignificant changes of -0.13% (SEM 0.11, 166/366) during the last 3 months, suggesting the standard of care was not sufficient to change underlying diabetes control. The immediate average pre-EpxDiabetes HbA1c for these patients was 8.89% (SEM 0.18). The average post-EpxDiabetes HbA1c was 8.17% (-0.72%, SEM 0.17, 95% CI -1.05 to -0.39; 106/166). The comparison of pre- and postintervention was statistically significant (P=.004).

A total of 22.6% (72/318) of patients had a baseline pre-implementation HbA1c >8%. For this group, prior to receiving the EpxDiabetes intervention, patients demonstrated nonsignificant changes of -0.005% (SEM 0.14, 104/318), respectively, during the prior 3 months. The immediate average pre-EpxDiabetes HbA1c was 9.81% (SEM 0.18). The average postimplementation HbA1c for this group was 8.66% (-1.15%, SEM 0.21, 95% CI -1.58 to -0.71, 72/106). The comparison of pre- and postintervention was statistically significant (P=.0018) (Figure 2).

Fasting Blood Glucose Analysis

The average postimplementation FBG as reported on EpxDiabetes was significantly lower from month 2 on intervention through time of analysis (Table 2). The EpxDiabetes system was also able to identify and alert providers in real time to 395 total acute hypoglycemic (FBG<70) or hyperglycemic (FBG>400) events. These alert notifications resulted in 228 patient-initiated calls and 83 provider-initiated calls and interventions. For average FBG changes over time, 153 patients had been on the intervention for at least 6 months. Average monthly FBG values over the 6 months were significantly lower at each month when compared to the sample's baseline average (Figure 3 and Table 2).

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Figure 2. Change in HbA1c from pretrial baseline at 4 months from initiation (error bars represent SEM; *P<.05 for change from baseline).

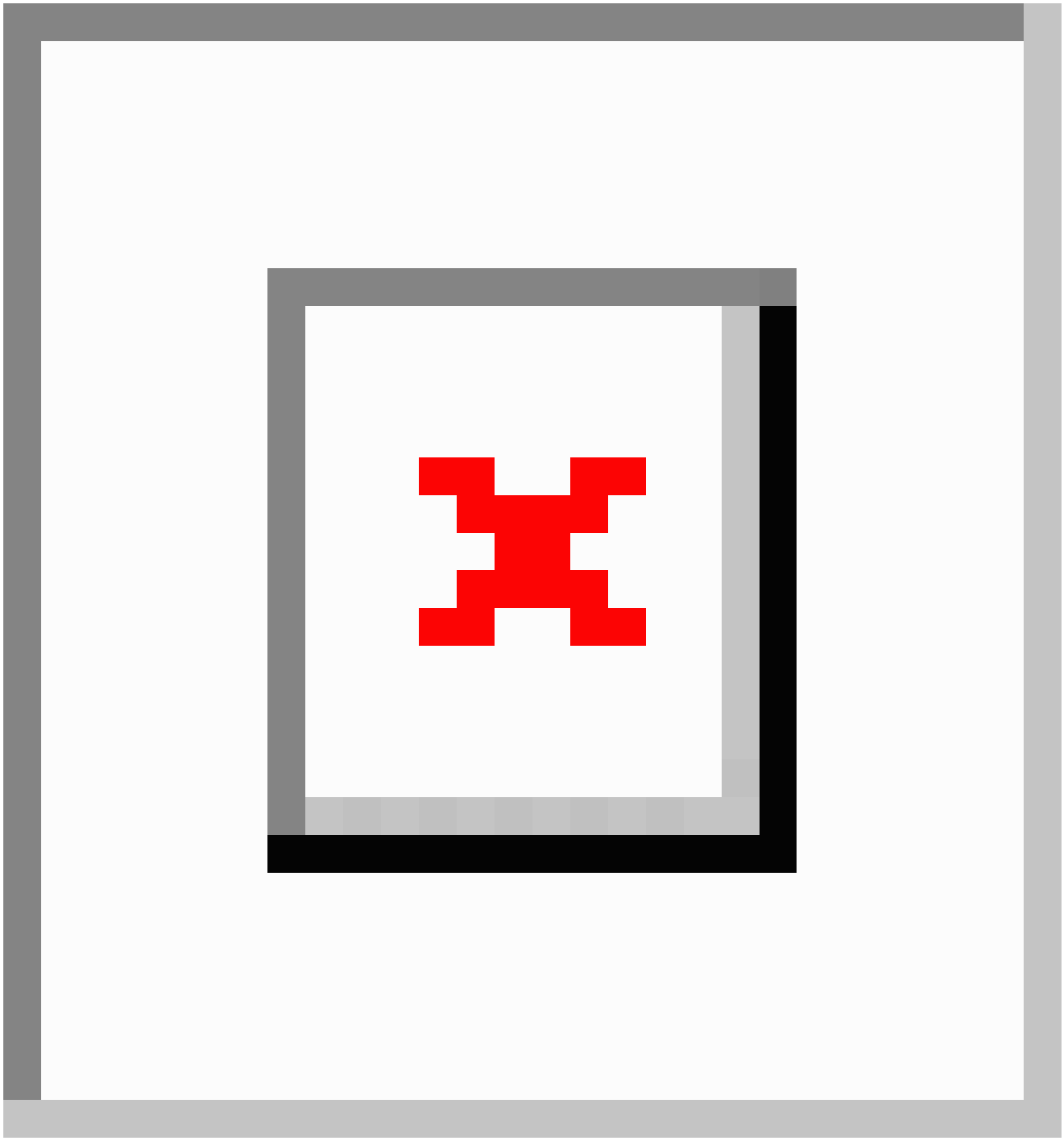

Table 2. Fasting blood glucose changes by month.

Month	1	2	3	4	5	6
Mean FBG (mg/dL)	160.4	154.3	149.8	146.2	146.6	148.4
SEM	3.037	2.678	2.455	2.398	2.468	3.43
Delta	N/A	-5.677	-10.19	-13.78	-13.41	-11.59
95% CI	N/A	-10.95 to -0.4017	-15.03 to -5.357	-18.51 to -9.047	-18.28 to -8.538	-18.37 to -4.813
P value (two tailed)	N/A	.035[a]	<.001[a]	<.001[a]	<.001[a]	.009[a]
N	308	247	223	189	169	153

[a]$P \leq .05$.

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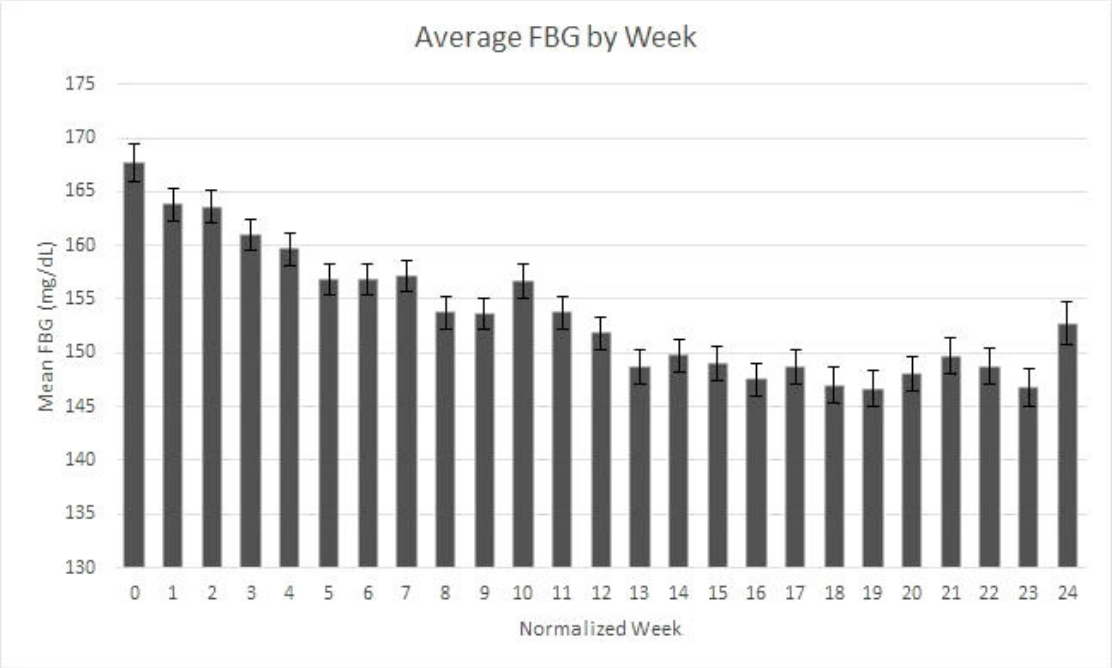
Response Rate

The EpxDiabetes system conducted a total of 55,730 FBG assessments during the 6-month implementation for a total of 396 patients. There were 80 patients who did not respond to the initial consent message and therefore did not receive any further text messages during the 6-month period trial and were excluded from engagement analysis. Of the 316 consenting patients, 41 never responded to any subsequent messages (13.0%). Of those who responded to at least one message, EpxDiabetes had an average of 95.6% patient response rate to messages at least once per month and had an average 71.1% (range 64.8-79.3) response rate to messages at least once per week. A total of 83 patients revoked the use of EpxDiabetes service via the "opt-out" feature wherein a patient could text "STOP" to the system, thereby discontinuing any further messages, showing an absolute dropout of 21%. The average weekly dropout was 1.1% of the total. We had a gross response rate of 55.7% to all messages sent through 6 months.

Figure 3. Average fasting blood glucose change over time (error bars represent SEM).



Discussion

Principal Considerations

Glycemic control remains a difficult goal to achieve among patients with diabetes. Current strategies to achieve outpatient HbA1c control prove inadequate for a large proportion of patients [14,15]. Electronic health care tools involving phone communication or mobile phone apps have been utilized to improve glycemic control [8,9,16], but their cost and the unidirectional nature of communication reduces accessibility and/or effectiveness among low socioeconomic and education populations.

Our intervention, EpxDiabetes, is a novel phone call and SMS-based communication tool specifically designed to address these limitations. The intervention aims to accelerate HbA1c reduction by providing caregivers with actionable automatically triaged patient-reported FBG data to facilitate a bidirectional loop of patient-provider communication. The study population, primarily consisting of middle- to older-aged individuals with a low median income and educational attainment levels, reflects our goal to produce a universally accessible, affordable, and user-friendly health care tool [17]. The cost to provide EpxDiabetes is substantially lower than required for many specialized telemonitoring devices. Our implementation shows a statistically significant HbA1c reduction from baseline for patients with baseline HbA1c >8%. The drop in HbA1c is corroborated by a significant decrease in self-reported average fasting blood glucose. Among participants, this reduction in FBG results in a 10.9% increase in patients reporting FBG<130, implying that EpxDiabetes accelerates HbA1c control by maintaining FBG control longitudinally. Based on previous results from the United Kingdom Prospective Diabetes Study, our HbA1c reductions demonstrated with the community implementation program are similar to those achieved with pharmacologic treatments and would represent a 37% decrease in the risk of microvascular complications and a 21% reduction in the risk of any diabetes-related complication or death, suggesting that this bidirectional communication between patient and provider could have important clinical implications [18].

We attribute the results of EpxDiabetes to increased patient investment in self-health combined with active monitoring and titration by their care teams. The patient-reported FBG data allow providers to perform care-plan adjustments based on actionable data and receive rapid feedback on these adjustments. This closed reactive feedback loop allows EpxDiabetes to

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complement treatment plans and accelerate glycemic control by optimizing current medications.

In contrast to FBG diaries and several electronic health tools utilizing specialized equipment and mobile phone apps [8,10], EpxDiabetes demonstrates high patient engagement. With over 85% of participants continuing to communicate with the system at least 1 month until their respective conclusions at 6 months, EpxDiabetes circumvents engagement limitations seen with other electronic interventions to keep patients engaged long term.

We attribute the high weekly and longitudinal patient engagement to two components of EpxDiabetes: the regularly scheduled proactive messages may serve as a "buddy," helping patients establish a habit of checking their glucose the same time every day. The bidirectional design also encourages involved providers to call following dysglycemic events, helping patients feel more connected to their health care providers, and further incentivizing patient engagement with the system [19-21]. These factors may explain the higher engagement rate for the intervention group compared to the nonintervention group. The overall findings suggest that EpxDiabetes provides a more engaging alternative to FBG diaries for both short-term and long-term FBG monitoring.

Study Limitations and Next Steps

Overall, the community implementation demonstrated encouraging trends in HbA1c and FBG reduction, particularly in the HbA1c >8% population. Given the positive outcomes associated with actively engaged patients and care teams, further educational messages to encourage lifestyle behavior modifications are an avenue worth exploring in future iterations of the system. This first report demonstrates the capability of EpxDiabetes to maintain high engagement with patients and impact a population change in HbA1c over a short time period with a simple low overhead system. We will report the results after 1 year to see if the system is able to maintain this HbA1c drop. Further study at 1 year and beyond will provide better data following increased enrollment and more time for patients to get their regularly scheduled HbA1c tested. Despite this limitation, the random sampling does suggest a change in HbA1c, when considering the same patients did not show significant change prior to use of EpxDiabetes, lending pre-post evidence to the hypothesis that EpxDiabetes was instrumental, at least in part, for the improvement in glycemic control. Furthermore, we are currently conducting a phase II/III, randomized controlled trial based on the results with a larger study size to characterize EpxDiabetes' effect on patient outcomes as compared to a simultaneous standard of care group.

Conclusion

The results of this study suggest that EpxDiabetes is an inexpensive, low-risk, noninvasive intervention that can be implemented in a variety of settings to accelerate glycemic control for patients with T2DM with baseline HbA1c >8%. The results merit future investigation of the long-term effects of EpxDiabetes on patient health outcomes.

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Conflicts of Interest

AS has a financial conflict of interest with Epharmix, Inc. He is Chief Medical Officer and a founder of the company.

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Abbreviations

CI: confidence interval
FBG: fasting blood glucose
HbA1c: glycated hemoglobin
SEM: standard error of the mean
SMS: short message service
T2DM: type 2 diabetes mellitus

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Original Paper

Examining the Impact of a Novel Blood Glucose Monitor With Color Range Indicator on Decision-Making in Patients With Type 1 and Type 2 Diabetes and its Association With Patient Numeracy Level

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Abstract

Background: Many patients struggle to interpret and respond appropriately to the numerical blood glucose results displayed on their meter, with many regularly taking no action or self-care adjustment for out-of-range results. We recently reported that a glucose meter that provides automatic onscreen information using a color range indicator (ColorSure Technology) improved the ability of patients to categorize their blood glucose results.

Objective: The objective of this study was to examine how ColorSure Technology (or color) affected patient decision making on blood glucose results and how patient numeracy levels influenced such decisions.

Methods: We invited 103 subjects (56 with type 2 diabetes and 47 with type 1 diabetes) to a face-to-face in-clinic visit in a diabetes care center and showed them glucose results with or without color via interactive computer or paper logbook exercises. Before participating in these exercises, subjects completed surveys on numeracy and their understanding of blood glucose information.

Results: Subjects preferentially acted on high glucose results shown with color (55%, 57/103) compared to results without color (45%, 46/103; P=.001). When shown identical pairs of results, subjects preferentially acted on results shown with color (62%, 64/103) compared to results without color (16%, 16/103) (P<.001). Subjects more accurately identified days of the week in which results were low, in range, or high when reviewing logbooks with color (83%, 85/103) than without color (68%, 70/103; P=.012). Subjects with lower numeracy were more likely to consider taking action for high glucose results shown with color (59%, 18/31) than without color (41%, 13/31) and preferentially would take action on results shown with color (71%, 22/31) compared to results without color (16%, 5/31).

Conclusions: Insulin- and noninsulin-using subjects were each more inclined to act when glucose results were shown with color, and associating glucose results with color was viewed as particularly beneficial by subjects with lower numeracy.

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KEYWORDS

color range indicator (ColorSure™ Technology); glucose ranges; blood glucose monitor; self-monitoring of blood glucose; numeracy

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Introduction

Self-monitoring of blood glucose (SMBG) remains a cornerstone of diabetes management. However, poor education on how to meaningfully interpret the numbers displayed, together with a lack of understanding about adequate responses to blood glucose (BG) levels, can diminish the value of self-monitoring [1]. Appropriate education addressing SMBG interpretation and response to "out-of-range" BG values has been identified as a prerequisite to the value of SMBG [2]. In people with type 1 diabetes (T1D), underutilization of SMBG and absence of guided clinical decision making have recently been identified as key contributors to poor glycemic control [3]. Furthermore, Cavanagh et al [4] described how low diabetes-related numeracy skills are associated with fewer self-management behaviors. Poor numeracy has also been associated with suboptimal glycemic outcomes in people with both type 2 diabetes (T2D) [5] and T1D [6].

We previously reported that although nearly all patients with T2D agreed they would take action for BG results under 70 mg/dl, 51% of these subjects stated they would not take action for any level of high BG result [7]. This is consistent with a study of 207 people with T2D that investigated perceptions of high BG results where only 28% of patients considered results >235 mg/dl as high, with a further 10% viewing only >290mg/dl as high [8]. This demonstrates a recurring tolerance (or lack of awareness) of high BG levels in people with T2D. We previously reported that a variety of blood glucose meters (BGM) using color range indicators improved the ability of patients with both T1D and T2D to interpret and classify BG readings into low, in range, or high glucose ranges [9]. In the current study, we investigated how color might influence decision making in people with T1D and T2D in terms of propensity to take action after low or high BG results. In addition, we explored the impact of numeracy on decision making and subject preference for results in color.

Methods

This single visit, open label study was conducted at a National Health Service (NHS) clinic in the United Kingdom (Highland Diabetes Institute [HDI], Scotland) and was approved by the relevant ethics committee. Subjects provided written informed consent before initiation of the study. Subjects were identified via the NHS patient electronic database, based on entrance criteria, and were invited to attend the clinic by a clinic research nurse. Inclusion criteria included at least 16 years of age, an ability to read and understand English, a diagnosis of diabetes (T1D or T2D) for at least 3 months, and self-reported SMBG of at least 1 time per day. The only exclusion criterion was conflict of interest, that is, subject was not or had previously not been employed with LifeScan Scotland, or had a family member or association with LifeScan Scotland. Subjects provided demographic, medical history, and current diabetes practice information to the study facilitator. In addition, the subject's most recent laboratory A1c result was obtained from the NHS database. All subjects received appropriate compensation for time and travel to the clinic site. HDI is a stand-alone facility in Inverness, Scotland, adjacent to a general hospital (Raigmore Hospital). HDI cares for more complex or difficult to manage people with diabetes who usually have been referred from general practice. Therefore, HDI typically has a higher proportion of more intensively managed patients (eg, multiple daily insulin injections or using pumps) than might be encountered if recruiting via general practice. This is reflected in our study demographics.

ColorSure Technology Feature

Subjects interacted with study materials using a computer or by handling paper-based study materials that described blood glucose information with the support of ColorSure Technology (CST) (LifeScan). CST describes a way of presenting blood glucose data to a patient (on a glucose meter or app) in association with color (blue, green, or red) to denote low, in range, or high glucose results, respectively (Figure 1). CST is used in OT Verio, OT Select Plus, and OT Verio Flex blood glucose meters (LifeScan). This feature automatically indicates whether a glucose result displayed on the screen is low (blue), in range (green), or high (red) (Figure 1). The determination of a low, in range, or high message depends on the glucose range set in the meter by the patient or health care professional (HCP). Low (<70mg/dl), in range (70-180mg/dl), and high (>180mg/dl) default limits are provided preset in the meter and were used in this study.

Assessing Glucose Data (With or Without) Color

Three different exercises were undertaken by each subject. Exercises #1 and #2 were facilitated using a tablet personal computer (PC) enabling each subject to view different meter screens and provide feedback by clicking directly on the tablet screen to record their response. Exercise #3 involved reviewing two different paper logbooks containing typical glucose results screens.

Exercise #1: Reviewing Low or High Glucose Results With or Without Color

Each subject was shown a single panel view of 12 low (<70 mg/dl) or high (>180 mg/dl) glucose result screens on the tablet PC (Figure 1). This single panel view consisted of 6 identical pairs of low and 6 identical pairs of high results shown with or without color. Subjects were asked to click directly on 6 of the possible 12 low and high result screens on which they would be more inclined to take action.

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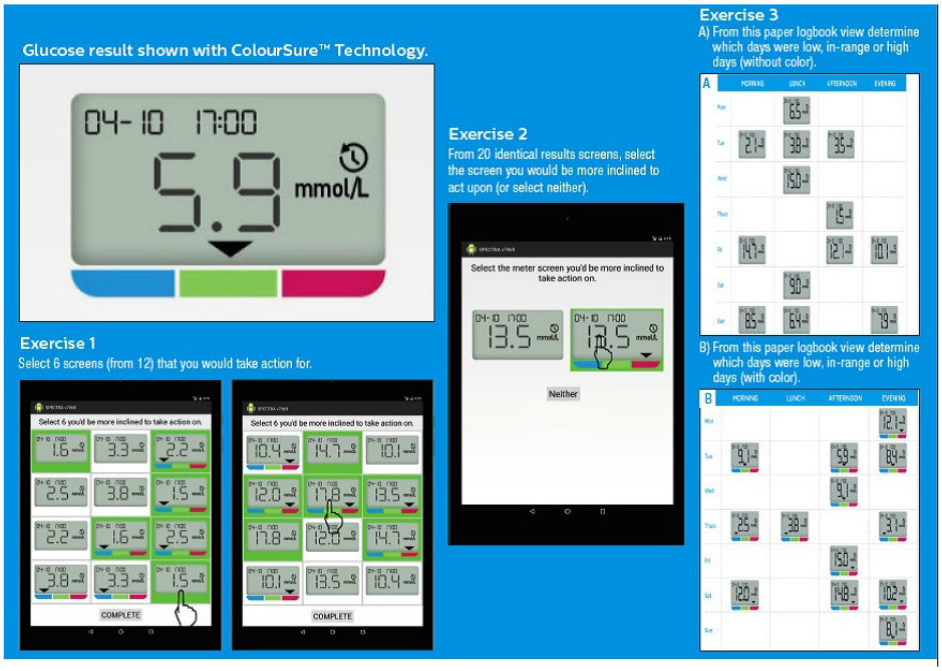
Figure 1. ColorSure technology and subject exercises.



Exercise #2: Reviewing Glucose Pairs With or Without Color

A series of 20 identical pairs of 20 different glucose results were shown one at a time on the tablet PC screen in random order (Figure 1). Each pair of numerically identical results screens was shown on the tablet PC simultaneously side-by-side: one result shown with color and the other result shown without color. Each subject was asked to select the results screen on which they would be more inclined to take action. Subjects could also select "neither," meaning no preference for results with or without color.

Exercise #3: Reviewing Blood Glucose Logbooks With or Without Color

Each subject reviewed two different one-page paper logbooks displaying a representative week of results. One logbook displayed 13 results with color, and the other logbook displayed 13 results without color (Figure 1). The two logbooks had glucose results placed on different days and were numerically only marginally different from each other. Within each logbook, 3 of the 7 days had specific results that exhibited a low, in range, or high blood glucose pattern. The facilitator first presented the logbook without color and then presented the logbook with color to each subject and asked them to identify which days of the week results were typically running low, in range, or high. Subjects were also asked preference questions after reviewing each form of logbook.

Timing of Exercises

In Exercises 1 and 2, both black/white and color visuals were presented in the same exercise simultaneously; therefore, no time advantage (or disadvantage) was implicit in the choice that was made by the subject when expressing a preference. Therefore, there was no rationale for measuring the time taken to conduct the exercises.

For Exercise 3 (using paper logbooks), a time limit of 2 minutes for interpretation of the black/white logbook and a further 2-minute time limit for interpretation of the color logbook was enforced.

Subjective Numeracy Scale Evaluation

All subjects took part in a subjective numeracy assessment using a validated subjective numeracy scale [10,11]. Subjects read 8 statements and chose from 6 potential responses (scored from 1-6, with 6 defining highest self-reported confidence or ability in terms of numeracy) that most represented themselves. A total subjective numeracy score (between 8-48) was determined for each subject. To facilitate the interpretation of numeracy scores, we classified results into 5 categories (8-16, 17-24, 25-32, 33-40, and 41-48) to facilitate understanding of lowest to highest subjective numeracy across subjects.

Subject Surveys

After all study procedures were completed, subjects completed surveys to investigate their knowledge of glucose ranges and explore how subjects interpret and react to low or high results. Finally, subjects expressed their perception of the value of the color feature with respect to managing their diabetes.

Statistical Analyses

Continuous demographic variables were described as median and range or mean and standard deviation (SD). Categorical demographic variables were described as percentages within categories. Test score changes were calculated as the percentage change from baseline. The null hypothesis "H_0: Pre-score=post-score" was tested using a paired *t* test with significance level of alpha=.05. Correlations with A1c and other variables were assessed using the Pearson correlation coefficient and were deemed significant with $P<.05$. Minitab 16.1.1 and SPSS 21.0 were used for all analyses.

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Table 1. Baseline patient demographics and medical history.

	All subjects (N=103)	T1D (n=47)	T2D (n=56)
Gender, n (%)			
Male	47 (45.6)	20 (42.6)	27 (48.2)
Female	56 (54.4)	27 (57.4)	29 (51.8)
Age (years), mean (SD)	61.6 (14.1)	55.4 (15.4)	66.7 (10.6)
Years conducting SMBG			
Mean (SD)	23.9 (9.4)	13.0 (6.6)	18.0 (9.6)
Median (range)	16.8 (1.8-39.8)	26.8 (2.8-39.8)	12.8 (1.8-31.8)
Frequency of SMBG, n (%)			
>5 times/day	20 (19.4)	20 (42.6)	
3-5 times/day	46 (44.7)	17 (36.2)	29 (51.8)
1-2 times/day	32 (31.1)	9 (19.1)	23 (41.1)
<1 time/day	5 (4.9)	1 (2.1)	4 (7.1)
Therapy, n (%)			
Insulin pump	8 (7.8)	8 (17.0)	17 (30.4)
Insulin injections	47 (45.6)	30 (63.8)	
Insulin injections and oral antidiabetes drugs	40 (38.8)	9 (19.1)	31 (55.4)
Oral antidiabetes drugs only	8 (7.8)		8 (14.3)
HbA1c (%)			
Mean (SD)	8.3 (1.4)	8.3 (1.3)	8.3 (1.4)
Median (range)	7.9 (5.4-12.4)	7.9 (5.4-12.4)	8.0 (5.6-12.0)

Results

Subjects

Baseline characteristics of subjects are shown in Table 1. In total, 47 subjects with T1D and 56 subjects with T2D participated. The majority (86%, 48/56) of the subjects with T2D used some form of insulin. All subjects were experienced SMBG users who performed BG tests relatively frequently (64%, 66/103), performing at least 3 tests per day.

Assessing Blood Glucose Data (With or Without) Color

In Exercise #1, there was no significant difference across the 103 subjects in terms of choosing to preferentially act whether the low result was shown with color (52%, 54/103) or without color (48%, 49/103). This outcome was not influenced by whether the subject had T1D or T2D. However, there was a significant difference across the 103 subjects in terms of choosing to preferentially act when identical high results were shown with color (55%, 57/103) compared to without color (45%, 46/103) (P=.001) (Figure 2). This preference for results with color was also observed across the 94 insulin-using subjects who chose to preferentially act when identical high results were shown with color (54%, 51/94) compared to without color (46%, 43/94) (P=.012) (Figure 2).

Similarly, in Exercise #2 there was a significant difference across the 103 subjects in the percentage of subjects choosing to preferentially act on a result shown with color (62%, 64/103) compared to the same numeric result shown without color (16%, 16/103) (P<.001) (Figure 3). The remaining subjects expressed no preference between color and no color. This preference for results with color was also observed across the 94 insulin-using subjects (61%, 57/94 vs 17%, 16/94; P<.001). In addition, this response preference for results with color was seen in the 47 subjects with T1D (color 61%, 29/47; without color 20%, 9/47) and the 56 subjects with T2D (color 64%, 36/56; without color 12%, 7/56), respectively (Figure 3).

Reviewing Blood Glucose Logbooks With or Without Color

In Exercise #3, more subjects correctly identified the 3 days when results were low, in range, or high when reviewing logbooks with color (83%, 85/103) compared to without color (68%, 70/103) (P=.012) This improvement was also evident across the 91 insulin-using subjects (82%, 75/91) compared to insulin users reviewing logbooks without color (66%, 60/91) (P=.01). Over half (55%, 57/103) of subjects responded that a logbook displaying results with color was easier to review compared to only 9% (9/103) who preferred a logbook without color. The remaining subjects expressed no preference between color and no color. Preference for reviewing glycemic trends

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using a logbook with color was also more pronounced in subjects using insulin, subjects with T1D, and subjects with T2D (Figure 4).

Subject Numeracy and Associations With Baseline Measures

Median subjective numeracy score was 34 (minimum possible score, 8; maximum possible score, 48) across all 103 subjects with a range of 8-48 (11-48 T1D; 8-48 T2D) (Figure 5). There was no correlation between numeracy and either A1c or SMBG frequency across all subjects or within subjects with either T1D or T2D.

Subject Numeracy and Associations With Color

In Exercise #1, subjects with lower numeracy levels (8-24) were more likely to say they would take action for high results shown with color (59%, 18/31) than without color (41%, 13/31). As numeracy level increased, subjects became noticeably less reliant on color to identify high results (Figure 6). For example, at the highest subjective numeracy level (score of 41-48), an equivalent number of subjects chose to take action for high results regardless of whether values were shown with or without color.

Figure 2. Preference for subjects to act on high BG results with and without color. All subjects (N=103); insulin-using subjects (n=94); T1DM (n=47); T2DM (n=56).

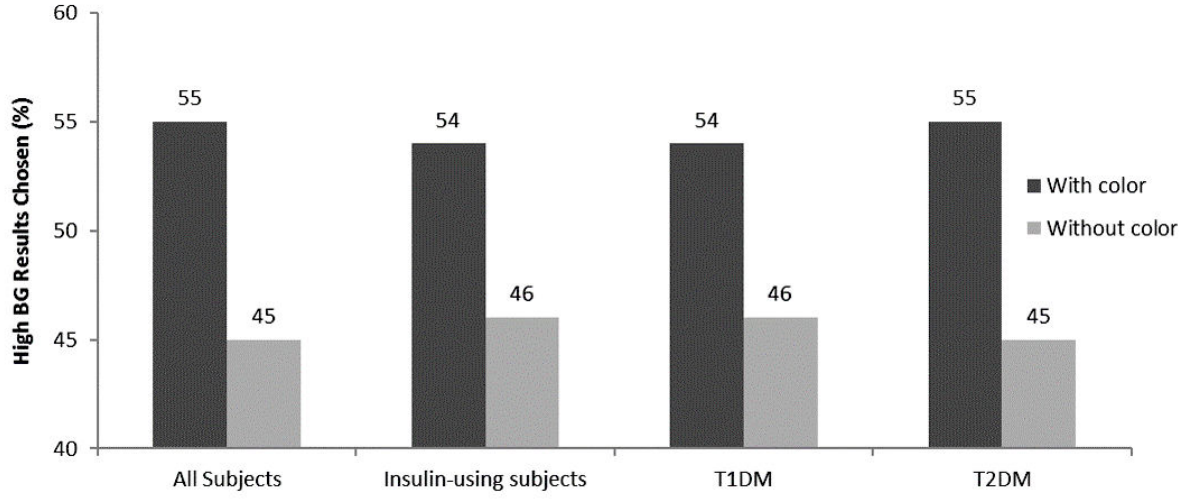

Figure 3. Preference of subjects to view individual BG results with or without color on a meter screen. The remaining subjects expressed no preference between color and no color. All subjects (N=103); insulin-using subjects (n=94); T1DM (n=47); T2DM (n=56).

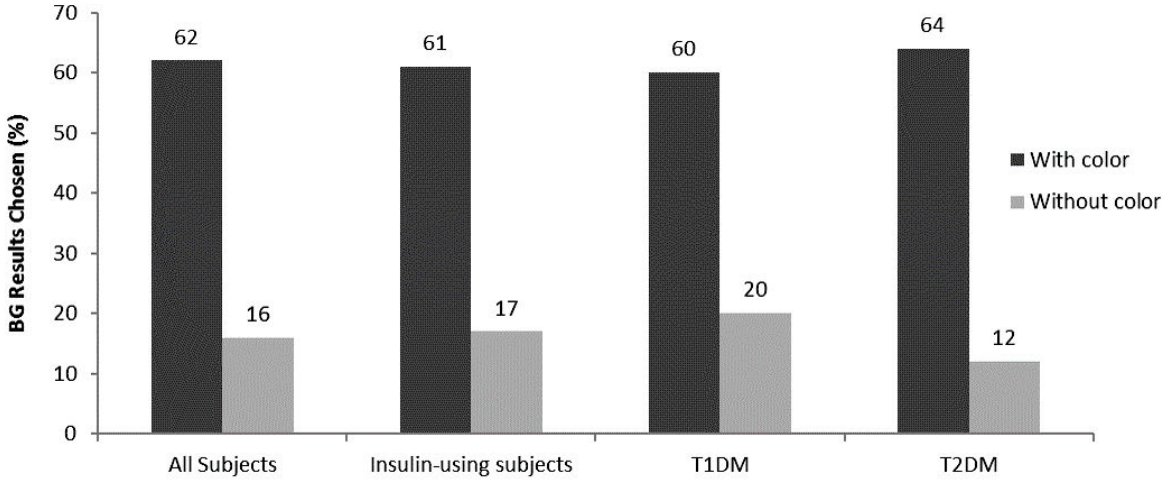

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Figure 4. Preferences for subjects to review BG data in a logbook with or without color. The remaining subjects expressed no preference between color and no color. All subjects (N=103); insulin-using subjects (n=94); T1DM (n=47); T2DM (n=56).

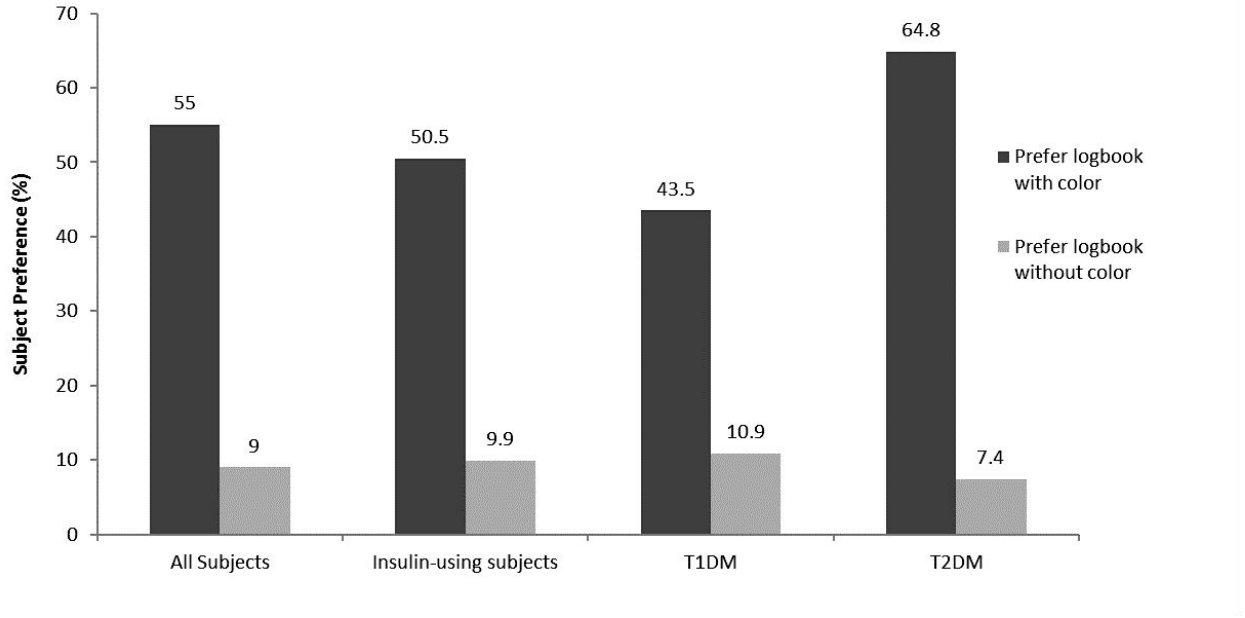

Figure 5. Numeracy level across subjects: Subjective Numeracy Scale scores in 103 subjects, T1DM (n=47) and T2DM (n=56). The 8-question scale has 6 items per question with a maximum score of 48 representing highest subjective numeracy evaluation and a minimum score of 8 representing lowest subjective numeracy evaluation. Numbers represent the number of subjects scoring in the range shown.

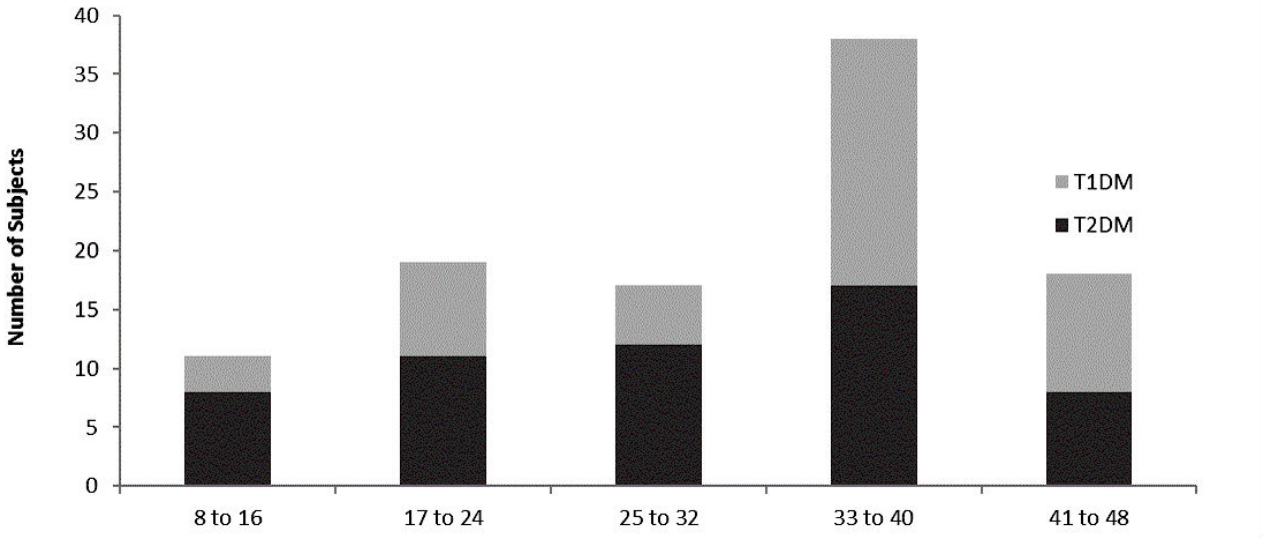

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Figure 6. Numeracy associations between subjects choosing high BG results when 6 identical BG results were shown with or without color.

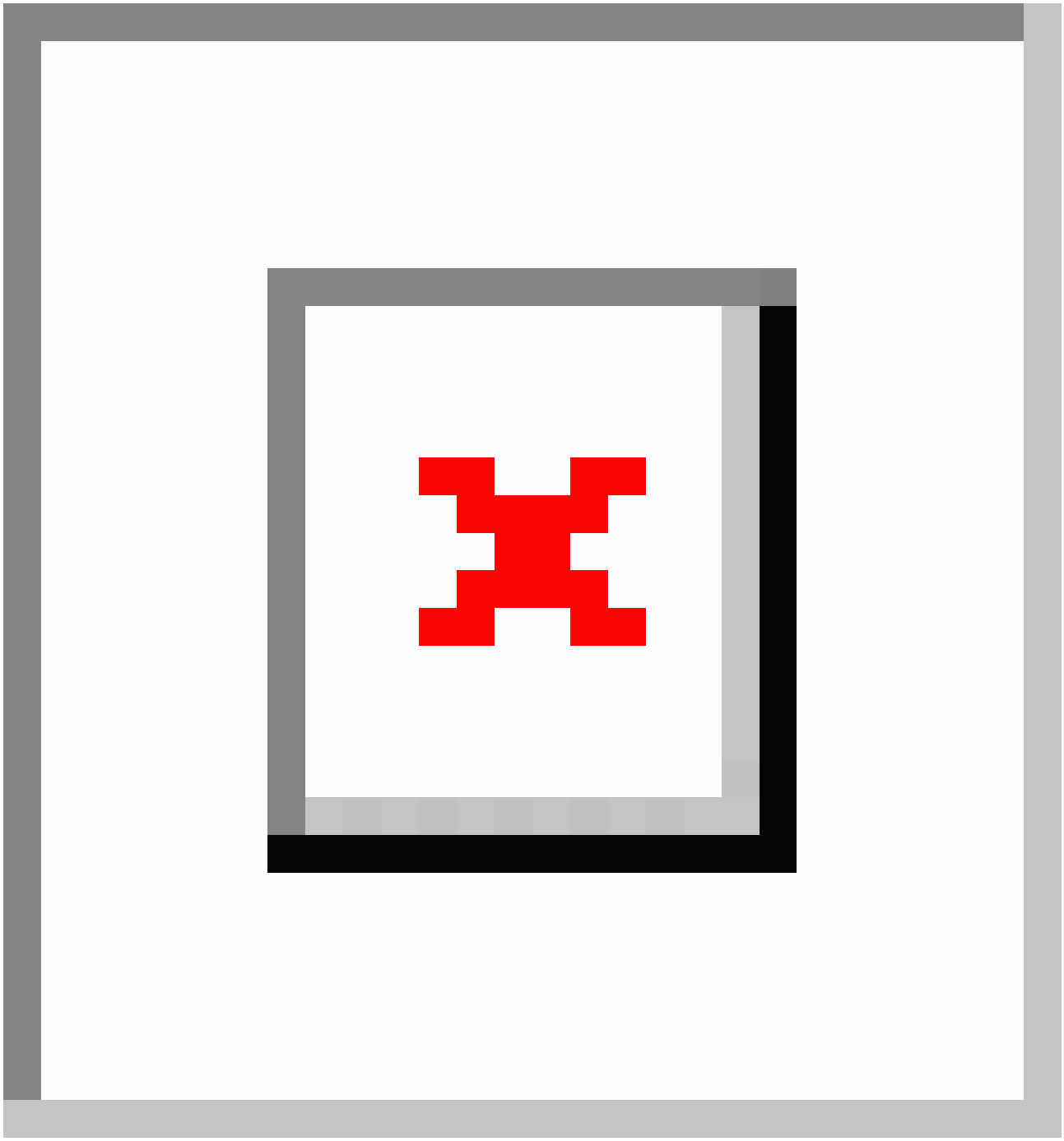

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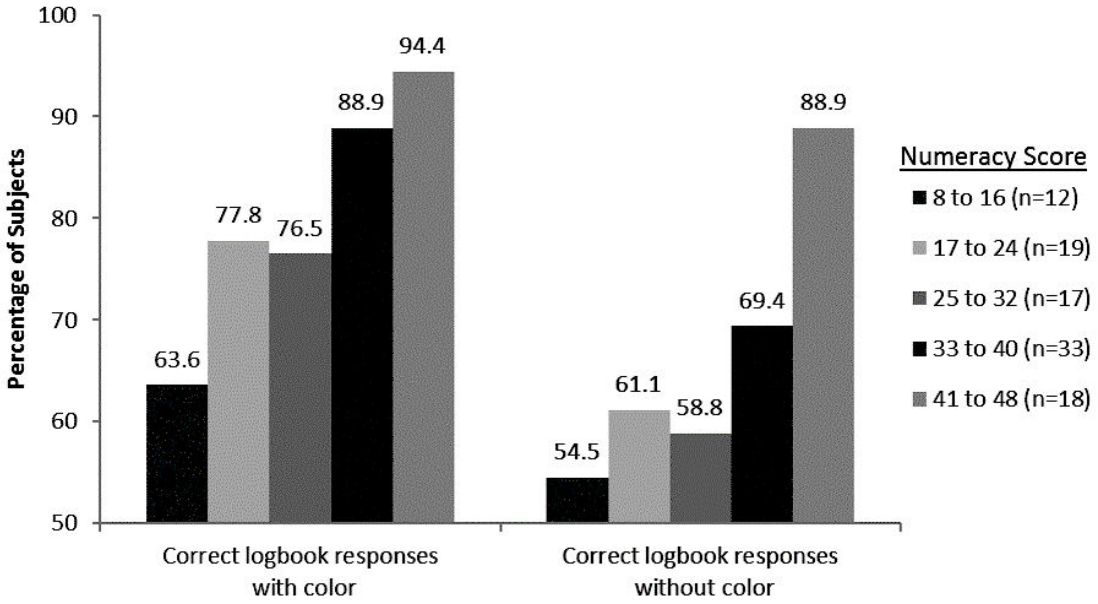
Figure 7. Association between numeracy and ability of subjects to correctly identify low, in range, or high days when results were shown with or without color in logbook format.



During Exercise #2, when reviewing identical pairs of glucose results shown with or without color, subjects with lower numeracy (8-24) preferentially selected action for results shown with color (71%, 22/31) compared to those without color (16%, 5/31). This preference to take action based on color declined as numeracy improved but was still evident even in subjects with the highest numeracy level where 53% (10/18) would preferentially take action for results shown with color compared to 16% (3/18) without color. During logbook Exercise #3, as numeracy improved, individual subjects were more successful at correctly identifying days of the week containing low, in range, or high glucose results (Figure 7). This trend was evident whether results were displayed with or without color. However, at every numeracy level, subjects were always more successful at identifying days of the week containing low, in range, or high results from logbook reviews with color (Figure 7).

Subject Perceptions of ColorSure Technology Feature

More than two-thirds (68%, 70/103) of subjects agreed or strongly agreed that showing a result with color (CST) makes it simpler to know when to act compared to a meter without color and that color could help them understand when they need to take action. In subjects with T2D, subjects agreed that color could help them improve awareness of when blood glucose is low (71%, 40/56) or high (66%, 37/56) and that showing a result with color could make it clearer when to take action (68%, 38/56). In T1D and T2D subjects with lower numeracy (equivalent to 51% [53/103] of all subjects based on a median numeracy score of <34), these subjects agreed that color could help them improve awareness of hypoglycemic (66%, 35/53) or hyperglycemic (70%, 37/53) results and that color would motivate them to stay in range (66%, 35/53) and feel more confident managing diabetes between scheduled HCP visits compared to a meter without color (64%, 34/53) (Table 2).

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Table 2. Subject responses to survey statements. Favorable responses are defined as a response of "strongly agree" or "agree" on a 5-point scale (5=strongly agree, 4=agree, 3=neither agree nor disagree, 2=disagree, and 1=strongly disagree). Neutral responses are a score of 3. Nonfavorable responses are a score of 1 or 2. All favorable response rates are statistically significant ($P<.05$).

	Nonfavorable response	Neutral response	Favorable response
All subjects (N=103)			
ColorSure could help me understand when I need to take action along with the BG number	12%	25%	63%
ColorSure provides extra awareness about what BG results mean[a]	16%	24%	60%
Showing a result with ColorSure makes it simpler to know when to act[b]	16%	16%	68%
ColorSure improves the testing experience compared to using a meter without any color	3%	34%	63%
Subjects with T2DM (n=56)			
ColorSure could help me improve my awareness of when my blood glucose is low	16%	13%	71%
ColorSure could help me improve my awareness of when my blood glucose is high	16%	18%	66%
ColorSure could give me more confidence to understand my results[a]	16%	21%	63%
ColorSure could make it clearer when I need to take action compared to a number only	16%	16%	68%
Showing a result with ColorSure makes you more inclined to act compared to seeing your result without color	20%	14%	64%
Subjects with low numeracy[c] (n=53; 21 T1DM, 32 T2DM)			
ColorSure could help me improve my awareness of when my blood glucose is low	11%	23%	66%
ColorSure could help me improve my awareness of when my blood glucose is high	11%	19%	70%
Using a meter with ColorSure could help me take the right steps to manage my blood glucose	10%	26%	64%
Using a meter with ColorSure could help me be more confident when I need to take action along with the BG number	9%	23%	68%
ColorSure would make me feel more confident managing my diabetes between scheduled HCP visits[a]	11%	25%	64%
ColorSure could motivate me to stay in-range between HCP visits[a]	11%	23%	66%
ColorSure could help me recognize signs and avoid trouble spots between HCP visits[a]	9%	25%	66%

[a]Compared to a meter without color.

[b]Compared to a result without color.

[c]Subjective Numeracy Scores less than the median of all study participants.

Discussion

Principal Findings

Building on our previous studies that showed that color enables patients with T1D and T2D to improve their ability to interpret blood glucose readings [7,9], we sought to demonstrate that color has the potential to improve the likelihood that patients will act on results. This is especially important given that many patients stop taking action over time, especially when they have high results, and often avoid taking any action whatsoever [8,12]. We demonstrated that color can positively influence the intention of subjects to act on glucose values and that this effect was particularly evident in subjects with lower numeracy. CST automatically highlights when individual results are within accepted glycemic ranges (low, in range, or high) and provides a simple association with color to reinforce how patients should interpret their results and facilitate appropriate action.

Our study demonstrated that color helped patients recognize when they should consider taking action in response to certain results, especially high results. The fact that color had less of an influence on whether subjects would consider taking action on low results may reflect the importance placed by HCPs on educating and reminding patients how to identify and react to hypoglycemia. In contrast, subjects responded more readily in terms of inclination to take action when high results were

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presented to them with color compared to high results shown without color. The strong subject preferences for intention to take action when viewing results displayed with color may point to a deficiency in education regarding what is a high value for that individual and what action could be taken in the moment or what prospective therapy or lifestyle changes could be adopted to minimize future high results. Interestingly, subjects with both T1D and T2D had similar preference for color when asked to consider a series of results on which they would preferentially intend to act. Our results imply that the immediate reassurance provided by color appeals equally to both groups even if anecdotally patients with T1D feel that color is less instructive to them given their higher testing frequency and greater familiarity reviewing blood glucose information.

A recent study in 7320 people with T2D not using insulin [13] found that in 1 of 6 people who practiced SMBG, neither the patient nor physician used any SMBG results to make treatment adjustments. These patients reported either diabetes was not a high priority for them or their HCP did not teach them how to adjust diet/medicines based on SMBG results. The reaction of the T2D population in our study (86%, 48/56 insulin users) who were performing SMBG at least 3 times a day is perhaps more similar to T1D subjects in terms of SMBG awareness or interpretation. This may explain why the reactions of subjects with T2D in our study to color were similar to the reactions of subjects with T1D.

It is well known that both patients and HCPs struggle to decipher glycemic pattern information from logbooks [14], which are often unclear or inaccurate [15]. We have found that a logbook presenting blood glucose results with color may overcome immediate barriers to deciphering trends within a logbook for patients with both T1D and T2D.

Strong trends were noted with respect to subject numeracy and reviewing SMBG data with color. In particular, subjects with lower numeracy were far more likely to say they would act on high results when presented with color. Consistent with this finding, Cavanagh et al [4] found 26% of 398 patients surveyed could not identify values within a target range of 60-120 mg/dl, and this declined further to 33% in those with the lowest numeracy. In contrast, patients with the highest numeracy were able to identify results within the target range 88% of the time. Additionally, in our study, about 2 out of 3 subjects with below-median numeracy felt that color would make them feel more confident managing diabetes between visits and could also help them recognize signs and avoid trouble between HCP visits.

The preference for viewing and acting on results with color may also have benefits in terms of reinforcing appropriate decision making over time. For example, there exists a disparity in the perception of patients and HCPs on how well patients can interpret SMBG data. A recent study noted that 38% of physicians perceived that nurses “always” assessed patients’ ability and knowledge with respect to SMBG and when to take action, whereas only 14% of the patients felt they were “always” taught how to perform SMBG or given information regarding treatment based on SMBG results [16]. Therefore, HCPs may be overestimating how effectively their patients can interpret SMBG data.

Limitations

HDI cares for more complex, intensively managing patients (eg, multiple daily insulin injections or using pumps) than might be encountered in general practice and this is reflected in our study demographics; 86% (48/56) of our T2D subjects were taking some form of insulin and 52% (29/56) performed SMBG ≥3 times per day, much higher than people with T2D in the general local population. Despite our intensively managing study population having familiarity with SMBG data and access to expert care from diabetes specialist nurses, it was encouraging that participants still appeared to benefit from, and exhibit strong preferences for, color-coded information. It is possible that the value of color insights may be even stronger in a more generalized T2D population who typically perform SMBG less frequently and may be less able to interpret numerical glucose data.

We acknowledge that there are relatively small numbers of subjects within the lowest numeracy level (8-16), which limits robustness of the data. However, there are clear overall trends associating changes in numeracy with subject performance or preference for color. The tablet PC system used to enable subjects to experience a wide range of glucose results (with or without) color is admittedly a simulation for results on an actual glucose meter, but it allowed subjects to quickly and easily visualize sequential meter screen images or meter screens in parallel and respond in the moment. These are the kind of assessments we expect patients to make after each glucose test at home (often multiple times per day). This concentrated experience, viewing a series of glucose values, is an efficient way to obtain an estimation of each subjects’ ability and perceptions concerning interpreting data with or without color.

The paper logbook exercises were not randomized; subjects always completed the black/white logbook assessment first followed by the color logbook assessment. Familiarity with the format of the materials and process may have helped some subjects. Justification for this order was that performing the color logbook first would provide additional education on what represented a low, in range, or high result, which could have influenced or improved interpretation of the standard logbook. It is also worth highlighting that subjects were given a time limit of 2 minutes to assess each logbook in turn and with the exception of 1 subject (a retired T2D male testing the minimum of 1 time per day) who provided 5 of the required 6 selections in time, no other subjects skipped any selections for any logbook in the required timeframe. On this basis, it is clear that even if we assume that there was a learning curve in witnessing the black/white logbook first, the fact that everyone completed the exercises in such a short time suggests it was not a clinically meaningful advantage.

Conclusion

Both insulin and noninsulin-using subjects may benefit from color to support interpretation of blood glucose results displayed either on a meter or in a logbook. Our study suggests strong preferences for viewing results with color and that subjects may

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be more inclined to act, particularly on hyperglycemic results, when presented with results in color. Displaying glucose results with color improves interpretation of SMBG results and can assist and encourage subjects to act on SMBG data, which may enable them to follow their HCP recommendations more closely between scheduled consultations.

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Conflicts of Interest

MG and HC are employees of LifeScan Scotland, Ltd. LBK, CSS, and BLL are employees of LifeScan, Inc.

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Abbreviations

A1c: hemoglobin A1c
BG: blood glucose
BGM: blood glucose monitor
CRI: color range indicator
HCP: health care professional
SD: standard deviation
SMBG: self-monitoring of blood glucose
T1D: type 1 diabetes
T2D: type 2 diabetes

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Case Report

iOS Appstore-Based Phone Apps for Diabetes Management: Potential for Use in Medication Adherence

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Abstract

Background: Currently, various phone apps have been developed to assist patients. Many of these apps are developed to assist patients in the self-management of chronic diseases such as diabetes. It is essential to analyze these various apps to understand the key features that would potentially be instrumental in helping patients successfully achieve goals in disease self-management.

Objective: The objective of this study was to conduct a review of all the available diabetes-related apps in the iOS App Store to evaluate which diabetic app is more interactive and offers a wide variety of operations such as monitoring glucose, water, carbohydrate intake, weight, body mass index (BMI), medication, blood pressure (BP) levels, reminders or push notifications, food database, charts, exercise management, email, sync between devices, syncing data directly to the prescribers, and other miscellaneous functions such as (Twitter integration, password protection, retina display, barcode scanner, apple watch functionality, and cloud syncing).

Methods: Data was gathered using the iOS App Store on an iPad. The search term “diabetes” resulted in 1209 results. Many of the results obtained were remotely related to diabetes and focused mainly on diet, exercise, emergency services, refill reminders, providing general diabetes information, and other nontherapeutic options. We reviewed each app description and only included apps that were meant for tracking blood glucose levels. All data were obtained in one sitting by one person on the same device, as we found that carrying out the search at different times or on different devices (iPhones) resulted in varying results. Apps that did not have a feature for tracking glucose levels were excluded from the study.

Results: The search resulted in 1209 results; 85 apps were retained based on the inclusion criteria mentioned above. All the apps were reviewed for average customer ratings, number of reviews, price, and functions. Of all the apps surveyed, 18 apps with the highest number of user ratings were used for in-depth analysis. Of these 18 apps, 50% (9/18) also had a medication adherence function. Our analysis revealed that the Diabetes logbook used by the mySugr app was one of the best; it differentiated itself by introducing fun as a method of increasing adherence.

Conclusions: A large variation was seen in patient ratings of app features. Many patient reviewers desired simplicity of app functions. Glucose level tracking and email features potentially helped patients and health care providers manage the disease more efficiently. However, none of the apps could sync data directly to the prescribers. Additional features such as graph customization, availability of data backup, and recording previous entries were also requested by many users. Thus, the use of apps in disease management and patient and health-care provider involvement in future app refinement and development should be encouraged.

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KEYWORDS

diabetes; telemedicine; blood glucose self-monitoring glucose monitoring; mobile applications; self-care; mobile health

Introduction

The Centers for Disease Control and Prevention define chronic diseases as "the most common, costly, and preventable of all health problems." This includes conditions such as heart disease, stroke, and cancer [1]. In the United States, approximately 70% or 1.7 million of all deaths are due to chronic diseases [2].

Diabetes is a chronic disease that occurs in three primary forms: type 1 diabetes mellitus (T1DM), type 2 diabetes mellitus (T2DM), and gestational diabetes mellitus [3]. T1DM is characterized by pancreatic beta cells that are destroyed and thus cannot produce insulin [3]. T2DM is characterized by insulin resistance, markedly in muscles, liver, and adipose tissues [3]. Obesity [4,5], family history [6], physical inactivity [7], and ethnicity [8] are some of the risk factors associated with diabetes. The prevalence of diabetes in the United States in 2014 was 9.3% (29.1 million) and continues to rise [9]. Among adults aged 18 to 79 years, there were an estimated 1.4 million new cases of diabetes diagnosed in 2014 [10]. If this trend continues, as many as 1 out of every 3 adults in the United States could develop diabetes by 2050 [9].

Diabetes is managed through pharmacologic therapy and lifestyle modifications such as exercise, diet, and glucose monitoring [11], T1DM is defined by the patient's inability to produce insulin, and thus, these patients are dependent on the administration of insulin for proper management of the disease. However, T2DM can be managed through the administration of oral hypoglycemic agents, insulin, non-insulin injectable agents, or a combination of agents [12]. Hemoglobin A1C and blood glucose values are used for diagnosis and management of diabetes [11]. Improper management of glycemic levels can lead to outcomes including, but not limited to, adverse cardiovascular outcomes, retinopathy, nephropathy, hyperglycemia, and hypoglycemia [13]. Nonadherence is one contributor to the improper management of diabetes as it is estimated that 50% of patients do not take their medications as prescribed by their physicians [14]. The New England Healthcare Institute estimates that nonadherence along with suboptimal prescribing, drug administration, and diagnosis could result in as much as US $290 billion per year in avoidable medical spending [15]. Therefore, compliance, or the proper use of medication by patients, plays a crucial role in the proper management of diabetes [16].

For patients diagnosed with diabetes, monitoring of blood glucose levels is the principal foundation of treatment planning and is performed through the use of a glucometer, a lancing device, and testing strips. Blood glucose values allow the patient or physician to adjust medication strength and also provide insight on disease progression. While A1C provides a 3-month average of blood glucose levels, it does not provide specific information that can support the adjustment of fasting plasma glucose or post-prandial glucose levels in the case of uncontrolled diabetes. An increased frequency of glucose level measurements has been associated with reduced Hemoglobin A1C levels [17]. Daily logging of self-monitored blood glucose levels may increase patient safety and awareness to therapeutic effectiveness as well as aid in adjustments to treatment planning.

With roughly half of the adult US population managing one chronic disease and 25% managing two or more chronic health conditions [1], it is becoming increasingly important to provide patients with the education and tools to self-manage their diseases. Nadkarni et al have shown that the implementation of a plan for self-monitoring behavior results in an increase in the frequency of blood glucose level measurements [18]. Moreover, it has been shown that rather than written documentation, electronic record-keeping may be of greater efficacy [19]. While mobile phones were once less accessible and desirable due to cost and limited functions, innovation has led to the mobile phone becoming ubiquitous throughout the United States and globally. Mobile phone ownership in 2015 among US adults ≥ 18 years old was an estimated 68% and 86% among those aged 18 to 29 years [20]. A variety of mobile phone apps tailored for the management of chronic diseases is available for download in the various app stores. Prior studies have shown that mobile phone app usage was correlated to patient behavioral patterns that facilitate diabetes self-management [21].

Prior studies have been conducted pertaining to a number of the apps included in this review [21,22,23]. However, some apps have been discontinued and many more have been added to the market since the publication of those studies. This review strives to provide a comprehensive analysis of currently available apps for tracking blood glucose levels.

The purpose of this article was to provide a qualitative review of the various apps related to diabetes self-management that are available on the iOS Apple App Store. A secondary objective was to provide a detailed analysis and comprehensive review of additional features with respect to the top 15 apps for tracking glucose levels, indicated by the number of reviews on the iOS App Store, in order to facilitate patient selection of apps.

Methods

Search Methodology

The search term used on the iOS App Store was "diabetes," which was entered on an iPad, resulting in 1209 apps as of 6th September, 2015. The iPad was selected instead of the iPhone-6 because of increased screen space and reduced tendency to crash. The search term "diabetes" produced an excessive number of results that led to crashes on an iPhone-6 while browsing through the pages. For instance, if 100 pages of search results were produced, a crash was possible at any point when changing pages, at which point a new search would have to be performed, resulting in a different order of results and thus making it more difficult to extract information.

In addition, the iPad was selected instead of a desktop because the desktop version of the App Store does not display the total number of results. The iOS App Store was also preferred over the Play Store for Android as the Play Store tends to

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overestimate results through generation of less relevant results [24,25]. Moreover, the scope of this research was to only to review the apps available for iOS. Hence, Google's Play Store was not reviewed. The broad search term "diabetes" was used to maximize the number of results pertaining to potential apps for tracking glucose levels.

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Table 1. List of diabetes self-management apps available in iOS App Store.

No.	App name	Average customer rating	Number of reviews	Price (US $)	Functions (1[a], 2[b], 3[c], 4[d], 5[e], 6[f], 7[g], 8[h], 9[i])
1	Bant	2.5	183	0.00	1, 5, 7
2	Best Diabetes Control	1	2	0.99 (Lite version available)	1, 2, 6, 9
3	Blood Diary	3	1	0.00	1, 2, 9
4	Blood Glucose Tracker (japps)	3.5	2	In-app purchases	1, 2, 3, 5, 9
5	Blood Sugar Diabetes Control	2.5	150	0.99	1, 2, 5, 6, 7
6	Dafne Online	0	0	0.00	1, 2, 5, 8
7	Dbees	3	16	0.00	1, 2, 5, 6, 9
8	Dblog	3	2	0.99	1, 7, 9
9	Diabetes 360	4	21	4.99	1, 2, 5, 7, 9
10	Diabetes App	4	2940	6.99	1, 2, 4, 5, 6, 7, 8, 9
11	Diabetes Assistant	4.5	5	1.99	1, 2, 3
12	Diabetes Companion	0	0	0.00	1
13	Diabetes Connect	4.5	67	In-app purchases	1, 2, 5, 7, 8, 9
14	Diabetes Diary	3.5	41	2.99	1, 2, 5, 9
15	Diabetes Factors	1	5	0.00	1, 5, 7, 8, 9
16	Diabetes Glucose Tracker app	2	85	2.99	1, 2, 3, 5, 7, 9
17	Diabetes Health Mate	4	17	0.00	1, 2, 3, 5, 9
18	Diabetes in Check	4	989	0.00	1, 2, 3, 4, 7, 9
19	Diabetes Kit	5	287	0.00	1, 2, 3, 5, 9
20	Diabetes Log	3	1948	0.00	1, 2, 7, 8, 9
21	Diabetes Logbook by mySugr	5	1684	In-app purchases	1, 2, 3, 5, 8, 9
22	Diabetes Logger	1	1	0.00	1, 2, 5, 9
23	Diabetes Management app	1	1	In-app purchases	1, 2, 7, 9
24	Diabetes Manager	5	2	4.99	1, 2, 5, 7, 9
25	Diabetes Pal app	4	183	0.00	1, 2, 5, 8, 9
26	Diabetes Parent	0	0	0.00	1, 2, 8, 9
27	Diabetes Passport	0	0	0.00	1, 2, 5, 7, 9
28	Diabetes Pilot Classic	4	221	24.99	1, 2, 4, 5, 7, 9
29	Diabetes Plus	4.5	8	3.99	1, 2, 5, 6, 7, 9
30	Diabetes Studio	0	0	0.00	1, 3, 5, 7, 8, 9
31	Diabetes Tracker with Blood Glucose/Carb Log by MyNetDiary	4.5	447	9.99	1, 2, 4, 5, 8, 9
32	Diabetes UK Tracker	0	0	0.00	1, 2
33	Diabetespal	4.5	6	2.99	1, 2, 5, 7, 9
34	Diabetesscs	0	0	0.00	1
35	Diabetesteam	0	0	0.00	1, 2, 5, 6, 7, 9
36	Diabetic Plus	0	0	0.00	1, 2, 3, 5, 6, 7, 9
37	Diabetic Plus	0	0	0.00	1, 2, 3, 5, 6, 7, 9
38	Diabetic Tracker Unlimited	2	25	1.99	1, 5, 7, 9
39	Diabeticplus	0	0	0.00	1, 5, 7, 8, 9
41	Diabetics Diary	4	1	0.00	1, 2, 6, 7, 9

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No.	App name	Average customer rating	Number of reviews	Price (US $)	Functions (1[a], 2[b], 3[c], 4[d], 5[e], 6[f], 7[g], 8[h], 9[i])
42	Diabetic's Diary	5	1	0.00	1, 2, 5, 6, 7, 9
43	Diabetik	5	79	0.00	1, 2, 3, 7, 9
44	Diabettes	0	0	0.00	1, 2, 6, 9
45	Diamedic	3.5	143	5.99	1, 2, 3, 5, 7, 9
46	Ditto Glucose Logbook	2	2	0.00	1, 2, 5, 7, 9
47	Dmdiary	5	1	0.00	1, 5, 7, 9
48	Easy Diabetes	4	29	0.00	1, 2, 5, 7, 9
49	Gestational Diabetes Manager	2.5	18	2.99	1, 2, 4, 6, 7
50	Glicontrol	1	1	In-app purchases	1, 2, 5, 7, 9
51	Glucocheck	0	0	0.00	1, 2, 5, 6, 9
52	GluCoMo	2	82	0.99	1, 3, 5, 9
53	Glucorecord	2	14	In-app purchases	1, 2, 5, 6, 7, 9
54	Glucose Buddy	4	6400	In-app purchases	1, 2, 3, 5, 7, 8, 9
55	Glucose Companion	4.5	888	1.99	1, 2, 3, 5, 7, 8, 9
56	Glucose Monsters	2	11	0.00	1, 2, 5
57	Glucose Readings	0	0	0.99	1, 5, 7, 9
58	Glucose Recorder	3.5	30	2.99	1, 2, 5, 8, 9
59	Glucose Tracker	2.5	17	1.99	1, 2, 5, 7, 9
60	Glucose Tracker - simple and complete app	5	6	0.99	1, 2, 3, 5, 7, 9
61	Glucose Wiz/Pro	4	61	1.99	1, 2, 3, 5, 7, 8, 9
63	Glucosurfer Free	0	0	0.00	1, 2, 5, 9
64	Glucosurfer	0	0	0.99	1, 2, 6, 7, 9
65	Glucosweet	2.5	7	6.99	1, 2, 5, 7, 8, 9
66	Glycemiaquicklog	2	1	2.99	1, 3, 5, 7, 9
67	Gmate	4	9	0.00	1, 2, 5, 6, 9
68	Healthediabetes	3.5	15	5.99	1, 2, 9
69	Glucose Monitor (HealthstomeG)	4.5	331	In-app purchases	1, 2, 3, 6, 7, 8, 9
70	Ibgstar Diabetes Manager	3.5	150	0.00	1, 2, 3, 5, 9
71	Iglu-bz	0	0	0.00	1, 2, 5, 6
72	Mdiabetes	0	0	0.99	1, 2, 4, 5, 7, 9
73	Mydiabetes	0	0	3.99	1, 2, 3, 5, 6, 7, 9
74	Mydiabetesapp	0	0	3.99	1, 2, 5, 6, 7, 9
75	Mysugr Junior	4	11	0.00	1, 2, 4, 7, 9
76	Onsync Diabetes Manager	2	28	0.00	1, 2, 5, 7, 9
77	Pomihealth	4.5	70	2.99	1, 2, 5, 9
78	Predict Bgl	5	3	0.00	1, 2, 4, 6, 9
79	Rapidcalc	4.5	25	7.99	1, 2, 5, 7, 9
80	Sidiary	3	9	5.99	1, 5, 8, 9
81	Simple Diabetes	0	0	0.00	1, 2, 7, 9
82	Sugar Sense	4.5	86	0.00	1, 2, 6, 7, 9
83	Sugarpal Diabetes Manager	3	1	3.99	1, 2, 5, 7, 9

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No.	App name	Average customer rating	Number of reviews	Price (US $)	Functions (1[a], 2[b], 3[c], 4[d], 5[e], 6[f], 7[g], 8[h], 9[i])
84	Track3	4.5	820	5.99	1, 2, 6, 7, 8, 9
85	Your Diabetes Diary	4	1	0.00	1, 2, 5, 6, 7, 9

[a]Logs glucose levels.

[b]Logs water and carbohydrate intake, weight, body mass index, medication, and blood pressure.

[c]Reminders or push notifications.

[d]Food database.

[e]Charts.

[f]Exercise management.

[g]Email.

[h]Sync between devices.

[i]Miscellaneous (Twitter, password protection, retina display, barcode scanner, apple watch functionality, cloud syncing, and miscellaneous functions).

Of these 1209 results, 85 were ultimately retained due to the presence of the ability to track users' glucose levels (Table 1). The 1124 apps excluded focused mainly on diet, exercise, emergency services, providing general diabetes information, and other nontherapeutic options, or they were duplicate apps (Figure 1). The glucose levels tracked were visible on most apps from the landing page description. Any apps in which this information was not on the landing page were found using an iPhone, searching by the name of the app so as not to interrupt the search on the iPad. As performing the same "diabetes" search at different times or on different devices (iPhones) would result in varying results (different order or quantity), for the purpose of this analysis, we used the results for the search term "diabetes" from a single device (an iPad), and the author continuously reviewed the description of all the apps without interruption (this task required about six hours to accomplish). This method ensured that the list of search results would maintain the same apps in the same order. Based on these factors, our study focused on apps available in the iOS App Store.

Apps Reviews and Analysis

After the inclusion criteria for the presence of glucose level tracking feature were met and the 85 apps were selected, the breakdown and recording of specific features for the respective apps was split amongst three of the authors (MM, EP, and IM). Information not available on the landing page was gathered by entering the specific app's page on the iPad and reviewing the features. Each person recorded the rating for the app, number of reviews, price, in-app purchase facility, features, and major pros and cons noted in user reviews.

An in-depth analysis was then performed by two authors (MM and LS) on the "Top 15" apps, based on the highest number of reviews, and the information is presented below and in Multimedia Appendix 1. The respective apps were downloaded on iPhones and used over the course of 2 weeks, with each author performing a qualitative analysis of the apps' ability to track glucose levels, carbohydrate intake, medication, weight, exercise, and blood pressure, as well as the apps' ease of use and graphs. The availability of additional features such as data export, back up, goal setting, forums, and integration with a meter were also recorded. Each author allotted a rating of good or poor to the qualitative features. A good rating was given if the feature demonstrated a majority of the following characteristics: being intuitive and useful, stable (the app does not crash if the feature is used), and well designed in terms of colors, font, clarity, and easily accessible from the menu. At the end of the 2-week trial period, the two authors independently completed their comprehensive reviews of the 15 apps and then came together to resolve any discrepancies in the ratings and finalize the results.

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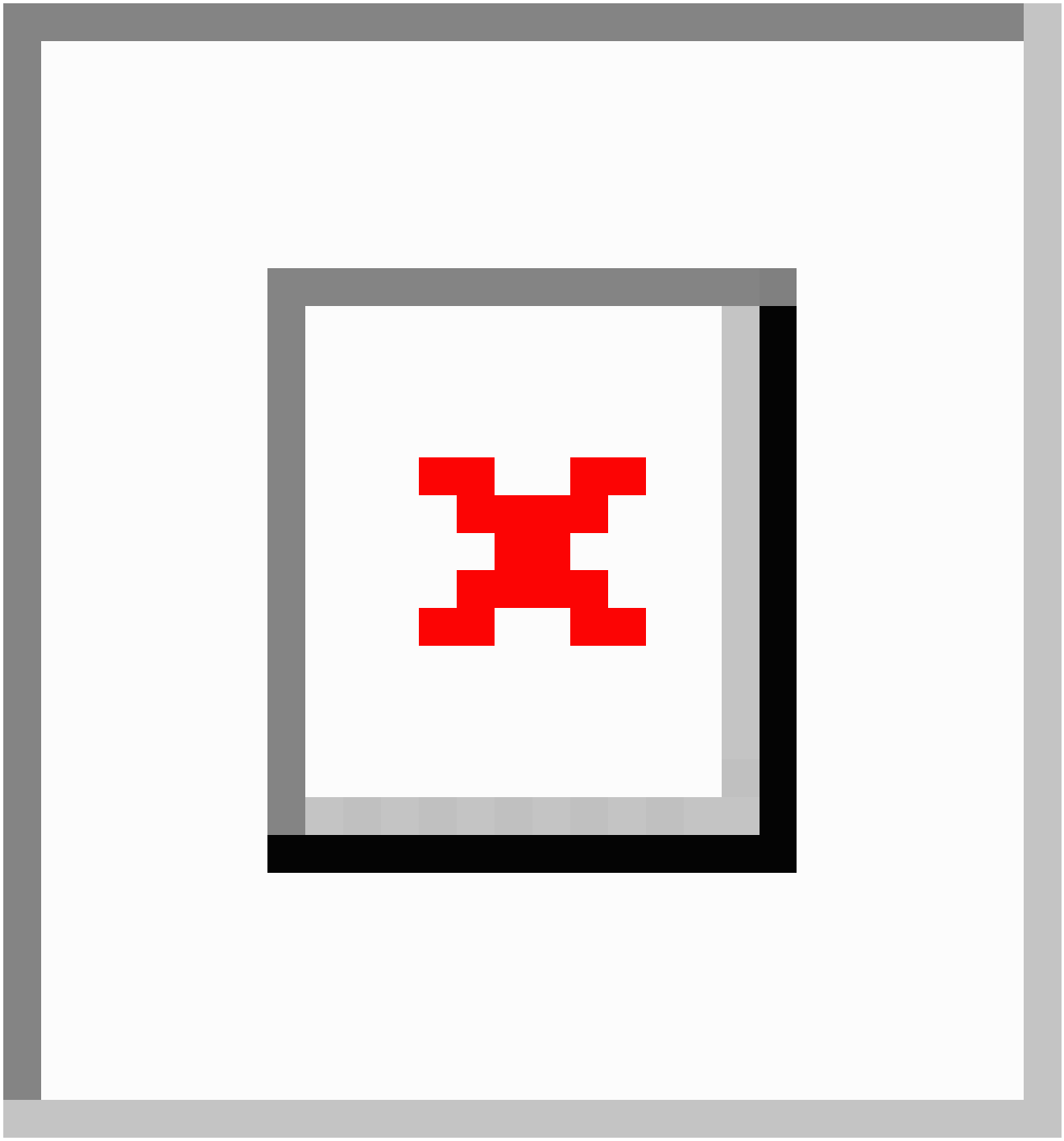
Figure 1. Selection algorithm of the top iOS apps for diabetes self-management.



Results

Among the top 15 apps tested, only 13% (2/15) featured integration with a meter (Multimedia Appendix 1). Only 13% (2/15) featured the ability to receive advice through a certified diabetes educator within the app. Availability of tracking features was 73% (11/15), 73% (11/15), 73% (11/15), 53% (8/15), and 46% (7/15) for tracking carbohydrate intake, medication tracking, weight tracking, exercise tracking, and blood pressure tracking, respectively. Despite 73% (11/15) of the apps having the feature of tracking carbohydrate intake, only 3 of the 15 apps had an integrated food database; most of the apps focused on the input of carbohydrate values as opposed to the input of food with carbohydrate values calculated by the app itself. Less than half of the apps featured the availability of adherence reminders, and among these, three did not offer the feature in the free version. We found that 93% (14/15) of the apps featured a method to export data, primarily by emailing values or graphs, and 73% (11/15) of the apps allowed the user to set goals in order to visualize when they failed to meet their goals, generally using a certain color to indicate hypoglycemia or hyperglycemia. Seven apps featured some form of advertisement within the app that could be removed by upgrading from the free to the paid version. Only one app (SugarSense) mentioned the use of guidelines and provided users with information citing the guidelines, while also providing a link directly to the American Diabetes Association (ADA) guidelines.

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Discussion

Principal Findings

Patient self-management of chronic illness is important to assist physicians in management of the disease and increase adherence. The use of apps has been shown to be useful not only in diabetes, but also in other chronic diseases such as cancer [26] as well as non-chronic diseases such as weight loss [27]. Data obtained from apps on blood glucose, blood pressure, diet, exercise, asthma exacerbations, and so forth could be instrumental in maintaining proper medication regimens and improving the effectiveness of targeted counseling from physicians, based on where the patient is failing or succeeding.

Subsequent to the review and comparison of the top 15 apps for tracking glucose levels, the primary differentiating factors among the apps were found to be their respective supplemental features such as carbohydrate-intake tracking, medication tracking, weight tracking, exercise tracking, blood pressure tracking, ease of use, food database, graph availability, adherence reminders, data export, data backup, goal setting, notes, advertisements, community forums, access to certified diabetes educators, and integration with a meter.

Our results reflected that patient reviews emphasized the desire for simplicity, but also the availability of more complex features (highly customizable graphs, data backup, and synchronization across devices). The best apps had a large number of features but did not overwhelm the user by displaying all of the features or customization options available. In the future, syncing data directly to prescribers could provide the patients' detailed blood glucose readings, medication adherence practices, and diet in a standardized format. The data could potentially increase health care outcomes by providing a larger pool of data to improve pharmacologic therapy and non-pharmacologic therapy counseling for patients.

Although all of the apps reviewed were for diabetes management, less than half of the top apps (7/15) had a medication adherence function (Multimedia Appendix 1). It was puzzling that although so many apps had a comprehensive list of features that ranged from tracking calories to cloud backup, they failed to implement reminders for medication, as forgetfulness is a factor of nonadherence. This may have been because many patients inject per sliding scale or with meals and the timing is nontraditional; nevertheless, reminders should be a requirement of self-management apps. One stand out feature only apparent in the Diabetes Logbook app by mySugr was the introduction of fun as a method of increasing adherence. The highest rated apps had myriad features and many comparable features between them, but having "fun" while inputting data may add the extra push that users need to continue to use the app and attain their therapeutic goals.

Limitations

There is neither regulatory body assigned to monitor the efficacy of wellness apps, nor a designated evidence base [28]. SugarSense was the only app in the top 15 that provided referenced information per ADA guidelines as well as a direct link to the ADA guidelines. Although this is important, usefulness for a patient who may be a layperson has to be evaluated. Kirwan et al have shown that an app supplemented with certified educator feedback via text messaging produced statistically significant improvement in the control of patients' blood glucose levels [29]. While text-message feedback was not incorporated in our review, two of the top 15 apps (Diabetes Logbook and Diabetes Kit) did provide the optional resource of a certified diabetes educator. User reviews reflected mixed positive and negative opinions regarding the feature. Further evaluation is needed regarding degree of usefulness.

While there are a medley of apps available for assistance in self-management of diabetes and other chronic diseases, it is important to determine exactly which features are instrumental to the success of patient goals in disease management. Patients are easily discouraged by an abundance of features, but they are equally discouraged by a lack of features and customization. The exact components of an ideal self-management app may already be possessed by the apps discussed here; it is just a matter of optimization by the removal of unnecessary features and the addition of missing features.

This study was limited in terms of the time when the apps were introduced to the market, as this may have impacted the number of reviews—apps that were available for a longer period of time for user download and use may have had reviews that were more positive or numerous. This study may have also yielded different results had we also included the paid only apps in the top 15 list (Diabetes Pilot Classic, Blood Sugar Diabetes Control, Diabetes Diary, Diamedic, and GluCoMo).

Conclusions

Apps may assist health care providers in inching closer to optimal prescriptions by increasing both patient involvement and availability of data. The use of phone apps for management of chronic diseases such as diabetes is not a novel concept, but the extent to which specific features may improve adherence along with real-world application by physicians has been minimally explored [25,30-35]. Features that should be considered by app developers are graph customization, availability of data backup, records of previous entries, and syncing directly from glucometers without the need for manual input of values. Two apps allowed syncing of glucose values directly from patient glucometers, which should increase ease of use. Ibgstar Diabetes Manager by Sanofi connects the glucometer directly to an iPhone or iPod touch and inputs glucose readings into the app. The Diabetes Pal App by Telcare provides similar functions and integration, but data from the glucometer is instead sent over wi-fi directly to the Telcare website, after which it can be synced to the app. The Telcare device was well received, whereas the Sanofi meter received a number of reviews complaining about lack of functions. Technology can assist in increasing patient compliance and quality of life in managing chronic illness; however, it is important for app developers to realize that ease, feasibility of customization, and number of functions is important for patient reliance, though developers should not get carried away and deviate from the original goal of working with patients and prescribers in order to improve health outcomes.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Attributes of the top 15 apps for diabetes self-management available in the iOS App Store.

[JPG File, 199KB - diabetes_v2i2e12_app1.jpg]

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Abbreviations

T1DM: type 1 diabetes mellitus
T2DM: type 2 diabetes mellitus
BMI: body mass index
BP: blood pressure

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Original Paper

Diabetes App-Related Text Messages From Health Care Professionals in Conjunction With a New Wireless Glucose Meter With a Color Range Indicator Improves Glycemic Control in Patients With Type 1 and Type 2 Diabetes: Randomized Controlled Trial

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Abstract

Background: Mobile diabetes apps enable health care professionals (HCPs) to monitor patient progress, offer remote consultations, and allow more effective and informed treatment decisions between patients and HCPs. The OneTouch Reveal app aggregates data from a blood glucose meter and provides analytics to help patients and HCPs visualize glycemic trends and patterns, enabling more informed treatment and lifestyle decisions. The app also allows patients and HCPs to keep connected by exchanging text messages (short message service [SMS]) or progress reports via email.

Objective: The primary objective of our study was to assess changes in glycemic control and overall experiences of patients and HCPs using the app in conjunction with the wireless OneTouch Verio Flex blood glucose meter.

Methods: We randomly assigned 137 adults with type 1 (T1DM) or type 2 diabetes mellitus (T2DM) and a glycated hemoglobin (HbA_{1c}) level of ≥7.5% and ≤11.0% to use the glucose meter alone or glucose meter plus the app for 24 weeks. The meter + app group were scheduled to receive diabetes-related text messages from their HCP every 2 weeks (total of 12 texts). Clinical measures and self-reported outcomes were assessed during face-to-face clinic visits between the participant and a diabetes nurse at baseline, week 12, and week 24.

Results: In 128 completed participants, HbA_{1c} decreased after 12 and 24 weeks in both the meter-only (n=66) (0.56% and 0.55%, respectively) and meter + app groups (n=62) (0.78% and 0.67%, respectively) compared with baseline (each $P<.001$). The difference in HbA_{1c} reduction between the 2 groups was not statistically significant at 12 or 24 weeks ($P=.12$ and $P=.45$, respectively). However, the decrease in HbA_{1c} was greater in T2DM participants using the meter + app after 12 weeks (1.04%) than in T2DM participants using the meter alone (0.58%; $P=.09$). In addition, decrease in HbA_{1c} in participants using the meter + app who received at least 10 diabetes-related text messages (1.05%) was significantly greater than in meter-only participants ($P<.01$).

Conclusions: Use of the OneTouch Verio Flex glucose meter alone or in combination with the OneTouch Reveal diabetes app was associated with significant improvements in glycemic control after 12 and 24 weeks. Improvements using the app were greatest in participants with T2DM and those participants who received the highest number of HCP text messages. This study suggests that real-time availability of patient data and the ability to send personalized diabetes-related text messages can assist HCPs to improve glycemic control in patients between scheduled visits.

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Trial Registration: Clinicaltrials.gov NCT02429024; https://clinicaltrials.gov/ct2/show/NCT02429024 (Archived by WebCite at http://www.webcitation.org/6sCTDRa1l)

(JMIR Diabetes 2017;2(2):e19) doi:10.2196/diabetes.7454

KEYWORDS

diabetes app; text message; color range indicator; blood glucose monitor, wireless

Introduction

The advent of mobile phones and smartphones provides a real opportunity to improve diabetes care by enabling patients and health care professionals (HCPs) to exchange information remotely (via text or email) with the potential to minimize or even eliminate the need for routine management office visits [1]. Systematic reviews have found that mHealth interventions improve diabetes care end points such as glycated hemoglobin (HbA_{1c}) and are particularly effective if such interventions connect patients with their HCP [2]. mHealth may also facilitate improved engagement in certain patient subgroups, such as adolescents, since a recent Web-based survey showed the most commonly used technology was text messaging (short message service [SMS]) [3]. Although mobile technologies have broad appeal, there is evidence that people with type 2 diabetes mellitus (T2DM) may derive as much, if not more, benefit as people with type 1 diabetes mellitus (T1DM). A meta-analysis showed that mobile phone interventions reduced HbA_{1c} by 0.5% over 6 months, with greater reductions in HbA_{1c} in people with T2DM (0.8%) than in those with T1DM (0.3%) [4]. Furthermore, a review of 13 trials found improved health outcomes in people with T2DM using automated brief messages compared with usual care [5].

Exchanging mobile phone texts or SMS between patients and their HCPs may have an impact on the clinical outcomes of patients. A single-arm study evaluating the effect of SMS text messages on glycemic control in Saudi patients with T2DM found that 5 to 7 texts per week were associated with reductions in HbA_{1c} after 4 months [6]. A study evaluating the effectiveness of daily SMS text messages from a nurse compared with weekly (then biweekly) telephone follow-ups found similar improvements in HbA_{1c} in each group, suggesting that SMS can be considered a valuable method to facilitate diabetes control [7]. Mobile solutions that allow HCPs to remotely visualize patient progress in real time enable HCPs to create personalized SMS text messages containing specific actionable advice. HbA_{1c} was reduced in a study in adults with poorly controlled T1DM or T2DM receiving an average of 13 personalized SMS text messages per week over 3 months [8].

Recent advances in cloud-based diabetes management software and apps have enabled new models of collaborative care between patients and HCPs [9]. We previously reported that using a Web-based version of the OneTouch Reveal app in patients with T1DM and T2DM was associated with a 0.4% reduction in HbA_{1c} after 12 weeks [10]. Certain patients may face other barriers to self-management such as numeracy challenges. Cavanaugh et al [11] described how low diabetes-related numeracy skills are associated with fewer self-management behaviors, and poor numeracy has also been associated with suboptimal glycemic outcomes in both people with T2DM [12] and those with T1DM [13]. The simple color-coded tools used within the OneTouch Verio Flex meter and the OneTouch Reveal app may be especially helpful for these patients. The app contains features such as an easy to personalize reminder to perform self-management activities (eg, medication, physical activity, insulin); graphics showing glucose testing metrics; color coding of low, in-range, or high results (ColorSure Technology); and high- and low-glucose pattern detection tools. The app can also create a 14-day summary report that can be emailed to the HCPs or accessed online by HCPs [14-16].

The primary end point of this study was to evaluate whether use of the app and receiving diabetes-related text messages every 2 weeks from an HCP based on app insights would improve glycemic control in participants with T1DM or T2DM over the 24-week study period. Secondary end points were evaluating text metrics and gathering participant responses to surveys pertaining to acceptance of the meter and the app.

Methods

Materials

Participants used a OneTouch Verio Flex blood glucose meter (LifeScan, Wayne, PA, USA); the OneTouch Reveal mobile diabetes app (LifeScan); and a Motorola Moto E smartphone (Basingstoke, UK) preloaded with the app to receive text messages.

Methods

This parallel 2-arm, open-label, randomized controlled study was conducted at 5 sites in the United Kingdom: Highland Diabetes Institute (Inverness); Edinburgh Royal Infirmary; Queen Elizabeth University Hospital (Glasgow); Heartlands Hospital (Birmingham); and BioKinetics Europe (Belfast). We obtained appropriate ethics approval and participant informed consent before study initiation and registered the trial (NCT02429024; Multimedia Appendix 1 [17]). Participants were existing patients at each clinical site and were identified from the clinic patient databases. Participants were between 16 and 70 years of age; had a diagnosis of T1DM or T2DM for ≥3 months; had a current HbA_{1c} of ≥7.5% and ≤11.0%; and were currently performing self-monitoring of blood glucose (SMBG). All participants received appropriate compensation for time and travel to the clinic site. The primary end point of the study was to determine the HbA_{1c} change from baseline in participants using the meter in conjunction with the app (meter + app) compared with meter-only participants after 12 and 24 weeks. Secondary end points were subgroup analysis of T1DM and T2DM and HbA_{1c} change from baseline at 12 weeks and 24

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weeks. Further exploratory end points were the number of texts sent and their association with change in HbA_{1c}, and the HCPs' time to create text messages over 24 weeks. We also explored participant responses to acceptance surveys regarding the meter and app.

Visit 1 (Screening)

The first visit was performed 1 week before baseline and included obtaining informed consent, collecting demographic and medical history information, and evaluating inclusion and exclusion criteria. Venous blood was drawn to establish the baseline HbA_{1c} value.

Visit 2 (Baseline)

We randomly assigned eligible participants to either the meter-alone or meter + app group. The responsible HCP at each site (diabetes nurse or physician) personalized the color range indicator on the meter for all participants with appropriate low- and high-glucose range limits and gave a full explanation of the meter. Minimum SMBG requirements were recommended based on current therapy (≥1/day for T2DM taking antihyperglycemic agents only; ≥2/day for T2DM on basal or premixed insulin; and ≥3/day for T1DM or T2DM on premixed insulin or multiple daily injections). Participants currently performing SMBG more frequently were encouraged to continue their regimen. HCPs explained all features of the app and ensured it was programmed with color range indicator settings identical to the meter.

Home Activities

Participants in the meter-only group were asked to perform SMBG, reflect upon insights provided by the meter, and make any diabetes-related adjustments consistent with their HCP's advice. Participants in the meter + app group were asked to perform SMBG, reflect upon insights provided by the meter, and frequently (at least weekly) review aggregated SMBG trends, patterns, and insights on the app. These participants also received text messages every 2 weeks from the site HCP containing specific diabetes-related advice or suggested adjustments.

HCP Text Messages

Real-time app data were automatically uploaded (via the cloud) from the participants' smartphone to a website version of the app accessible by site HCPs on their office computer. A text messaging program (Textlocal; Txtlocal Ltd, Chester, UK) was installed on each HCP's computer to enable them to easily manage, create, and send texts across multiple participants. HCPs reviewed the 14-day app progress report to assist in formulating diabetes-related text messages sent to the participants' phone (Figure 1). HCPs completed a log summarizing the content and time taken to create each text message.

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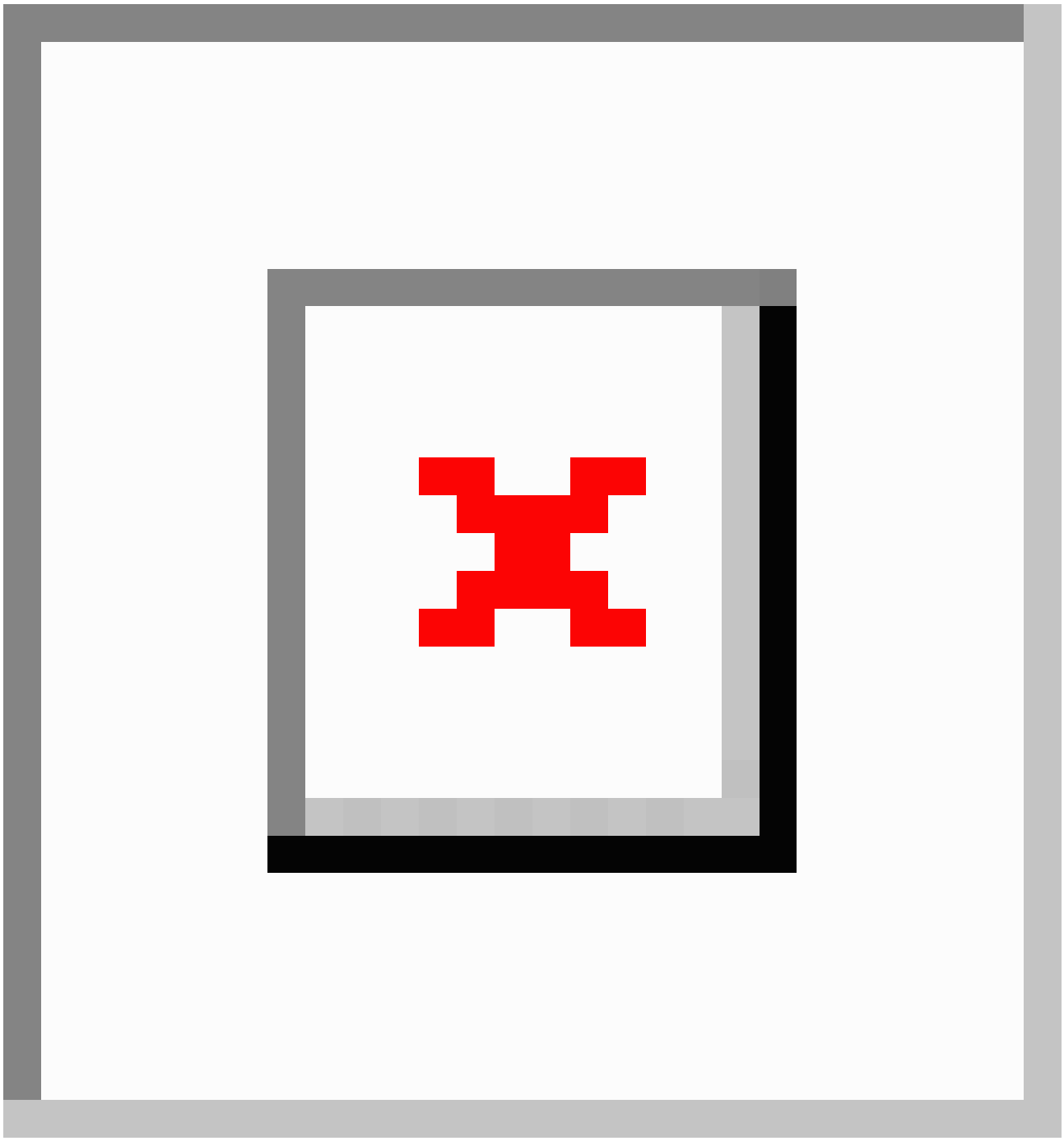
Figure 1. Study data flow. All participants used the OneTouch Verio Flex meter to conduct self-monitoring of blood glucose (SMBG). SMBG data were transmitted wirelessly from the meter to the smartphone containing the diabetes management app OneTouch Reveal. SMBG data were automatically uploaded via the cloud to a Web-based version of the app accessible by site health care professionals (HCPs) on their office computers. HCPs reviewed the 14-day app report for each participant to assist in formulating diabetes-related text messages sent to the participant's smartphone.



Visit 3 (12 Weeks)

Venous blood was drawn for HbA_{1c} measurement. HCPs discussed progress with all participants; downloaded from the meter the first 12 weeks of SMBG data (via cable); and collected any adverse events.

Visit 4 (24 Weeks)

Venous blood was drawn for HbA_{1c} measurement and the site HCPs discussed progress with all participants. Participants completed surveys regarding their impressions of the meter and app. HCPs downloaded from the meter the last 12 weeks of SMBG data and collected any adverse events.

Randomization and Statistical Analyses

We randomly assigned 137 participants to the meter-alone or meter + app group within each study site using a stratified block randomization design with 2 stratification variables, each with 2 levels: baseline HbA_{1c} (7.5% to <9.0% or ≥9.0% to 11.0%) and diabetes type (T1DM or T2DM). Using a pooled HbA_{1c} standard deviation of 1.0% from previous mHealth studies (data on file), we estimated sample size at 64 participants per group to achieve 80% power at 5% significance to detect a 0.5%

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decrease in HbA_{1c}. We described continuous demographic variables by median and range (minimum to maximum) or mean and standard deviation. Analysis of covariance was used to assess the mean changes in HbA_{1c} from baseline. Correlations with HbA_{1c} were assessed using the Pearson correlation coefficient and deemed significant at a 5% significance level. We used Minitab v17.0 (Minitab Inc) and IBM SPSS v21.0 (IBM Corporation) for all analyses. We assessed associations between change in HbA_{1c} based on the receipt of per protocol HCP text messages as an exploratory end point. In addition, we analyzed the number of SMS text messages sent by HCPs, including initial observations regarding the content of individual texts. We also completed a full analysis of the meter and app acceptance surveys.

Results

Participants

Table 1 shows baseline characteristics of all 128 participants who completed the study; 9 participants either withdrew or were lost to follow-up during the 24 weeks. Meter-only and meter + app participants had similar baseline characteristics, with a mean HbA_{1c} of 8.9% and mean duration of diabetes of about 17 years. Over 70% of participants (94/128) reported performing SMBG ≥3 times per day. Of all 128 participants, 111 (86.7%) were on some form of insulin therapy. The great majority of participants (117/128, 91.4%) had no diabetes apps on their current phone; 122 of 128 (95.3%) had never used diabetes management software; and only 12 of 128 (9.4%) responded that their HCP had ever downloaded SMBG data during consultations.

Changes in Glycemic Control (HbA_{1c}) in all Participants

Figure 2 shows HbA_{1c} at baseline and at 12 and 24 weeks for the meter-only and meter + app groups. HbA_{1c} decreased significantly compared with baseline by 0.56% and 0.55% after 12 and 24 weeks, respectively, in the meter-only group (each $P<.001$). HbA_{1c} was decreased compared with baseline by 0.78% and 0.67% after 12 and 24 weeks, respectively, in the meter + app group (each $P<.001$). Decreases in HbA_{1c} in participants using the meter + app after 12 and 24 weeks were greater by 0.22% and 0.12%, respectively, than in those using the meter alone, but these differences were not statistically significant ($P=.12$ and $P=.45$, respectively).

Changes in Glycemic Control (HbA_{1c}) in Participants With T1DM and T2DM

Similar to results in all participants, HbA_{1c} in participants with T1DM decreased compared with baseline both in the meter-only and in the meter + app groups ($P<.001$), and the difference between groups was not significant at 12 or 24 weeks ($P=.62$ and $P=.98$, respectively) (Figure 3). However, in participants with T2DM, the decrease in HbA_{1c} from baseline was more pronounced in participants using the meter + app than in those participants using the meter alone. At 12 weeks, this difference (1.04% vs 0.58%) was significant at $P=.09$ (Figure 3).

Associations Between Glycemic Control (HbA_{1c}) and Text Messaging

HbA_{1c} decreased by 1.08% (n=20) in those participants using the app who received at least 10 of the maximum 12 text messages, compared with a 0.54% decrease (n=66) in HbA_{1c} in participants using the meter alone after 12 weeks (Figure 4). This additional HbA_{1c} decrease ($P<.01$) was maintained after 24 weeks. In contrast, there was no difference in the decrease in HbA_{1c} in participants who received fewer than 10 texts compared with participants using the meter alone. Participants (n=21) receiving between 10 and 12 diabetes-related texts from their HCP were sent 223 texts in total over 24 weeks (mean 10.7, SD 0.6 texts) compared with 40 participants receiving 9 or fewer texts (257 texts in total over 24 weeks; mean 6.2, SD 2.4 texts).

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Table 1. Baseline participant demographics.

Characteristics	Meter only (n=66)	Meter + app (n=62)	All participants (n=128)
Sex, n (%)			
Male	39 (59)	34 (55)	73 (57)
Female	27 (41)	28 (45)	55 (43)
Age in years, mean (range)	45.1 (20-71)	44.0 (19-69)	44.6 (19-71)
Diabetes type, n (%)			
T1DM[a]	41 (62)	38 (61)	79 (62)
T2DM[b]	25 (38)	24 (39)	49 (38)
Hemoglobin A_{1c}, mean (range)			
All participants	8.9% (7.5%-10.7%)	8.9% (7.5%-10.8%)	8.9% (7.5%-10.8%)
T1DM	8.9% (7.5%-10.7%)	8.8% (7.5%-10.8%)	8.9% (7.5%-10.8%)
T2DM	8.9% (7.5%-10.7%)	8.9% (7.5%-10.7%)	8.9% (7.5%-10.7%)
Duration of diabetes in years, mean (range)			
All participants	16.7 (3.9-43.0)	17.1 (3.7-45.4)	16.9 (3.7-45.4)
T1DM	19.0 (5.1-43.0)	20.5 (3.7-45.4)	19.7 (3.7-45.4)
T2DM	13.0 (3.9-23.7)	11.8 (4.3-23.0)	12.4 (3.9-23.7)
Self-monitoring of blood glucose frequency, n (%)			
≥5 times/day	12 (18)	13 (21)	25 (20)
3-4 times/day	39 (59)	30 (48)	69 (54)
1-2 times/day	13 (20)	13 (21)	26 (20)
Other	2 (3)	6 (10)	8 (6)
Treatment therapy[c] for overall/T1DM/T2DM, n			
Basal + bolus	46/39/7	38/33/5	84/72/12
Premix	8/2/6	8/3/5	16/5/11
Basal only	2/0/2	6/1/5	8/1/7
Bolus only	1/0/1	2/1/1	3/1/2
Antihyperglycemic agents only	9/0/9	8/0/8	17/0/17

[a]T1DM: type 1 diabetes mellitus.

[b]T2DM: type 2 diabetes mellitus.

[c]Participants taking insulin may or may not also have been taking antihyperglycemic agents.

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Figure 2. Glycated hemoglobin (HbA_{1c}) at baseline and after 12 and 24 weeks of home use for participants using the meter only or the meter + app. Data shown are mean (SEM). Differences from baseline were significant in each group at 12 and 24 weeks (P<.001). Differences between the meter-only and meter + app groups were not statistically significant at 12 or 24 weeks.

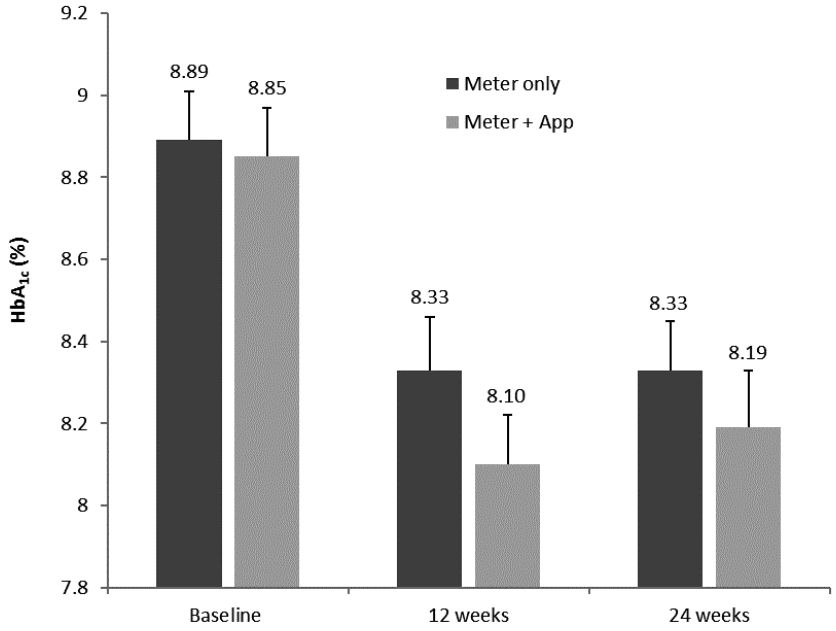

Figure 3. Decrease from baseline in glycated hemoglobin (HbA_{1c}) after 12 and 24 weeks of home use in participants with type 1 (T1DM) or type 2 diabetes mellitus (T2DM) in the meter-only and meter + app groups. Data shown are mean (SEM) changes. Differences from baseline were significant in each group at 12 and 24 weeks (P<.001). The reduction in HbA_{1c} from baseline was more pronounced in the meter + app group than in the meter-only group, especially at 12 weeks (P=.09).

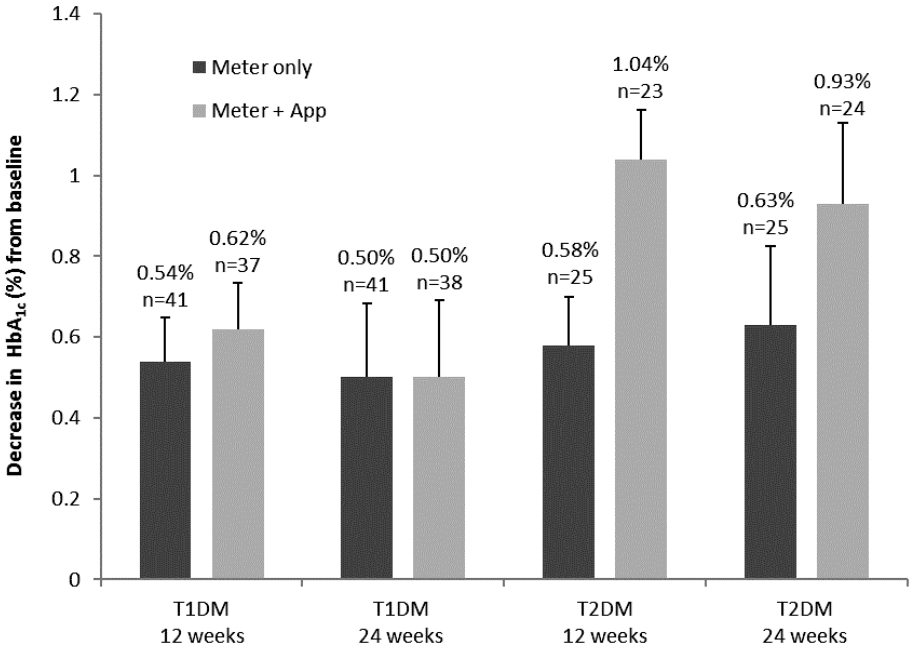

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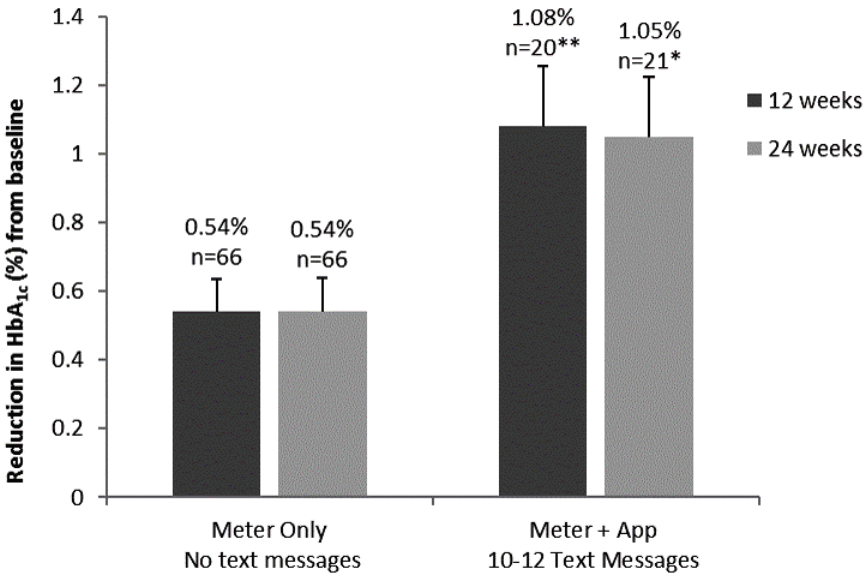
Figure 4. Decrease from baseline in glycated hemoglobin (HbA_{1c}) after 12 and 24 weeks of home use for participants who received 10 to a maximum of 12 text messages versus the meter-only group (no text messages). Data shown are mean (SEM) changes. * P<.05; ** P<.01. Results in the meter + app group were statistically different from the corresponding meter-only group at 12 weeks (P<.01) and 24 weeks (P<.05).



HCP Text Content, and Time and Impact of App-Based Texts on Routine Patient Care

A total of 480 text messages were sent by all HCPs. These texts contained 641 specific instances of advice, including 102 text messages containing advice to adjust bolus or premixed insulin and 84 text messages containing advice on basal insulin. Participants with T1DM and T2DM received similar text advice relating to SMBG. As expected, participants with T2DM received more text advice regarding medications and texts confirming that their diabetes management or SMBG was on track than did participants with T1DM.

The time to review the app 14-day progress report and create a text message was <5 minutes (106/480, 22.1%), 5-10 minutes (244/480, 50.8%), 10-20 minutes (98/480, 20.4%), and >20 minutes (12/480, 2.5%), with 4.2% (20/480) of HCPs not recording times. In terms of managing patients in a clinical setting, the HCPs postulated they would have postponed 12 (9.7%) of the 124 scheduled study visits based on the participant being on track with their diabetes management. Of consultations that would have proceeded, HCPs expected 41 (33%) visits to be shorter and a further 41 (33%) visits to be more focused or to include better-quality conversations given they had the advantage of remote access to glycemic data in advance via the app. If this had been routine clinical practice, in 37 (29.8%) occasions HCPs postulated they would have brought forward this visit earlier or contacted the patient immediately due to concerns identified remotely. Detailed information on the exchange and content of text messages including analytics and experiences of participants using the app will be summarized in a follow-up publication.

Safety and Tolerability

A total of 60 adverse events and 10 serious adverse events were reported by the 128 participants over the course of the 24-week study. None were related to the meter or the app.

Participants' Perceptions of the Glucose Meter and App

Table 2 summarizes participants' responses to survey statements regarding their opinion of the meter (all participants) and those using the app. Of all 126 participants who responded to the survey, 112 (88.99%) agreed that the simple color range indicator on the meter made it easy for them to manage their blood sugar because they quickly knew whether they were low, in-range, or high; 103 (81.8%) agreed that the low indicator on the meter may help them better manage lows and avoid hypoglycemic events. For app participants, 53 of 56 (95%) agreed that the colorful visuals and pattern messages in the app told them when they were doing well and when they needed to pay more attention; and 53 of 56 (95%) also wished they had had the app when first diagnosed because they felt it would have made their diabetes journey easier. In the 58 meter + app group respondents, 51 (88%) said the simple color range indicator on the meter together with the app could help them to stay on track between visits to their HCP, and 52 (90%) said that the meter and app combination provided a seamless way for them to stay connected with their HCP.

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Table 2. Participants' responses to survey statements.

Statement category	n (%)[a]
OTVF[b] glucose meter (n range 123-126)	
The OTVF meter logs my past readings so I don't have to worry about writing them down	117/124 (94.4)
The OTVF meter keeps a real-time logbook of my readings that I can carry around with me anywhere	118/125 (94.4)
It's reassuring to know that with OTVF I have my blood sugar information at my fingertips	113/125 (90.4)
OTVF with its simple color range indicator made it easy for me to manage my blood sugar because I quickly knew whether I was low, in-range, or high	112/126 (88.9)
I think the OTVF meter is for people on the go	109/124 (87.9)
The OTVF meter makes testing my blood sugar easy so I can get on with my life	107/124 (86.7)
I found the simple color range indicator feature on OTVF to be a very helpful tool to indicate how I was managing my diabetes	108/126 (85.7)
I love that the range indicator arrow instantly points to the appropriate color bar after each test so that I quickly know if I am low, in-range, or high	106/125 (84.8)
The low range indicator on OTVF may help me better manage my lows and avoid hypoglycemic (low blood sugar) events	103/126 (81.7)
The high range indicator on OTVF may help me better manage my highs and avoid hyperglycemic (high blood sugar) events	100/125 (80.0)
The color range indicator on the OTVF meter made me feel confident about managing my blood sugar	96/123 (78.0)
The simple color range indicator on the OTVF meter made it easier for me to follow my HCP's[d] recommendations	98/126 (77.8)
The low indicator on the OTVF meter may help me to avoid hypoglycemic (low blood sugar) events	97/126 (77.0)
OTR[c] app (n=56)	
The colorful visuals and pattern messages in the OTR app tell me when I am doing well and when I need to pay more attention	53 (94.6)
I wish I had had the OTR app when I was first diagnosed. It would have made my journey easier	53 (94.6)
OTR app made it easier for me to manage my diabetes than using my meter and a paper logbook	50 (89.3)
OTR app reduces the tedious work of daily tracking and logging so I can focus on other important things in life	48 (85.7)
OTR app simplified my daily decisions using my blood sugar information	47 (83.9)
OTR app is a versatile tool and fits into my lifestyle	47 (83.9)
OTR app was simple and easy to use	47 (83.9)
This is a true innovation from OneTouch, a brand that I have come to trust	47 (83.9)
OTR app helps me get to the big picture fast, right in the palm of my hand	47 (83.9)
OTVF glucose meter + OTR app (n=58)	
The OTVF meter together with OTR app could support me in three ways: in the moment, on the go and over time	53 (91.4)
The OTVF meter together with the OTR app gave me instant information such as 14 day averages which helped me to discuss my progress with my HCP	52 (89.7)
The OTVF meter together with the OTR app provided a seamless way for me to stay connected with my HCP	52 (89.7)
The simple color range indicator on the OTVF meter together with the OTR app could help me stay on track between visits to my HCP	51 (87.9)
The simple color range indicator on the OTVF meter together with the OTR app could help me be more proactive with my diabetes management	51 (87.9)

[a]Percentages shown are favorable responses defined as a response of "strongly agree" or "agree" on a 5-point scale (5=strongly agree; 4=agree; 3=neither agree nor disagree; 2=disagree; and 1=strongly disagree). All favorable response rates are statistically significant ($P<.001$).

[b]OTVF: OneTouch Verio Flex.

[c]OTR: OneTouch Reveal.

[d]HCP: health care professional.

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Discussion

This study demonstrated improved glycemic control (HbA_{1c}) after 12 and 24 weeks in participants using a new blood glucose meter. This reduction in HbA_{1c} with the new meter alone was more than might be reasonably attributed to just being in a clinical study (the Hawthorne effect) and for many patients in our study exceeded the reduction in HbA_{1c} typically observed when switching patients to other new meters. For example, in a study comparing participants with T2DM who were receiving multiple daily injections of insulin either trained on a new meter (Abbott Freestyle Lite) or using flash glucose monitoring (Abbott Libre), HbA_{1c} reductions of 0.31% and 0.29%, respectively, were observed after 24 weeks from a baseline HbA_{1c} of 8.8% [18]. The OneTouch Verio Flex meter used in our study features ColorSure Technology, which has been shown previously to improve the ability of patients to interpret blood glucose readings [15,16], perhaps contributing to the benefits observed in this study. To maximize the benefits of the meter, site HCPs personalized the color feature in terms of low- and high-glucose ranges for that participant and described appropriate actions to consider in response to color information. Participants using the meter may also have derived new insights from color-coded information that translated into therapy or behavioral modifications. It would have been interesting to record the extent of these modifications, perhaps using home diaries, but we did not implement these so as to avoid placing an additional burden on participants. However, in feedback surveys, 78% of participants agreed the meter made it easier to follow their HCP's recommendations, and over 80% responded that color information on the meter helped them to better manage lows (or highs) and avoid both hypoglycemic and hyperglycemic events.

In the meter + app group, HCPs were able to remotely review participants' SMBG progress in real time by analyzing app data on their office personal computer. On this basis, they considered how best to respond with appropriate diabetes therapy advice using personalized text messages directly to the participants' smartphones. The protocol instructed that text messages be sent to participants every 2 weeks to synchronize with the HCP's review of the 14-day app progress report. However, most participants did not receive the full complement of 12 diabetes-related texts over the 24-week period, although 34% (21/62) did receive 10 to 12 texts. It is possible that this lower than prescribed frequency of text contact may have limited glycemic improvement in the meter + app group compared with the improvements in the meter-alone group. This notion is supported by the decrease in HbA_{1c} observed in app participants receiving at least 10 texts, whereas participants receiving fewer texts did not lower their HbA_{1c} any more than participants using the meter alone.

Text messages based on a review of app data was an important factor in driving improved glycemic control between scheduled consultations by prompting either specific actions (eg, changes to insulin dosing, or suggesting participants reflect on diet, exercise, or SMBG trends) or by suggesting other adjustments. It is worth highlighting that the study population was recruited from hospital-based clinics caring for relatively complex diabetes cases. About 94% (58/62) of app participants were taking some form of insulin, including over 83% (20/24) of participants with T2DM. Therefore, it is not surprising that a high proportion of texts included advice to adjust bolus or basal insulin. There were expected differences between text content for participants with T1DM and T2DM. For example, participants with T2DM received a higher proportion of advice on medications than did participants with T1DM. In clinical practice, a key attribute of HCP text feedback between scheduled visits may be simply to reassure patients and encourage positive patient behaviors that have been observed remotely via real-time access to data. In this regard, it was interesting that the highest proportion of texts to participants with T2DM provided reassurance on progress, explaining that they were essentially on track.

A recent meta-analysis showed that a wide variety of telemedicine solutions (including text messaging) can improve glycemic control and lower HbA_{1c} [19]. Despite evidence of improved glycemic control, there remains concern among HCPs that mHealth connections may contribute an additional burden between scheduled office visits. It was encouraging to discover that in our study over 70% of the HCP app report review and text composition took less than 10 minutes and 22% took less than 5 minutes. Furthermore, the time required to review reports and send texts decreased over time, presumably as HCPs became more proficient using texting software and more adept at reviewing the app summary. We would expect that in routine clinical practice, texting will be patient specific depending on the changing circumstances of each patient, such as transitions to different insulin therapies or adjustments to medications, as well as the patients' desire for remote contact with their HCP. Allowing HCPs the flexibility to offer a more intensive patient-specific text frequency may further improve clinical outcomes.

Having patients use a mobile app enabled HCPs to visualize real-time participant progress and monitor remotely how well (or otherwise) each participant was doing. With this in mind, we asked site HCPs to assume that each participant was a patient they were managing in routine clinical practice and to consider whether they would have approached their next consultation differently armed in advance with knowledge of the patient's status. HCP feedback indicated that many visits could have been postponed because the patient was on track. Additionally, one-third said that visits would have been shorter or more focused, with higher-quality conversations during the visit. This feedback highlights the practical value of an mHealth solution, such as our app, and may offset the concern that such solutions increase workload burden. Tools such as this app offer HCPs more flexibility and choice in managing the individual needs of patients with diabetes. Patient engagement with technology will be a key factor to successfully managing diabetes as they consider therapy or behavioral adjustments that could contribute to improvements in glycemic control.

Study Limitations

It is conceivable that differences in glycemic reductions between the meter + app group and meter-only group were masked by

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the greater than anticipated decrease in HbA_{1c} observed in the meter-only group. Previous studies have shown the value of color features on the meter [14-16] and, in hindsight, it would have been useful to have an additional group in which participants continued using their current glucose meter. However, given that our participants had significant SMBG experience, we did not anticipate such marked reductions in HbA_{1c} when participants were switched to the new meter. As a further consideration, providing participants with a separate phone to review app insights and receive HCP texts (and to send confirmation or clarifications back to the HCP) may have diminished time spent using the app compared with having the app on the participants' personal smartphone. However, we sought to ensure a consistent app experience on the phone and minimize any bias resulting from different types of phones. Finally, certain system upgrades occurred during the study period, which resulted in participants having to reload the app and in HCP texts being repurposed to assist participants in ways unrelated to diabetes management. This resulted in a lower number of diabetes-related texts to many participants, which may have compromised their glycemic improvement.

Conclusion

Using the OneTouch Verio Flex glucose meter alone or in combination with the OneTouch Reveal diabetes app was associated with significant improvements in glycemic control after 12 and 24 weeks. Improvements when using the app were greatest in participants with T2DM and in those who received the highest number of HCP text messages. This study suggests that real-time availability of patient data and the ability to send personalized diabetes-related text messages can assist HCPs to improve glycemic control in patients between scheduled visits.

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Conflicts of Interest

MG and HC are employees of LifeScan Scotland, Ltd. BLL and LBK are employees of LifeScan Inc.

Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.1.

[PDF File (Adobe PDF File), 535KB - diabetes_v2i2e19_app1.pdf]

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Abbreviations

HbA $_{1c}$: glycated hemoglobin
HCP: health care professional
SMBG: self-monitoring of blood glucose
SMS: short message service
T1DM: type 1 diabetes mellitus
T2DM: type 2 diabetes mellitus

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Original Paper

One Drop | Mobile: An Evaluation of Hemoglobin A1c Improvement Linked to App Engagement

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Abstract

Background: Three recent reviews evaluated 19 studies testing the hemoglobin A1c (HbA1c) benefit of 16 diabetes apps, including 5 publicly available apps. Most studies relied on small samples and did not link app engagement with outcomes.

Objective: This study assessed both HbA1c change in a large sample of people using the One Drop | Mobile app and associations between app engagement and changes in HbA1c.

Methods: The One Drop | Mobile app for iOS and Android is designed to manually and passively (via Apple HealthKit, Google Fit, and the One Drop | Chrome blood glucose meter) store, track, and share data. Users can schedule medication reminders, view statistics, set goals, track health outcomes, and get data-driven insights. In June 2017, we queried data on people with diabetes using the app who had entered at least 2 HbA1c values in the app >60 and ≤365 days apart. Multiple imputation corrected for missing data. Unadjusted and adjusted mixed effects repeated measures models tested mean HbA1c change by time, diabetes type, and their interaction. Multiple regression models assessed relationships between using the app to track food, activity, blood glucose, and medications and HbA1c change.

Results: The sample (N=1288) included people with type 1 diabetes (T1D) (n=367) or type 2 diabetes (T2D) (n=921) who were 35% female, diagnosed with diabetes for a mean 9.4 (SD 9.9) years, and tracked an average 1646.1 (SD 3621.9) self-care activities in One Drop | Mobile between their first (mean 8.14% [SD 2.06%]) and second HbA1c entry (mean 6.98% [SD 1.1%]). HbA1c values were significantly associated with user-entered average blood glucose 90 days before the second HbA1c entry (rho=.73 to .75, P<.001). HbA1c decreased by an absolute 1.07% (unadjusted and adjusted F=292.03, P<.001) from first to second HbA1c entry. There was a significant interaction between diabetes type and HbA1c. Both groups significantly improved, but users with T2D had a greater HbA1c decrease over time than users with T1D (F=10.54, P<.001). For users with T2D (n=921), HbA1c decreased by an absolute 1.27% (F=364.50, P<.001) from first to second HbA1c entry. Finally, using One Drop | Mobile to record food was associated with greater HbA1c reductions even after adjusting for covariates and after also adjusting for insulin use for users with T2D (all P<.05).

Conclusions: People with T1D and T2D reported a 1.07% to 1.27% absolute reduction in HbA1c during a median 4 months of using the One Drop | Mobile app. Using the app to track self-care was associated with improved HbA1c. More research is needed on the health benefits of publicly available diabetes apps, particularly studies associating app engagement with short- and long-term effects.

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KEYWORDS

type 1 diabetes; type 2 diabetes; mobile app; tracking; self-care; glycemic control

Introduction

There are over 1500 mobile apps in the marketplace assisting with diabetes self-management but limited research on their clinical benefit. In the past year, a handful of systematic reviews and meta-analyses evaluated the impact of diabetes apps on glycemic control or hemoglobin A_{1c} (HbA_{1c}) [1-4]. Three reviews included a total of 19 studies evaluating 16 unique apps. Only 5 of those apps were publicly available (ie, dBees [5], Diabeo [6], Glucose Buddy [7], mDiab/Mobil Diab [8,9], and WellDoc [10,11]).

The trials evaluating publicly available apps offer insights into their clinical value. For example, people with type 1 diabetes (T1D) using the dBees self-care and glucose tracking app had no HbA_{1c} improvement over time or compared to people tracking with a paper logbook [5]. Children and adolescents with T1D using mDiab/Mobil Diab [8] lowered their HbA_{1c}, but not significantly more than a conventional care control group. In contrast, people with type 2 diabetes (T2D) using mDiab/Mobil Diab lowered their HbA_{1c} significantly more than the usual care control group [9]. In 2 separate randomized controlled trials (RCTs), people with T1D using the Diabeo insulin dosing app [6] or the Glucose Buddy tracking app [7] lowered their HbA_{1c} significantly more than controls did. Finally, people with T2D using the WellDoc tracking and coaching app substantially lowered their HbA_{1c} relative to controls [10,11].

Limited clinical evidence supporting publicly available diabetes apps is promising, but there are still many unknowns. In the 7 trials reporting data, no studied sample was greater than 200 people, which has implications for generalizability. Moreover, effects on glycemic control were linked to being exposed to an entire intervention or app and not using the app or different aspects of it.

Qualitative studies indicate people with diabetes (PWD) want apps with automated self-care tracking [12], medication reminders [13,14], data sharing with peers and providers [15] including reports [16], and a Bluetooth-connected meter [17]. Publicly available apps offer these and other features (eg, One Drop | Mobile), but studies linking engagement with such features to health outcomes are limited.

Additional studies are needed to broaden generalizability by testing with larger samples and associating app engagement to health outcomes. To address these gaps, we assessed HbA_{1c} changes among a large sample of people with T1D and T2D (N=1288) using the One Drop | Mobile app. We also assessed if using the app resulted in significant changes in glycemic control as measured by HbA_{1c} values.

Methods

One Drop | Mobile

The One Drop | Mobile app was launched in April 2015. It is available for free on iOS, WatchOS, and Android operating systems.

One Drop | Mobile has a variety of features to support diabetes management (see Figure 1). Users can manually and passively (via HealthKit, Google Fit, and the Bluetooth-enabled One Drop | Chrome blood glucose meter) store and track blood glucose readings, medication doses, physical activity, and foods consumed. In addition, users can view daily, weekly, and monthly summary statistics regarding these data. A built-in food library facilitates tracking food. An optional medication scheduler reminds users when a dose is due and facilitates tracking medications. Users can also view the percentage of in-range blood glucose readings over time and store and track HbA_{1c} values and body weight. Importantly, they can set daily goals (for time in range, medication adherence, carbohydrate intake, and physical activity) and monitor their progress toward these goals. Users can also access a wide array of diabetes-relevant information by using an in-app newsfeed that delivers health tips, articles, infographics, user polls, expert interviews, and scientific study results. A community section lets the user view and learn from other users' data. A map displays dots representing other One Drop | Mobile users in a local area, anywhere, and provides an option to view another user's data and give badges to offer support and encouragement. A notifications inbox delivers data-driven insights, achievements, reminders, and lists badges accumulated from other users.

Measures

User Characteristics

All One Drop | Mobile users complete a profile and can self-report gender, diabetes type, and year of diagnosis. We calculated years of diagnosed diabetes as the difference between a user's year of diagnosis entered in the app and the year his or her One Drop | Mobile profile was created. We used passively collected time zone data to determine user location. Because few users outside the United States had entered 2 HbA_{1c} values required for inclusion, we dichotomized location to United States versus outside the United States in analyses.

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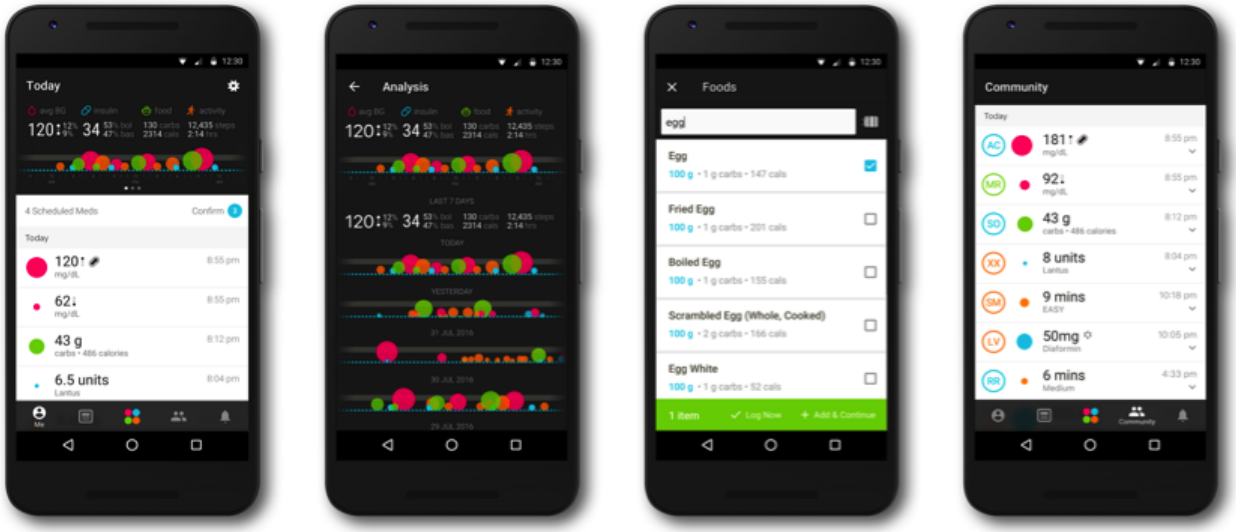
Figure 1. The One Drop | Mobile app.



Self-Care

One Drop | Mobile users can track blood glucose, medication, and physical activity manually and passively (via HealthKit, Google Fit, and the Bluetooth-enabled One Drop | Chrome blood glucose meter) in the app. They can also track their food consumed (measured in grams of carbohydrate). We summed data tracked between HbA_{1c} entries to obtain counts of blood glucose, medications, activity, and food tracked during that time.

Glycemic Control

Users can also self-report HbA_{1c} test results and test dates. HbA_{1c} values can be displayed in mmol/mol or percent but are stored as percent. Shortly after a One Drop | Mobile account is created, an in-app pop-up asks each user to enter his or her HbA_{1c} information. This reminder appears again 3 months after the previously entered HbA_{1c} test date. We used HbA_{1c} test dates to calculate the number of days between HbA_{1c} entries and converted days to months using the factor 30.42 (365 days/12 months.

Study Oversight

Solutions Institutional Review Board approved analyses and reporting of One Drop | Mobile's data for research purposes.

Analyses

Summary statistics characterized the sample overall and stratified by diabetes type. Distributions of continuous variables were asymmetrical, so Mann Whitney U tests compared mean ranks of continuous user characteristics, app-tracked data, and HbA_{1c} percent. Chi-square tests assessed differences in dichotomous variables by diabetes type. To examine and exclude invalid self-reported blood glucose and HbA_{1c} data, we converted each user's 90-day average blood glucose to an estimated HbA_{1c} using the formula HbA_{1c}=(90-day mean blood glucose+77.3)/35.6 [18]. We calculated the difference between the converted HbA_{1c} and self-reported HbA_{1c} and excluded users with more than a 2.0% difference. For the remaining users, Spearman's rho correlations tested the relationship between self-reported HbA_{1c} values and the prior 90-day average blood glucose to ensure consistency with the literature [19]. Because most users enter their first HbA_{1c} when they initiate using the app, we were unable to assess the relationship between 90-day average blood glucose prior to the first self-reported HbA_{1c}.

Missing data were handled using multiple imputation [20]. We used predictive mean matching (PMM) [21,22] to impute 100 datasets. PMM is a multiple-imputation method robust to violations of distributional assumptions (eg, normality) [23,24]. Multiple imputation was carried out in SPSS 23.0 (IBM Corp).

Next, 3 mixed effects repeated measures models tested mean HbA_{1c} change by time (pre- to posttest), diabetes type (T1D vs T2D), and their interaction. Only these effects were in the first model (ie, the unadjusted model). The second model adjusted for a priori covariates: gender, location (US vs non-US), years since a diagnosis of diabetes, and the number of months between the first and second HbA_{1c} entries. We restricted the third model to users with T2D, excluded the time by diabetes type interaction term, and adjusted for gender, location, years since diagnosis, number of months between HbA_{1c} entries, and insulin use.

Finally, 4 multiple regression models assessed the relationships between change in HbA_{1c} and using the app to track blood glucose, activity, medications, and food. The first, unadjusted model assessed the relationships between HbA_{1c} change and the 4 types of self-care tracking. The second model included diabetes type (T1D vs T2D), and the third model included gender, location, years since diagnosis, and number of months between the first and second HbA_{1c} entries. We restricted the fourth model to users with T2D and included insulin use as well as the a priori covariates. Given the skewness of self-care data and assumption violations for statistical testing, we dichotomized each variable to indicated tracking or nontracking of blood glucose, medications, activity, and food.

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Results

As of June 6, 2017, 2365 One Drop | Mobile users had entered 2 HbA_{1c} values into the app at least 60 days but no more than 1 year apart. They reported a diagnosis of T2D (1526/2365, 64.5%), T1D (591/2365, 25%), prediabetes (122/2365, 5.2%), latent autoimmune diabetes in adults (LADA) (72/2365, 3.0%), gestational diabetes (9/2365, 0.4%), other types of diabetes (eg, surgically or chemically induced diabetes; 29/2365, 1.2%), or did not enter a diabetes type (16/2365, 0.7%).

We restricted analyses to users reporting a diagnosis of T1D or T2D and confirmed the diagnosis through examination of the names of diabetes medications logged or scheduled in One Drop | Mobile. A total of 408 T1D or T2D users were excluded from the sample because they had either no medication data or because the medications logged or scheduled were inconsistent with their stated diabetes type (eg, T1D on metformin or sulfonylurea, T2D setting an auto basal insulin).

We excluded an additional 288 users with >2.0% HbA_{1c} difference between their second self-reported HbA_{1c} and the HbA_{1c} calculated from their 90-day mean blood glucose. This criterion resulted in correlations of rho=.75 and rho=.73 between the 90-day mean blood glucose and second self-reported HbA_{1c} for subjects with T1D (n=367) and T2D (n=921), respectively (both P<.001). This is consistent with previous cohort studies reporting correlations between average blood glucose and HbA_{1c} varying from 0.71 to 0.86 [19].

Three of the up to 14 variables included in analyses had missing data: gender (242/1288, 18.8%), location (14/1288, 1.1%), and duration of diagnosed diabetes (325/1288, 25.5%). Multiple imputation was used to make corrections for missing data on these variables.

Analyses included N=1288 users (see Table 1) who were 35% (454/1288) female, diagnosed with diabetes for a mean 9.4 (SD 9.9) years, and tracked an average 1646.1 (SD 3621.9) self-care activities in One Drop | Mobile between their first (mean 8.14% [SD 2.06%]) and second (mean 6.98% [SD 1.1%]) HbA_{1c} (calculations prior to multiple imputation).

Table 1 presents preimputed median and interquartile range (IQR) or n (%) with P values for differences between diabetes type on app-entered user characteristics, app-tracked data, and HbA_{1c} entries. Chi-square tests compared dichotomous variables. Mann Whitney U tests compared mean ranks of continuous variables in Table 1.

Table 1. Sample characteristics with tests of difference by diabetes type.

Characteristics	Total N=1288	Type 1 diabetes n = 367	Type 2 diabetes n=921	P value
Gender, n (%)				
Male	592 (46.0)	154 (42.0)	438 (47.6)	.61
Female	454 (35.2)	152 (41.4)	302 (32.8)	
Other	2 (0.2)	1 (0.3)	1 (0.1)	
Location, n (%)				
America/United States	1077 (83.6)	292 (80.7)	785 (86.1)	.001
Europe	111 (8.6)	51 (14.1)	60 (6.6)	
Asia	44 (3.4)	7 (1.9)	37 (4.1)	
Pacific	16 (1.2)	4 (1.1)	1.3 (14)	
Australia	19 (1.5)	5 (1.4)	1.5 (3)	
Africa	6 (0.5)	3 (0.8)	3 (0.3)	
Atlantic	1 (0.1)	0 (0.0)	1 (0.1)	
Insulin, n (%)				
Yes	717 (55.7)	367 (100)	350 (38)	.001
Diabetes duration in years, median (IQR)	6 (15)	10 (19)	5 (12)	.001
Food entries, n (%)	4 (88)	10 (99)	3 (82)	.04
Activity entries, n (%)	271.5 (809)	182 (786)	294 (814)	.09
Blood glucose entries, n (%)	72 (200)	102 (356)	67 (165)	.001
Medication entries, n (%)	118.5 (366)	121 (609)	117 (331)	.02
Months between HbA_{1c} entries, median (IQR)	4.0 (3.1)	4.6 (1.5)	3.9 (2.7)	.001
First HbA_{1c} %, median (IQR)	7.6 (2.4)	7.65 (2.1)	7.6 (2.5)	.43
Second HbA_{1c} %, median (IQR)	6.9 (1.4)	7.30 (1.5)	6.7 (1.3)	.001

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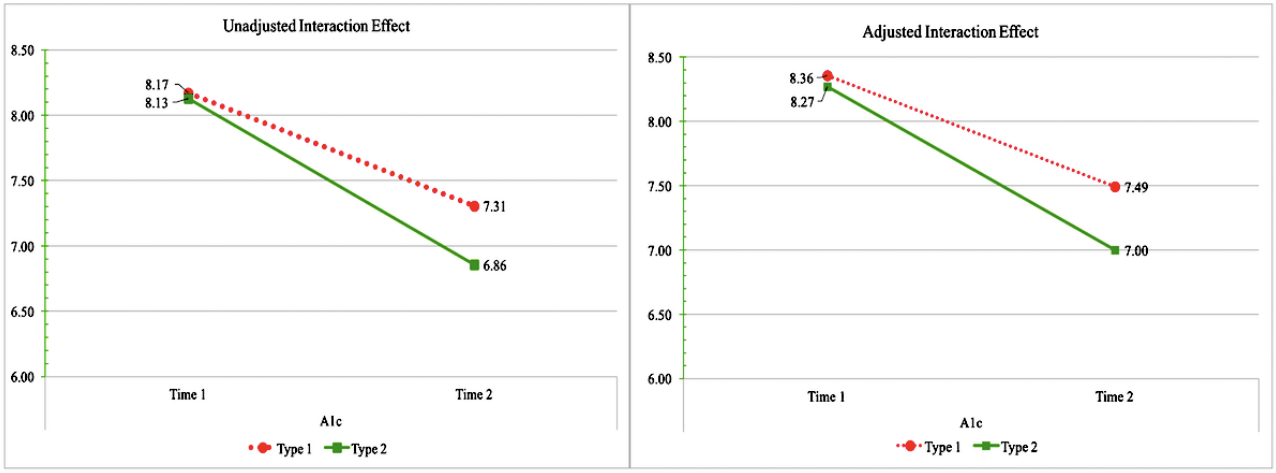
Compared to users with T2D (367/1288), users with T1D (921/1288) were diagnosed with diabetes for more years (U_{958}= 71,571, z=–7.07, P<.001), had more months between their first and second HbA_{1c} (for both U_{1286}=140,143.5, z=–4.79, P<.001), and tracked more food (U_{1286}=156,703.5, z=–2.09, P=.04), blood glucose (U_{1286}=147,630, z=–3.56, P<.001), and medications (U_{1286}=155,500, z=–2.26, P=.02). They were also more likely than users with T2D to log or schedule insulin in the app ($\chi^2_{1,N=1288}$=408.7, P<.001), use the app in Europe ($\chi^2_{1,N=1274}$=24.1, P<.001), and report a higher second HbA_{1c} (U_{1286}=125,966.5, z=–7.14, P<.001).

In the unadjusted model (Multimedia Appendix 1), HbA_{1c} decreased by an absolute 1.07% (F=292.03, P<.001) in the median 4.0 (IQR 3.1) months from first (mean HbA_{1c} 8.15%) to second entry (mean 7.08%). Users with T1D (mean 7.74%) had an absolute .25% (F=9.52, P=.002) higher HbA_{1c} than users with T2D (mean 7.49%). There was a significant interaction between diabetes type and HbA_{1c} entry (Figure 2). Both groups improved over time, but users with T2D had a greater HbA_{1c} decrease over time than users with T1D (F=10.54, P<.001).

After adjusting for gender, location, duration of diabetes, and months between HbA_{1c} entries, HbA_{1c} continued to decrease by an absolute 1.07% (F=292.03, P<.001; Multimedia Appendix 1) from first (mean HbA_{1c} 8.31%) to second entry (mean HbA_{1c} 7.24%). Regardless of time, users with T1D (mean 7.92%) continued to have a higher HbA_{1c} (.29% HbA_{1c} difference; F=11.66, P<.001) than users with T2D (mean 7.63%). In the adjusted model, the interaction between diabetes type and HbA_{1c} entry persisted (Figure 2). Users with T2D continued to have a greater HbA_{1c} decrease over time than users with T1D (F=10.54, P<.001). After adjusting for gender, location, duration of diabetes, months between HbA_{1c} entries, and insulin use, users with T2D reported a 1.27% absolute HbA_{1c} reduction (F=364.43, P<.001) from first (mean HbA_{1c} 8.16%) to second entry (mean HbA_{1c} 6.89%).

Finally, using the app to record food was associated with greater HbA_{1c} reductions even after adjusting for covariates and after further adjusting for insulin use for users with T2D (Multimedia Appendix 2, P<.05).

Figure 2. The unadjusted and adjusted interaction between diabetes type and hemoglobin A1c over time.



Discussion

Principal Findings

We assessed changes in HbA_{1c} for people with T1D or T2D who used the One Drop | Mobile app over a period of 1 year. We also evaluated relationships between tracking self-care with the app and HbA_{1c} change during that time. App users reported up to a 1.27% absolute decrease in HbA_{1c} depending on their diabetes type. Using the app to track food intake was associated with greater HbA_{1c} reductions.

Landmark studies, including the Diabetes Control and Complications Trial [25] and United Kingdom Prospective Diabetes Study [26], found lowering HbA_{1c} closer to normal levels reduced the risk of diabetes complications. According to recent reviews, diabetes apps are associated with reduction of HbA_{1c} [1-3], but their effectiveness varies widely across studies and by diabetes type.

One review reported people with T1D who used diabetes apps had a 0.36% HbA_{1c} reduction in 3 to 9 months [1]. For people with T1D using the dBees self-care and blood glucose tracking app, there was no HbA_{1c} reduction over time or relative to controls using a paper logbook [5]. In another trial, 34 children and teenagers with T1D using the mDiab/Mobil Diab tracking and self-care support app reduced their HbA_{1c} by 0.72%, but HbA_{1c} also fell by 0.98% in the control group [8]. In a nonrandomized controlled trial, 90 adults with T1D and HbA_{1c}≥8% using the Diabeo digital diary and insulin calculator lowered their HbA_{1c} by 0.91% relative to controls [6]. Among 36 people with T1D in Australia using the Glucose Buddy tracking app, HbA_{1c} was reduced by 1.10% [7].

Based on 367 people with T1D using the One Drop | Mobile app, we found HbA_{1c} declined by 0.86%—an amount consistent with other studies evaluating publicly available apps but more than two-fold larger than the overall effect of diabetes apps

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tested among people with T1D [1]. Moreover, unlike the previous trials described above, we related HbA_{1c} change to tracking self-care with an app, and found, regardless of diabetes type, using the app to track food consumption was associated with a greater HbA_{1c} reduction.

For people with T2D, an evaluation of 10 studies testing diabetes apps found an average HbA_{1c} reduction of 0.49% [3]. One of those studies was an RCT evaluating the publicly available WellDoc app (now available as Bluestar) that reported a 2.03% drop in HbA_{1c} among 15 people with T2D in one urban area. Our observational study with no control group or randomization included a sample of 921 people with T2D, and found HbA_{1c} decreased by 1.27%. This HbA_{1c} improvement is comparable to the difference in HbA_{1c} improvement between the WellDoc intervention and control groups and more than double the effect of diabetes apps used by people with T2D in a recent meta-analysis by Hou et al [3]. In that meta-analysis, one other trial evaluated a publicly available app [9]. The trial evaluated the mDiab/Mobil Diab app as used by 40 people with T2D in Butembo, Democratic Republic of Congo [9]. HbA_{1c} improved by 1.78% [9]. The baseline HbA_{1c} was 0.54% higher than in our study.

Limitations

This study has limitations. There was no control group or randomization. Multiple potential confounding factors may have contributed to the observed results, making it impossible to ascribe causal relationships between using the One Drop | Mobile app and HbA_{1c} change. The significant relationship between using the app to track self-care and HbA_{1c} benefit enhances confidence of a direct link. Users were also self-selected in terms of their using the app and self-reporting 2 or more HbA_{1c} values, introducing external validity and generalizability concerns. This possibility, however, is also a concern with any RCT in which participants self-select to participate. Our sample also reflects people willing to use a diabetes app. It is plausible to assume these people are younger, have a higher socioeconomic status (ie, a higher income, education) and are more comfortable using technology. To protect privacy, One Drop | Mobile does not collect user age, precluding the ability to describe this and other characteristics (eg, education, income, insurance status) of the sample or adjust for them in analyses. One Drop | Mobile also has other features we did not relate to HbA_{1c} change or adjust for in our analyses. HbA_{1c} was self-reported rather than assessed with a laboratory assay. Because the app is a tool for the user and not subject to review by others, it is unlikely users altered their HbA_{1c} values in response to social desirability bias. Consistent with prior studies that used laboratory HbA_{1c} values, we found a greater HbA_{1c} improvement among people with T2D than people with T1D [1]. Also, self-reported HbA_{1c} was highly correlated with average blood glucose 90 days before the HbA_{1c}, increasing confidence in its utility as an indicator of glycemic control in this study. Finally, our sample included over 1200 PWD from both within and outside the United States, differentiating it from other studies that included people from only one country or region.

Conclusion

There are currently no best practices for evaluating mobile health apps [27], and clearly more research is needed. This study adds to that body of work. Diabetes app developers collect data that can both improve product offerings and user experience and evaluate how users may be benefiting.

We believe people want and deserve mobile health apps that address their self-care needs and enhance their ability to improve the management of their chronic health condition [17,28]. Selecting an app is challenging. There are over 1500 diabetes apps to choose from with more being developed. A review of 65 publicly available diabetes apps concluded 86% were unfit for promoting self-management [29]. Ratings by consumers can be a poor indication of an app's clinical efficacy [30]. The results of carefully developed clinical evaluations will help consumers select better apps and assist providers in recommending efficacious apps to patients.

Conflicts of Interest

Chandra Y Osborn, Mark Heyman, Brian Huddleston, and Jeff Dachis are full-time employees and have equity in Informed Data Systems Inc, manufacturer of the One Drop | Mobile app. Joost van Ginkel received a consulting fee to assist with analyses but otherwise has no conflict of interest. Informed Data Systems Inc has paid David Rodbard of Biomedical Informatics Consultants LLC for services unrelated to this study. David G Marrero serves as a clinical advisory board member for the One Drop | Experts program on which this study does not report.

Multimedia Appendix 1

Tests of mean hemoglobin A_{1c} change by time, diabetes type, and their interaction.

[PDF File (Adobe PDF File), 37KB - diabetes_v2i2e21_app1.pdf]

Multimedia Appendix 2

Tests of the relationships between tracking food, activity, blood glucose, and medications in One Drop | Mobile and hemoglobin A1c change.

[PDF File (Adobe PDF File), 70KB - diabetes_v2i2e21_app2.pdf]

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Abbreviations

HbA $_{1c}$: hemoglobin A_{1c}
IQR: interquartile range
LADA: latent autoimmune diabetes in adults
PMM: predictive mean matching
PWD: people with diabetes
RCT: randomized controlled trial
T1D: type 1 diabetes
T2D: type 2 diabetes

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Original Paper

Views of Patients on Using mHealth to Monitor and Prevent Diabetic Foot Ulcers: Qualitative Study

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Abstract

Background: People with diabetes are at risk for diabetic foot ulcers (DFUs), which can lead to limb loss and a significant decrease in quality of life. Evidence suggests that mHealth can be an effective tool in diabetes self-management. mHealth presents an opportunity for the prevention and monitoring of DFUs. However, there is a paucity of research that explores its effectiveness in the DFU patient population, as well as the views and attitudes of these patients toward technology and mHealth.

Objective: This study aimed to explore the views, attitudes, and experiences of a diabetic patient population with or at risk of DFUs regarding technology, mHealth, and the diabetic foot.

Methods: We used a qualitative research approach using in-depth interviews with 8 patients with DFUs. Questions were structured around experience with technology, current health practices related to diabetic foot care, and thoughts on using an mHealth device that prevents and monitors DFUs. We transcribed and thematically analyzed all interviews.

Results: All patients had positive responses for an mHealth intervention aimed at preventing and monitoring DFUs. We found 4 themes in the data: diversity in use of technology, feet-checking habits, 2-way communication with health care professionals (HCPs), and functionality. There were varying levels of familiarity with and dependence on technology within this patient population. These relationships correlated with distinct generations found in North America, including baby boomers and Generation X. Furthermore, we found that most patients performed daily feet checks to monitor any changes in health. However, some did not perform feet checks prior to the development of a DFU. Patients expressed interest in 2-way communication with HCPs that would allow for easier appointment scheduling, sharing of medical data, decreased number of visits, and use of alerts for when medical attention is required. Patients also identified conditions of functionality for the mHealth intervention. These included consideration of debilitating complications because of diabetes, such as retinopathy and decreased mobility; ease of use of the intervention; and implementation of virtual communities to support continued use of the intervention.

Conclusions: Our patient population expressed an interest in mHealth for preventing and monitoring DFUs, although some participants were not frequent users of technology. mHealth continues to show potential in improving patient outcomes, and this study provides a foundation for designing interventions specific to a DFU population. Further research is needed to confirm these findings.

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KEYWORDS

mHealth; telemedicine; diabetic foot ulcer; diabetes; qualitative research

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Introduction

Diabetes affects 1 in 10 people worldwide, many of whom do not have regular access to health care. One of the most devastating consequence of diabetes is the loss of a limb (lower extremity amputation) due to complications resulting from a diabetic foot ulcer (DFU) [1,2]. Diabetic patients have a lifetime risk of 15% to 25% of developing a DFU [3], which can lead to significant decreases in the quality of life, limitations in mobility, function, and independence, and increases in susceptibility to depression and anxiety [2,4]. Moreover, DFUs and lower extremity amputation can lead to loss of livelihood; in 2011, 50% of Canadians with a diagnosis of diabetes were of working age, between 25 and 64 years [5], costing the health care system Can $570 million annually [6]. The prevention of DFUs is of high concern, as the percentage of Canadians at risk for developing diabetes is projected to increase.

The use of mobile technologies in health care is becoming increasingly commonplace. In the United States in 2016, US $867 million was raised by mHealth companies from investors to develop technologies in wearables and sensors, telemedicine, and digital medical devices [7]. mHealth aims to improve the health care service delivery process through support and services to health care providers, or to improve communication between patients and health care services [8]. This makes mHealth a key driver in making health care more accessible to the general population. Over 1100 diabetes-related mHealth apps are available for download, including diabetes self-management and education apps [9]. There is a growing body of evidence supporting the potential for mHealth to have a positive effect on the diabetic population [10-13]. However, there is insufficient evidence on the effectiveness of mHealth interventions for the diabetic foot [14,15]. Also, there is an increase of innovative technology to diagnose DFUs that could be complemented with mHealth, such as infrared thermography and diagnostic algorithms [16,17].

The goal of this study was to explore the views of individuals with DFUs on technology, mHealth, and the diabetic foot.

Methods

Design and Ethics

We used a qualitative, descriptive research methodology with face-to-face semistructured interviews to gain in-depth data from consenting patients with diabetes at an outpatient clinic at a tertiary care hospital [18]. We obtained ethics approval from the local institutional research ethics board.

Study Participants

The study recruited men and women with diabetes from the wound care clinic at a large, tertiary care center. We used a maximum variation purposive sampling approach in this study to maximize diversity and capture common themes relating to the intervention across a range of participants with differing characteristics [18]. Individuals with diabetes received face-to-face invitations to participate in interviews.

Data Collection

Face-to-face interviews with diabetic patients were conducted by a researcher using a standardized interview guide (Multimedia Appendix 1). A visual pamphlet (Multimedia Appendix 2) and a physical prototype of a DFU prevention and monitoring device developed by an industrial partner was presented during the interview to guide discussion around the development of an mHealth tool. The device is an imaging tool that uses near-infrared light that is attachable to mobile phones. The intended use for the device includes the monitoring of active DFUs and the prevention of DFUs. The only interaction with the device that participants had was during the interview. We conducted interviews rather than focus groups to encourage participants to express opinions that were not influenced by other individuals with diabetes. The content of the interview questions was based on the literature on the evaluation of mobile apps for people with diabetes [19], views of mHealth in a diverse diabetic population [20,21], and the theory of technology adoption [22]. We audiorecorded and transcribed the interviews with each participant's consent.

Data Analysis

We used data organization, coding, and thematic analysis to find relationships from the data we collected [18]. We then used an inductive coding approach to develop themes from the raw data [16]. Coding categories were developed and thematic analysis was conducted, using the qualitative analysis software Dedoose (v7.6.6; SocioCultural Research Consultants, LLC), by 2 independent researchers and presented to 2 researchers at our center. Any discrepancies were discussed and resolved to avoid bias in the data.

Results

Participants

We invited 7 men and 2 women to participate in the interviews. One man declined participation due to lack of interest in the study. The age of participants ranged from 36 to 77 years with a mean of 53.5 years: 2 participants were older than 65 years, 3 participants were between the ages of 45 and 64 years, and 3 participants were under the age of 44 years. Among the participants, 1 did not have an active DFU, 4 had type 1 diabetes, and 3 did not own a mobile phone, while all participants owned a computer.

Emergent Themes

All participants were receptive to the concept of an mHealth-based intervention in the prevention and monitoring of DFUs. The participants expressed their views on personal challenges with diabetes and DFUs and their relationship with technology. A total of 4 key themes emerged from the data: diversity in use of technology, feet-checking habits, 2-way communication with health care professionals (HCPs), and functionality.

Diversity in Use of Technology

Diabetes and its complications affect individuals of all ages. This makes developing an effective mHealth intervention more difficult, as it needs to target a diverse population. All of our

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study participants were open to the concept of an mHealth-based intervention in the prevention and monitoring of DFUs. While each participant had a unique relationship with technology, we found correlations between peers of similar age groups and their views on technology.

Participants aged 65 years and older acknowledged that they had limited use for technology. Technology did play a role in their lives, but on a very limited scale. The most frequent use of technology was for communication, such as accessing emails and connecting with friends and family. Both participants described that they did not have the need or use for technology. It did not fit their lifestyles.

> *I actually don't do a lot with my phone other than I use it for emails and for phone calls. I am not a techy guy to use my iPhone all the time...It's a different generation I'm in...I have no need for it. That's the whole point of technology, it's gotta suit your needs. And it doesn't. I don't need it, so I don't use it.* [Male, 68 years old]

Participants younger than 40 years used technology more consistently and frequently. All younger participants owned both a mobile phone and a computer. They described technology as an important source of information and a means to satisfy daily needs, such as generating income, providing entertainment, and connecting with others via social media. This age group expressed the most dependence on technology when compared with other groups in this study.

Middle-aged participants, between the ages of 45 and 65 years, had a less distinctive pattern of technology use and had the most diverse relationship with technology within their own age group. Their experience with technology varied from not owning a mobile phone to frequent daily use of one. Their use of and familiarity with technology related to their daily lifestyle and specific needs. One participant described that he did not own a mobile phone because he spent most of his day in front of his computer and valued the time he had away from it. Another participant had a greater dependence on his mobile phone than did other participants in his age group, but it was not as integrated into his life as it was among participants in the younger age group. He used it as a productivity tool for work, communication, and a few entertainment purposes.

Feet-Checking Habits

At-risk people with diabetes are encouraged to check their feet every day for pre-DFU signs and to monitor active DFUs. All participants had a routine they performed for feet checking. Of the 7 participants with active DFUs, 6 checked their feet every day. Most participants inspected their feet themselves, and a few had someone else look at their feet if they could not see, especially the bottom of their feet. Some used a mirror to assist in viewing the bottom of their feet. Others used their hands to feel for abnormalities, and 2 participants mentioned that they checked their feet every day due to the formation of their DFU. This implies that feet checking was not a regular practice prior to the DFU. The participant who did not check his feet every day understood the importance of feet checking but let other priorities prevent him from doing so, such as the responsibilities of being a full-time student.

Although most participants checked their feet, not all had the physical ability to conduct a thorough assessment. The complications from diabetes, such a loss of mobility and poor vision, can prevent individuals from doing a full feet check, especially in the older population. One participant described that some days his joints and muscles were stiffer, which made it more difficult to bend his leg to check his feet. Instead, he would ask his wife to check his feet.

Two-Way Communication With Health Care Professionals

mHealth has the potential to enable patients to engage in 2-way communication with their physicians. Most participants were receptive to the idea of being able to communicate with and send physiological readings to their HCP via a mobile phone app. Specifically, they liked the idea of being able to send images of their feet or DFU and receiving an alert of its status. Participants were interested in the convenience of receiving health services from the comfort of their own home and in avoiding going to a clinic if services can be done through mHealth. One participant mentioned the inconveniences of going to the clinic, such as travelling and traffic. Participants also said that they hoped it can assist in contacting their HCP, as some participants had experienced difficulties in doing so in the past. However, a few participants mentioned that the effectiveness of the intervention would depend on the physician's response time on the app. If a timely response cannot be guaranteed, then the participants would not want to use the app. They described some negative consequences, such as untimely care for health issues and introducing unnecessary worry to patients stemming from the wait for a response.

Although interest was high among participants, older individuals also expressed that they would not want their doctors to be replaced by mHealth. They preferred in-person visits and mentioned that it's what their generation is used to. They also valued the relationship between the doctor and the patient, and described it as an integral part of care given to patients. One participant described the value of in-person interactions with his doctor.

> *No, I would still want to go to [doctor name] every 3 weeks, or whatever he feels appropriate. He's a great guy, we're very good friends...the relation between the patient and the doctor is—well I've been very spoiled, but I know what it can be—it's crucial.* [Male, 77 years old]

Functionality

For mHealth interventions to be successful, certain factors about the targeted population must be considered to increase adoption. Participants provided feedback on the presented prototype and mentioned specific features that can increase the usability of the device. One of the most frequent suggestions was to maximize ease of use, as this device might also be used by older patients. A few participants suggested being trained by a professional before being given the device, or to have a manual provided with the device to assist in learning to use the novel

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technology. Two participants made recommendations for such interventions to better suit the needs of individuals living with complications from diabetes, as they can impair use of a device designed for someone without diabetic complications. One participant suggested the use of bright colors in the app to overcome vision issues caused by retinopathy. Another suggestion was to consider the decreased mobility in individuals with diabetes, which could limit people's use of this mHealth technology if it depended on certain functional movements, such as taking an image of the user's foot.

Encouraging prolonged use of an mHealth intervention is another challenge that must be considered in a DFU population. Some participants expressed ideas on how to maintain interest in and use of the device, as depression has been linked to people with diabetes. Some participants suggested incorporating some sort of community into the app, as this can keep users excited to continue self-reporting and to stay updated with other users' status. This would provide another reason to keep using the device that is not just centered on the patient's health.

Discussion

This qualitative study explored attitudes and perceptions toward technology and mHealth in individuals with and at risk of DFUs and reflected on specific conditions from the patient's perspective for increased mHealth adoption in diabetic foot care. We found that individuals responded positively to an mHealth intervention aimed at preventing and monitoring their DFUs. This study contributes to the literature by identifying potential users' DFU-related practices and by highlighting issues related to the development and integration of mHealth interventions.

Preventing and treating DFUs requires patients with diabetes to be proactive in the care of their own feet, including carefully checking their feet daily for preulcerative signs and wound healing [23]. Current efforts, such as multidisciplinary clinics and patient education, are found to be cost effective, as they relieve the economic burden on the health care system by preventing DFUs and providing higher standards of care [24-26]. However, there is no systematic foot screening program in place for at-risk diabetic patients. Therefore, innovative solutions are required to improve the systems in place for DFU prevention and care, and ideally to focus on mechanisms that would allow for thorough foot assessments outside of the clinical setting. Leveraging the strengths of mHealth may improve current patient practices in DFU prevention and care; although the evidence is mixed, there appears to be potential to increase adherence to chronic disease management [27]. In addition, caution should be taken when implementing similar interventions in this population, as individuals with DFUs are at a much higher risk of morbidity and death [28]. Future studies should further explore the effectiveness of the use mHealth for DFU prevention and care using larger sample sizes and longer follow-ups.

This study focused on participants' current DFU monitoring practices. All participants were conscious about their foot health, and most patients checked their feet every day. We found that the thoroughness of a participant's foot checks depended on their mobility and stage of diabetes. If an individual had poor mobility, increased joint stiffness, or vision problems, it was more difficult for them to inspect all parts of their feet. Some required aids such as mirrors or having someone else inspect their feet. Moreover, some did not start checking their feet daily until the formation of a DFU, which may reflect a lack of education regarding the need for monitoring rather than treatment when it comes to the development of DFUs with diabetes. Future studies should explore the daily feet-checking routine of at-risk people with diabetes to further explore potential barriers in this crucial practice.

We also identified varying levels of experience with technology among our study participants. This is consistent with the fact that DFUs affect individuals with diabetes of all ages [29]. Varying levels of familiarity with technology in a target population poses a challenge in satisfying the needs of the target users [30,31]. Specifically, older participants displayed lower familiarity with technology. This may be due to a digital divide, where older people tend to be excluded from benefiting from Internet technology [32]. This lack of familiarity with technology has been identified by other studies as a barrier to mHealth adoption [30,31,33,34], and suggests that future studies should explore how mHealth can be effective in a population where familiarity with technology is diverse.

We also identified conditions for a successful mHealth tool from the perspective of an individual with a DFU. Participants identified ease of use as an important factor, which has also been mentioned in other studies where rates of adoption increased among baby boomers and older generations [30,33,35,36]. Ease of use encourages adoption among individuals who are not familiar with technology and prevents early negative experiences that may discourage the use of the intervention [22]. Mobility and vision problems were mentioned frequently in our study (and are frequent in people with diabetes), and technology designed for this patient population must take these challenges into account [33,37]. Depression was also mentioned as a factor that can prevent mHealth adoption, and is associated with lower health-related quality of life and higher mortality in a diabetic population [38,39]. Participants suggested that communities and online forums should be integrated into mHealth interventions to encourage initial and continued use. This would allow patients to share their thoughts and experiences and to develop relationships for peer support. Health-related virtual communities have been found to be an effective way to provide information to members and provide socioemotional support where members gained psychosocial benefits, although more evidence is required to confirm this [40]. However, this does not come without the inherited risks of social media. Risks include poor quality of information shared between patients, which can lead to deviation from a professional's advice in care and risks of patient privacy breaches [41]. Therefore, careful considerations must be made when implementing such communities by including measures to protect both patients and HCPs [41,42].

Participants in this study also expressed interest in a 2-way communication channel with an HCP via the mHealth intervention. They expressed that having this channel would allow for easier appointment scheduling, sharing of medical

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data, decreased number of visits, and use of alerts for required medical attention. Providing a way for patients to communicate with their HCP would make access to health care services more pervasive, especially for people living in remote areas or people with decreased mobility. A review of telemedicine technologies that require an HCP to respond, either in real time or with a delay, to the clinical information transmitted via telemedicine found that it has the potential to be an effective tool for delivering more frequent and timely health care to people with chronic conditions at a distance and for improving access to health care [43]. This shows that 2-way communication with an HCP can improve health outcomes of individuals with DFUs. However, some older participants were reluctant to have technology replacing their HCPs. Future research should explore how to best implement this to ensure effective communication between patients and HCPs while sustaining the patient-doctor relationship.

Although the considerations mentioned above have been found to be important in the development of an mHealth tool, how it is implemented into an HCP's workflow is crucial for its success [44]. The adoption of such interventions does not come without change in the routine of HCPs and must be considered. Two studies qualitatively investigated conditions that would need to be addressed for successfully introducing telemedicine in diabetes foot care from the perspective of HCPs [45,46]. These included training for HCPs, concerns for whether an mHealth approach would reduce the hands-on skills and multidisciplinary approach specialized in wound care, change to communication channels within the clinical environment, and having a telemedicine champion in the work setting [45,46]. Consequently, the development of mHealth tools must consider the impact on both patients and HCPs.

Strength and Limitations

A strength of this study was the approach to include patients of all ages with DFUs, which provided the study with an accurate representation of the perspective of a typical DFU population. Conversely, having a wide variation of participants can be a limitation, as it weakens the content saturation of the study. Future research should increase the sample size or recruit individuals from similar age groups to increase content saturation in this field.

A limitation of this study was also its relatively small sample size. This may decrease the strength of the results presented. However, the exploratory objective of this study will hopefully influence future studies with larger sample sizes in this field.

Participants were also exposed to the mHealth device only during the interview session. Therefore, their views were based solely on this interaction and information from the interviewer via the pamphlet and conversation. However, the results presented are focused on their views on mHealth in general rather than direct feedback on the prototype itself.

We recruited participants from only 1 wound care clinic, and our findings cannot be generalized outside the population in this sample due to regional differences. However, regions with similar characteristics may offset these limitations. The small sample size further limits the generalizability of our findings. This study did not capture the views of individuals who are not active in the health system, and our findings may not represent their views. The findings from this study are accounts of the views of the sample's perspective on mHealth, technology, and the diabetic foot.

Conclusions

The population we studied expressed generally positive views on mHealth for preventing and monitoring DFUs. This indicates the potential for mHealth to improve health outcomes for individuals with and at risk of DFUs. Although only a small portion of the patient population were using technology for health reasons, they were open to the idea of using an mHealth technology if it would improve their quality of life. This is an important indicator that mHealth may be a platform for solutions moving forward as the health care system continues to be burdened by patients with diabetic complications. This study further improves on the understanding of opportunities and challenges of developing an mHealth intervention for individuals with diabetes and provides a foundation for interventions specific to a DFU population.

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Conflicts of Interest

Authors GL and KC, as well as St Michael's Hospital, have an equity interest in a spin-off company translating this work into an mHealth device.

Multimedia Appendix 1

Interview guide used by the researcher during the one-on-one interviews with participants.

[PDF File (Adobe PDF File), 395KB - diabetes_v2i2e22_app1.pdf]

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Multimedia Appendix 2

Pamphlet shown to participants by the researcher to assist in the explanation of the presented mHealth prototype device.

[PDF File (Adobe PDF File), 498KB - diabetes_v2i2e22_app2.pdf]

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Abbreviations

DFU: diabetic foot ulcer
HCP: health care professional

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Original Paper

The Value of Children's Voices for a Video Game Development in the Context of Type 1 Diabetes: Focus Group Study

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Abstract

Background: Children with type 1 diabetes mellitus (T1DM) face daily challenges performing self-care tasks, controlling symptoms, and dealing with psychosocial issues. The use of video games to improve health is a successful support for persons with chronic diseases, promoting adequate self-management through simulations of real life. Involving future users in the development of games is essential to generating innovative, creative, and effective programs.

Objective: Our goal is to identify what children with T1DM need to know about their disease and their self-care tasks as well as their preferences in video games.

Methods: Children with T1DM provided input about their learning needs, self-care tasks, and preferences in video games. Three categories were identified through qualitative content analysis: dealing with emotions and knowledge, practical skills and awareness, and game preferences.

Results: Children expressed concerns about the difficulties of self-care, lack of knowledge about diabetes, and lack of awareness about the consequences of behaviors related to self-care, which contribute to inappropriate behaviors and significantly impact self-management of their disease. They expressed enthusiasm for a video game for children with diabetes that considered their needs and preferences.

Conclusions: Findings support the potential benefits when children's input is considered in game design. Consideration of customer needs and preferences is a powerful resource in the development of video games with enhanced learning experience.

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KEYWORDS

type 1 diabetes mellitus; video games; qualitative research; pediatric nursing; serious games; self-management

Introduction

Type 1 diabetes mellitus (T1DM) is one of the chronic diseases that most affect children and adolescents [1-3]. Adherence to a treatment regimen is a key component in its management; however, poor management is a common problem among children with diabetes due to lack of knowledge that leads to inadequate behaviors and undeveloped skills [1]. The lack of disease understanding [4] and challenges of being a child with T1DM [5,6] may be associated with treatment nonadherence. This scenario demands educational interventions that take into account individuals and consider their clinical care routine and psychosocial needs. These interventions must engage parents

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and health professionals and use psychoeducational principles and behavioral procedures [7,8] and the design of new technologies [9].

Video games have been cited in the literature as tools that capture children's attention and promote understanding and learning about their condition. Some studies report the positive effects of using video games on health determinants [10] and clinical outcomes [1]. These games use strategies that can motivate positive behavioral changes, thereby assisting in disease self-management and health promotion [3,11]. Video games aimed at children with T1DM began to be developed in the 1990s [13]. In general, studies have shown positive results from the use of these games, such as a reduction in the number of urgent care visits, improvement in self-efficacy and self-care, and improved communication about the disease among children, parents, and friends [12-16]. The best results are achieved when there is a familiarity between the player and the main character in the game, whether in the physical appearance or similar clinical conditions [15,16]. Conversely, some studies specifically aimed at children and adolescents with diabetes by using fantastical characters and themes such as elephants, card games, and plane trips [17,18]. Prompted by the potential of these tools for health improvement, our long-term objective is to develop a video game for children with T1DM that focuses on knowledge about the disease and self-care tasks.

Video games designed for children and adolescents with T1DM and type 2 diabetes mellitus (T2DM) have been the focus of literature reviews [12,14], research interventions [13,14,19], and studies on the use of conceptual frameworks for game development in this field [8,20,21]. However, few studies considered the needs and preferences of the target population during videogame development.

A recent study [22] investigated the contribution of children's experiences about diabetes self-care during the early stages of development of a video game about insulin injections. Considering the input from future users is an important step in the development of successful approaches for interactive technologies [22,23]. The following components should be considered: cognitive aspects; language abilities; literacy level [24]; particularities concerning age and culture; and needs, preferences, and experiences [3].

Although barriers that may interfere in the self-management of diabetes are well recognized in the literature, the reasons for nonadherence to treatment are linked to differences in each individual and group and these must be investigated [25]. Although video games can provide health benefits, they cannot achieve their goals unless the profile, needs, and preferences of children are considered.

Therefore, in order to improve the design of a future video game, we conducted a qualitative study that included the following research questions: What are the main learning needs related to understanding the disease and self-care tasks from the perspective of children with T1DM? How should the video game be designed to appeal to the children with TIDM? Our goal is to identify what children with T1DM need to know about their disease and their self-care tasks as well as their preferences in video games.

Methods

Participants

A total of 19 children, 5 boys and 14 girls with a mean age of 9.8 (SD 1.8) years and the mean time since diagnosis of 3.5 years, participated in the study. The mean hemoglobin A_{1c} value was 9.8% in the last year of follow-up. Of the 19 children, 15 (79%) were using regular and neutral protamine Hagedorn insulin, 3 (14%) were using rapid and long-acting analogs, and 1 child (5%) used an insulin pump. All children were living in urban areas and attending school. Children were recruited at the Endocrinology and Childhood Diabetes Outpatient Clinic from educational group meetings. The clinic's multidisciplinary team provides diabetes education during weekly group meetings. For the past 5 years, these group meetings have been led by one the authors of the present study (V Sparapani), who is a nurse with experience in research, children, and parents.

The eligibility criteria included children (boys and girls) aged 7 to 12 years with a diagnosis of T1DM, regardless of the time of diagnosis. The exclusion criterion was any form of developmental delay that could interfere with the data collection strategy. The presence of developmental delay was evaluated using information provided by the health team and medical records. The lead nurse explained the activity to the children and parents, who were participants in educational group meetings, and presented the study goals, potential risks and benefits, and their rights to withdraw from participating at any time. The researcher allowed parents some time to freely consent to their children's participation in the activity. The study was approved by the institutional review board of the university and hospital. All parents of study participants provided written informed consent, and children also gave their assent to participate.

Focus Groups

The focus groups technique, a method which promotes an environment of interaction and discussion on a given topic among participants [8], has been widely used in research [11,17,20]. This technique is also used in the development of interactive technologies because it considers the user involvement in the process of technology development from conception to final evaluation. We adopted a user-centered design (UCD) approach [3,8,24,26] for this study, an approach requiring utilization of focus groups.

Data were collected from December 2012 to May 2013. The study included 6 40- to 60-minute focus group meetings consisting of 4 to 6 children per group, 6 groups in total. Four children participated twice, totaling 23 participations. These double participations resulted from the number of follow-up consultations the children had at the outpatient clinic and their willingness to participate, not configuring restrictions or exclusions from the focus groups. Focus groups were moderated by the main author of this study; a research assistant took notes from verbal and nonverbal communication. The meetings were held in a private room in the hospital concurrent to the educational meetings conducted with the children's parents. Children were aware that their parents were nearby.

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According to recommendations in the literature [8], the moderator tried to create a comfortable and trustworthy atmosphere to motivate participants to share their experiences and feelings. The children were invited to sit in a circle on the floor, received name tags, and were introduced to each other to break the ice before the session started.

Because young children demonstrate differences in comprehension levels, abilities, sensitivities, abstraction capabilities, styles [8,27,28], and capabilities with video games of different complexity levels, children were assigned to 1 of 2 focus groups according to their age (7 to 9 and 10 to 12 years old). This strategy enabled us to identify age-appropriate tasks for video game development. The researcher discussed the focus group and study goals with the children and described what was expected of them. The groups were audiotaped with the children's and parents' permission. The following open-ended questions guided the activity: Why is insulin necessary? What is the most difficult task in the diabetes treatment? Why is that task difficult? What kind of video game do you like most? What would you like to see in a video game for children with diabetes? Every child had the opportunity to answer to every question. The researchers finalized the data collection through the focus group sessions when the data set from these focus groups was sufficient to reach the study's objectives.

Data Analysis

The focus group data were analyzed following deductive and inductive content analysis guidelines [29,30]. The resulting information was organized into 3 phases: preparation, organization, and reporting. During the preparation phase, data were fully transcribed and read several times until the researcher was acquainted with the contents. In the organization phase, the researcher made careful notes, defined text headings, and elaborated categories and subcategories based on data analysis [29,30]. The children's excerpts were selected to support the discussions in the reporting phase [29,30].

Results

Qualitative analysis identified 3 main categories representing learning needs related to knowledge about the disease, self-care tasks, and the children's video game preferences.

Dealing With Emotions

The children's statements brought up emotions that interfere with the proper performance of self-care tasks. Fear , insecurity, and pain were emotions linked to insulin injection.

> *The insulin needle is tiny, but I'm scared of it.* [Girl, 11 years]

When I take the insulin syringe, I have a bad feeling! It's not really that I'm scared, I'm scared to make a mistake somewhere in my body, you know? [Boy, 11 years]

> *I don't shoot it because it hurts.* [Girl, 8 years]

The children reported anger about having to self-monitor blood glucose (SMBG) several times per day and therefore did not monitor appropriately. One child said that she does not like to perform this task, fails to execute it, and chooses when she wants to perform it.

> *I don't like doing the test. I switch the days that I do the test. If I do the test today at dinner, tomorrow, I don't do it... It's bad, and I also forget to do it. I don't like doing the test* [Girl, 13 years]

Learning how to deal with desire was also an identified need. The children reported uncontrollable emotions related to consuming foods in large quantities, particularly sweets.

> *I am nibbling food all the time! I can't control myself. I will ask the doctor to be hospitalized. If I am at the hospital, I can comply with the diet correctly.* [Girl, 8 years]

Children were also demotivated regarding healthy eating habits. Some participants do not feel motivated to eat vegetables because they do not like them. Conversely, other children would like to comply with a proper diet; however, they find themselves demotivated due to the lack of support from parents. One child shared that she asked her mother to buy fruits and vegetables because they are not frequently available in her home.

> *I probably don't eat vegetables because of my mother. She doesn't make salads frequently... When I ask, she says, 'Tomorrow I buy it' or 'Wait' or 'I'll go to the grocery store later.'* [Girl, 12 years]

Children also have no incentives to practice physical activities. They do not accomplish this self-care task and provided several reasons for not doing it.

> *I don't have a bicycle. There's no place for walking or hiking. There is a park, but with no covered area. There are rocks all over the floor...and a lake around it. I like it, but it's bad to go there alone. My mom doesn't like it.* [Girl, 8 years]

Knowledge, Practical Skills, and Awareness

Learning needs related to understanding the disease and self-care, practical skills required for self-care, and awareness about the consequences of favorable or unfavorable behaviors related to self-care were identified. One child demonstrated her lack of knowledge about the causes and deficiencies in T1DM.

> *I think I have diabetes because I had too much sugar in the pancreas. It couldn't take it, and it stopped working.* [Girl, 12 years]

The children demonstrated learning needs regarding the function of insulin. According to the statements, the insulin has the role to "kill," "break," or "dissolve" the sugar present in the blood.

> *My body has no insulin to kill sugar. Insulin kills the sugar...* [Girl, 8 years]

The children demonstrated not knowing the food groups and different energy contents. A child talked about a hypoglycemia episode and questioned the moderator about what had caused the glycemic level drop since she had eaten at a barbecue place. According to the girl, she did not understand the explanation given by a relative, who said that she had to ingest other kinds of food and not just meat.

> *I was at a barbecue. When I got back home, I was feeling sick. I did the blood glucose test, and it was 25. I asked my aunt why it was 25 as I had eaten, and*

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she said, 'It is the roast beef...' I didn't quite understand, but she said that when we go to a barbecue and only eat meat, we also have to eat other things. I didn't quite understand. [Girl, 12 years]

Moderator: *Does meat have a lot or little energy?*

I think that it has a lot! [Girl, 12 years]

Moderator: *Is meat in the potato group?*

No. [Girl, 12 years]

Moderator: *To which food group does meat belong?*

Proteins. [Girl, 12 years]

Moderator: *And does meat have more or less carbohydrate?*

Less. Is it because of this? [Girl, 12 years]

The dialogue demonstrated the lack of practical skills required to carry out effective self-care. The children reported inappropriate techniques and doubts regarding the delimitation of injection sites and what to do with air bubbles in the syringe or in the insulin pen.

Can I apply insulin here [showing the inner thigh]? I apply here! I became accustomed to doing it. [Girl, 12 years]

The deficiency in practical skills related to carbohydrate counting was observed in several children, a potential reason for nonadherence to this task.

My mother and I weren't able to do the carbohydrate counting. We thought it very difficult. Sometimes my mother would go to work, and I couldn't make the counting alone. [Girl, 11 years]

Some children reported that they use the same SMBG lancet more than once because they do not have the practical skills to change the needle in the lancing device and usually puncture the same body site.

I change the lancet device only after a long time in use because then it does not stick anymore. [Girl, 11 years]

I find it hard to change the needle in the lancing device. It seems that the needle will fall, and I'm afraid to stick my finger on it. [Girl, 8 years]

The participants showed injuries on their fingers indicating that they use only the middle finger and index finger to perform the test. The children's lack of awareness was evident about the consequences of favorable or unfavorable behaviors to self-care. Many participants acknowledged that they had lipodystrophy because they do not use all available body sites for insulin application. The moderator asked, "And do you know why this lump is over there?" The child answered, "Because I apply here a lot."

Other children mentioned that although they know about the standard diet that would help them maintain adequate blood glucose levels, they do not follow it.

The doctor explained to me that when there are pasta and rice I can only choose one to eat. If I want to choose both, I can get half portion of one and a half portion of the other. I don't want to! I want everything, or I don't want any. [Girl, 12 years]

The participants do not perform correct monitoring records using excuses such as "I forgot." Many of the children assumed they do not perform the SBMG when there is some possibility of nonideal results.

Once I woke up at an early hour and ate half of the chocolate bar from my sister... Then, I didn't even measure the blood glucose in the morning. [Girl, 9 years]

The participants reported a significant number of hypoglycemia episodes, especially during physical activity. They demonstrated a lack of awareness regarding the consequences of eating chocolates and other sweets during these hypoglycemia episodes. A child told us about the food she uses for treating hypoglycemia episodes.

Sweets. My mom gives me candy, cookies, and chocolate. [Girl, 9 years]

Game Preferences

The children provided opinions about the video games they like to play. They also presented ideas about what a video game for children with diabetes should be like. Many participants expressed an interest in seeing what happens inside their bodies as the result of diabetes through a video game.

It could be a game in which the character had a spaceship. He could enter through our mouths and go inside of us. He would go through everything we have inside our body, and thus, the game stages would unfold. [Boy, 10 years]

The character should answer three questions to pass through stages. These questions would be related to what he saw inside the body... [Girl, 12 years]

The children would like to learn how to better control their diabetes, mostly about what they can or cannot eat.

I would like to play an eating game... A game in which we could choose what we should eat. The amount of sugar and carbohydrates. I saw a video game equal to that at the mall. I played it. [Boy, 10 years]

The participants would like to see a task about carbohydrate counting in the video game for diabetes. They want the opportunity to learn how to perform this task properly.

Somewhere in the game, it could have a restaurant that you entered or you'd have to click on. In this location, you could have an explanation on the easiest way to make the carbohydrate counting. I think that I could learn in this way. [Girl, 11 years]

According to their preferences, they want to learn how to perform insulin injections properly and how to train on other materials.

I would like to see the game character applying insulin in a doll. [Girl, 10 years]

The children said that physical activities, such as swimming or cycling, could help them understand diabetes.

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> *The game could help us counting energy levels. Each movement burns a little amount of energy and the game could go on explaining this to us.*. [Girl, 13 years]

The participants also contributed with ideas for components such as the game environment, scoring system, and characters. They emphasized their preferences for adventure games.

> *It could be an adventure game. A space travel.* [Girl, 11 years]

> *In another world... We want to go to new places... A park, a zoo, a forest! ... But I would like the game to talk only about diabetes.* [Girl, 10 years]

The researcher also asked the children how they could win in the game or collect points during the story.

> *If we make the right choices, we'll be getting stronger.* [Boy, 10 years]

According to the children's preferences, they would like to participate interactively in the construction of characters, choosing their physical form and clothes.

> *We could create the characters! We could choose the gender and the color of their eyes, hair, and their clothes and shoes.* [Girl, 12 years]

Yet, they would like to have someone to play the game with them:

> *We want friends.* [Girl, 12 years]

Discussion

Principal Findings

Accomplishing diabetes self-management demands knowledge about the disease and fulfillment of a care plan, which is not easy for any person and especially difficult for children because of their developmental stage and maturity [31,32]. The analysis of statements enabled us to identify gaps in the participants' knowledge about T1DM and reasons why they should perform proper self-care. In addition, empirical data show emotions that contribute to the understanding of behaviors of nonadherence to treatment or failure to perform self-care tasks. Our findings corroborate previous studies that present fear and anxiety associated with needles [33], depression, and difficulty controlling desires related to nutritional therapy [5,33]. Some studies discuss the importance of knowledge about the disease to the appropriate performance of self-management tasks [34,35], while other studies describe the difficulties related to practical skills for self-care and the lack of awareness of these difficulties [36].

Parents' attitudes considerably influence their child's behavior, which shows the importance of parental encouragement and support in promoting appropriate self-care, such an appropriate diet [36].

This data analysis mirrors aspects already presented in the literature, demonstrating interactions between emotions, knowledge, difficulties in practical skills for self-care, and lack of awareness towards these difficulties. These interactions have a significant influence on diabetes management. The discussion that we propose has not been presented in previous studies or in studies about using video games to learn about T1DM.

In this study, participants demonstrated insecurities regarding insulin injections, which are intensified by their fear of needles. They do not feel safe performing the technique, especially in handling needles, because they fear damaging their bodies. Some of their deficiencies in these practical skills reflect doubts regarding appropriate injection sites and removal of bubbles inside the syringe, which increase the children's insecurity about self-application.

The children who participated in this study revealed that they avoid performing insulin injection in the abdomen or upper buttocks because they are afraid of feeling pain. The rotation of sites chosen for insulin injection is strongly recommended to prevent lipohypertrophy [37], which was a complication observed in this study. Lipohypertrophy is the result of fat accumulations in the subcutaneous tissue where insulin is applied due to multiple injections in the same site [38]. The observation of injections in lipohypertrophy sites demonstrates the children's lack of awareness about possible complications such as reduction in insulin absorption [38]. Although some children demonstrated awareness of some complications, their lack of knowledge about the function of insulin generated doubts as to whether or not the consequences of this action are adequately understood. The fear of insulin injections is associated with many complications such as poor glycemic control, clinical complications, and psychological comorbidity [39].

These data demonstrate the need for children with T1DM to learn how to deal with their emotions and to acquire practical skills related to insulin injections. Fear and pain are themes of studies that discuss the need to address these emotions in interventions with these children [39,40]. A video game called *Koodak-e-Tavana* was designed to teach children about diabetes and insulin injections and aimed at reducing fear and anxiety [22]; this study is one of the few involving children in the first step of the process that identifies needs and tasks which should be included in the game [22]. Insecurity, fear, and pain are not topics commonly discussed in video games developed for children with T1DM. However, creative and innovative approaches such as video games may be able to promote a simulated environment that involves the children and enables them to learn how to deal with these emotions. The fact that children were motivated to learn about their disease and how to manage it was evident when they wished for a game that showed them how to inject insulin and allowed them to practice injecting insulin in a doll. These tools can increase awareness about complications and improve practical skills for proper insulin injection. Behavioral changes can contribute to increased adherence to insulin therapy.

Children participating in this study stated that the recommended number of SMBG tests per day caused anger and that the use of a new lancet and new pricking site was painful: they keep using the same lancet or pricking the same finger for several days to avoid pain. According to Floch et al [41], the reuse of lancets and pricking sites demonstrates a deficiency in the children's practical skill for this task. That study concluded that

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the pain and cutaneous finger injuries on pricking sites are related to frequently pricking the same sites, corroborating our results. These data indicate learning needs about facing pain and anger to improve the performance of these practical skills.

Similarly, blood glucose level evidenced by SMBG is another reason why the children say this is a bad task, because the results can reveal their nonadherence to treatment. The children's lack of understanding of the importance of this task is evident when they report their failure to monitor their glucose levels as needed. SBMG is an instrument for patients, parents, and health staff that provides for improved glycemic control [42].

There are few studies in the literature that discuss the use of video game applications aimed at motivating children to perform the SBMG in detail [17]. One study encouraged 4 24-year-old patients with T1DM to perform the SMBG and transfer the results to the game system. The game gives players the opportunity to earn reward points based on blood glucose values. However, the study does not show if patients have increased the amount of tests performed [19]. Topics such as coping with pain and how to deal with emotions such as anger and awareness about the SMBG were not covered in that study [19] or in other published studies. A video game that considers these learning needs could be very useful in providing information and encouraging the appropriate performance of SMBG by children, which, consequently, would improve T1DM self-management.

The children's awareness of the role of SMBG can be beneficial to the understanding of the influence of food on glycemic control, allowing them to make safer food choices. Learning about food groups and their energy loads and impact on glycemic control can support children in using practical skills related to nutritional therapy, such as planning meals. Carbohydrate counting was another learning need identified in this study. Carbohydrate counting is a technique for planning meals that aims to improve glycemic control and allows flexibility in food choices [43]. Children participating in this study stated that they would like to play a game that not only helps them to better select food choices but also provides an easier understanding about carbohydrate counting.

Dealing with the desire to consume sweets and other foods is another learning need identified in the children's statements. Our results are similar to other findings [5,33,44] showing that uncontrolled desire and anxiety related to nutritional therapy are self-management barriers. There are few game strategies that address coping with these emotions [22]. *Captain Novolin*, a video game released in 1992, shows the main character fighting evil doughnuts, milkshakes, sodas, and other sweets to keep normal glucose levels [14]. A video game that promotes awareness about the effects of high consumption of sugars and other foods—presenting routines with parents and friends eating together and offering healthy food options [43]—can promote better results for coping with desires and anxieties related to food intake.

The participants also demonstrated demotivation regarding the consumption of healthy foods. The lack of parents' incentives was demonstrated as a variable influencing this demotivation. A study by Baranowski et al [45] evaluates the influence of fruit and vegetable intake in the life of a child, the availability and accessibility of these foods at home, the role of parents as role models, and the purchase of these foods as impact factors. A video game developed to change the eating behavior of children by increasing fruit and vegetable intake achieved positive results; a game that promotes training parents to increase vegetable consumption in their preschool children is also cited in the literature [46]. An environment designed to explore the positive involvement of parents and friends in children's daily routine can increase the frequency of healthy choices, helping them to deal with anxieties, desires, and demotivation that prevent adherence to the nutritional therapy.

The lack of motivation is also present in the practice of physical activities. Children are less physically active than recommended and provided several excuses [47]. However, the children mentioned preferences for an adventure video game, located in forests or in a zoo and requiring several exercises. Encouragement toward increasing physical activity and reducing sedentary behaviors is a usual theme in video games designed to reduce risks of obesity and T2DM [8,26]. Studies demonstrate that the major barrier to participating in physical activities is the child's fear of hypoglycemia [31]. However, this issue was not identified in the dialogs from the children in our study who demonstrated inappropriate management of hypoglycemia episodes by eating foods with high amounts of fats such as chocolates or ice cream. This fact may be linked to the children's desire for candy consumption. Fat consumption is not considered effective to treat hypoglycemia because it can slow down the absorption of carbohydrates [48], another learning need identified in this study.

The children expressed a desire to learn about energy expenditure during exercises in the video game. A video game script specifically designed for children with T1DM might work as an excellent strategy to motivate physical activity. It can lead to the development of a taste for exercising and promote understanding of the relationships between food, physical activity, and insulin in the control of diabetes [47]. Thus, the participation of family members and friends in playing the game can influence the children's decision about becoming more active [8]. According to Brennan and Fink [49], family, friends, and people from other social relationships can have an influence on the children's decisions about incorporating or avoiding certain behaviors.

The lack of knowledge about diabetes demonstrated by the participating children was related to insulin function, causes of diabetes, and the role of foods in the body. An increase in understanding of the disease has been shown in studies that used video games with goals of changing health behaviors through the use of educational interventions [17,50,51]. In this study, the children's suggestions indicate their desire to experience what happens inside the body after insulin injections, meals, or physical activity through a video game. However, there are no reports in the literature about video games on the theme of understanding T1DM. This design strategy could be an innovative method of enabling children with T1DM to understand the disease in an easier manner and achieve the knowledge required for its management.

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The implications for the development of a video game are related to valuing the participation of the target population in this crucial stage. The study included children who were participating in a diabetes education group. Perhaps if we had included children who had not participated in these educational groups, we could identify different needs and preferences.

Conclusions

The findings of this study corroborate the importance of involving the children in the design of a video game. The analysis of the children's experiences and ideas showed potential interactions between emotions, knowledge about the disease and self-care, difficulties in practical skills for self-care, and lack of awareness toward these difficulties.

The children's input demonstrated the significant impact of identifying learning needs in diabetes self-management to develop improved learning experiences. Our future studies will focus on health behavior theories and behavioral determinants and their influence on the learning needs identified in this study to guide our long-term intervention goal, which is the development of a video game for children with T1DM.

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Conflicts of Interest

None declared.

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Abbreviations

SMBG: self-monitor blood glucose
T1DM: type 1 diabetes mellitus
T2DM: type 2 diabetes mellitus
UCD: user-centered design

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Original Paper

Mutual Involvement in Families With Type 2 Diabetes Through Web-Based Health Care Solutions: Quantitative Survey Study of Family Preferences, Challenges, and Potentials

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Abstract

Background: Type 2 diabetes (T2D) is a prevalent chronic disease that affects not just patients but entire families. Both the patient and the rest of the family may benefit from gaining knowledge about the disease and from supportive interfamilial interaction. The Internet is becoming a widely-used resource for health information, so a Web-based solution could potentially promote awareness and knowledge on how to manage T2D as a family, while also providing support for the family.

Objective: We aim to assess the usage of online diabetes information by patients with T2D and their relatives, and explore the families' needs and preferences regarding online information on diabetes.

Methods: A quantitative self-reported questionnaire survey was performed with Danish families that had at least one family member diagnosed with T2D. The survey consisted of 36 closed questions on demographics, usage of the Internet, preferences in the source of information, interest in online information on six problem domains within family life related to T2D, preferences towards the delivery format of online information, and peer-to-peer communication. Two open-ended questions were also included to elicit any additional comments or suggestions about improving online information on T2D regarding family life.

Results: Fifty participants from 22 families with T2D answered the questionnaire individually. Relatives (25/28, 89%) and patients (22/22, 100%) indicated that information on T2D is relevant for them, while indicating that the Internet is the first or second preferred source when in need of information on T2D (25/28, 89% vs 21/22, 95%). Only a minority of the participants indicated that they had searched the Internet to gain knowledge on T2D regarding family life (9/28, 32% vs 10/22, 46%). Also, patients were more likely to have used the Internet to gain information on T2D (P=.027). Both groups indicated a preference for watching videos or reading about T2D in relation to family life while a minority of the participants indicated an interest in peer-to-peer communication. Regarding the six problem domains, the domains Support, Knowledge, and Everyday Life were slightly more popular. These three domains were considered interesting by at least 79% (22/28) and 73% (16/22) of the relatives and patients respectively, while the domains Communication, Worries, and Roles were considered interesting by at least 46% (20/28) and 50% (11/22).

Conclusions: Despite an interest in online information on T2D, there appears to be an unsatisfied need for more supportive online information on T2D aimed at Danish families with T2D. Based on family preferences, online information should focus on the six problem domains and be presented through text and videos by health care practitioners and peers. Peer-to-peer communication elements may be beneficial, but are only expected to be used by a very limited number of families.

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KEYWORDS

online; health information; diabetes; support; family

Introduction

Type 2 diabetes (T2D) affects more than 300 million people worldwide and projections indicate that more than 1.1 billion people will be either living with diabetes or at high risk of diabetes in 2040 [1]. Most patients with T2D provide more than 90% of their own daily care, so health behavior interventions often seek to improve the patient's lifestyle, medication adherence, and diabetes management [2]. Many of these interventions have found social support, such as the involvement of the patient's relatives (eg, spouses, family, offspring, close friends) to be an effective means of improving the patient's health behavior or self-care [3]. With the rapid development of the World Wide Web, the Internet can facilitate supportive interaction while also being an increasingly popular method to gain educational information on diabetes [4-6].

Social support is an important positive factor related to the patient's diabetes management, either by facilitating healthy behaviors (eg, buying or preparing healthy meals) or by helping the patient overcome stress and frustrations through communication [3]. Contrarily, relatives can also have a negative impact on the patient's diabetes management by representing a barrier (rather than a facilitator) towards healthy behaviors, or by being supportive in an unappreciative way [3]. Relatives who are living in the same household as a patient with T2D may also be affected by the patients' disease through changes in the family's everyday life and family roles, while also being at increased risk of developing T2D, mainly due to genetics, lifestyle, and a lack of awareness about this risk [7,8]. Promoting mutual involvement between patients and relatives is often met by multiple barriers such as: families not perceiving the relevance of including relatives in the management of T2D, individuals who are at risk of developing T2D being apparently less engaged in risk-reducing health behavior, and patients with T2D seldom expressing serious concerns about relatives developing T2D [9-12]. Despite the seemingly important factor of social support in T2D, few intervention studies on T2D management have included the whole family (ie, the patient and their relatives) [3]. A study by Zrebiec and Jacobson found that an online discussion group on different diabetes topics moderated by health care providers (HCPs) was a useful method to engage both patients and relatives in receiving emotional support and exchanging information [4]. However, most diabetes websites do not provide sufficient information to support patients, making it unlikely that the information is sufficient for the rest of the family [6,13]. Web-based interventions for other chronic diseases have found improvements in interfamilial communication, knowledge on managing symptoms, medication adherence for the patients, and reduced stress levels for relatives in the role of caregivers [14-17]. Online information has also been assessed as a useful supplement to the information gained from consultations with HCPs [18].

Although the literature suggests that Web-based solutions could be a promising tool for families with T2D, research on the whole family's preferences regarding online information aimed at families with T2D is lacking. Previous studies investigating online health information on T2D have primarily focused on the patient, and assessments of the information aimed at supporting the whole family are needed, together with more evidence on the effects of Web-based health care solutions for families with T2D. Hillard et al argued that there is a need for research to better understand both patients' and relatives' reasons for, or their barriers to, participating in diabetes online communities [19]. More research on family preferences and their needs related to information on T2D is needed to develop more personalized (and potentially more effective) Web-based health care solutions for the whole family. In addition to the content of online information, several studies highlight the need for presenting relevant information in an understandable and compelling format to the end-user; a focus that is often left out in scientific research [20,21].

In a previously reported comprehensive qualitative study, we investigated problems and challenges associated with family life in families with T2D [22]. We described six problem domains: *Support*, *Knowledge*, *Communication*, *Worries*, *Roles*, and *Everyday Life* [22]. The study described here serves as an extension of this qualitative study, and will provide quantitative data on families' interests and preferences in terms of online information. The main objective of this study was to use these six problem domains to provide insight into the needs of families with T2D related to online information, while discussing the challenges and potentials of supporting mutual involvement in families with T2D via Web-based health care solutions.

Methods

To investigate the objectives of this project, we developed a questionnaire to determine the preferences of families with T2D on information content and the presentation of online information on T2D. The inclusion criteria in this study were: Danish families who had access to the Internet, and at least one family member diagnosed with T2D. Participating family members had to be between 15 and 80 years old. Families were excluded if the patient did not include at least one of his/her family members in the survey. Families were recruited between April and May of 2016. The sample size of the study was 50 participants from 22 families with T2D.

Recruitment Process

The recruitment process of study participants was undertaken with the assistance of 38 HCPs who were identified with help from the Danish Diabetes Association and subsequently contacted by email. These HCPs had previously been involved in the initial phase of the project regarding family needs and problems in relation to family life with T2D, and they were therefore familiar with the scope of the study [22]. Of these 38 HCPs, 9 did not respond and 21 replied that they were interested in recruiting participants for this project. Of the interested HCPs, 6 recruited at least one family with T2D. The occupations of these 6 HCPs were: nurse (2), dietician (2), health consultant (1), and coordinator in a health care facility (1). Each HCP came

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from a different city across Denmark. The HCPs contacted patients with T2D through consultations, diabetes schools, emails, and phone calls. Patients who were interested in participating in the study were contacted by the person responsible for the project (TV) by email or telephone, and were asked how many relatives were interested in participating in the study. One questionnaire was sent for each participating family member. Patients were excluded if none of their relatives were participating, and relatives were excluded if the family member with T2D withdrew from the study. Nonrespondents were sent a reminder email after 2 weeks, followed by a maximum of two further reminders.

Questionnaire Design

With no validated instrument to investigate family perceptions of online health care information, a quantitative self-reported questionnaire was developed. The questionnaire was inspired by the work by Jones et al [23] and consisted of 38 questions, including 6 questions on participant characteristics, 5 on preferences in the source of information on T2D, 3 on Internet usage, 12 regarding interest in online information on six problem domains within family life related to T2D, and 10 questions on preferences regarding the presentation of online information and peer-to-peer communication. Questions regarding the participants' preference in the source of information on T2D were answered by rating 5 choices from 1-5, with lower scores indicating a higher preference. Questions regarding families' interests and preferences in the six problem domains and in the presentation of online information were answered using a 5-point and a 6-point Likert scale, respectively. These questions were developed based on comprehensive qualitative data from similar settings that focused on the relationships and interactions within families with T2D [22]. The analysis of this study's results was done with these qualitative findings in mind. Furthermore, the six domains used for this project were identical to the problem domains identified by Grabowski et al [22] and consisted of *Support*, *Knowledge*, *Communication*, *Worries*, *Roles*, and *Everyday Life*. Two questions were asked for each domain. Regarding the presentation of online information, participants were asked to indicate their preference towards information delivered through text and video format, their preference towards information delivered by HCPs and other families with T2D, their interest in references for additional information, and the relevance of providing differentiated information based on the reader (eg, is the reader a patient or a relative). Two open-ended questions were included at the end of the questionnaire to elicit any additional comments or suggestions for improving online information aimed at families with T2D. Answers from these two open-ended questions were, however, excluded from the results due to a lack of relevant answers. The questionnaire was tested with two families prior to the collection of data to ensure that questions were unambiguous and had the right focus. During the data collection phase, the questionnaire was first sent to 10% of the participants to assess data quality. Each family member was instructed to answer the questionnaire individually.

Statistical Analysis

The results from the questionnaire were transposed from self-completed paper or Word questionnaires into an Excel (version 10; Microsoft for Windows) spreadsheet and SPSS (Version 23; IBM for Macintosh) software for further analysis. Shapiro-Wilk tests were performed to test for normality. Independent t-tests were used when data were normally distributed, and Mann-Whitney U tests were used when data was not normally distributed. Significance was taken at 5% level.

Ethical Considerations

The Danish Research Ethics Committee has approved the study (reference number H-15006088). All participants gave informed consent.

Results

Thirty-two patients with T2D were recruited by the HCPs but four did not respond when contacted by the person responsible of the project (TV). One patient withdrew before being included and five patients were excluded for not including their relatives in the study. A total of 22 families were included in the project, incorporating 50 respondents (28 relatives and 22 patients), which corresponded into a response rate of 69%. Seventeen families (17/22, 77%) consisted of the patient and one relative (eg, spouse, parent, offspring, or friend), four families (4/22, 18%) included three family members, and one family (1/22, 5%) included four family members. 12 families answered the questionnaire by letter and 10 families answered by email.

Demographics of Participants

The group of relatives were mostly male (15/28, 54%), between 50-59 years old (7/28, 25%), and most often a spouse or partner to the patient (18/28, 64%). The group of patients were mostly female (16/22, 73%), between 60-69 years old (11/22, 50%), and had been diagnosed with T2D for less than 10 years (13/22, 59%). Most respondents in each group used the Internet on a daily basis (27/28, 96% vs 20/22, 91%), perceived information on T2D to be relevant (25/28, 89% vs 22/22, 100%), and had a higher education of 2-3 years or a primary school education/equivalent (9/28, 32% vs 8/22, 36%). None of the relatives were diagnosed with T2D. The population characteristics of the relatives and the patients are presented in Table 1 and Table 2, respectively.

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Table 1. Participant characteristics for relatives.

Characteristics	N=28, n (%)
Females	13 (46)
Usage of the Internet daily	27 (96)
Perceives information on T2D to be relevant	25 (89)
Education	
Primary school, skill in craft or equivalent	9 (32)
2-3 years of higher education	9 (32)
3-4 years of higher education	6 (21)
>4 years of higher education	4 (14)
Age	
Mean age (years)	50
<30	3 (11)
30-39	5 (18)
40-49	4 (14)
50-59	7 (25)
60-69	6 (21)
>70	3 (11)
Relationship to the patient	
Spouse/partner	18 (64)
Offspring	8 (29)
Friend	2 (7)

Table 2. Participants characteristics for patients.

Characteristics	N=22, n (%)
Females	16 (73)
Usage of the Internet daily	20 (91)
Perceives information on T2D to be relevant	22 (100)
Education	
Primary school, skill in craft or equivalent	8 (36)
2-3 years of higher education	8 (36)
3-4 years of higher education	4 (18)
>4 years of higher education	2 (9)
Age	
Mean age (years)	60
<30	1 (5)
30-39	2 (9)
40-49	1 (5)
50-59	4 (18)
0-69	11 (50)
>70	3 (14)
Diagnosis	
Diabetes duration <10 years	13 (59)
Mean diabetes duration (years)	9

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Preferences in Access to Diabetes Information

The group of patients clearly indicated a preference for information delivered by HCPs, with a mean score of 1.2 (lower mean scores indicate a higher preference for the source of information on T2D). Most of the patients (18/22, 82%) rated the HCP as their first pick, while the Internet was a clear second pick for the majority of respondents (3/22, 14%; mean score=2.3). The group of relatives were somewhat split between the Internet (11/27, 41%; mean score=2.0) and HCPs (13/27, 48%; mean score=2.2) as their preferred source of information on T2D, which could suggest that relatives do not have the same relationship to HCPs regarding T2D as patients do. The mean difference between the two groups' preference for information from HCPs resulted in a statistically significant difference (*P*=.006). A lower self-perceived preference for receiving information on T2D through online forums was similar for both groups, along with family and friends, and books (0-7%, mean scores=3.2-4.1). There was, however, a statistically significant difference between the two groups regarding their preference for information from family and friends (*P*=.016) with relatives generally indicating a higher preference than patients (Table 3). A Mann-Whitney U test was performed to assess whether the difference between the groups was statistically significant.

Usage of the Internet to Search for Information on Type 2 Diabetes

In terms of searching for general online information on T2D, most relatives (16/28, 57%) and patients (19/22, 86%) responded that they had done so, or had others search for information on their behalf. Patients were significantly more likely to have used the Internet to gain information on T2D than relatives (*P*=.027). Despite the relatively large number of participants who had searched for general information on T2D, only a minority of relatives (9/28, 32%) and patients (10/22, 46%) had used the Internet for information regarding how T2D can affect the whole family. Of the relatives and patients who had searched for online information on T2D regarding family life, most indicated that they found what they were looking for (Table 4). A Mann-Whitney U test was performed to assess whether the difference between the groups was statistically significant.

Interest in Online Information on Type 2 Diabetes Regarding Family Life

Families generally perceived all six domains as relatively interesting although there was a tendency for the three domains of *Support*, *Knowledge*, and *Everyday Life* to be slightly more popular. These three domains were perceived as "Interesting" or "Very interesting" by 73-95% of the patients and by 79-85% of the relatives (Q1-Q4, Q11, and Q12). The remaining three domains (*Communication*, *Worries*, and *Roles*) were perceived as "Interesting" or "Very interesting" by a smaller majority: 50-73% of the patients and 46-71% of the relatives (Q5-Q10). These three domains also received a larger amount of "Neither nor" responses as compared to the other domains, suggesting difficulties in understanding or relating to the questions. The findings may indicate that families perceive information on *Support*, *Knowledge*, and *Everyday Life* as the most relevant and relatable domains. A tendency for all six domains was that the group of relatives more often responded "Uninterested" or "Very Uninterested" to the questions compared to the group of patients. These uninterested responses may partly be explained by the relatives who indicated that information on T2D was irrelevant for them. The questions in Figure 1 were translated and shortened to ease the reading of the figure.

Table 3. Preferences in the source of information on T2D

Information source	Relatives (N=27)[a] mean score (%)	Patients (N=22) mean score (%)	P-value
The Internet (eg, fact-based website)	2.0 (41%)	2.3 (14%)	.319
HCP	2.2 (48%)	1.2 (82%)	.006
Online social forums	3.4 (7%)	3.6 (0%)	.681
Family and friends	3.2 (4%)	4.0 (5%)	.016
Books	4.1 (0%)	3.8 (0%)	.306

[a]One relative made an invalid data entry and was excluded.

Table 4. Usage of online information on T2D.

Specifics of search	Relatives (N=28) (%)	Patients (N=22) (%)	P-value
Searched for general online information on T2D	16 (57%)	19 (86%)	.027
Searched for online information on T2D regarding family life	9 (32%)	10 (46%)	.341
Found what they were looking for (only including those who searched for online information on T2D regarding family life	19 (67%)	15 (70%)	.879

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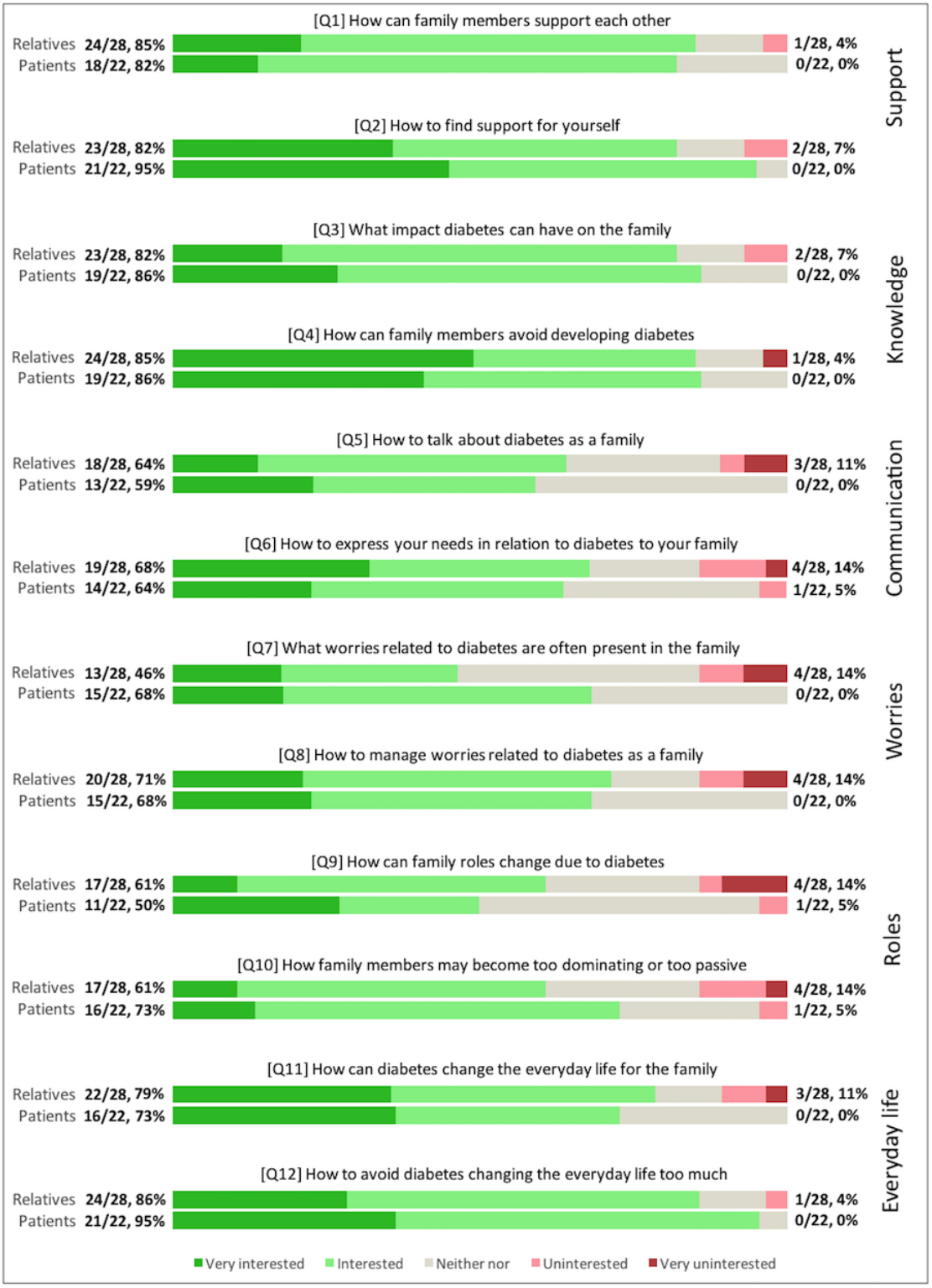
Figure 1. Interest in online information on type 2 diabetes regarding family life for all participants. The absolute values and cumulative percentages of the responses for both groups are displayed at the end of each bar.



A total of 71% of the relatives and 68% of the patients indicated an interest in watching educational videos of peers, while videos of HCPs were considered interesting by 86% and 82% of the relatives and patients respectively (Q13, Q14). Regarding the reading of relevant experiences written by peers, 75% of the relatives and 86% of the patients indicated interest, while 82% and 86% of the relatives and patients were interested in reading experiences by HCPs (Q15, Q16). Patients were more likely to respond "Yes, definitely" for reading experiences by HCPs compared to peers. With regards to communicating with peers online, patients generally responded more positively than relatives. Although 71% of relatives and 73% of patients indicated that they could be interested in reading relevant posts in an online forum (Q17), only 25% of relatives and 41% of patients indicated that they were likely to make a post themselves (Q18). Furthermore, only 7% of relatives and 36%

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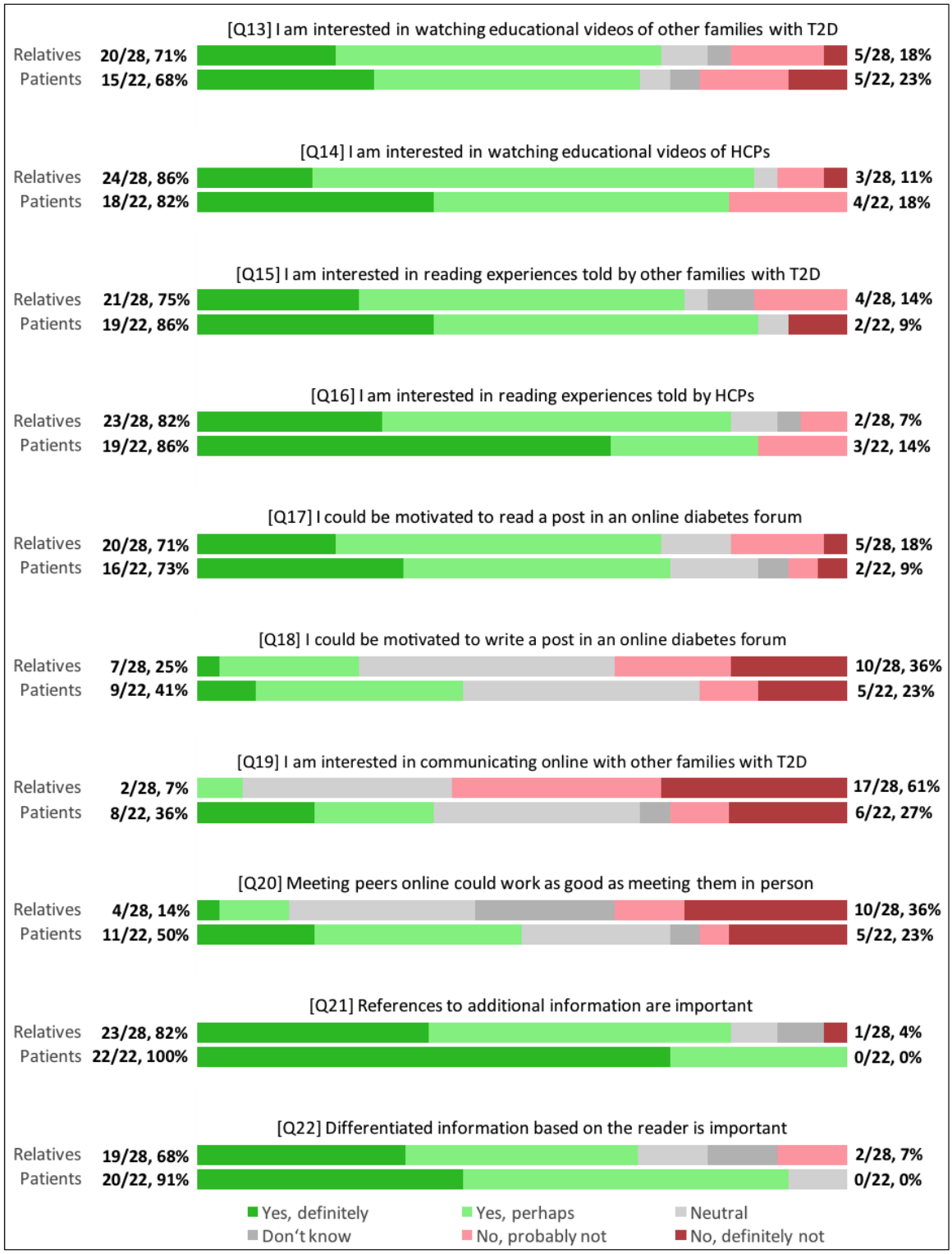
of patients perceived communicating directly with peers as interesting (Q19). Communicating with peers online was considered to be as good as communicating with peers in person by 14% of the relatives, while 50% of the patients thought so (Q20). Overall, the questions on online communication with peers received a considerably higher amount of "Don't know" and "Neutral" responses, suggesting difficulties in understanding or relating to the questions for many family members. Lastly, 82% of relatives and 100% of patients highlighted the importance of having references to additional information (Q21), while 68% of relatives and 91% of patients indicated a need for information that is differentiated based on whether the reader is a patient or relative (Q22). The questions in Figure 2 were translated and shortened to ease the reading of the figure.

Figure 2. Preferences in the presentation of online information on type 2 diabetes and peer-to-peer communication for all participants. The absolute values and cumulative percentages of the responses for both groups are displayed at the end of each bar. HCP: heath care provider.



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Discussion

Families' Strategies to Find Online Information on Type 2 Diabetes

Overall, most of the patients and relatives in this study indicated that information on T2D was relevant for them and that the Internet was the first or second preferred source when they needed information on T2D. Online information is more accessible and not time dependent compared to a consultation with a HCP, so Web-based solutions could be a relevant and appropriate way for families to gain support and offer an opportunity to establish an appropriate knowledge base on T2D. Relatives were generally less likely to have searched for online information on T2D than patients, suggesting that many relatives either receive information elsewhere (eg, from the patient) or that relatives do not receive (or seek) information on T2D at all (Table 4). Furthermore, there was a discrepancy between the families' interest for online diabetes information on problem domains within family life and their likelihood of having searched for this information. These findings may illustrate a challenge in involving the whole family in the care of the patient's T2D, as existing literature has previously concluded [9,10,22]. In addition to this challenge, families may also experience difficulties in locating relevant online information, since much of the educational information on T2D that exists on the Internet has been assessed as insufficient [6,13]. The lack of quality information on the Internet may result in a risk of uncorrected misinformation, misunderstandings, and frustrations for the user [18]. Therefore, since families have indicated an interest in online information on T2D, it would be relevant to ensure that families have easy access to validated, reliable, and user-friendly information on T2D regarding family life.

Presenting Online Information on Type 2 Diabetes

Overall, the participants in this study indicated a preference for one-way communication (ie, read, watch, or listen to information) compared to two-way communication (ie, communicating with peers or HCPs). Families had a small tendency to prefer educational videos of HCPs over videos of peers, which may suggest that information from HCPs is perceived as more trustworthy than information from other families with T2D. The families' preferences could also be explained by the concept of the "mere-exposure effect", suggesting that the increased preference for HCPs as the source of information may be due to families being more familiar with receiving health information from HCPs than from peers [24]. With regards to receiving information from texts or videos, a study by Walthouwer et al [25] found that there are no significant outcome differences between receiving health related text information compared to information presented through videos. However, participants who receive information in their preferred delivery format are significantly more likely to use the information. Therefore, to promote the likelihood of families using online information on T2D, it would be relevant to provide users with information presented through both video and text.

Online Peer-to-Peer Communication

Online forums were considered to be one of the less preferred routes for receiving information, with patients being more interested in peer-to-peer communication than relatives. Due to the challenges of engaging the whole family in the patient's T2D, families may not be able to identify the relevance of communicating with other families or be able to assess its benefits. Although most of the families in this study indicated no interest in communicating with peers online, online communities for families with T2D have been shown to be a useful tool for exchanging information and for emotional support [4,5]. One barrier for online forums is that new or potential users of online forums are often cautious and reticent about taking an active role in a forum. This barrier makes it difficult to develop an online community, and its success in the start-up phase is often dependent on subtle prodding from moderators and existing users [26]. A common issue for online communities is a lack of active users, which may weaken the effect of an online community, and as stated by Richardson et al, "size does matter in an online community" [27]. However, if new users become familiar and comfortable in an online community, they tend to become more actively involved and appreciative of the forum over time [26]. Since most families in this study indicated that they would read online posts written by peers–thereby indicating that they would use the online forum as a one-way communication form–it is possible that a professionally moderated online forum could engage motivated families with T2D to communicate with each other. More research regarding family perceptions of online social forums is needed to identify the challenges and potential of online communities for families with T2D.

Strengths and Limitations of the Study

A major strength of the presented study was its unique focus on the whole family in relation to their needs and preferences, while building on existing evidence regarding the six problem domains for families with T2D. Only a minority of studies have previously focused on mutual involvement, support, and empowerment for the whole family in families with T2D. One strength of the questionnaire survey was its combination of questions on both content and delivery of online information. Although research on user perspectives regarding both content and delivery of online information is uncommon, it appears to be a relevant and appropriate method to gain valuable insight on what content the user is interested in and how the content should be presented [20,21]. A limitation of this study was its sample size and gender imbalance, which questions the statistical power and the lack of knowledge regarding the relatives' level of engagement in the patient's disease management. The study does, however, build on recent comprehensive qualitative data and serves as a needs assessment in a significant yet under-researched area. The sample size may also highlight challenges in recruiting families with at least one family member diagnosed with T2D for research projects. Lastly, the study lacks clarity on whether the presented findings might be applicable for different population groups. As identified elsewhere, it will be relevant for future research to investigate whether generic information aimed at families with T2D is sufficient, or if information should be differentiated based on age, gender, ethnicity, or socioeconomic status [28].

Web-based solutions could be a promising tool to inform and support families with T2D by being highly accessible and

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providing options for differentiated information based on the user's competences. Since families have indicated an interest in receiving health information through the Internet, improvement of the available online information on T2D regarding families is needed. Findings from this study suggest that information should be presented through both video and text, as families valued both information formats. Online social forums for families with T2D appear to be difficult to develop, but require more research to better understand the potentials and challenges of these platforms.

Implications for Diabetes Websites

Findings from this study indicate that most families with T2D are interested in using the Internet to gain knowledge on T2D regarding family life. Still, the literature indicates that much of the online information on T2D is insufficient and improvements may be needed to better support families with T2D [6,13]. Previous studies suggest that Web-based solutions aimed at families with a chronic disease could be a supportive instrument for the whole family [29,30]. Therefore, ensuring access to relevant online information of an acceptable quality may be useful for interested families with T2D. Based on findings from the questionnaire, it will be relevant to provide families with online information on six problem domains related to family life with T2D: *Support*, *Knowledge*, *Communication*, *Worries*, *Roles*, and *Everyday Life*. Previous studies have also identified similar domains for families with chronic diseases, while also assessing diet and heredity as popular topics [4,5,31]. With regards to the presentation of online information, families appear to be interested in educational information delivered through text and videos, and relevant experiences told by HCPs and peers, while also indicating that references to additional information is important.

Implications for Health Care Practice

Previous studies have highlighted the importance of making information appropriate, practical, and accessible for families with T2D. Consequently, considerations on how families become aware of the information are important [32]. Since families have indicated an interest for online information on T2D regarding family life, HCPs are encouraged to refer families to websites with tailored information aimed at families with T2D. However, if the current information on T2D regarding family life is as insufficient as the literature suggests, improvements may be needed before HCPs can refer families to diabetes websites with comprehensive information. In addition, it will be relevant to consider how to approach families of different socioeconomic statuses, who may have problems accessing online information.

Implications for Future Research

This study has identified preferences and needs for online information in families with T2D, but there is still a need for further studies focusing on online information aimed at families with T2D. With the presented findings on family preferences, it will be relevant to assess whether diabetes websites meet these preferences, while also measuring the quality of the information. Previous research has assessed online information on T2D to be insufficient, and a comparison of the literature suggests that online health educational information on cancer, cardiac diseases, and cardiovascular diseases is of a higher quality than that on T2D [6,13-17]. In addition, previous studies have found that people with low health literacy levels are less likely to use online health information, and that they tend to prefer short concise health information rather than longer and more detailed information [28,33,34]. As found by Mayberry et al [34], future research should investigate the barriers and facilitators for using online information in individuals with different levels of health literacy, while also investigating how family members may support each other in accessing and understanding online health information. Lastly, it will be relevant to investigate the effects of providing families with tailored information on T2D to determine which characteristics of the information have the most positive effects.

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Conflicts of Interest

None declared.

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Abbreviations

HCP: health care provider
T2D: type 2 diabetes

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Original Paper

Transitional Needs of Australian Young Adults With Type 1 Diabetes: Mixed Methods Study

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Abstract

Background: Young adulthood is marked by transitions that impact diabetes self-management behaviors, which require ongoing diabetes education and support. Traditional diabetes education programs and services currently do not meet the needs of many young adults with type 1 diabetes mellitus (T1DM) as they continue to fall through the cracks of clinical services. Age-centered diabetes education programs and services present an opportunity for young adults to meet in a supportive environment and gain a better understanding about diabetes management.

Objective: The aim of the study was to identify the health and well-being needs of Australian young adults aged between 18 and 35 years with T1DM to develop appropriate solutions to keep them engaged with diabetes self-management.

Methods: In total, 13 semistructured individual interviews and self-reported surveys were obtained to understand participants' experiences with diabetes education programs and services. Together with survey data, transcribed interviews were analyzed into themes and categories using comparative analysis to identify the health and well-being needs of young adults with T1DM during young adulthood.

Results: Diabetes education and service needs for young adults with T1DM related to improving access to existing diabetes education programs and services, having credible informational resources, as well as having personalized diabetes management advice. Participants especially valued relevant and real-time information and opportunities for peer support, mostly sourced from Web-based platforms.

Conclusions: There is a need for diabetes education programs and services to be age-appropriate and easily accessible, to provide relevant and credible information, and to provide opportunities for peer support to better support young adults with T1DM. These findings also support the use of diabetes education programs or services delivered online through mHealth systems in this population.

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KEYWORDS

type 1 diabetes; mHealth; young adults; transition

Introduction

Young adults with type 1 diabetes mellitus (T1DM) have different needs compared with the pediatric and older adult populations as they are required to adapt their diabetes management against more dynamic and significant turning points encountered in young adulthood [1]. Turning points can be significant life events that represent a change in an

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individual's life pattern, such as starting university, full-time employment, moving out of home, developing new relationships, or starting a family [1]. These critical life events are often stressful and can impact a young adult's diabetes-related decision-making process [1].

Navigating Through Life Transitions

As young adults navigate through life transitions, they are more likely to experience depressive symptoms and diabetes distress compared with older adults [2,3]. Additionally, competing life demands may ultimately displace self-care and diabetes management from being a priority, which may result in glycemic control deterioration [1,4]. Significant health-related turning points such as developing diabetes-related complications may further impact young adults' diabetes management [1].

As young adults start to adapt and transition through turning points presented during the tumultuous period of young adulthood, they begin to acknowledge the importance and long-term health benefits that accompany an investment in self-care [4]. With renewed motivation, young adulthood presents as an opportunity for diabetes education programs and services to engage young adults who are ready for positive behavior change [4].

Diabetes education programs and services are crucial to promote health literacy in people with diabetes through the provision of skills and knowledge for efficient diabetes self-management [5]. Health literacy is a concept that expands beyond literacy and numeracy skills to how individuals access, understand, and use information to make appropriate decisions to promote and maintain good health [6,7]. Poor health literacy has been associated with inadequate health-related knowledge, lack of social support, and poor communication skills with health care professionals [8]. Collectively, these factors correlate with increased rates of hospitalization and use of emergency services [8]. Low levels of health literacy have also been associated with a lower motivation to engage in diabetes self-management and greater communication difficulties with health care professionals [9].

Meeting the Needs of Australian Young Adults With Diabetes

Unfortunately, current diabetes education programs and services do not meet the needs of Australian young adults with T1DM [10]. Young adults face a host of barriers, which discourages access to current diabetes education programs and services [11]. Common barriers to access can be separated into logistical challenges, such as time constraints, cost, and distance needed to travel, and emotional barriers, such as feeling disempowered and disillusioned from appointments and a fear of judgment from health care professionals [11]. Enablers to diabetes education programs and services access corresponded with previously identified barriers such as continuity of care, time of day of clinical appointments, and proximity of clinic to home [11]. Additionally, although enablers to engage young adults in diabetes education programs and services have been identified and suggested to diabetes clinics, subsequent implementation status of these changes or patient outcomes is not known [11].

A major concern associated with low engagement in diabetes education programs and services is the lack of health care professional support for young adults with diabetes as they progress from pediatric health care services [10]. From the 2012 Australian Youth Transition Survey, it was found that only 42% of young adult respondents with diabetes aged between 18 and 24 years attended a diabetes clinic, which is the primary source of diabetes education provided to this population [10]. In contrast, 71% of adolescent respondents aged between 14 and 17 years attended a diabetes clinic [10]. A majority of young adults with diabetes who do not regularly receive clinical follow-up may subsequently have poorer glycemic control and increased risk of diabetes-related complications [11]. Low diabetes clinic attendance rates also reflect the lack of appropriate diabetes education program and services tailored for young adults [10].

Young adulthood is a complex period for young adults with T1DM where additional ongoing support would be of benefit as they learn to balance diabetes self-management with dynamic life changes. However, there is a paucity of research to inform diabetes education programs and service delivery to support and empower young adults with T1DM with their diabetes self-management as they transition through turning points. The aim of this study was to identify the diabetes education and service needs of young adults with T1DM during these turning points.

Methods

Study Design

A mixed-methods approach that included semistructured interviews and cross-sectional surveys was utilized to gain an understanding of the health and well-being needs of young adults with T1DM. Concepts derived from constructivist grounded theory influenced the qualitative approach of the study [12]. Cross-sectional surveys provided additional quantitative information around participants' health literacy levels, emotional well-being, and diabetes distress level. Ethics approval was granted by Deakin University Human Research Ethics Committee, and the study has fulfilled the consolidated criteria for reporting qualitative research (COREQ) guidelines for reporting [13].

Participants and Recruitment

Participants were Australian young adults living with T1DM aged between 18 and 35 years. Inclusion criteria included English proficiency and access to the Internet either through a smartphone or through a Web browser to complete a Web-based survey. There were no predetermined exclusion criteria. Recruitment was conducted online through flyers that were posted on relevant Australian diabetes-related social media channels and online support groups. Snowball sampling was used for recruitment until data saturation was achieved from qualitative interviews.

Semistructured Interviews

Interviews were offered in person or online and took approximately an hour to complete. A set of guided questions included topics around events that impacted participants'

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diabetes management and their experiences and recommendations to improve diabetes education programs and services. The question guide was reviewed and piloted by independent researchers to ensure questions were easy to understand and follow. Interviews were organized and conducted by AN, a PhD candidate with a dietetics background and lived experience with diabetes. AN's background was only disclosed to participants when she felt it would help develop rapport. Face-to-face interviews were conducted at Deakin University (Burwood, Australia). A secure Web-based communication platform, Zoom videoconferencing software (California, United States of America), was used for Web-based interviews. To minimize bias from AN's lived experience with diabetes, all interviews were audiotaped and field notes were recorded to critically reflect on the guided questions and interview to ensure objectivity was maintained. Guided questions were further refined if necessary after discussion of field notes with BR. After the interviews, participants were sent a one-page summary by email of the main points discussed during the interview to confirm and validate the data through a process called member-checking [14]. Participants were then asked to complete a Web-based survey, which was a compilation of validated questionnaires to gather information on their level of health literacy, emotional well-being, diabetes distress, and demographic details. The Web-based survey was administered through Qualtrics (Utah, United States of America), which uses a secure cloud storage platform.

Health Literacy Questionnaire

The health literacy questionnaire (HLQ) is a self-administered 44-item questionnaire, which covers 9 domains of health literacy concepts that support effective self-management of chronic health conditions [15]. The 9 domains are as follows: (1) feeling understood and supported by health care providers, (2) having sufficient information to manage health, (3) active management of health, (4) social support for health, (5) appraisal of health information, (6) ability to actively engage with health care providers, (7) navigating the health care system, (8) ability to find good health information, and (9) understanding health information well enough to know what to do. Scores were averaged for each domain with scores toward the higher end of the scale indicating strength, or greater literacy, within that health literacy domain.

Diabetes Distress Scale

The Diabetes Distress Scale (DDS) is a 17-item self-administered questionnaire, which comprises the following 4 subscales that contribute to overall diabetes distress: emotional distress, physician-related distress, regimen-related distress, and diabetes-related interpersonal distress [16]. DDS uses a 5-point Likert scale to rate statements related to living with diabetes. A higher overall score indicates greater diabetes-related distress, whereas subscale scores provide an indicator to the primary source of concern.

World Health Organization-5 Well-Being Index

The World Health Organization-5 Well-Being Index (WHO-5) consists of 5 positively worded items relating to mood, vitality, and general interest over a 2 week period [17]. The self-administered questionnaire uses a 6-point Likert scale where participants are asked to rate the frequency of experiencing a feeling. Summated scores are converted into a percentage; with scores below 50 indicating a low mood and scores of 28 and lower indicating the likelihood of depression.

Well-Being Questionnaire 12

The Well-being Questionnaire 12 (W-BQ12) is a 12-item self-administered questionnaire, which uses a 4-point Likert scale to describe how often participants experienced a feeling in the past few weeks [18]. For this study, the 4-item positive well-being subscale of the W-BQ12 was used. A higher overall score correlates with greater general well-being.

Data Analysis

Interviews were recorded and transcribed by AN and analyzed using NVivo (QSR International, Australia, Melbourne). Transcripts from interviews underwent line-by-line coding, categorization, and subcategorization in line with the process of constructivist grounded theory as described by Charmaz [19]. Codes with similar meaning or context identified through line-by-line coding from the interviews were integrated into a category or theme by AN in a process known as thematic comparative analysis. Through this process, turning points experienced by participants as well as their associated transitional needs to be able to successfully transition through those turning points were identified. Categories and subthemes were reviewed by BR and TC, and discrepancies were discussed until a consensus was reached. A one-page summary of findings from the interviews was then provided to participants for further feedback.

Descriptive statistics were used to analyze demographic and other quantitative cross-sectional data from the Web-based questionnaire.

Results

Participant Characteristics

From 20 initial expressions of interest, 13 participants completed both the interview and the Web-based survey. Reasons cited for nonparticipation included unwilling to complete an interview and lack of time. On average, participants were predominantly female, aged between 19 and 35 years, lived with diabetes between 2 and 25 years, and managed their diabetes with an insulin pump. Other participant characteristics are described in Table 1.

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Table 1. Summary of participant characteristics (N=13).

Characteristics	Participants with T1DM[a]
Gender	
Female, n (%)	10 (77)
Male, n (%)	3 (23)
Age in years, mean (SD[b])	20 (5)
Diabetes duration in years, mean (SD)	8 (6)
Diabetes management	
Insulin pump, n (%)	8 (62)
Multiple daily injections, n (%)	5 (38)
Residential area	
Metropolitan area, n (%)	10 (77)
Regional area, n (%)	2 (15)
Undisclosed, n (%)	1 (8)
Employment status	
Working full time, n (%)	7 (53)
Studying full time, n (%)	3 (23)
Studying part time, n (%)	1 (8)
Other, n (%)	1 (8)
Undisclosed, n (%)	1 (8)

[a]T1DM: type 1 diabetes mellitus.

[b]SD: standard deviation.

Health Literacy and Emotional Well-Being

Table 2 summarizes participant scores across all quantitative measures within the Web-based survey, which includes the HLQ, DDS, W-BQ12, and WHO-5. On average, participants scored toward the higher end across each HLQ domain, indicating adequate health literacy levels toward self-management. Average scores from the DDS and subscales were not indicative of any overall moderate diabetes distress. However, individual scores demonstrated that moderate distress existed within each domain, with moderate distress reported by 75% (9/12) of participants within the emotional burden subscale, 50% (6/12) of participants within the interpersonal burden subscale, 33% (4/12) of participants within the regimen burden subscale, and 25% (3/12) of participants within the physician domain subscale. Overall, participants reported satisfactory emotional well-being and positive well-being.

Key themes identified from the qualitative data fell into two major categories and included events considered as turning points in participants' diabetes management and transitional needs to successfully navigate a turning point. The following section will focus on the transitional needs of young adults and subthemes identified, supported with descriptive quotes.

Transitional Needs

As participants described their transition through turning points, they highlighted several factors or needs that enabled them to modify their diabetes self-management to cope and adapt. These transitional needs included receiving support from health care professionals; awareness of and easier access to existing diabetes education programs and services; access to credible, relevant, and timely information; and peer support.

Health Care Professional Support

Although 8 participants acknowledged the value of health care professionals in their diabetes management, they described an absence of rapport due to a lack of continuity of care. As a result, participants expressed difficulty in the ability to communicate their needs with health care professionals. Participants who are within the public health care system had no guarantee to see the same health care professional during clinical appointments. Without rapport, young adults reported being less likely to receive personalized health advice in response to their current needs and circumstances from health care professionals. One participant stated:

> *There's no ongoing relationship. It's like seeing a new GP fresh from the start every time you go in. So, we see a new specialist and you'd have to keep giving the background every time and it doesn't get to the point where they get to know you well enough to understand what could help you. So, I find that it is a bit of a waste of time.* [Female, 29]

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Table 2. Participant scores across quantitative measures.

Quantitative measures	Mean (SD[a])
Health literacy questionnaire domains (n=13)	
1. Feeling understood and supported by health care professionals	3.06 (0.58)
2. Having sufficient information to manage my health	3.02 (0.55)
3. Actively managing my health	3.31 (0.56)
4. Social support for health	2.80 (0.61)
5. Appraisal of health information	2.91 (0.36)
6. Ability to actively engage with health care providers	3.38 (0.53)
7. Navigating the health care system	3.37 (0.53)
8. Ability to find good health information	3.63 (0.71)
9. Understanding health information well enough to know what to do	4.02 (0.49)
Diabetes distress scale (n=12)	
Emotional burden	2.83 (1.03)
Physician burden	1.93 (0.71)
Regimen burden	2.08 (0.70)
Interpersonal burden	2.42 (1.04)
Total score	2.32 (0.72)
Emotional well-being (n=12)	
Well-being questionnaire 12 4-item subscale	59.33 (19.88)
World Health Organization-5 Well-Being Index	6.33 (3.31)

[a]SD: standard deviation.

Out of the participants, 4 young adults reported feeling judged by health care professionals during clinical appointments when their lab results were outside target ranges. Participants perceived that health care professionals assumed young adults with poor glycemic control held negative attitudes toward their health. One participant stated:

> *I have had negative comments and feedback from [health care professionals] who haven't bothered to understand why I haven't controlled my diabetes. They've kind of just made judgements and made me feel like I'm failing with my diabetes.* [Female, 30]

Awareness of Diabetes Education Programs and Services

Of the participants, 7 reported that they were not always aware of available diabetes education programs, or services offered to them, which could inform their diabetes management choices. Additionally, 3 participants described that most topics offered through diabetes-related information sessions or workshops were not relevant to their current needs or situation. Consequently, participants were less likely to attend diabetes services if they perceived them to be of little value. One participant stated:

> *I know there is a little bit of a dead spot at this sort of age group. You get a whole lot of support when you're an adolescent and a child and for things like pregnancy. But I think you definitely have to go looking if you're a young person with type 1 diabetes.* [Female, 24]

Participants were more likely to hear of a diabetes education program or service through their local diabetes organization or social networks rather than during appointments. However, one participant still felt that diabetes information sessions or peer support were not readily promoted to those who would benefit from them. Another participant believed that it would be better received by young adults and more appropriate for health care professionals to connect them with upcoming diabetes information sessions and services. One participant stated:

> *I don't think [diabetes education programs and services] as widely advocated by the health care professionals. But I think there's a wide range if you know what you're looking for and you need to know someone who's kind of promoting these things.* [Female, 35]

Unsurprisingly, 5 participants agreed that it was crucial to improve awareness around existing diabetes education programs and services to young adults with diabetes. Although participants understood the importance of such services in helping people to cope or adapt to life with diabetes after accessing them, they felt that it needed further emphasis to reach those who need it most. One participant stated:

> *The biggest suggestion I would have is letting people know that [diabetes education programs and services are] available. Through social networking, I guess, promoting its importance and doing that not only through social networks but through GPs, through*

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> *endocrinologists, through other people with diabetes out there.* [Male, 35]

Although participants highlighted the desire for health care professionals to promote greater awareness of diabetes services, they valued their independence to seek out such services at a time when they feel ready. Turning points are a time where young adults report feeling motivated and ready to engage in health behavior change and therefore present as a prime opportunity to promote diabetes education programs and services. Of the participants, one shared her experience of completing the Dose Adjustment for Normal Eating (DAFNE) workshop for the second time as an example of the importance of timing to be engaged with information presented for effective education:

> *To do education like DAFNE you need to be in the right mindset, you need to be engaged and have a little bit of motivation to take the information on board. Or you can go and do the course and come away thinking I wasn't in the right space to do it, which was why I did it for the second time.* [Female, 30]

Diabetes Education Program and Service Access

Participants reported that they were aware of some diabetes education programs and services they could access. However, a significant challenge encountered by 6 participants was the ability to find time to attend clinical appointments or diabetes services, such as peer support groups or educational sessions. Participants talked about the need to juggle multiple commitments against a busy lifestyle, which made it difficult for them to prioritize a continued investment into their health. Services offered by the public health care system often fell within business hours, alongside participants' other commitments such as work and study. Participants perceived taking leave from paid work or study time as a major disruption to their career development. One participant stated:

> *I work full time obviously, like most people, so it's hard to get away and get the time to seek out [diabetes education] as well.* [Male, 35]

When participants did access clinical services, they expressed frustration at long wait times to see health care professionals. Especially within the public health care system, participants reported spending up to 3 hours in the waiting room before being attended to. Although diabetes services offered beyond clinical settings were reported to be readily available, they only benefited those who lived within metropolitan areas. Due to the long travel distance, young adults who lived in regional areas missed out on valuable diabetes-related information events, which could help them navigate turning points such as addressing their mental health. One participant stated:

> *I get some things in the mail occasionally for seminars…but I had moved 2 hours away and so it was more of an inconvenience to go. So, I never really went.* [Female, 21]

Another participant stated:

> *I think mental health is important and the stress of diabetes can affect some people…I was never offered any mental health support or help that I needed. It was never there.* [Male, 33]

As an alternative to face-to-face services, 8 participants discussed using the Internet to search for diabetes-related information when they were unable to access relevant information sessions or ask their health care professional.

One participant stated:

> *It's very helpful to be able to look up a website and get the information that you need.* [Female, 34]

Another participant stated:

> *I probably get information online more than anything else.* [Female, 24]

Access to Credible, Relevant, and Timely Information

Turning points are dynamic events in young adults' lives during which participants have reported a need for real-time and ongoing support outside clinical appointments. In total, 9 participants stated that they turned to alternative sources for diabetes-related information, which largely included online search engines and social media, when health care professionals were unavailable. For these young adults, the convenience of having information at their fingertips through their smartphones was well suited to meet their needs when transitioning through turning points. Additionally, participants who are on the cusp of a transition were able to search for relevant information discreetly in their own time. Participants also regarded Web-based sources of information and flexible communication methods as being cost- and time-effective compared with physically attending an appointment with their health care professional.

One participant stated:

> *I wish I had an educator that I could drop a quick email or a text or a phone call to ask, "can you help me with this." I definitely wouldn't have needed a face-to-face appointment but having that access to somebody in a professional capacity would be good.* [Female, 30]

Another participant stated:

> *If I had to find something out that I couldn't get an answer from the public hospital system, I would Google it. I've had to Google to find out what my sugar levels would do at altitudes because I was going overseas.* [Female, 29]

Despite the heavy reliance on Web-based sources for diabetes-related information, participants questioned the reliability and credibility of the information they would come across. Of the participants, 5 stated that they felt competent enough to filter inaccurate information through their own experience and common sense.

One participant stated:

> *The information on the net is really unreliable. I mean some of it is great but you don't know what's accurate*

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> *and what's not. What's kind of a peer-reviewed article versus somebody stating this happened to me therefore it is the case for all people with diabetes. There's reliable and then there's blogs, which can be helpful in hearing what other people have experienced.* [Female, 32]

On the contrary, some participants felt intimidated by the wealth of information on the Internet, which further compounds on the often-stressful nature of transitioning through a turning point. Subsequently, participants lacked the confidence to identify evidence-based facts and credible Web-based sources as highlighted by a young adult:

> *You do a search on Google and you don't even know where to begin. Like what's real and what's reputable…so I wouldn't know where to begin.* [Female, 32]

Participants valued evidence-based updates around various aspects of diabetes management, such as nutrition and exercise, as they transition toward positive health behavior changes in response to a maturation in their perception of health. Specifically, 6 participants wanted practical tips around making healthy food choices, managing diabetes around alcohol, and information on how different exercises affect blood glucose levels.

One participant stated:

> *The right [nutrition] messages aren't that easy to interpret because people go to the shops and something claims to be healthy but it's not necessarily healthy.* [Male, 35]

Additionally, as participants explored various diabetes management strategy options to adapt to changes in their lives, 4 young adults were keen to receive more information and user reviews of various diabetes technologies available in Australia. However, some participants found it challenging to navigate through the plethora of information available online. One participant stated:

> *There is so much [information online]. It's hard to sift through what's going to be useful and what's not and there's a lot of people making money off it as well. So, it would be nice to know what programs and what meters are useful, all of that sort of thing.* [Female, 24]

Participants also expressed the need for tips and guidance around factors that indirectly affect diabetes management such as budget assistance and mental health support. Among the participants, 4 stated that health care professionals generally failed to recognize the importance of emotional well-being in diabetes management. Consequently, participants felt isolated as they attempted to navigate information or services to help them cope or validate the emotional aspect that accompanies living with chronic condition. One participant stated:

> *I think having psychological support isn't something I've found generally offered but it's something that everybody needs regardless of what age you've been diagnosed.* [Female, 30]

Overall, majority of participants wanted easy access to credible diabetes-related information, through an easy-to-navigate Web-based resource. Convenience and perceived value were important considerations to participants, especially during stressful periods as they transition through a turning point. Young adults needed to be reassured that their efforts in their search for information would not be wasted. One participant stated:

> *[I would like] something that I can access at 5 am in the morning when I'm feeding my baby and have got nothing else to read. It sounds really bad but things that can fit into my lifestyle because I don't have time.* [Female, 34]

Peer Support

Overall, 7 participants regarded peer support as a highly valuable source of information and support in general as well as through turning points. Primarily, participants appreciated the ability to relate with others who understood or have experienced similar turning points, which reduces the sense of isolation. As a result, participants credited peer support as a positive impact on their emotional well-being through reciprocal support and encouragement toward their own diabetes management. Such a level of understanding and support was rarely received from health care professionals, unless the participant's health care professional, often a diabetes educator, also lived with diabetes.

One participant stated:

> *It's kind of nice knowing people who understand if you're having a tough time or you need a little bit of advice, knowing someone else who lives with diabetes is probably more likely to understand than a health care professional.* [Female, 30]

Another participant stated:

> *I spoke to a few people [with diabetes] and said I drank too much one night and they said "yeah, well I've done that heaps of times." It felt good to go "oh, I'm not alone in this."* [Male, 33]

Discussion

This study aimed to identify the health and well-being needs of young adults with T1DM during life transitions. Although it appeared that quantitative measures of health literacy, emotional well-being, and diabetes distress, on average, did not reflect major difficulties faced by participants in their diabetes management, individual scores showed otherwise. These findings were further supported by the qualitative data. Additionally, a significant gap in appropriate and relevant diabetes education and services for this population was highlighted through qualitative interviews. Transitional needs to manage turning points identified by participants included health care professional support, improved awareness and access to current diabetes services, resources with credible and relevant information delivered in a timely manner, and opportunities for peer support.

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Principal Findings

Turning points are often described as stressful events in a young adult's life, which can result in glycemic changes that subsequently affect their well-being [1]. For a positive transition from a turning point to occur, the needs of young adults must be addressed through breaking down barriers for them to access the relevant information and support they require [20].

Young adults are required to balance competing life demands while they navigate turning points, which may displace self-care behaviors from being a priority [1,21]. Erratic schedules are commonly seen within the young adult population, which further compounds on positive health behavior required for diabetes self-management [22,23]. As majority of diabetes education programs and services are provided during typical business hours, participants considered attendance to be intrusive on their schedules, especially if the value of attendance is perceived to be low. Findings from this study suggest that the use of Web-based events held outside business hours and flexible communication methods with health care professionals may overcome these logistical barriers young adults face in attending diabetes education programs and services.

Apart from logistical barriers, many identified transitional needs that are closely aligned with the definition of health literacy and the HLQ [15]. For example, participants scored the lowest within the *social support for health* domain of the HLQ, which was reflected as they emphasized the importance of peer support to aid transitions through turning points. Psychosocial support motivates individuals toward positive health behavior changes and has been continuously recognized for its positive impact on emotional well-being [24,25]. Peers with diabetes understand and relate to the unique challenges of living with diabetes through their own experiences [1]. As they share past experiences, peers provide practical informational support, which helps other young adults with diabetes to build upon their problem-solving skills [24]. The importance of peer support was highlighted in this study as young adults described how connecting with other people with diabetes removed the isolation of living with T1DM through their shared experiences. Through the creation of a sense of normality for young adults with T1DM, they are further encouraged to continue with their efforts of diabetes self-management.

Effective communication between health care professionals and people with diabetes preface the concept of patient-centered care, which is closely intertwined with health literacy [26]. Patient-centered care posits that the person living with diabetes should lead the way in his or her self-management plan, under the guidance and support of health care professionals [26]. Participants often encountered a lack of continuity of care within the health care system and found it a challenge to build rapport with health care professionals. As a result, young adults perceive that without rapport, health care professionals are less likely to provide personalized diabetes management advice, which is relevant to their changing needs and circumstances. These findings are concerning as previous research identified that young adults who were made to feel disempowered or disillusioned by their health care professionals are then less likely to attend a follow-up appointment [11].

Life transitions during young adulthood comprise several sensitive topics such as experimenting with alcohol, managing diabetic ketoacidosis episodes, and starting a family, including contraceptive options [27]. Without readily available access to relevant diabetes education and services, a majority of participants turned to Web-based sources for diabetes-related information. The Internet allows young adults to maintain anonymity as they search for information required to make decisions in relation to their turning points [27]. Web-based sources of health-related information hold several advantages such as the absence of physical and geographical limitations to access, a sense of anonymity, and its cost-effectiveness. [1,28]. However, some participants reported lack of confidence to identify credible sources of information, which relates to the *appraisal of health information* domain of the HLQ, the second lowest scoring domain in this study.

Strengths and Limitations

Although inferential statistics could not be drawn from quantitative measures because of the small sample size, its data provided additional value to the qualitative data drawn from participants' interviews. As such, the main strength of the study was the use of a mixed-methods approach to determine the health and well-being needs of young adults with T1DM.

Conclusions

Young adults living with T1DM would benefit from learning to adapt their diabetes management to cope with a host of significant life- or health-related events. As young adults encounter a turning point that subsequently impacts their health, there can be an increase in motivation for positive health behavior change. However, adequate support from health care professionals and peers; access to appropriate, credible, and timely information resources; and targeted diabetes education and services tailored for young adults are required to enable a successful transition from a turning point. Findings from this study highlight a significant gap within present diabetes education programs and services and put forward the benefits in the use of mHealth for young adults with T1DM during life transitions.

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Authors' Contributions

As the PhD candidate, AN contributed to the study conception and design, data collection, data analysis, and drafting and critically revising the paper. As the primary supervisor, BR contributed to the study conception and design, data analysis, and critical revision of the paper. As the co-supervisor, TC contributed to the study conception and design, data analysis, and critical revision of the paper. As the co-supervisor, KB contributed to the critical revision of the paper.

Conflicts of Interest

None declared.

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Abbreviations

DAFNE: Dose Adjustment for Normal Eating
DDS: Diabetes Distress Scale
HLQ: Health Literacy Questionnaire
T1DM: type 1 diabetes mellitus
W-BQ12: Well-being Questionnaire 12
WHO-5: World Health Organization-5 Well-Being Index

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Original Paper

The Effect of Telehealth on Quality of Life and Psychological Outcomes Over a 12-Month Period in a Diabetes Cohort Within the Whole Systems Demonstrator Cluster Randomized Trial

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Abstract

Background: Much is written about the promise of telehealth and there is great enthusiasm about its potential. However, many studies of telehealth do not meet orthodox quality standards and there are few studies examining quality of life in diabetes as an outcome.

Objective: To assess the impact of home-based telehealth (remote monitoring of physiological, symptom and self-care behavior data for long-term conditions) on generic and disease-specific health-related quality of life, anxiety, and depressive symptoms over 12 months in patients with diabetes. Remote monitoring provides the potential to improve quality of life, through the reassurance it provides patients.

Methods: The study focused on participant-reported outcomes of patients with diabetes within the Whole Systems Demonstrator (WSD) Telehealth Questionnaire Study, nested within a pragmatic cluster-randomized trial of telehealth (the WSD Telehealth Trial), held across 3 regions of England. Telehealth was compared with usual-care, with general practice as the unit of randomization. Participant-reported outcome measures (Short-Form 12, EuroQual-5D, Diabetes Health Profile scales, Brief State-Trait Anxiety Inventory, and Centre for Epidemiological Studies Depression Scale) were collected at baseline, short-term (4 months) and long-term (12months) follow-ups. Intention-to-treat analyses testing treatment effectiveness, were conducted using multilevel models controlling for practice clustering and a range of covariates. Analyses assumed participants received their allocated treatment and were conducted for participants who completed the baseline plus at least one follow-up assessment (n=317).

Results: Primary analyses showed differences between telehealth and usual care were small and only reached significance for 1 scale (diabetes health profile-disinhibited eating, P=.006). The magnitude of differences between trial arms did not reach the trial-defined minimal clinically important difference of 0.3 standard deviations for most outcomes. Effect sizes (Hedge's g) ranged from 0.015 to 0.143 for Generic quality of life (QoL) measures and 0.018 to 0.394 for disease specific measures.

Conclusions: Second generation home-based telehealth as implemented in the WSD evaluation was not effective in the subsample of people with diabetes. Overall, telehealth did not improve or have a deleterious effect quality of life or psychological outcomes for patients with diabetes over a 12-month period.

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KEYWORDS

telehealth; self-monitoring; health-related quality of life: diabetes-specific quality of life

Introduction

The increasing demands of diabetes care on health resources in many countries [1] has led to the development of innovative information-communication-technology–based interventions that facilitate patient self-care and the monitoring and communication of disease status to health care professionals [2]. The range of technologies includes disc- and computer-based systems [3], Web-based interventions [4,5], mobile apps [6], remote monitoring systems [7,8], and combinations of these. One system gaining traction in the last 10 years is telehealth, which involves the remote exchange of physiological or symptom data between a patient and health care professional [9,10]. Algorithms within systems logging the data sent can alert health care professionals when disease-specific clinical parameters are breached; allowing the potential for earlier intervention, which can reduce the frequency with which expensive hospital-based care is required, and thereby improving patient outcomes (eg, reducing avoidable hospitalizations, improving clinical parameters) and health-related quality of life (HRQoL), the latter of which is the focus of this paper.

Primary studies and systematic reviews that have examined the effect of telehealth on HRQoL in people with diabetes, typically conclude that telehealth leads to QoL improvements, potentially because of improved care processes and health status, and reductions in worry about timely interventions as physiological and physical status are being monitored by health care professionals. For example, one potential pathway by which telehealth impacts patient outcomes is the increased feelings of reassurance participants get by being more closely monitored by the health care team, the other potential mediating mechanism it that increasing knowledge of the condition and increasing confidence leads to improvements in self-care behaviors, such as checking feet regularly, and so on [11]. However, in 1 systematic review [12], it was not possible to quantitatively synthesize the evidence on patient outcomes due to the heterogeneity of the patient-reported outcomes (PROMS). The authors found 5 studies that measured HRQoL, and of these 4 reported no significant differences [13-16], which is consistent with a recent randomized controlled trial (RCT) that found no differences in PROMs in a UK-based telehealth service [7]. In contrast, Chumbler et al. [17] found statistically significant improvements in 3 of 8 short-form (SF-36) subscales (role functioning, bodily pain, and social functioning) after 1 year of home telehealth. A further source of heterogeneity in the studies is the mixture of generic versus disease specific measures of HRQoL.

Few studies, however, have examined psychological distress. This is despite some contention about whether telehealth, despite monitoring benefits, can have potentially detrimental effects increasing patient burden and distress [18], through greater isolation and reduced face-to-face contact with health care professionals [19], and at times low acceptability of telehealth [20].

The evidence base for telehealth in people with diabetes is characterized by methodologically weak studies that generate equivocal findings and the studies have been critiqued for their variability in quality (small samples, poor methodology, few RCTs) and heterogeneity (in systems examined and outcomes measured) that has made the information produced difficult to interpret or synthesize [12]. The effectiveness of telehealth, in terms of QoL benefits, has yet to be substantiated in high-quality trials. Furthermore, few studies have used diabetes-specific QoL instruments, which are more sensitive to changes in this population than generic QoL measures, and few studies have extended the psychosocial outcomes to examine anxiety and depression.

The current study was part of the Whole Systems Demonstrator (WSD) programme, commissioned by the UK Department of Health. A previous paper has already reported on the effect of telehealth on HbA1c control in the larger diabetes trial cohort [21]. This paper reports on a subsample of the cohort providing data on the PROMs. It aimed to address the inconsistencies in data observed in previous research in telehealth and patient-reported QoL outcomes, and evaluated the effectiveness of telehealth in a sample of people with diabetes, examining its effect on HRQoL and psychological distress in the short and long term. It was hypothesized that should telehealth demonstrate significant improvements in QoL measures, these would be detected in disease-specific measures to a greater degree than generic QoL measures; and that telehealth would significantly improve psychological distress due to the reassurance the monitoring systems would provide to patients.

Methods

Design and Randomization

The WSD evaluation was one of the largest trials evaluating telehealth and telecare in the United Kingdom. The detailed protocol and design for the WSD evaluation has been reported elsewhere [22]. Within the evaluation, the WSD Telehealth Trial (n=3230) was a multicenter, pragmatic, cluster-RCT of telehealth across 3 regions in England (Cornwall, Kent, and the London Borough of Newham) with a nested questionnaire study, the WSD Telehealth Questionnaire Study (1573/3230, 48.7%).

Participants in the trial were allocated to a trial arm (ie, telehealth or usual care) using cluster randomization, based on participants' registration with a general practice. Allocation was balanced for region (WSD site), practice size, deprivation index, non-white proportion and prevalence of diabetes, chronic obstructive pulmonary disease, and congestive heart failure, using an algorithm by the trial statistician. For individual participants, trial arm allocation was maintained from the main trial, through to the questionnaire study and diabetes participant analyses. The WSD Telehealth Questionnaire Study involved a total of 204 general practices recruited across the 3 WSD Sites, of which 111 contributed participants to the diabetes questionnaire analysis; 46.8% (52/111) in the control and 53.2% (59/111) in the intervention trial arm.

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Participants diagnosed with diabetes were recruited between May 2008 and December 2009 from 4 primary care trusts across the 3 WSD regions. Final 12-month follow-ups were conducted in December 2010. Participants in the trial were invited to take part in a nested questionnaire study measuring PROM. Neither participants nor assessors could be blinded to trial arm allocation, due to the nature of the intervention. Participants not allocated to receive telehealth were informed that they would be offered the technology at the end of the trial period, following a reassessment of need.

The study protocol was approved by the Liverpool Research Ethics Committee (Reference number: 08/H1005/4). Full consent procedures are available in the protocol papers by Bower et al. [22] and Cartwright et al. [8]. In brief, practices at each of the sites signed memorandums of agreement to participate in the trial. Telehealth trial participants provided signed, informed consent to share data with the trial team; with those going onto the questionnaire study, providing further signed consent.

Participants

Adult patients at participating general practices were deemed eligible for the study if they were diagnosed with diabetes according to: (1) the Quality Outcomes Framework register in primary care, (2) a confirmed diagnosis in medical records as indicated by general practice Read Codes or the International Statistical Classification of Diseases and Related Health Problems-10 codes, or (3) confirmation of diabetes by a clinician involved in their care. Participants were not excluded because of additional co-morbidities. However, they were required to have sufficient cognitive capacity and English language skills to complete a self-reported questionnaire and use telehealth kit.

Participants were also required to have a landline telephone for broadband Internet connection, and in the London Borough of Newham an additional requirement was a television set. Local WSD project teams paid for financial costs associated with the telehealth (including phone calls to the monitoring centers, broadband service, and data transmission to the monitoring centers).

Telehealth Treatment: Intervention Arm

WSD sites delivered variations of a ‘second generation’ telehealth [23] that had a focus on monitoring vital signs, symptoms, and self-management behaviors, and providing health education in common. A full description of the intervention is published elsewhere [8].

In general, participants with diabetes in the trial arm received a glucometer and blood pressure monitor, plus additional peripherals depending on clinical need (eg, weighing scales, pulse oximeter, peak-flow meter, thermometer). The peripheral devices were attached to a home monitoring system comprising a base unit with a liquid-crystal display screen to allow questions about health and educational messages to be transmitted to participants or set-top box that connected to a television allowing symptom questions, educational videos, and a graphic history of clinical readings to be accessed via a dedicated channel. Participants were asked to take measurements via the peripherals on a schedule determined via individual circumstances (eg, daily readings, twice weekly readings).

Data transmitted by participants to a monitoring center were processed via an algorithm for unusual patterns, out of range values, and/or missing data. Contravening a rule triggered an alert to an operator at a monitoring center who would follow a decision tree to determine an appropriate response. The range of responses included: doing nothing—wait and see approach; requesting a repeat reading through the telehealth kit, contacting the participant or their named informal carer, arranging a visit to the participant’s home by their community matron, or referring to another health care service, as appropriate. The intervention arm participants received the telehealth in addition to usual health and social care. At the end of the 12-month trial participants were given the option of keeping telehealth or having it removed from their home.

Usual-Care Treatment: Control Arm

Participants randomized to the control arm received usual health and social care in line with local protocols for the 12-month duration of the trial (eg, combination of community matrons, district nurses, specialist nurses, general practice, and hospital services based on clinical need). At the end of the trial control participants were offered the installation of telehealth services in their homes, if they were still eligible following a needs assessment.

Trial Assessment Procedures

Outcome measures were self-completed by participants. At baseline, a trained researcher was on hand to explain or clarify the meaning of particular questions or assist with the completion of the questionnaire. Two further assessments were conducted at short-term follow-up conducted at approximately 4 months (median duration = 128 days; interquartile range [IQR] = 47 days) and a long-term assessment, conducted at approximately 12-months (median duration = 366 days; IQR = 54 days).

The short-term follow-up questionnaire was primarily administered as a postal survey with 1 reminder letter for nonresponders; some participants also received telephone reminders. Long-term follow-up surveys were posted to participants, with nonresponders contacted to arrange home interviews with a trained researcher in line with the baseline protocol. Participants who withdrew from the trial, including intervention participants who asked for the telehealth equipment to be removed before the end of the trial period, were not sent further questionnaires.

Outcome Measures

Generic and disease-specific HRQoL was assessed by: (1) the SF-12 [24] subscales for physical component summary (PCS), and mental component summary (MCS), (2) EuroQual (EQ-5D) York-Tariff [25], 1990, which produces a summary index over 5 domains (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), (3) the diabetes health profile (DHP) [26] with subscales measuring psychological distress, barriers to activity and disinhibited eating, and (4) study-specific diabetes HRQoL measures of social marginalization and social conspicuousness. Measures were also taken of anxiety with the

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brief state trait anxiety inventory (STAI) [27] and depressive symptoms by the 10-item Center for Epidemiologic Studies Depression scale (CESD-10) [28]. Higher scores on the QoL instruments pertained to better QoL and higher scores on the anxiety and depression instruments indicated greater psychological distress.

Demographic information recorded included age, sex, ethnicity, number of co-morbid conditions, and level of education. Participants' levels of deprivation were allocated using an Index of Multiple Deprivation score [29] as assessed through postcodes.

Sample Size Calculation

For the disease-specific aspects of the questionnaire study, a power calculation was conducted on the basis of detecting a small effect size, equivalent to a Cohen *d* of 0.3 [30], allowing for an intracluster correlation coefficient of 0.05, power of 80% and $P<.05$. This indicated that between 420 and 520 participants would be required to allow sufficient power to detect this small difference taking account of the cluster design. These numbers were inflated by 10% to allow for the maximum possible increase in sample size due to variable cluster size. The required minimum sample size increased to 550.

Statistical Methods

Missing data rates (at the scale/item level used in analyses) among those returning questionnaires at short and long term were low (≤3%) and were imputed (m=10) using the SPSS MCMC function within each administration. Thereafter, standard multiple imputation procedures were employed [31]. Details of multiple-imputation processes are available from the authors.

Sample Characteristics

Frequencies and mean scores are reported for each trial arm at each follow-up. Analyses were conducted on a modified intention-to-treat basis (ie, available case analyses—where data was available for baseline plus at least 1 follow-up point).

Detecting Telehealth Effects

Repeated measures in each outcome over the 1-year follow-up period were analyzed with linear mixed-effects modeling procedures to detect: trial-arm effects, time effects, and their interaction. This method took account of the hierarchy within the data observations (ie, assessment points, were nested within participants, nested within general practices). Data are presented as estimated marginal means (EMMs) with standard errors (SE).

Covariates to adjust for case-mix differences between trial arms were: age, sex, deprivation, ethnicity, co-morbidities, highest education level, WSD site, number of devices, and baseline outcome score. For all parameter tests the alpha level was set to .05; Sidak's adjustment was used to compensate for post hoc multiple comparisons; 95% confidence intervals (CI) were used to account for the uncertainty in the estimates. Effect sizes for the trial arm effects of each outcome were reported as Hedge's g. Analyses were conducted in SPSS v19.

Results

Sample Recruitment and Attrition

Of the 3230 participants in the WSD Telehealth Trial, 23.6% (763/3230) were indexed as participants with diabetes. Of the 1573 participants in the nested telehealth questionnaire study, 28.9% (455/1573) were people with diabetes; of these 54.1% (246/455) were in the intervention arm and 45.9% (209/455) were in the usual care arm. Figure 1 shows participants per trial arm within the questionnaire study.

Sample Characteristics

Baseline sample characteristics by trial arm of the 455 questionnaire participants are reported in Table 1. The mean age of the sample was approximately 65 years with most participants being of white, British/Irish ethnicity. Most participants came from the London Borough of Newham WSD Site, and were mainly male. The sample had on average 2 co-morbid conditions and the majority (247/455, 54.3%) had received little formal education. On average, the intervention group received just short of 3 telehealth devices. In the telehealth arm 237 glucometers were distributed, with 232 blood pressure monitors, 185 weight scales, and 56 pulse oximeters.

Unadjusted means by trial arm for baseline PROM data are presented in Table 1. CIs calculated around each mean suggested differences between the telehealth and usual care groups were not statistically significant in any measure at baseline.

Physical and mental health component scores for the SF12 and EQ5D health status measures were lower/equal than population averages, but were considered appropriate for a population in this age range with long-term conditions [24,25]. Both anxiety and depression levels were slightly high with the depression level means close to the cut-off point for screening clinical levels of depression. The diabetes health profile (DHP) scales and additional social-based HRQoL scales (social conspicuousness and social marginalization) did not indicate problems with diabetes specific QoL, and showed a relatively well-functioning long-term condition sample.

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Figure 1. All sites CONSORT diagram for the WSD Telehealth Diabetes Trial.

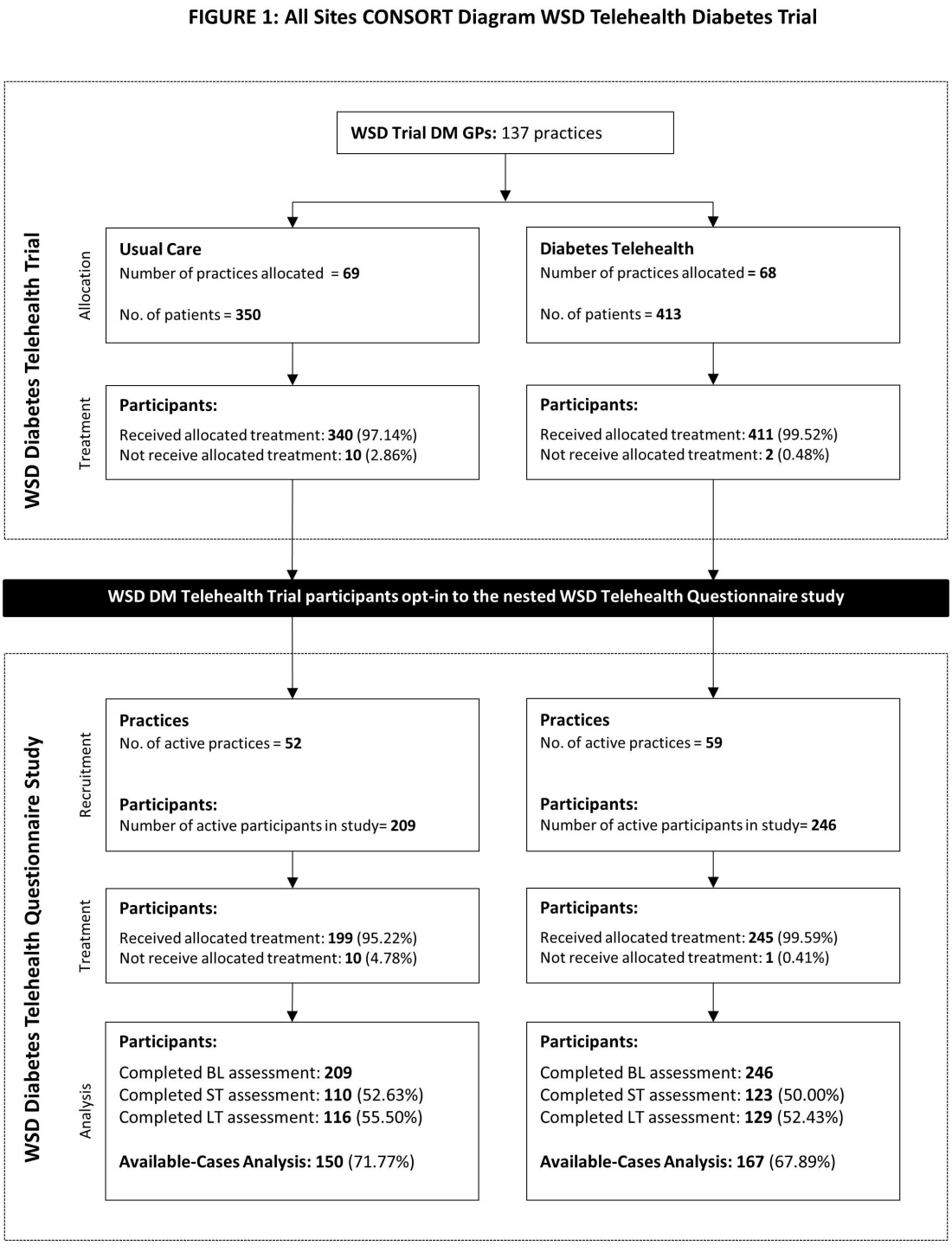

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Table 1. Site, sex, and ethnicity frequencies per trial arm of the questionnaire participants with diabetes.

	Intervention (n=246) n (%)	Control (n=209) n (%)	Total (N=455) n (%)
Site[a]			
Cornwall	64 (26.0)	55 (26.3)	119 (26.2)
Kent	44 (17.9)	46 (22.0)	90 (19.8)
London Borough of Newham	138 (56.1)	108 (51.7)	246 (54.1)
Sex[a]			
Female	115 (46.7)	84 (40.2)	199 (43.7)
Male	131 (53.3)	125 (59.8)	256 (56.3)
Ethnicity			
Non-white	79 (32.1)	72 (34.4)	151 (33.2)
White British / Irish	167 (67.9)	137 (65.6)	304 (66.8)

[a]Not multiply imputed.

Table 2. Baseline sample characteristics per trial arm of questionnaire participants with diabetes.

	Intervention (n=246) Mean (standard error)	Control (n=209) Mean (standard error)	Total (N=455) Mean (standard error)
Age, years[a]	64.72 (.874)	65.27 (.875)	64.97 (.620)
Deprivation score	35.12 (.957)	33.70 (.896)	34.47 (.661)
Number of Comorbidities[a]	2.11 (.118)	2.17 (.128)	2.14 (.087)
Amount of telehealth - number of devices[a]	2.89 (.047)	0.16 (.051)	1.64 (.073)
Level of education	0.83 (.078)	0.97 (.088)	0.89 (.059)
SF-12[b] Physical Component Scale	30.31 (0.61)	30.75 (0.66)	30.51 (0.45)
SF-12 Mental Component Scale	35.27 (0.57)	35.38 (0.61)	35.32 (0.42)
EQ5D[c] scale	0.50 (0.02)	0.52 (0.03)	0.51 (0.02)
State Anxiety scale (Brief STAI[d])	11.37 (0.29)	10.92 (0.31)	11.16 (0.21)
Depression scale (CESD10[e])	11.10 (0.44)	10.32 (0.45)	10.74 (0.32)
Disinhibited Eating DHP[f]-subscale	42.44 (1.28)	41.39 (1.24)	41.96 (0.90)
Psychological Distress DHP-subscale	23.84 (1.54)	24.03 (1.66)	23.93 (1.12)
Barriers to Activity DHP-subscale	32.58 (1.44)	32.81 (1.65)	32.69 (1.08)
Social Impact DHP-subscale	12.20 (1.03)	11.79 (1.04)	12.01 (0.73)
Social Marginalization DHP-subscale	13.61 (1.09)	13.64 (1.13)	13.62 (0.79)
Social Conspicuousness DHP-subscale	10.30 (1.21)	9.22 (1.17)	9.81 (0.84)

[a]Not multiply imputed.
[b]Short-Form 12 item survey.
[c]EuroQual EQ-5D.
[d]State Trait Anxiety Inventory.
[e]Center for Epidemiologic Studies Depression scale.
[f]Diabetes Health Profile.

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Table 3. Parameter estimates for trial arm and time in the linear mixed-effects modeling analysis for available cases (n=317).

	Trial Arm			Time			Time × Trial Arm		
	Estimate	Standard error	Significance	Estimate	Standard error	Significance	Estimate	Standard error	Significance
SF 12 - PCS[a]	0.338	1.801	0.851	0.335	0.703	0.634	−0.298	0.976	0.760
SF 12 - MCS[b]	1.806	1.776	0.309	−0.024	0.639	0.970	0.024	0.881	0.978
EQ5D[c]	0.087	0.068	0.201	0.021	0.026	0.417	−0.050	0.036	0.167
Anxiety	−0.232	1.053	0.825	0.604	0.415	0.146	−0.250	0.568	0.660
Depression	0.488	1.364	0.720	0.100	0.528	0.849	−0.189	0.734	0.797
Psychological Distress	−1.161	4.63	0.802	0.042	1.826	0.982	3.491	2.64	0.187
Barriers to Activity	3.561	4.524	0.431	1.779	1.694	0.294	−1.293	2.441	0.596
Disinhibited Eating	10.674[d]	3.847[d]	0.006[d]	1.754	1.649	0.287	−0.649	2.386	0.786
Social Marginalization	−3.476	3.677	0.345	−0.703	1.493	0.638	2.288	2.087	0.273
Social Conspicuousness	−2.275	3.374	0.500	0.764	1.427	0.592	1.610	1.973	0.415

[a]Short Form 12-item Physical Component Summary.

[b]Short Form 12-item Mental Component Summary.

[c]EuroQual EQ-5D.

[d]Significant effects (P<.05).

Detecting Telehealth Effects

Table 3 presents key parameter estimates for the effect of trial arm, time, and their interaction from linear mixed-effects modeling analyses (adjusting for case-mix) conducted for each outcome (parameters for covariates are not presented). Only 1 effect from the 10 PROMs was significant, on the DHP disinhibited eating subscale—where a significant trial arm effect was detected. Adjusted means (EMMs) for each outcome measure by trial arm and time point are presented in Figure 2, (for unadjusted means see Multimedia Appendix 1).

Parameter estimates indicate that being a member of the telehealth intervention trial arm provides an approximately 10-point advantage on the DHP disinhibited eating scale (after the intracluster correlation, all covariates and data hierarchy are taken into account), as indicated by EMM of the DHP disinhibited eating scale of the control (mean=35.512, SE=2.074) and intervention arms (mean=45.861, SE=2.086; $F_{1,757.625}$=7.697, P=.006). Effect-size estimates reveal this to be a small to medium effect, however the effect size had large 95% CIs, which crossed the 0 border (Figure 3).

The only measure to have ES CI that did not cross the 0 mark was the EQ-5D. However, the estimated effect size was very small (Cohen criteria) and the upper CI did not exceed 0.2, suggesting that although this is a robust ES, its magnitude is unlikely to have a substantial clinical impact.

Sensitivity analyses (ie, analyses per protocol, with complete cases, and/or excluding covariates) indicated similar trends in effects.

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Figure 2. Covariate adjusted mean scores (with 95% confidence interval) for each patient-reported outcomes by trial arm. ST: short-term, LT: long-term.

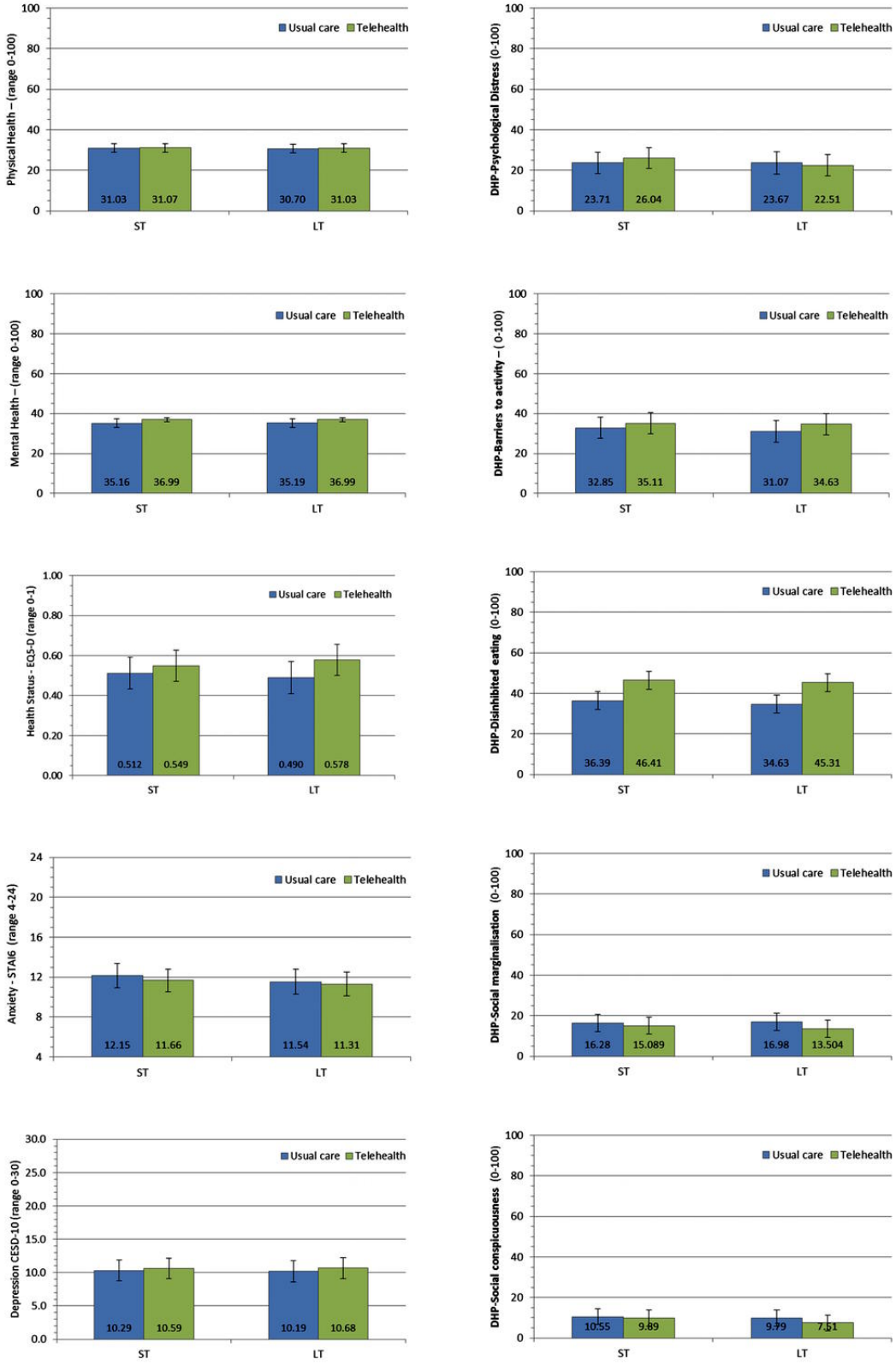

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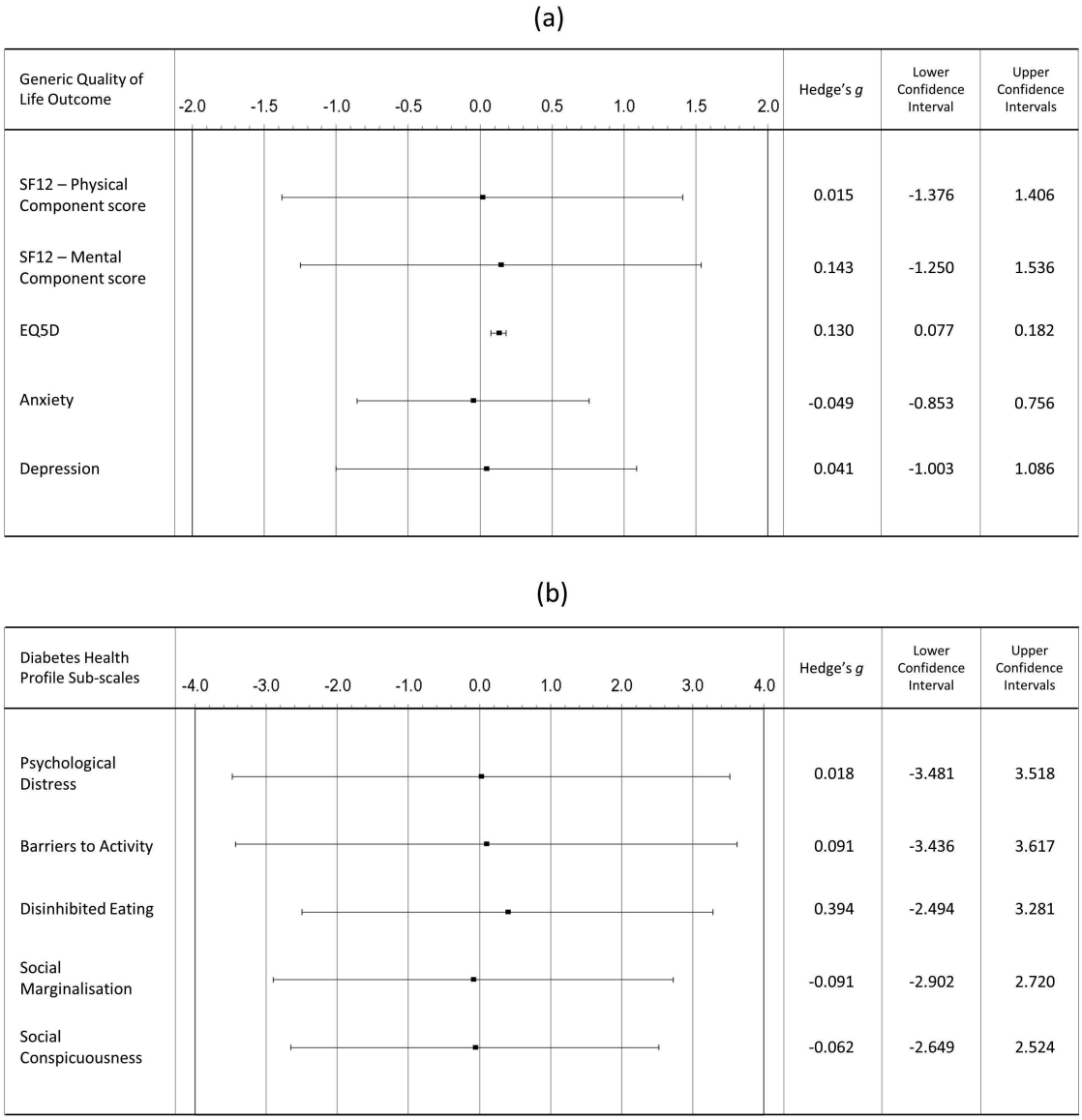
Figure 3. Effect size estimates for the (a) generic quality of life (QoL) and psychosocial well-being outcomes, and (b) the disease-specific QoL outcome measures.



Discussion

Principal Findings

This analysis examined the effect of telehealth on participant reported outcomes in a relatively large sample of patients with diabetes, who partook in the WSD telehealth trial. Overall scores for the sample indicate that physical and mental health component scores for the SF12 and EQ5D health status measures were similar to a population with diabetes. Both anxiety and depression levels were slightly high, with the depression level means close to the cut-off point for screening clinical levels of depression. The DHP scales and additional social-based HRQoL scales (social conspicuousness and social marginalization) did not indicate problems with diabetes-specific QoL, and indicated a relatively well-functioning long-term condition diabetes sample.

The telehealth group means generally indicated marginally better generic HRQoL outcomes for the telehealth group; and the usual care better marginally better outcomes on the disease-specific and psychological distress scales. However, overall these differences did not reach statistical significance, with the results suggesting that telehealth, relative to usual care, does not significantly impact upon patients HRQoL (generic and disease-specific) or their psychological distress over a period of 12 months. Nor does the status of these participants' PROMs greatly alter over the 12-month period, regardless of their treatment group.

The only significant effect across the analyses of the PROMs was found on the DHP disinhibited eating subscale—where a significant trial arm effect was detected. Parameter estimates indicated that being a member of the telehealth intervention trial arm provided an approximately 10-point increase on the DHP disinhibited eating scores. This may have indicated that with telehealth patients are more likely to undertake disinhibited

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eating (eg, lack eating control, emotional eating), perhaps as a response to knowing that should any effects of lacking eating control become extreme, they are being monitored and health care professionals will be able to suitably intervene. The provision of telehealth has the potential to increase individual's empowerment and self-care behaviors to manage their conditions through remote monitoring, rather than leading to a reliance of health care professional control. The mechanisms of such unexpected negative effects need further investigation in relation to theoretical constructs of behavioral change. Furthermore, effect-size estimates revealed this effect on disinhibited eating to be a small to medium effect, with large CIs that crossed the 0 border, indicating poor reliability in this estimate.

The only outcome with an effect size CI that appeared robust was with the EQ5D measure. However, the magnitude of this effect indicated that it would unlikely be clinically significant. The lack of effects on these PROM could also be because patients with diabetes are used to monitoring their conditions, in terms of checking blood glucose, monitoring their diets, and activity levels [32,33], and the potential benefits of the additional remote connections to health care professionals do not add value to their self-monitoring behaviors.

Despite lack of effects on PROMs, the WSD diabetes cohort showed modest gains in glycemic control [21], which was similar to another UK-based RCT [7]. There was also evidence that the telehealth trial was effective at reducing hospital admissions and mortality [34]. There were no differences on diabetes specific QoL, self-care behaviors, self-efficacy, which is consistent with recent pragmatic multicenter RCT in the UK [7], and other long-term conditions in the WSD trial [8,35]. However, these results demonstrated no substantial decreases in these outcomes either. To gain improvement in PROMS, the telehealth system may need to be broader than self-monitoring of blood glucose and designed to target the behavioral antecedents to these PROMs in individuals with impaired mood and HRQoL. Telehealth services may need to be more tailored to the individual, so that there is a match between the person and the technology to increase its impact.

This study also examined the use of novel social functioning with diabetes scales of social marginalization and social conspicuousness. Overall, the results showed that there are only small impacts in these 2 areas of social life and that they are not impacted upon by telehealth as delivered in this study. However, it may be the case that non–home-based remote monitoring, other technology-enabled care systems or mobile monitoring [3-6] would have a greater impact in these areas.

Strengths and Limitations

This clustered RCT addresses many of the methodological limitations identified in previous studies and adds evidence to an important gap in the literature. However, caution is required as although this was a relatively large sample of patients with diabetes compared with past studies, in the available cases analyses, the sample size did fall short of the recommended number required to detect a small effect. Despite recruiting 455 patients at baseline, the required number was not met due to attribution. This highlighted the difficulties in recruiting and maintaining participants in a trial of this size and complexity; nevertheless, a larger sample may help narrow the CIs of effect sizes and identify further statistically significant effects.

Also, the WSD trial was a pragmatic trial, but with associated limitations. While it has good ecologic validity, 1 potential criticism is the number of confounding factors (eg, the nature of the telehealth intervention delivered at each of the regional WSD sites/participating). Like other studies in this area, there is a high risk of selection bias given that the numbers of eligible patients the study sample were drawn from is unknown. Nevertheless, the WSD trial recruited a large number of patients with diabetes, is 1 of very few UK-based studies conducted in the National Health Service, and benefits from high generalizability across different centers, given the inclusion of a many general practices (n=204) delivering telehealth or standard care to patients with diabetes. However, in his study we did not examine differences between patients using insulin as well as oral medication and those who were only using oral medication. It is likely that insulin use will have a greater effect on HRQoL than medications alone, and thus insulin users may have a greater potential for the support via telehealth. This potential impact requires further investigation, especially in relation to the timeframes within which telehealth may have positive impacts upon HRQoL and psychological distress in each group of patients with diabetes.

Importantly, as an RCT, this study did not aim to specifically examine the mechanisms by which telehealth may impact PROMs. The differences in the types of telehealth and how they may differentially affect outcomes needs better investigation—as they likely use different mechanisms for action on HRQoL and psychological distress, making it problematic to compare the effectiveness of trials. Telehealth solutions also need to be described in sufficient detail, to determine how their use in the complex health care environment of diabetes management, may lead to improved HRQoL outcomes. Monitoring and interpreting readings in diabetes self-management is only 1 domain of a complex set of behaviors patients are advised to follow. Thus, the complexity of interventions, including the integrated role of telehealth across services, need to be adequately described with the mediating and moderating variables also examined. Furthermore, additional types of technology that patients with diabetes may use in addition to the telehealth services provided by the general practitioner/local authority also need to be considered, as they may mask effects specific to these services.

Implications and Future Research

The findings have implications for mainstreaming telehealth. Providing telehealth alone, in the absence of monitoring and enhancing the mediating mechanisms (eg, self-care behaviors, self-efficacy [Cartwright et al. Unpublished data], acceptability [20], and reducing dropout [36]) will not necessarily lead to improvements in HRQoL. In the future, further improvements to these complex interventions maybe required for telehealth to be used as a tool to improve patients' self-care and HRQoL. For example, evidence-based self-management interventions could be delivered via telehealth to facilitate the management of long-term conditions, such as diabetes and the capability of mobile monitoring may need to be integrated into home-based telehealth packages.

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Conclusions

This study found no substantial impacts of telehealth on either generic or disease-specific HRQoL measures in a population with diabetes. However, this study also demonstrated that there were no substantial decreases in HRQoL with the introduction of telehealth. Coupled with moderate improvements in glycemic control, there is potential promise for telehealth interventions, but more effective telehealth interventions aimed specifically at improving outcomes measured by PROMs are needed. Self-monitoring using telehealth is insufficient to improve PROMS by itself, but we recommend using evidenced based self-management techniques targeting self-care and QoL delivered via telehealth, as a tool to facilitate the delivery of the intervention.

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Authors' Contributions

SN was the chief investigator of the Whole Systems Demonstrator Trial. SH, MC, MB, and LR were responsible for the day-to-day running of the trial. SH ran the analysis and all authors contributed to the preparation of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Unadjusted mean scores (with 95% confidence interval) for each patient-reported outcome by trial arm. BL: base line; ST: short term; LT: long term.

[JPG File, 653KB - diabetes_v2i2e18_app1.jpg]

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Abbreviations

CESD-10: Center for Epidemiologic Studies Depression scale
CI: confidence interval
DHP: diabetes health profile
EMM: estimated marginal means
EQ5D: EuroQual 5D
HRQoL: health-related quality of life
IQR: interquartile range
MCS: mental component summary
PCS: physical component summary
PROMS: patient-reported outcomes
RCT: randomized controlled trial
SE: standard errors
SF: short-form
STAI: state trial anxiety inventory
WSD: whole systems demonstrator

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Original Paper

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

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Abstract

Background: Filipino Americans have a high prevalence of obesity, type 2 diabetes (T2D), and cardiovascular disease compared with other Asian American subgroups and non-Hispanic whites. Mobile health (mHealth) weight loss interventions can reduce chronic disease risks, but these are untested in Filipino Americans with T2D.

Objective: The objective of this study was to assess feasibility and potential efficacy of a pilot, randomized controlled trial (RCT) of a culturally adapted mHealth weight loss lifestyle intervention (Pilipino Americans Go4Health [PilAm Go4Health]) for overweight Filipino Americans with T2D.

Methods: This was a 2-arm pilot RCT of the 3-month PilAm Go4Health intervention (phase 1) with an active waitlist control and 3-month follow-up (phase 2). The waitlist control received the PilAm Go4Health in phase 2, whereas the intervention group transitioned to the 3-month follow-up. PilAm Go4Health incorporated a Fitbit accelerometer, mobile app with diary for health behavior tracking (steps, food/calories, and weight), and social media (Facebook) for virtual social support, including 7 in-person monthly meetings. Filipino American adults ≥18 years with T2D were recruited from Northern California. Feasibility was measured by rates of recruitment, engagement, and retention. Multilevel regression analyses assessed within and between group differences for the secondary outcome of percent weight change and other outcomes of weight (kg), body mass index (BMI), waist circumference, fasting plasma glucose, HbA1c, and steps.

Results: A total of 45 Filipino American adults were enrolled and randomized. Mean age was 58 (SD 10) years, 62% (28/45) were women, and mean BMI was 30.1 (SD 4.6). Participant retention and study completion were 100%, with both the intervention and waitlist group achieving near-perfect attendance at all 7 intervention office visits. Groups receiving the PilAm Go4Health in phase 1 (intervention group) and phase 2 (waitlist group) had significantly greater weight loss, −2.6% (−3.9 to −1.4) and −3.3% (−1.8 to −4.8), respectively, compared with the nonintervention group, resulting in a moderate to small effect sizes (d=0.53 and 0.37, respectively). In phase 1, 18% (4/22) of the intervention group achieved a 5% weight loss, whereas 82% (18/22) maintained or lost 2% to 5% of their weight and continued to maintain this weight loss in the 3-month follow-up. Other health outcomes, including waist circumference, BMI, and step counts, improved when each arm received the PilAm Go4Health, but the fasting glucose and HbA1c outcomes were mixed.

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Conclusions: The PilAm Go4Health was feasible and demonstrated potential efficacy in reducing diabetes risks in overweight Filipino Americans with T2D. This study supports the use of mHealth and other promising intervention strategies to reduce obesity and diabetes risks in Filipino Americans. Further testing in a full-scale RCT is warranted. These findings may support intervention translation to reduce diabetes risks in other at-risk diverse populations.

Trial Registration: Clinicaltrials.gov NCT02290184; https://clinicaltrials.gov/ct2/show/NCT02290184 (Archived by WebCite at http://www.webcitation.org/6vDfrvIPp)

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KEYWORDS

randomized controlled trial; mobile health; Filipino American; type 2 diabetes; weight loss; physical activity; diet

Introduction

Background

As the fastest growing US racial/ethnic group, Asian Americans represent 6.4% (approximately 21 million) of the US population [1] and are at a high risk for early development of type 2 diabetes (T2D) at lower body mass index (BMI) than non-Hispanic whites [2]. Filipino Americans (FA) are the third largest US Asian subgroup (2,717,844) and the largest California Asian population (1,474,707) [3]. Filipino Americans have the highest burden and prevalence of obesity and T2D among Asian American subgroups and non-Hispanic whites, and have early cardiovascular-metabolic disease risk, with higher mortality rates [4]. Yet, there is limited and incipient preventive health research focused on the Filipino American health disparity [5,6]. Thus, it is imperative to identify effective interventions to reduce these critical health disparities.

Weight loss lifestyle interventions promoting increased physical activity (PA) and a healthy diet (with as little as 5%-7% weight loss) have been shown to reduce obesity and related T2D risks by 58% [7]. The American Heart Association and Healthy People 2020 recommends such interventions, particularly for high-risk racial/ethnic minority populations [8-10]. However, intensive lifestyle interventions, such as the Diabetes Prevention Program (DPP) requiring 16 sessions, may be burdensome for participants and labor intensive to deliver [7]. Alternatively, education, coaching, and social support can be delivered virtually via the Internet, providing real-time feedback promoting adherence to healthy behaviors. Combining mobile health (mHealth) technologies, including commercially available apps and PA trackers (eg, pedometers), offers optional intervention delivery mechanisms that can be scalable and cost-effective [11].

US demographics support the delivery of lifestyle intervention programs via mHealth technology. Approximately 95% of US adults own a mobile phone (77% smartphones) and 76% access Facebook daily [12]. A recent study found that Filipino AmericansA (81.7%) ranked highest for mobile technology ownership and usage compared with whites (69.9%) [13]. A systematic review found mHealth interventions to be beneficial for increasing PA and weight loss [14] and effective for T2D self-management [15]. A meta-analysis found that mHealth weight loss interventions had a medium effect size of 0.43, supporting its continued development and use with lifestyle interventions [16].

Objective

Therefore, we conducted a pilot randomized controlled trial (RCT) called the Pilipino (ie, Filipino) Americans Go4Health (PilAm Go4Health). PilAm Go4Health was an mHealth culturally adapted weight loss lifestyle intervention promoting PA and healthy eating for Filipino Americans with obesity and T2D to reduce subsequent cardiovascular risks. The purpose of this paper is to report the feasibility of PilAm Go4Health (measured by recruitment, engagement, and retention) and potential efficacy (measured by percent weight and weight [kg] change). Positive findings will support a follow-on full-scale RCT to test the effectiveness of a culturally adapted mHealth weight loss lifestyle intervention for Filipino Americans with T2D. Qualitative assessments from participants' responses of the PilAm Go4Health's acceptability and cultural relevance (measured by process evaluations and postprogram interviews) were previously reported [17].

Methods

Design

This was a pilot RCT of the PilAm Go4Health, a 3-month culturally adapted mHealth weight loss lifestyle intervention for Filipino Americans with obesity and T2D, followed by a 3-month follow-up maintenance period. This 2-arm trial consisted of an intervention group and an active waitlist control (waitlist) group. Institutional approval from the Committee on Human Research was obtained before the implementation of the study. Before enrollment, all participants provided written informed consent.

PilAm Go4Health consisted of a weight loss lifestyle intervention based on the DPP [7] that was modified to incorporate mobile technologies (Fitbit accelerometer plus app with diary) and private Facebook group for healthy behaviors tracking, real-time feedback, coaching, and virtual social support. The overall PilAm Go4Health weight loss goal was a 5% weight reduction from baseline by 3 months.

Participants

Participants were recruited from the San Francisco Bay Area from December 2014 to December 2015. Recruitment was primarily through word of mouth, community events, and snowball methods.

Online recruitment strategies included the following: San Francisco Bay Area Craigslist (a San Francisco company providing websites for local classified ads of sale items and

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services), a dedicated study Facebook website, and an institutional website. Complete recruitment details are published elsewhere [18]. Those who met the screening and eligibility criteria (N=45) were enrolled and randomized into the study (Figure 1).

Inclusion Criteria

Eligibility was based on the DPP criteria and American Heart Association metabolic syndrome risks [7,19]. Key inclusion criteria were self-identified Filipino; ≥18 years; BMI >23 kg/m^2 for Asians; physician diagnosis of T2D (non-insulin dependent); own a smartphone, tablet, or laptop with Internet access; and English language proficient.

Exclusion Criteria

Exclusions included disabilities precluding walking for 20 min; on a special exercise program; participation in a weight loss program in the past year; uncontrolled T2D (fasting plasma glucose >200 mg/dL); endocrine or glucose metabolism associated disease (eg, Cushing syndrome or polycystic ovary syndrome); and uncontrolled hypertension. A detailed list of screening and eligibility criteria are reported in a previous publication [18].

Theoretical Framework

Social cognitive theory and the transtheoretical model for health behavior change helped to guide the study design [20,21]. According to the social cognitive theory, role models along with sociocultural and environmental feedback (positive or negative) can influence engagement and adherence to healthy lifestyle behaviors, including healthy eating and PA. Social support may also enhance self-efficacy for healthy weight loss behaviors. To enhance social support, PilAm Go4Health incorporated a private Facebook group and welcomed family members to in-person research office visits.

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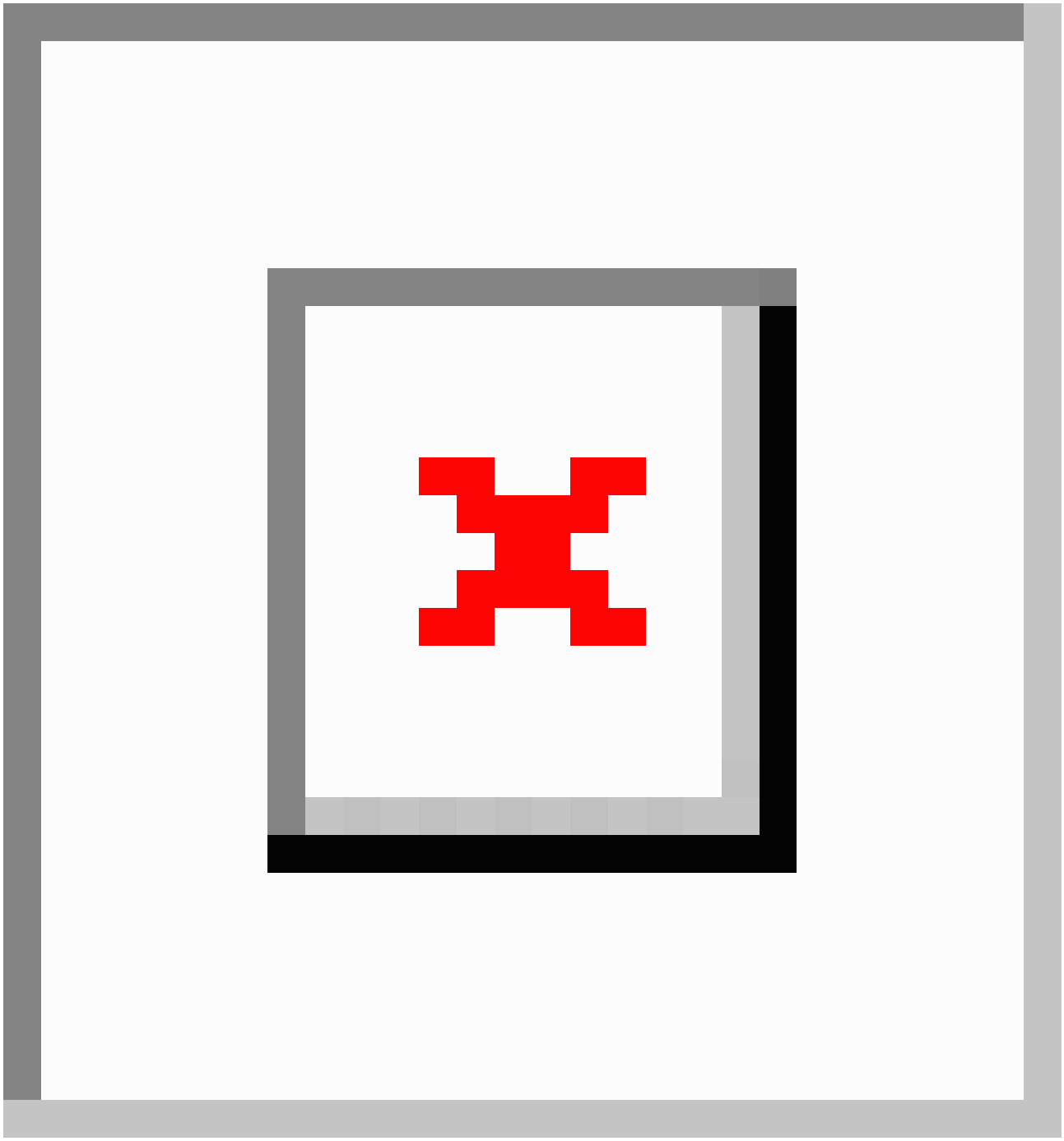
Figure 1. Consolidated Standards of Reporting Trials (Consort) flow diagram.



The transtheoretical model posits that health behavior change involves progress through 6 stages of change: precontemplation, contemplation, preparation, action, maintenance, and termination [21]. Applied research has demonstrated dramatic improvements in recruitment, retention, and engagement using stage-matched interventions and proactive recruitment procedures. To confirm that potentially eligible participants were stage-matched (ie, preparation for change stage) with the PilAm Go4Health, we incorporated a 2-week run-in period to assess readiness for change to help facilitate assessment of both feasibility and potential efficacy of this intervention program.

Cultural Adaptation

Before the study, the PilAm Go4Health was culturally tailored for Filipino Americans according to recommended published cultural adaptation guidelines [22] that include the following 5 components: (1) peripheral, (2) evidential, (3) constituent involving, (4) sociocultural, and (5) linguistics. Examples of each are provided in Table 1. A comprehensive description of the adaptation strategies used in the study is provided in a previous publication [18].

Screening Baseline Visit and Run-In Period

Eligible participants who passed the telephone screening were invited for a screening baseline visit that included a physical exam (weight, height, BMI, waist and hip circumference, and

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blood pressure), fasting blood draw (eg, fasting plasma glucose and hemoglobin A1c), and questionnaires. Those who passed the screening baseline visit and fasting blood draw received a Fitbit Zip accelerometer and Fitbit app with diary with training and were then enrolled in a 14-day run-in period.

A study run-in period was incorporated to assess whether participants were in the transtheoretical model's *readiness or preparation for change stage* [21]. The run-in period was designed to screen out potential noncompliant participants. Although this may minimize the sample size, it increases the statistical power [24] to reduce the possibility of erroneously rejecting the PilAm Go4Health as a potentially efficacious weight loss intervention. This helps to determine whether the intervention was feasible (acceptable and practical) and potentially efficacious (able to generate beneficial results under ideal circumstances) [25].

Participants in the run-in period were asked to wear the Fitbit Zip daily for at least 10 hours/day and send photos of all food and drinks consumed for 3 consecutive days. Those who complied at least 70% of the time with the run-in requirements demonstrated readiness for behaviors change and were enrolled and randomized into the study. Further details on the run-in protocol were previously published [18].

Randomization

A total of 45 participants were enrolled and randomized in a 1:1 ratio (computer-generated random allocation sequence) and then stratified by gender in permuted randomly selected block sizes of 2 and 4 to an intervention group (n=22) or an active waitlist group (n=23; see Figure 1). Due to the nature of a lifestyle intervention, only the lab technicians and statistician were blinded, but research investigators, staff, and participants were not.

Intervention Group

Trained research staff implemented the PilAm Go4Health intervention. In phase 1 (baseline to 3 months) immediately after randomization, intervention participants were trained on using the Fitbit accelerometer to self-monitor real-time PA steps and associated app with diary to self-report daily food/calorie intake and weekly weight. They joined the study's private Facebook group for virtual social support, coaching, and weekly education topics posted by research staff. Participants were encouraged to join the Facebook discussions at least once a week. At this training visit, they were given tailored short- and long-term weight loss goals based on the participant's baseline weight, PA, and diet information. Depending on their progress with tailored goals, research staff provided each participant tailored feedback, coaching, and support during research office visits at 1, 2, and 3 months. Table 2 outlines the PilAm Go4Health components delivered at each visit and weekly Facebook discussion topics posted by research staff.

In phase 2 at the 3-month office visit, intervention participants transitioned to a 3-month follow-up and were removed from the private Facebook group. Participants were asked to continue using their Fitbit and app with diary to track health behaviors and maintain their weight loss goals. Follow-up office visits were scheduled at 4 and 6 months. Intervention participants completed the study at 6 months. Further PilAm Go4Health intervention details are reported elsewhere [18].

Table 1. Examples of Pilipino Americans Go4Health [PilAm Go4Health] cultural adaptation strategies.

Components	Example
Peripheral	Photos of common Filipino foods were used in Filipino food pamphlet
Evidential	Health education sessions included information on the high prevalence of and factors associated with type 2 diabetes among Filipino Americans
Constituent involving	Filipino American community stakeholder (leaders, members, organizations, and health providers) input from individual interviews and focus group helped to inform the study design
Sociocultural	To align with a Filipino American family-centric culture, family members were welcome to attend the participant's scheduled office visits
Linguistics	Healthy lifestyle education pamphlets translated in Tagalog for Filipino Americans were provided by the National Heart, Lung, and Blood Institute [23]

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Table 2. Pilipino Americans Go4Health [PilAm Go4Health] intervention sessions (physical exam includes height, weight, body mass index, waist circumference, and blood pressure).

Schedule	Lifestyle education and coaching
Phase 1 (baseline to 3 months) Pilipino Americans Go4Health [PilAm Go4Health] intervention	
Baseline visit (individual)	Lifestyle balance and social networking
	Initiating physical activity and healthy eating plan with short- and long-term goals for weight loss
	Physical exam, blood draw, and surveys
	Fitbit Zip, app and diary training for tracking steps, food/calories, and weight and private Facebook group training
1-month visit (family members welcome)	Progress report and coaching on healthy behaviors
	Benefits and ways to be physically active
	Social support for physical activity
	Filipino dancing (Zumba, cha cha), basketball, and walking
	Monitoring physical activity steps
2-month visit (family members welcome)	Progress report and coaching on healthy behaviors
	Benefits and ways of healthy eating and limiting fat
	Social support for healthy eating
	Healthy Filipino food alternatives and recipes
	Monitoring weight
3-month visit (family members welcome)	Progress report + relapse prevention, problem-solving, and staying motivated
	Handling barriers to healthy behaviors
Transition to phase 2	Social support for maintaining healthy behaviors
	Physical exam, blood draw, and surveys
	Postintervention process evaluation interview
Private Facebook group	
Baseline to 3 months only; removed from Facebook group at 3-month visit	Research staff monitored and posted 12 weekly discussions covering topics such as the following: benefits of regular exercise, healthy fruits and vegetables, water and low-calorie drinks, tracking weight, healthy recipes, handling barriers to weight loss and healthy lifestyle behaviors, benefits of social support for weight loss, maintaining glycemic control, and medication adherence
	Weekly prompts to post and share photos, recipes tried, progress reports or barriers encountered, and encouragement for Facebook peers
Phase 2 (3 to 6 months) follow-up maintenance	
4-month visit (family members welcome)	Progress report, continue using Fitbit and app with diary to track steps, food, and weight
	Personal Facebook support group
	Reviewed relapse prevention, maintaining healthy behaviors, and dealing with barriers to healthy lifestyle
6-month visit (individual)	Progress report and relapse prevention, handling barriers
	Coaching to maintain healthy behaviors
	Physical exam, blood draw, and surveys
	Poststudy process evaluation interview

Waitlist Control Group

In phase 1 at the baseline randomization visit, waitlist participants received only the Fitbit accelerometer and training for daily wear. They returned for 1- and 3-month office visits when they received hepatitis B and C education, respectively.

In phase 2 at the 3-month office visit, waitlist participants transitioned to receive the PilAm Go4Health intervention and

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returned for 3 office visits at 4, 5, and 6 months (Table 2). Waitlist participants completed the study at 6 months.

Data Collection

All participants' anthropometric measures—weight (kg), height, BMI (kg/m^2), waist circumference (cm), blood pressure, serum labs (eg, plasma glucose and HbA1c)—were collected at baseline, 3 months, and 6 months during research office visits and stored in secure study data servers. All Fitbit steps and self-reported app and diary data (calorie/food and weight) were wirelessly uploaded and transmitted in real time directly to secure Fitbit data servers. Each participant's secure Fitbit account was also linked to a secondary Fitabase account (Fitabase, a San Diego based corporation) where data were uploaded and stored on secure confidential Fitabase data servers [26]. Facebook group data were wirelessly uploaded to secure Facebook data servers. All participant data were subsequently uploaded to secure institutional study data servers. Only approved research staff and investigators had access to study data. For further details on data collection protocol, see previous publication [18].

Outcome Measures

Primary Outcome

Feasibility was based upon three criteria: recruitment, engagement, and retention. Recruitment goal was to have 45 eligible participants recruited, enrolled, and randomized for this study. Engagement goal was to have participants attend 5 out of 7 intervention office visits (receipt of 9 of the 16 DPP sessions) as a measure for completing the program. This threshold was based on the Centers for Disease Control and Prevention's (CDC) required number of DPP sessions considered for program completion [27]. Retention goal was to have at least 80% of randomized participants complete the study, as defined by attending 5 of 7 office visits and complete all required study assessments (physical exams, labs, and surveys) at baseline, 3-month, and 6-month visits.

We monitored adherence to tracking target health behaviors using the Fitbit Zip and Fitbit app with diary. These additional engagement measures described the uptake and acceptance of the PilAm Go4Health program by participants. The criteria for mobile technology tracking by participants were as follows: (1) logging weight at least once/week, (2) logging daily food/calories at least once/week, and (3) wearing Fitbit Zip at least 5 days/week. However, currently there are no standard thresholds for frequency of mHealth app use to evaluate feasibility of an intervention. Any such thresholds would be arbitrary. Therefore, we chose not to use adherence as a measure of engagement to evaluate feasibility.

Secondary Outcome

Percent weight change was used to assess potential efficacy during phase 1 and 2 for each arm. In phase 1, the intervention group received the PilAm Go4Health from baseline to 3 months, whereas the waitlist group only used the Fitbit Zip without coaching. In phase 2, the waitlist group received the PilAm Go4Health from 3 to 6 months, whereas the intervention group transitioned to the follow-up maintenance phase.

Other Outcomes

For each arm, change in weight (kg) was measured weekly for 6 months, and change in BMI, waist circumference, fasting plasma glucose, and HbA1c were measured at baseline, 3 months, and 6 months, whereas daily step counts were measured in real time via the Fitbit Zip.

Statistical Analysis

Descriptive analyses for demographic, clinical, and outcome measures were computed using IBM SPSS for Windows version 24. Descriptive statistics were obtained by using *t* test, Mann-Whitney *U* test, Wilcoxon signed-rank test, or chi-square test for continuous, nonparametric, or categorical variables as appropriate. Between-group differences in percent weight change categories over time were analyzed using a bootstrap chi-square test, including the Mantel-Haenszel test of trend.

The feasibility outcome for recruitment was based upon achieving the target sample size. We reported the simple proportion (%) of participants within each randomized group who met the various target behavior threshold criteria for engagement and retention during the 3-month PilAm Go4Health.

The question for each secondary outcome was whether the change during both study phases was greater for the group receiving the PilAm Go4Health than the nonintervention group. Multilevel regression (aka linear mixed models or hierarchical linear models) was employed to test differences between the 2 arms in their change trajectories. This effect is also called the cross-level interaction between time and group [28,29]. In addition to the primary test of between-group change, the simple slopes were also tested to determine whether the change was significant *within* each group.

For these analyses, there were no missing data for the 2 groups. Therefore, a multilevel regression models approach was used over more traditional repeated measures analysis of variance (since missing data were not an issue) [28,29]. The use of multilevel regression allowed for the use of bootstrapping when the assumption of normality was not tenable. Bootstrapped full information maximum likelihood models were estimated to obtain nonparametric, bias-corrected bootstrapped CIs (BC CI) for estimation and inference regarding hypotheses [30-32]. These analyses were carried out with Stata/SE version 14 [33,34]. Primary analysis included intention to treat. Significance was evaluated using a 2-sided alpha of .05.

Results

Sociodemographic Results

A total of 113 potential participants were screened; 45 were eligible, enrolled, and randomized (see Figure 1). Mean age was 57.6 (SD 9.8), with 62% (28/45) female. The majority were immigrants (38/45; 84%). Overall, participants were categorized as obese with mean BMI 30.1 (SD 4.6) (Table 3). The only sociodemographic variable with a difference between the 2 groups was "Years lived in the United States" (often used as a proxy for acculturation). Although a majority of participants were immigrants, they were highly acculturated (Marin Acculturation Scale [35], mean score=3.5). As there were no

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between-group differences in acculturation scores, the outcome analyses were not adjusted for years lived in the United States.

Primary Outcomes

Results of all primary outcomes indicated that the PilAm Go4Health intervention program was feasible. For the study, 45 eligible participants were recruited, passed the run-in period, and enrolled and randomized over a 1-year period (Figure 1). Word of mouth was the dominate recruitment strategy that yielded the highest number of potential participants, followed by in-person invitation to join the study at local Lion's Club faith-based weekly health fairs. Feasibility engagement was measured by attendance at intervention office visits. Both the intervention and waitlist group achieved near-perfect attendance at all 7 intervention office visits (95% [21/22] and 100% [23/23], respectively), well above the standard CDC threshold for DPP completion. Finally, all 45 participants (100%) completed the study at 6 months, meeting the retention rate goal (Table 4).

Adherence to additional mHealth engagement measures, including logging weight and food/calories and wearing the Fitbit, was similar between the intervention and waitlist groups. With the exception of logging weight at least once/week, both groups demonstrated relatively high adherence to tracking weekly health behaviors in excess of 80% of the time when they received the 3-month intervention (Table 4).

Table 3. Pilipino Americans Go4Health [PilAm Go4Health] participant baseline sociodemographics, anthropometrics, and serum labs.

Variable	Overall (N=45)	Intervention (n=22)	Waitlist (n=23)	*P* value
Age in years, mean (SD[a])	57.6 (9.8)	57.4 (9.8)	57.7 (10.0)	.90
Race (Filipino), n (%)	45 (100)	22 (100)	23 (100)	.99
Gender (female), n (%)	28 (62)	14 (63)	14 (60)	.85
Marital status, n (%)				.06
Never married	5 (11)	1 (5)	4 (17)	
Divorced/widowed	10 (22)	7 (32)	3 (13)	
Married/cohabitating	30 (67)	14 (64)	17 (70)	
Education, n (%)				.67
College 1-4 years	36 (80)	18 (82)	18 (78)	
Graduate school	9 (20)	4 (18)	5 (22)	
Employed, n (%)				.21
Full or part time	31 (69)	17 (77)	14 (61)	
Unemployed	2 (4)	1 (5)	1 (4)	
Retired, n (%)	12 (27)	4 (8)	8 (35)	
Years lived in the United States, n (%)				.003
US born	7 (16)	0 (0)	7 (30)	
≥5-10+ years	38 (84)	22 (100)	16 (70)	
Marin acculturation score				
Mean (SD)	3.5 (0.6)	3.5 (0.6)	3.5 (0.7)	.91
Low score <2.99, n (%)	9 (20)	4 (18)	5 (22)	.77
High score >2.99, n (%)	36 (80)	18 (82)	18 (78)	
Weight in kg				
Mean (SD)	75.8 (15.4)	72.6 (10.8)	78.8 (18.6)	.19
Median	74.5	72.7	74.9	
Body mass index in kg/m^2 (SD)	30.1 (4.6)	28.6 (3.6)	31.5 (5.1)	.03
Waist circumference in cm (SD)	99.6 (10.7)	97.1 (8.7)	101.9 (12.1)	.13
Fasting glucose in mg/dL (SD)	135.3 (25.8)	133.0 (20.8)	137.4 (30.1)	.57
HbA1c, % (SD)	7.42 (0.87)	7.39 (0.82)	7.44 (0.93)	.84
Steps per day (SD)	7101 (2391)	7483 (2416)	6736 (2363)	.30

[a]SD: standard deviation.

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Table 4. Pilipino Americans Go4Health [PilAm Go4Health] office visit attendance and adherence to target health behaviors by group.

Target behaviors (N=45)	Intervention group (n=22) rate of adherence (0 to 3 months) n (%)	Waitlist control group (n=23) rate of adherence (3 to 6 months) n (%)
Attended all 7 intervention office visits	21 (95)	23 (100)
Logging weight at least once/week[a]	17 (79)	15 (64)
Logging food/calorie intake at least once/week[a]	20 (89)	19 (83)
Wear the Fitbit at least 5 days/week[a]	21 (97)	21 (91)

[a]Adherence signifies weekly mean of participants adhering to target behavior over the 12-week intervention period.

Secondary Outcomes

The results of the analysis for the main secondary outcome (percent weight change) are compelling, as are the results of the other secondary outcomes (Table 5). *All statistically significant (indicated by no zero in 95% BC CI) simple slopes and cross-level interactions are highlighted in italicized type*. The estimated simple slopes in Table 5 represent *within*-group changes, and cross-level interactions represent the *between*-group differences.

All the cross-level interactions for phase 1 were significant and in the expected direction (Table 5). For example, in the column for the cross-level interaction, the point estimate for weight shows that the decrease was 2 kg greater for the intervention group than for the waitlist group. The BC CI for the 2 kg decrease shows that the population difference might be as great as 3 kg or as small as 1.1 kg, but it is not 0. This weight change had a moderate effect size of 0.53 (Cohen *d*). Close examination of the simple slope for the intervention group was significant but not that of the waitlist group—just what we would expect. The intervention group's weight loss was equivalent to a significant 2.9% loss in their baseline weight (BC CI: −3.9 to −2.0). This is in contrast in to the waitlist group's insignificant 0.3% loss in their baseline weight (Figure 2).

As one might expect in phase 2, when the intervention group transitioned to the follow-up and the waitlist group received the PilAm Go4Health intervention program, the results were inverted. Waitlist group's mean weight decreased 2.5 kg more than the intervention group (BC CI: 1.4 to 3.5). This is between a weak and medium effect (Cohen *d*=0.37). The intervention group's simple slope showed a trivial 0.28 kg increase in weight (BC CI: −.24 to .83), whereas waitlist group's phase 2 simple slope decreased 2.2 kg (BC CI: −3.1 to −1.3). In phase 2, the cross-level interaction showed a 3.3% greater decrease for the waitlist group (BC CI: −1.8 to −4.8), and the simple slope for the waitlist group's 3.0% decrease in weight loss was significant (BC CI: −4.2 to −1.7), but the intervention group's increase of 0.35% in the simple slope was not (BC CI: −.37 to 1.1).

Intervention Group—Percent Weight Loss Goals Achieved

The overall PilAm Go4Health weight loss goal was a 5% weight reduction. In phase 1, about 18% (4/22) of the intervention group achieved a 5% weight loss, whereas 82% (18/22) of the group's remaining participants maintained or lost 2% to 5% of their weight. During maintenance in phase 2, over 90% (20/22) of the intervention group continued to maintain or lose 2% to 5% more weight (Table 6).

Waitlist Group—Percent Weight Loss Goals Achieved

In phase 1, over 83% (19/23) of the waitlist group maintained or gained 2% to 5% more weight (see Table 6). This pattern was reversed in phase 2 with 70% (16/23) of the waitlist participants receiving PilAm Go4Health having maintained or lost between 2% and 5% of their weight. Most notably, 30% (7/23) of waitlist participants achieved the 5% weight loss goal, almost twice that of the phase 1 intervention group.

Other Outcomes

A similar pattern of weight effects was also observed for other outcomes, waist circumference, BMI, and step counts, with mixed improvements in fasting glucose and HbA1c (Table 5). Significant cross-level interactions were detected for fasting glucose in both phases for the PilAm Go4Health activated groups. The simple slope (within group) for the intervention group was *significant*, indicating that the fasting glucose value had *increased* significantly during follow-up (10.7 mg/dL [3.4-18.5]). However, the simple slope for the waitlist group was not significant in phase 2, although it was in the expected direction (−8.9 mg/dL [−21.0 to 1.7]).

Opposing and mixed patterns were displayed in the HbA1c's outcomes. In phase 1, the intervention group's cross-level interaction was not significant, although the group's simple slope was significant and in the expected direction (−.49% [BC CI: −.80 to −.21]). In contrast, the waitlist group's HbA1c's cross-level interaction in phase 2 was significant and in the expected direction, but not the simple slope, although it was in the expected direction.

Overall step counts significantly increased for each study arm that received the PilAm Go4Health in phase 1 and phase 2 compared with the nonintervention group. The greater number of assessments (14 weeks in phase 1; 13 weeks in phase 2) allowed for a more sensitive examination of the linear and quadratic components of change for the 2 groups and phase-related changes in trajectories. The cross-level interactions and simple slopes for both linear and quadratic slopes were significant for the PilAm Go4Health intervention group for phase 1 and the PilAm Go4Health waitlist group during phase 2 with expected significant large effect sizes.

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Table 5. Pilipino Americans Go4Health [PilAm Go4Health] multilevel regression analyses of secondary outcomes for phase 1 (baseline to 3 months) and phase 2 (4 to 6 months) (N=45; intervention group: n=22; and waitlist group: n=23). All statistically significant (indicated by no zero in 95% BC CI) simple slopes and cross-level interactions are highlighted in italicized type.

Outcome measures	Intervention[a] mean (SD[b])	Intervention simple slopes[c] (95% BC CI)[d]	Waitlist[a] mean (SD)	Waitlist simple slopes[c] (95% BC CI)[d]	Cross-level interactions[e] (95% BC CI)[d]	Effect size Cohen *d*
Percent weight change						
P1 (phase 1)	−2.9 (2.4)	*− 2.9 (−3.9 to −2.0)*[f]	−0.28 (2.0)	−.28 (−1.0 to .56)	*− 2.6 (−3.9 to −1.4)*	
P2 (phase 2)	−2.5 (3.0)	.35 (−.37 to 1.1)	−3.3 (3.4)	*− 3.0 (−4.2 to −1.7)*[f]	*− 3.3 (−1.8 to −4.8)*	
Weight (kg)						
BL (Baseline)	72.6 (10.8)		78.8 (18.6)			
P1	70.5 (10.6)	*− 2.1 (−2.9 to −1.4)*[f]	78.6 (19.2)	−.12 (−.72 to .59)	*− 2.0 (−3.0 to −1.1)*	0.53
P2	70.8 (11.0)	.28 (−.24 to .83)	76.4 (19.8)	*− 2.2 (−3.1 to −1.3)*[f]	*2.5 (1.4 to 3.5)*	0.37
Body mass index (kg/m^2)						
BL	28.5 (3.6)		31.5 (5.1)			
P1	27.7 (3.6)	*− .81 (−1.1 to −.56)*[f]	31.5 (5.5)	−.05 (−.29 to .24)	*− .77 (−1.2 to −.41)*	
P2	27.8 (3.6)	.10 (−.11 to .31)	30.5 (5.6)	*− .92 (−1.3 to −.51)*[f]	*1.0 (.55 to 1.5)*	
Waist circumference (cm)						
BL	97.1 (8.7)		101.9 (12.1)			
P1	94.6 (9.2)	*− 2.5 (−3.8 to −1.4)*[f]	102.1 (12.4)	.16 (−1.1 to 1.5)	*− 2.7 (−4.5 to −.91)*	
P2	94.2 (9.5)	−.43 (−1.5 to .54)	99.9 (13.0)	*− 2.2 (−3.5 to −1.1)*[f]	*1.8 (.23 to 3.4)*	
Fasting glucose (mg/dL)						
BL	133 (20.8)		137.4 (30.1)			
P1	118 (20.3)	*− 15 (−25 to −5.3)*[f]	141.0 (32.1)	3.5 (−4.2 to 11.2)	*− 18.5 (−31.4 to −6.5)*	
P2	128.7 (30.6)	*10.7 (3.4 to 18.5)*	132.0 (33.0)	−8.9 (−21.0 to 1.7)[f]	*19.6 (6.7 to 33.6)*	
HbA1c (%)						
BL	7.4 (0.82)		7.4 (0.93)			
P1	6.9 (0.67)	*− .49 (−.80 to −.21)*[f]	7.3 (1.0)	−.14 (−.41 to .05)	−.34 (−.70 to .04)	
P2	7.1 (0.98)	.15 (−.03 to .37)	7.1 (1.2)	−.18 (−.42 to .07)[f]	.32 (.01 to .64)	
Step counts						
P1 Linear	7483 (2415)	*L560 (210 to 862)* [f]	6735 (2363)	L −93 (−205 to 15)	*L654 (275-975)*	1.74
Quadratic	10,178 (4593)	Q −35 (−56 to 13)[f]	6469 (2936)	Q 2.4 (−6.6 to 11.8)	*Q −37 (−60 to −14)*	
P2 Linear	9524 (3626)	L −206 (−477 to 39)	7208 (2719)	*L 403 (56-770)* [f]	*L −610 (−1064 to −187)*	1.44
Quadratic	8546 (4416)	Q10.9 (−6.2 to 29.3)	7538 (4025)	*Q −27 (−55 to −2)* [f]	*Q 38 (7.8 to 72)*	

[a]Observed values.

[b]SD: standard deviation.

[c]Estimated simple slope.

[d]Nonparametric bias-corrected bootstrapped CI (BC CI) is significant if "0" not in confidence interval.

[e]Difference between groups.

[f]Received PilAm Go4Health.

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Figure 2. Percent weight change over 6 months by group—multilevel regression (phase 1—intervention group received PilAm Go4Health [Pilipino Americans Go4Health] weight loss intervention; phase 2—waitlist control group received PilAm Go4Health weight loss intervention).

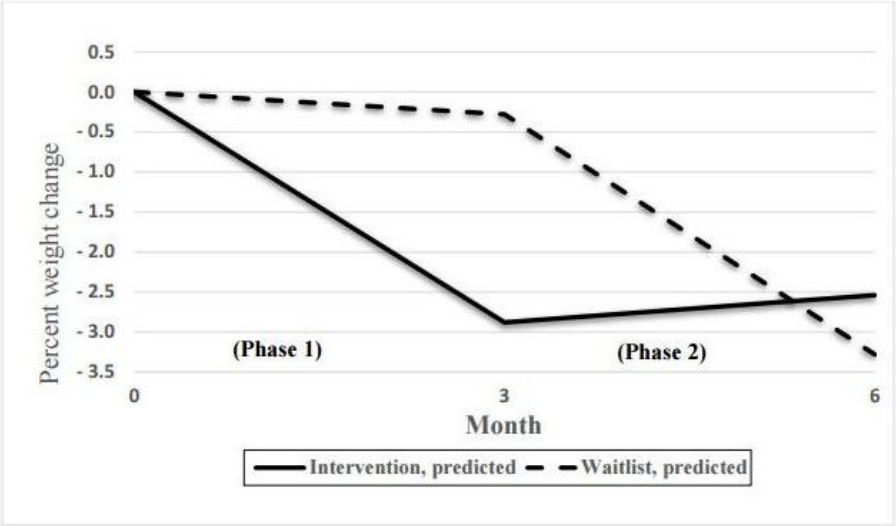

Table 6. Percentage weight change achieved by group (N=45).

Phases	Gained ≥2% to <5% n (%)	Stable + <2% n (%)	Lost ≥2% to <5% n (%)	Lost ≥5% to <10% n (%)	*P* value[a]
Phase 1					.001
Intervention[b] (n=22)	0 (0)	10 (45)	8 (36)	4 (18)	
Waitlist (n=23)	4 (17)	15 (65)	4 (17)	0 (0)	
Phase 2					.001
Intervention (n=22)	2 (9.1)	16 (72)	4 (18)	0 (0)	
Waitlist[b] (n=23)	0 (0)	10 (43)	6 (26)	7 (30)	

[a]*P* value for Mantel-Haenszel chi-square test for trend.

[b]Received PilAm Go4Health.

Discussion

Key Findings

The PilAm Go4Health was feasible as measured by achieving the recruitment, engagement, and retention threshold goals. Results demonstrated potential efficacy of the PilAm Go4Health in reducing weight in Filipino Americans with overweight and T2D. Each group receiving the PilAm Go4Health program (intervention group in phase 1 and waitlist group in phase 2) demonstrated significant weight loss, underscoring the PilAm Go4Health potential efficacy. In phase 1, over half of the intervention participants lost weight. Although only 18% (4/22) achieved the overall 5% weight loss goal by 3 months, the weight loss trajectory matched that of the typically longer DPP-based interventions [36]. More importantly, in the phase 2 follow-up, most of the intervention participants continued to maintain or lose weight.

Primary Outcome

Full participant recruitment was achieved within 1 year for this difficult-to-reach population. Acceptance criteria presented an interesting conundrum, in that the inclusion and exclusion criteria were stringent and at odds with one another. Participants had to be overweight/obese non-insulin–dependent T2D, with controlled hypertension, yet still capable of walking 30 min per day and willing to deal with a time-consuming protocol and inconvenient blood tests and office visits. Potential participants were approached using various indirect and in-person recruitment strategies, resulting in 185 referrals, yielding only 45 qualified and willing to participate. Yet, despite these recruitment obstacles, the study was feasible.

Recruitment was successful, engagement (office visit attendance) was close to 100%, and a 100% retention rate was achieved, possible due to the culturally adapted intervention and use of a community health worker model to successfully recruit and administer the study. Although cultural adaptation strategies were not quantitatively measured for adherence and feasibility, qualitative process evaluations through semistructured interviews were conducted at the 3-month and 6-month visits to assess cultural acceptability and relevance of the intervention for Filipino Americans. As detailed in a previous publication [17], over half (58%; 26/45) stated that “the culturally tailored support (eg, Filipino research staff) enhanced their engagement” in the study. Furthermore, a

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majority of participants (64%; 29/45) reported that the intervention helped boost their self-confidence in managing their health. Thus, Filipino American participants deemed the culturally adapted PilAm Go4Health intervention acceptable and relevant.

Adherence to using mobile technology was excellent for wearing the Fitbit to track PA and logging foods to monitor calorie intake. However, adherence for self-monitoring weight was markedly lower. This could be due to the negative feedback that can occur with self-weighing, particularly among those with overweight/obesity. There is debate about self-weighing because in some overweight/obese individuals, it appears to generate negative psychological conditions, such as depression, anxiety, and stress [37,38]. Future studies should assess barriers and facilitators for tracking weight to improve intervention strategies promoting weight loss.

Due to the small sample size of our study, we were unable to assess the relative contribution of the mobile app use to weight loss outcomes. Such analyses may be feasible in future studies with a larger sample size. Nevertheless, the PilAm Go4Health adherence data add to the body of knowledge that mobile apps are useful for tracking health behaviors in weight loss interventions.

More importantly, our participants' mean age was 57.6 years, which demonstrated that older adults can successfully learn and use mobile technology to self-monitor health. In our previous publication, overall, participants highly endorsed and adopted the Fitbit as a means for tracking PA and reported that the mobile technology helped improve accountability for monitoring target health behaviors [17]. Previous studies have shown that a majority of older adults go online and own a smartphone, but few engage in using mobile technology [39,40]. Future mHealth lifestyle intervention studies should evaluate whether older adults will continue to engage in the use of mobile technology after receiving an mHealth-based intervention.

Secondary Outcomes

Evidence indicates that weight loss of 5% to 7% by 6 months is associated with preventing or reducing T2D and cardiovascular risks [10,40-42]. Even a modest weight loss of 5% in patients with T2D is associated with significant clinical improvements (eg, systolic blood pressure, glucose, HbA1c, and triglycerides). Due to the short 3-month intervention duration, PilAm Go4Health study participants may not have had sufficient time to achieve the 5% weight loss goal set forth in other 6-month weight loss lifestyle interventions [36].

Overall, 24% (11/45) of intervention group and waitlist group participants achieved the study's primary 5% weight loss goal after completing PilAm Go4Health, and 31% (14/45) achieved a 2% to 5 % weight loss (Table 6). However, considering the reduced number of office visits and educational meetings condensed into 3 months, the trajectory for PilAm Go4Health participant weight loss rates was similar to those of longer DPP-based studies [36]. Increasing the PilAm Go4Health duration to 6 months may be necessary to achieve the 5% to 7% weight reduction for optimum health benefits.

Notably, compared with phase 1 when only 18% (4/22) of intervention participants achieved the 5% weight loss goal, nearly twice the number of waitlist participants, 30% (7/23), achieved their 5% weight loss goal in phase 2. When waitlist participants received PilAm Go4Health, they had already been self-monitoring PA steps for the prior 3 months. During phase 1, the waitlist group was asked to only self-monitor PA steps using the Fitbit app. This prior PA tracking behavior may have contributed to the greater number of waitlist participants achieving the 5% weight loss goal in phase 2 compared with the intervention group.

Other Outcomes

Our study results highlight the important relationship between weight management and diabetes control. Not surprising, the other outcomes of weight (kg), waist circumference, and BMI mirrored the results of the secondary outcome for reduced percent weight over 3 months when both study arms received the PilAm Go4Health. Similarly, the PilAm Go4Health had a large effect on PA measured by increased steps over time. Furthermore, improvements in fasting glucose and HbA1c give promise to the efficacy of the PilAm Go4Health mHealth intervention to enhance diabetes self-management. There were clear improvements in diabetes self-management and control as reflected in the significant cross-level interactions (with the exception of phase 1 for HbA1c); however, long-term studies are needed to detect whether serum levels for diabetes control can be improved and sustained.

Strengths

PilAm Go4Health intervention program has several noteworthy strengths. This is one of the first rigorous lifestyle intervention studies focused on Filipinos with obesity and T2D to reduce further cardiovascular-metabolic complications. The efficacy of the PilAm Go4Health program was evident in the (1) 100% (45/45) participant study completion rate, demonstrating the excellent participant recruitment and engagement of this hard-to-reach Filipino population; (2) ability to promote weight loss among Filipino Americans with overweight and T2D (in both study arms receiving the intervention) in only 3 months; and (3) sustained intervention group weight loss in the subsequent 3 months.

There are multiple intervention factors (eg, intensity, Facebook, self-monitoring behaviors, cultural adaptation) that may have contributed to the PilAm Go4Health potential efficacy. Although relative contributions of each factor are unknown, previous studies indicate that each may have had a positive impact on the outcomes. First, intensive interventions with multiple components have shown that participants are able to lose 5% of their baseline weight over short durations [36,43,44]. PilAm Go4Health findings are consistent with these studies.

Second, evidence indicates that self-monitoring lifestyle behaviors improve weight loss and health outcomes [7,45]. Furthermore, higher adherence to activity tracking was associated with greater weight loss and increased PA [46,47]. Our findings support these 2 premises in that the waitlist group's self-monitoring (tracking) of PA alone in phase 1 was not sufficient to achieve a significant weight reduction by 3 months.

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However, in phase 2, when the waitlist group received the PilAm Go4Health intervention, tracking PA in combination with tracking food calories and weight resulted in significant weight reductions or weight stabilization in 3 months.

A third intervention factor was cultural relevance, an integral element of the PilAm Go4Health design. Culturally relevant interventions have been shown to improve health outcomes, especially in diverse immigrant populations [48,49]. Cultural tailoring is an important strategy to improve recruitment, engagement, and retention in a hard-to-reach vulnerable population [18,22]. Cultural adaptation strategies used in the study design reflected Filipino family and community preferences by welcoming family members at research office visits for in-person social support and incorporating a private Facebook group for virtual social support with peers. Therefore, these culturally adaptations may have influenced the weight loss achieved by a primarily immigrant population.

Incorporating mobile technology was a fourth factor in the PilAm Go4Health study design. Including a mobile phone app to supplement standard lifestyle counseling had positive impact on PA and diet, even over short 3-month intervention periods such as that of the PilAm Go4Health [43,50]. Furthermore, our findings are consistent with other studies that show technology-based interventions are feasible, acceptable, and efficacious among older adults [16,51]. On the basis of FA's prolific use of mobile technology and social media [13], PilAm Go4Health incorporated this technology to promote participant engagement and motivate self-monitoring of lifestyle behaviors to achieve weight loss goals. The addition of virtual social networking via Facebook in our study may have contributed to adherence for tracking health behaviors. Virtual social media has also been shown to improve health outcomes. For example, Facebook has also been used in weight loss interventions, with positive results among overweight/obese adults and college students [52,53].

Our study supports evidence that older individuals can successfully use mobile technology to improve diabetes self-management. The Pew Research Center reported that older adults with higher education more easily adopt mobile technology compared with less-educated older adults [51]. On the basis of our study's previously reported qualitative outcome [17], our highly educated older Filipino American adults seemed to readily adopt the mobile technology to track health behaviors for diabetes management. The mobile technology used in our study may have influenced adherence to healthy behaviors, contributing to weight reduction and improvements in other health outcomes. Further research is needed to evaluate the relative influence of the mHealth components used in the PilAm Go4Health program.

Limitations

There are several limitations of note. The duration of this pilot RCT 3-month lifestyle intervention with a 3-month follow-up was shorter than a typical DPP-based 6-month weight loss program. This may have influenced participants' ability to achieve the overall study's 5% weight loss goal. The small sample size consisted of a highly educated immigrant Filipino population from a geographic area of Northern California, limiting the internal validity and generalizability. The study was also limited to those who were English literate and owned smartphones with Internet access. This may have resulted in a biased sample excluding non-English speakers and those less likely to afford mobile devices requiring Internet service. The sample size also limited statistical analyses of this multifactorial intervention program, restricting the ability to determine the relative contribution of each factor influencing weight loss and other outcomes. Nevertheless, many secondary/other outcomes (eg, percent weight, weight [kg], and fasting glucose change) were statistically significant, indicating that power (and therefore the sample size) was sufficient to support the potential efficacy of the PilAm Go4Health [54,55].

The run-in period to assess participant eligibility may have biased retention levels and study outcomes as it may have excluded noncompliant potential participants. However, out of 52 potential PilAm Go4Health participants completing the run-in, only 4% (2/52) were categorized as noncompliant (see Figure 1). Furthermore, a recent meta-analysis of interventions in which weight loss was the primary outcome showed studies did not differ significantly in weight loss with or without a run-in period [56] and thus did not compromise generalizability.

Implications

These study findings have practical clinical implications for health care providers. As the obesity epidemic grows, health care providers should routinely address the issues of obesity and inactivity that are associated with poor health outcomes. Our results will help inform clinicians about commercially available mHealth tools and social media for patients' use to improve health outcomes. Clinicians can tailor patient weight loss goals using these tools to promote engagement and adherence to healthy lifestyle behaviors. In our study, real-time feedback from the Fitbit accelerometers along with the associated mHealth app with diary for tracking weight and food/calories may have been an important motivational factor. Utilizing Facebook capabilities for virtual social support among peers in tandem with health education postings may have also influenced improvements in health behavior change [34].

Conclusions

PilAm Go4Health demonstrated that a mobile technology–based culturally adapted lifestyle intervention was feasible and potentially efficacious in weight reduction among older understudied Filipino Americans with obesity and T2D. Results are promising for targeted, culturally tailored lifestyle interventions in achieving short-term weight loss. Therefore, a larger RCT is warranted to test effectiveness of the PilAm Go4Health in maintaining long-term weight loss to reduce T2D and cardiovascular-metabolic risks in this vulnerable population.

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Acknowledgments

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Authors' Contributions

MSB is the principal investigator who conceived the study idea and methodology; oversaw the intervention cultural adaptation, implementation, data collection, and analysis; and drafted the manuscript, along with some tables and figures. BAC, the statistician, helped condition the data, performed the statistical analysis, drafted the data analysis section, drafted Figure 2, and critically reviewed the manuscript draft. LGP provided guidance for organizing the paper, interpreted the data to formulate input for the Results and Conclusions sections, drafted the initial Discussion section, and critically reviewed the manuscript draft. SA provided guidance for organizing the paper, performed additional statistical analysis and data interpretation, provided the initial Results and Discussion drafts, drafted several of the tables, and critically reviewed the manuscript. SP helped in the participant recruitment; assisted with intervention implementation, data collection, and management; and helped prepare manuscript citations and edit references.

Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT - EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 680KB - diabetes_v2i2e30_app1.pdf]

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Abbreviations

BMI: body mass index
BC CI: bias-corrected bootstrapped confidence interval
CDC: Centers for Disease Control and Prevention
DPP: Diabetes Prevention Program
mHealth: mobile health
PA: physical activity

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PilAm Go4Health: Pilipino Americans Go4Health
RCT: randomized controlled trial
T2D: type 2 diabetes

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Original Paper

Assessing Diabetes-Relevant Data Provided by Undergraduate and Crowdsourced Web-Based Survey Participants for Honesty and Accuracy

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Abstract

Background: To eliminate health disparities, research will depend on our ability to reach select groups of people (eg, samples of a particular racial or ethnic group with a particular disease); unfortunately, researchers often experience difficulty obtaining high-quality data from samples of sufficient size.

Objective: Past studies utilizing MTurk applaud its diversity, so our initial objective was to capitalize on MTurk's diversity to investigate psychosocial factors related to diabetes self-care.

Methods: In Study 1, a "Health Survey" was posted on MTurk to examine diabetes-relevant psychosocial factors. The survey was restricted to individuals who were 18 years of age or older with diabetes. Detection of irregularities in the data, however, prompted an evaluation of the quality of MTurk health-relevant data. This ultimately led to Study 2, which utilized an alert statement to improve conscientious behavior, or the likelihood that participants would be thorough and diligent in their responses. Trap questions were also embedded to assess conscientious behavior.

Results: In Study 1, of 4165 responses, 1246 were generated from 533 unique IP addresses completing the survey multiple times within close temporal proximity. Ultimately, only 252 responses were found to be acceptable. Further analyses indicated additional quality concerns with this subsample. In Study 2, as compared with the MTurk sample (N=316), the undergraduate sample (N=300) included more females, and fewer individuals who were married. The samples did not differ with respect to race. Although the presence of an alert resulted in fewer trap failures (mean=0.07) than when no alert was present (mean=0.11), this difference failed to reach significance: $F_{1,604}$=2.5, P=.11, ^{2}=.004, power=.35. The modal trap failure response was zero, while the mean was 0.092 (SD=0.32). There were a total of 60 trap failures in a context where the potential could have exceeded 16,000.

Conclusions: Published studies that utilize MTurk participants are rapidly appearing in the health domain. While MTurk may have the potential to be more diverse than an undergraduate sample, our efforts did not meet the criteria for what would constitute a diverse sample in and of itself. Because some researchers have experienced successful data collection on MTurk, while others report disastrous results, Kees et al recently identified that one essential area of research is of the types and magnitude of cheating behavior occurring on Web-based platforms. The present studies can contribute to this dialogue, and alternately provide evidence of disaster and success. Moving forward, it is recommended that researchers employ best practices in survey design and deliberately embed trap questions to assess participant behavior. We would strongly suggest that standards be in place for publishing the results of Web-based surveys—standards that protect against publication unless there are suitable quality assurance tests built into the survey design, distribution, and analysis.

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KEYWORDS

crowdsourcing; diabetes mellitus; survey design; survey methodology; survey quality; mechanical turks; MTurk; data accuracy

Introduction

Study 1

Diabetes Self-Care

Diabetes is a complex, chronic illness in which a patient's body has difficulty regulating the amount of glucose in the blood. This illness requires continuous self-care, which is critical to the prevention of acute and long-term complications. In 2013, the International Diabetes Federation estimated that 382 million people worldwide had diabetes, and that number is expected to increase to 592 million people by 2035 [1]. In the context of these projections, there is concern that the cost-heavy treatment of this disease may outstrip existing healthcare resources. Monies spent on the treatment of diabetes will then limit the funds available for the prevention of this disease, as well as the prevention of other chronic conditions.

As a result, research continues to investigate biological methods for treating diabetes. Because researchers estimate that 95% of care associated with the disease is personal behavioral self-care [2], research is also underway to examine the psychosocial markers of how well someone manages the disease. For example, DePalma et al found in a small, largely Non-Hispanic white sample, that greater perceptions of personal responsibility for disease onset were related to poorer diabetes self-care [3]. In a subsequent investigation of these variables in an American Indian and Alaska Native sample, DePalma et al failed to replicate this finding and instead found that diabetes self-efficacy was a strong predictor of more effective diabetes self-care [4]. Because of the possibility that racial, ethnic, or cultural differences played a role in these disparate findings, the researchers bore the responsibility of continued investigation on groups that are disproportionately affected by diabetes (eg, Asian Americans, African Americans, and Latinos). In order to eliminate health disparities, research will depend on our ability to obtain such select groups of people (ie, samples of a particular racial or ethnic group with a particular disease); unfortunately, researchers often experience difficulty recruiting samples of sufficient size [5].

The Need for Sample Diversification

There are obvious and practical reasons why the bulk of research is on undergraduates, but there has been a strident call to work toward sample diversification, particularly in health research. This concern is not new; the limitations of using undergraduate samples for conducting research have been discussed for decades. Given that this is particularly true in the social and behavioral sciences, Arnett evaluated the diversity of psychological research by analyzing 4037 studies from six different American Psychological Association journals published over 20 years [6]. Analyses showed that in 2007 alone, 67% of American studies published in the *Journal of Personality and Social Psychology* used undergraduate psychology participants. In countries other than the United States, undergraduates were used in 80% of studies [6]. Henrich et al estimated that when participants are selected for research, an American undergraduate is 4000 times more likely to be selected than is a non–Western individual [7]. Arnett argued that "the rich get researched" [6].

Of course, researchers should be cautious when extending results from undergraduate participants to diverse adult populations. Why would observations of samples of 18-22 year old undergraduates who are primarily white and increasingly female [8] be expected to generalize to phenomenon describing diverse health, business, and social behaviors? Using a series of large-scale meta-analyses, Peterson showed that, when compared with responses from non-student samples, undergraduate psychological and behavioral responses were more homogenous and the associated effect sizes often differed in magnitude and direction [9]. This could be especially problematic when investigating disparities that exist in a behavioral health context. Notably, Peterson and Merunka observed "...even if theory testing is the study purpose, few researchers using convenience samples of college students appear to recognize that their investigation possesses the characteristics of a limited laboratory test that cannot generalize to other samples" [10].

In addition to concerns about response homogeneity, some researchers have also questioned the quality of undergraduate data. Chen utilized data from the National Survey of Student Engagement (NSSE) involving undergraduates from 587 US colleges and universities [11]. About 11% of first year and 7% of fourth year undergraduates failed to answer 30% or more of the 85 Web-based survey questions. Students who responded to the Web-based version provided more responses of lower quality than did those responding in a paper-and-pencil format. Chen expressed concern that participants may not properly understand survey questions or that their responses may be careless, negatively affecting the quality of the resultant data.

Web-Based Samples Can Be More Diverse

Although the extensive reliance on undergraduate samples remains in practice, an increasing amount of survey research is now being conducted on the Internet, which allows researchers to quickly and easily collect data from local and global participants [12]. While there are certainly students on these survey platforms, a researcher is no longer restricted to samples of undergraduate psychology students.

Amazon Mechanical Turk (MTurk)

MTurk, a Web-based crowdsourcing platform for conducting survey research, is touted as providing an economical, diverse sample [13]. Based on their research, Crump et al dramatically conclude that Amazon MTurk (AMT) "...is a revolutionary tool for conducting experiments. It offers the ability to run experiments with large numbers of subjects in a matter of hours. This has the potential to transform behavioral research. Additionally, AMT provides an opportunity to reach a more representative population that varies widely in age, education, and ethnicity and geographic location" [14]. Amazon

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Mechanical Turk seemed to have the potential to fulfill our need to obtain a specific sample efficiently and inexpensively.

On MTurk, "Requesters" post Web-based Human Intelligence Tasks (HITs) to be completed by "Workers" who are paid to complete the HIT. There are typically more than 100,000 HITs that are readily available for MTurk Workers [13]. For example, HITs might include completing basic surveys or performing accounting tasks. An MTurk Worker then earns a HIT quality "approval rating" based on the number of HITs accepted by the Worker compared to the number of times Requestors reject the completed work for being of low quality. Accepted work then receives compensation ranging between US $.01 and several dollars per HIT. In essence, a survey researcher could conceivably collect 1000 responses from a 10 min survey in less than one week for US $100 [15]. It is easy to see how this rapid and inexpensive mode of data collection could be attractive.

The primary draw for our research team was the purported diversity of MTurk participant pools. Kraut et al contend that internet-based surveys "...can provide a large, diverse sample at low cost" [16]. Mason and Suri report that MTurk Workers "...tend to be from a very diverse background, spanning a wide range of age, ethnicity, socioeconomic status, language, and country of origin" [17]. MTurk includes more than 500,000 Workers from 190 countries [13], including the United States (47%) and India (34%) [18]. Of the US MTurk Workers, there are currently more women (64.85%) than men (35.15%), and many have a higher educational level than the general US population [18]. Although Berinsky et al report that MTurk samples are largely white in terms of racial composition, these samples are considered comparable to adult participants found in other convenience samples [19].

In addition, college samples are not an efficient option for conducting some types of health research because these groups tend to be too young to produce significant sample sizes of people with diabetes and other chronic illnesses. Thus, MTurk is likely to be superior to a college population whenever the researcher is examining health issues that are not widely present in undergraduate samples. Finally, although it is important to note that MTurk samples are expected to be more diverse because they would include anyone over the age of 18, be larger than one cohort of students, and extend beyond a single college campus, it is also important to emphasize that this would not necessarily result in more socioeconomically diverse samples. Individuals who do not have access to computers and the Internet will not be represented in these samples.

Web-Based Sample Quality

There is no conclusive answer regarding the quality of MTurk responses as the available data offer a conflicting report. Some evidence suggests that Web-based samples are of worse quality than undergraduate samples. Rouse reported that MTurk responses to a personality measure were less reliable than responses reported for an adult community sample [20]. MTurk Workers also tend to score slightly higher on social desirability [21]. The desire to please researchers may be detrimental because the Worker may provide the answer they believe the researcher wants or look to outside sources for more information to "correctly" answer questions [22,23]. Kees et al contend, however, that lower quality MTurk data is largely the result of using MTurk Workers who have non-US IP addresses [24].

In addition, some people have expressed concern that only a limited number of participants are accounting for a significant proportion of the data produced by MTurk Workers [25]. For example, Kumar suggests creating a reusable list of Workers who routinely provide high quality data [26]. Although this may be an excellent strategy for individual HITs that are using Workers for "work," this would defeat any use of these pools for research conducted for the purpose of collecting generalizable data.

However, other research evidence suggests that Web-based samples produce data comparable to, or substantially better than, those obtained using traditional samples. However, there is the added benefit of potentially being more diverse [27]. For example, Paolacci et al compared the data collected on MTurk Workers to a traditional subject pool from a Midwestern US university [18]. MTurk Workers were not more likely to cheat than undergraduate participants, nor was there evidence suggesting that Web-based methods produced poorer quality data. The authors concluded that data collected through MTurk Workers can be comparable to data collected from more traditional means. Mullinix and colleagues compare population-based data and MTurk data across 20 studies and conclude that there is considerable similarity in treatment effects, supporting the potential utility of MTurk samples [28]. Clifford and Jerit provided even more striking data that showed that student samples self-reported cheating at rates between 24-41%, while comparable MTurk self-reports hovered between 4-7% [29]. The authors acknowledge, however, that it could be that MTurk respondents were less likely to report cheating behavior because of the impact such an admission might have on their approval rating or pay. However, in a direct comparison of MTurk and undergraduate samples, Hauser and Schwarz report that, across three studies, MTurk respondents were significantly more attentive to specific instructions contained in manipulation checks than were respondents from undergraduate subject pools [30].

Purpose

Based on previous research, we hypothesized that a judgment of responsibility for the onset of diabetes would be related to disease self-care. MTurk's diversity attributes would offer a promising tool to examine this hypothesis in a large and diverse sample.

However, preliminary analysis of the data revealed significant inconsistencies. These irregularities spurred the investigation of the quality of our initial data for health-relevant material, and prompted a second direct test of the quality of MTurk data.

Study 2

Survey Design Practices

Of course, researchers bear the responsibility of being continually vigilant and cognizant of the quality concerns for all self-report data, independent of whether the participant is physically present or on the Internet. Even if care has been

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exercised in the recruitment of respondents, participants can occasionally subvert the onboarding process and contribute responses that would be unhelpful at best and misleading at worst. Maniaci and Rogge present evidence that poor quality data may reduce power and effect sizes and obscure findings that are visible in the responses of attentive respondents [31]. Thus, researchers could incorporate survey design practices to attempt to increase quality. Researchers can choose from attention checks or reminders, alerts, or actual trap questions; however, each of these methods has strengths and weaknesses.

Attention Checks

Goodman et al suggest the use of methods to gauge participant attention [32]. Attention filters are "trick" questions that require a respondent to answer in a particular way in order for the survey to continue; that is, the survey process does not continue until the "correct" box is checked. However, Paolacci and Chandler contend that having these types of attention checks are no more beneficial to having higher quality data than just working exclusively with Workers who have high approval ratings [22].

Alerts

Some research suggests that the use of a warning message or an alert will produce higher quality data. Clifford and Jerit found that the presence of an item asking respondents to be attentive and honest produced more reliable responses [33]. While some researchers have expressed concern that these types of affirmations may be interpreted negatively in light of a reference to participant honesty, Clifford and Jerit report that respondents were not visibly upset by their survey manipulation that specifically asked participants not to use outside sources to find a correct answer [29]. These "honesty affirmation" items may prod people to be more conscientious, but these items will not provide a way to evaluate whether participants were actually conscientious in their responses.

Trap Questions

Trap questions can be included within surveys to identify respondents who are not reading carefully (or at all) or who are using automated response methods. Examples of trap questions include simple requests to choose a specific answer from a subsequent response list. Or, the response of a participant who answered "yes" to being a biological male could be compared to his response on the question: "have you ever been pregnant?" Downs at al suggest that researchers should deliberately embed trick questions to measure whether participants answer conscientiously [34]. These "catch trials" would help researchers determine which subjects were not paying close attention.

Worker Qualifications

When creating a HIT, it is possible to manage the level of qualifications a Worker needs in order to be able to participate. For example, one could increase the approval rating to 95% and increase the required number of previous HITs that have been completed successfully. Another strategy is to restrict the survey to MTurk Masters, who are "...an elite group of Workers, who have demonstrated superior performance while completing thousands of HITs for a variety of Requesters across the Mechanical Turk Marketplace" [35].

Purpose

The potential for the conduct of research through the Internet is staggering. In fact, a 2011 article published in *Science* presented the MTurk platform as likely to become a "mainstream" form of data collection [36]. Published studies are now appearing that use MTurk participants; however, few provide information on the quality of the resultant data. Although there appears to be significant potential for MTurk to be a "revolutionary tool" that could assist in reaching more diverse samples, there remains significant concern over the quality of the resultant data as well as the degree to which these samples are truly diverse..

Therefore, the present study utilized both an undergraduate and an MTurk sample and hypothesized that the conscientiousness of the participants' responses could be evaluated using trap questions as well as the time of survey completion. In addition, we randomly assigned half of the participants to receive an alert statement. We hypothesized that an alert statement would positively influence response quality. This study was designed to employ stronger restrictions and directly test whether MTurk can be a reliable data collection method for health-related information gathered from a diverse sample.

Methods

Study 1

Materials and Procedure

Subsequent to Institutional Research Board approval, a 25-min "Health Survey" was posted on MTurk. To investigate the psychosocial determinants of diabetes care in the United States, only US Workers who had a HIT approval rating of greater than 90% could "accept" the HIT, which allowed them to access the survey.

Qualification Questions

A preliminary qualification question required Workers to disclose whether or not they had any of the following diseases: diabetes, heart disease, asthma, osteoporosis, or none of the above. If diabetes was not selected, the participants were directed out of the survey and thanked for their interest. Workers who did select diabetes were prompted with a secondary age qualification question. Only Workers who specified that they were at least 18 years of age were allowed to continue to an informed consent page, where they again confirmed that they were 18 years of age or older, with diabetes.

Survey Questions

If the participants successfully met the relevant criteria, they completed a 40-question survey that included multiple choice, fill-in-the-blank, and Likert-type scale items. Workers first answered basic demographic questions (eg, age, sex, and race). Additional scales were included to measure psychosocial aspects of diabetes self-care. Participants were also prompted about their own disease status: "With which type of diabetes have you been diagnosed?" Answers included "type 1," "type 2," "I don't know," or "I don't have diabetes." At the conclusion of the survey, participants who entered a valid MTurk ID received a

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code to obtain their compensation of US $0.25. A debriefing statement was subsequently provided.

Study 2

Participants and Procedure

A 10-min survey on "Health Issues and Health Organizations" was created using Qualtrics and, following Institutional Research Board approval, released on MTurk and the SONA systems platform (a local Web-based survey management system) for approximately 15 weeks. Restrictions were imposed such that only one response could be entered from a particular IP address. After providing informed consent, participants were directed to the survey, which ultimately concluded with a CAPTCHA and a debriefing statement.

Sample 1: MTurk

The survey was posted as a HIT available only to US MTurk Masters with a 95% approval rating over 1000 HITs. At the conclusion of the survey, participants who entered their MTurk IDs received a compensation of US $0.75.

On MTurk, 377 participants accessed the survey, but only 83.8% (316/377) of the participants finished the survey (138 were male, 176 were female, and 2 did not provide a response to this question). Demographic information for these samples can be found in Table 2. The individuals ranged in age from 20-69 years (mean=37.67, SD=11.83).

Sample 2: Undergraduate Sample

Undergraduates were recruited from introductory psychology classes to complete a Web-based SONA survey for which they received extra credit in a course. These undergraduates were recruited from non-majors courses and participants spanned the academic range from first-year students to seniors. Although 330 undergraduate participants accessed the survey, only 90.9% (300/330) finished the survey. Participants ranged in age from 17-62 (mean=19.37, SD=2.97; see Table 2).

Materials

Primary Measures

In a survey that was pre-tested to take less than 10 min, participants responded to basic demographic items (eg, age, sex, and race), an assessment of personal and family health history regarding different diseases (eg, diabetes and lung cancer), as well as their personal diabetes information (eg, type of diabetes, treatment, and medication).

Alerts

Approximately half of the participants were randomly assigned to an alert condition that examined whether an emphasis on conscientiousness would positively influence the quality of the participants' survey responses. The alert was preceded by the word "IMPORTANT" in large bold red font, followed by the message "The following is a health survey that relies on your conscientiousness. We ask that you be attentive because your input will strengthen our understanding of an important area of research for the health community. Please also note that not being truthful breaches research (MTurk) guidelines. Thank you. We greatly appreciate your participation."

Trap Questions

The Web-based survey included a total of 26 potential trap questions to measure participant conscientiousness. Participants were first asked to record the current date. They were also asked about family disease history. In a list of diseases, nine trap failures were embedded to check if responders claimed to have been diagnosed with, or had a family member diagnosed with, a fictitious disorder (eg, hyperemblyopia). There were 13 linked trap questions, which are those that are mutually exclusive. For example, if a participant identified his biological sex as "male" and responded "yes" to having been pregnant, trap failure would be noted. Finally, a trap failure would be recorded if participants noted at the beginning of the survey that they had diabetes and then later indicated that they did not, or indicated that they had both type 1 and type 2 diabetes.

Secondary Measures

As part of our cover story, we presented exploratory questions regarding health-related organizational "footprints." These questions measured the participants' knowledge and the perceived visibility of different health organizations. In addition, behavioral and lifestyle risk factors have been shown to be related to the onset of diabetes and heart disease (eg, sedentary living and poor dietary choices). Several studies have shown robust effects such that the perception that one could control disease onset will result in higher levels of perceived responsibility for disease onset, as well as higher ratings of blame [37]. To examine the ability to replicate these findings in the present sample, participants were also randomly assigned to evaluate a vignette that presented individuals with a disease (diabetes or heart disease) reportedly caused by either genetics or lifestyle choices. Using a Likert-type scale ranging from 1 (strongly disagree) to 5 (strongly agree), participants rated their emotional reaction toward the individual (ie, perceived responsibility, anger, and blame).

Results

Study 1

Participant Information

Using the MTurk platform, 4165 responses to the Health Survey were recorded over 6 months. However, initial data analyses revealed that an unusual number of data points had been entered in close temporal proximity from the same IP address. Further examination of this finding prompted a complete shift in the data analysis plan. The sample was abandoned for the original purposes, and we began a new focus on investigating the quality of the resultant data.

Of the original 4165 survey responses, 2667 responses (64.03%) came from individuals who made one attempt to take the survey, but did not meet the qualifications. Two hundred and fifty two individuals (6.05%) met the criteria for inclusion in the study. However, 1246 data points (29.92%) came from duplicate IP addresses. These 1246 data points had been entered by individuals coming from 533 distinct IP addresses (see Table 1). This subgroup of participants attempted to take the survey from two to six times (mean=2.34 attempts).

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Table 1. Number of attempts per distinct IP address.

Number of attempts per IP address	n	Total number of responses
2	400	800
3	101	303
4	19	76
5	11	55
6	2	12
Total	533	1246

Of the 533 participants making repeated attempts, 48.0% (256/533) made multiple attempts reporting diseases other than diabetes. The remaining 277 participants (52.0%, 277/533) reported having diabetes in at least one of their attempts. Most of these participants (n=210) began taking the survey reporting diseases other than diabetes or no disease at all; they were subsequently excluded from the study. However, these participants returned moments later, after multiple attempts, to ultimately indicate that they had diabetes. Of these 210 participants, 185 participants "developed" diabetes within 60 s. A much smaller group (n=13) began the survey by indicating they already had diabetes, but later reported on a subsequent attempt that they did not have diabetes. However, it took much longer for these participants to be "cured" of their diabetes - approximately 3.57 h.

Had we not examined the data for the duplicate IP addresses, we would have simply restricted our sample to those respondents who indicated that they had diabetes on the qualifications page. This method would have resulted in a sample of 559 participants, or 13.42% (559/4165) of the original response pool. With a prevalence rate of 9.3% in the United States [38], 13.42% of the sample reporting diabetes is a larger percentage than one might expect in a national sample. However, this finding would not have been remarkable; it is consistent with the idea that people with diabetes might be drawn to a "Health Survey."

The Remaining 252 Participants

Six percent of the initial pool of 4165 respondents made only a single attempt to take the survey and reported having diabetes (n=252). Demographic information for this subsample can be found in Table 2. Individuals ranged in age from 18-74 (mean=38.93, SD=13.6). With respect to diversity, the sample was predominantly non-Hispanic white, female, married, and had earned at least some college credit.

Disease Misrepresentation

As noted earlier, there were two initial qualifications pages on which participants indicated that they had diabetes and were 18 years of age or older. In addition, when participants provided informed consent, they clicked on a "submit" button to confirm that they were 18 years of age or older, with diabetes. Recall, however, that participants were also prompted about their disease status later in the actual survey with the question, "With which type of diabetes have you been diagnosed?" Of the 252 participants, 61 indicated they had type 1 diabetes (24.2%), 146 had type 2 diabetes (57.9%), 11 individuals did not know which type of diabetes they had (4.4%), and 3 individuals said they did not have diabetes (1.2%). Notably, 12.3% (31/252) of this subsample left this question blank. Therefore, it was necessary to exclude even more assuredly non-conscientious responses. Three people were excluded for indicating on this question that they did not have diabetes. One could also make an effective argument for excluding the 31 individuals (12.3%) who failed to answer this question.

Survey Completion Times

Pre-testing indicated that the survey would take approximately 25 min to complete. The average MTurk survey completion time was 12 min and 40 s (SD=19 min 3 s), ranging from completion in 8 s to 4 h and 45 min. Further analysis of the survey completion times indicated that 19.4% (49/252) completed the survey in less than 5 min. When our research team members were explicitly given instructions to barely skim the survey questions and answer randomly without thinking about their answers, the mean completion time was above 5 min. By all accounts, data from these 49 participants who completed the survey in less than 5 min (at the very minimum) should also be excluded from further analyses.

Fundamentally, in these instances we were examining the conscientious behavior of our participants. The Oxford English Dictionary defines conscientious as: "Wishing to do one's work or duty well and thoroughly." Did the participants take the time to read the material carefully and thoroughly? Did they misrepresent their disease status? It is important to note that the small subsample of 252 individuals comprised participants we could not exclude from the sample for *not* being conscientious in their responses. Given that of these 252 participants, further examination indicated that at least 52 more responses should not be considered for evaluation, we could not, in good conscience, analyze any of the data for our original intent. Clearly, if one is not vigilant with survey design and Web-based parameter settings, the results can be disastrous. Therefore, our second survey was specifically designed to test a means by which to improve the likelihood of conscientious behavior, and to provide a way to detect cheating if it occurred.

Study 2

Types of Trap Failures

Table 3 presents the descriptive data associated with the different types of trap failures. Trap failures were recorded for individuals who entered the incorrect date at the beginning of the survey, or who indicated that they, or a member of their family, had the fictitious disease of "hyperemblyopia." Trap failures were also recorded for sex-specific trap questions (a male who indicated

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that he had been pregnant), as well as for individuals who alternately indicated that they had, and then did not have, diabetes.

Table 2. Demographic characteristics across each of the three samples.

Characteristics	Study 1, n (%); Original Sample	Study 2, n (%); MTurk	Study 2, n (%); Undergraduates
Biological sex			
Male	95 (37.7)	138 (43.7)	67 (22.4)
Female	153 (60.7)	176 (55.7)	232 (77.3)
Did not specify	4 (1.6)	2 (0.6)	1 (0.3)
Race			
Non-Hispanic white	172 (68.3)	244 (77.2)	222 (74.0)
American Indian or Alaska Native	7 (2.8)	2 (0.6%)	3 (1.0)
Asian American, Native Hawaiian, or other Pacific Islander	19 (7.5)	24 (7.6)	21 (7.0)
Hispanic or Latino American	16 (6.3)	12 (3.8)	16 (5.3)
Non-Hispanic black or African American	25 (9.9)	26 (8.2)	17 (5.7)
Other	10 (4.0)	7 (2.2)	18 (6.0)
Did not specify	3 (1.2)	0 (0.0)	3 (1.0)
Marital status			
Single	62 (24.6)	150 (47.5)	291 (97.0)
Married or partnered	119 (47.2)	115 (36.4)	7 (2.4)
Divorced	38 (15.1)	42 (13.3)	1 (0.3)
Separated	6 (2.4)	4 (1.2)	0 (0.0)
Widowed	8 (3.2)	5 (1.6)	0 (0.0)
Did not specify	19 (7.5)	0 (0.0)	1 (0.3)
Educational level			
No High School Diploma	12 (4.8)	3 (0.9)	0 (0.0)
High School Diploma, GED[a] or Equivalent	30 (11.9)	36 (11.4)	72 (24.0)
Some College Credit	85 (33.7)	97 (30.7)	208 (69.3)
Associate's Degree	21 (8.3)	39 (12.3)	11 (3.7)
Bachelor's Degree	62 (24.6)	114 (36.1)	7 (2.4)
Master's Degree	21 (8.3)	22 (7.0)	1 (0.3)
Professional Degree	2 (0.8)	3 (1.0)	0 (0.0)
Doctorate	2 (0.8)	2 (0.6)	0 (0.0)
Omitted	17 (6.8)	0 (0.0)	1 (0.3)
Total number of participants	252	316	300

[a]GED: general education diploma.

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Table 3. Different types of trap failures.

Trap category	Number of failures in MTurk sample	Number of failures in undergraduate sample	Total number of failures
Date (1 question)	19	10	29
Fictitious disorder 9 questions)	0	2	2
Sex-specific (13 questions)	7[a]	2	9
Diabetes (2 questions)	2	0	2
Survey completion time	13	5	18
Total	41	19	60

[a]This represents 3 participants with 1 failure and 2 participants with 2 failures.

Table 4. Percentage of trap failures.

Number of traps failed	MTurk, %	Undergraduate, %	Combined samples, %
0	88.0	95.0	91.4
1	11.1	4.0	7.6
2	0.9	0.7	0.8
3	0.0	0.3	0.2

Survey Completion Times

The time it took for participants to complete the survey was calculated for all items presented *after* the alert statement. The survey pretested at an average of just over 7 min (mean=7 min 14 s). Participant survey completion time ranged from 1 min and 24 s to 1 h 19 min (mean=5 min 39 s, SD=4 min 22 s). Univariate general linear modeling indicated that, on average, participants who received the alert took longer to complete the remainder of the survey (mean=5 min 47 s) than those who did not receive an alert (mean=5 min 32 s), but this difference failed to reach significance: $F_{1,610}$=.40, P=.53, ^{2}=.001, power=.10. Notably, the effect size associated with the alert hovered near zero. On average, MTurk participants completed the survey 1 min and 37 s faster (mean=4 min 47 s) than did the undergraduate sample (mean=6 min 24 s): $F_{1,610}$=16.97, P<.001 ^{2}=.027, power=.98.

For the purposes of trap failure, any person who exceeded three standard deviations above the mean time (18 min 45 s) received a trap failure notation. Given the large standard deviation associated with completion time (SD=4 min 22 s), using a similar three standard deviation rule below the mean was not sufficient and would have permitted the inclusion of a completion time of 0 s. Simply randomly completing the survey without reading the questions or the answers takes more than 2 min. Therefore, any person who took less than 2 min to complete the survey received a trap failure notation.

Trap Failure Rates

There were a total of 26 trap opportunities embedded within the survey (see Tables 3 and 4). Trap failure responses ranged from zero to three trap failures. The modal trap failure response was zero, while the mean was 0.092 (SD=0.32). There were only 60 trap failures in a context where the potential number of trap failures could have exceeded 16,000.

Univariate general linear modeling was then used to examine trap failure rates across the participant sample, biological sex, as well as within the alert statement manipulation. A significant difference emerged between the MTurk and undergraduate samples: $F_{1,604}$=4.33, P=.04, ^{2}=.007, power=.55. Although the overall magnitude of trap failures was actually quite low (mean=0.09), the MTurk sample had approximately twice as many trap failures (mean=0.12) than did the undergraduate sample (mean=0.06).

Moreover, although the presence of an alert resulted in fewer trap failures (mean=0.07) as compared with when no alert was present (mean=0.11), this difference failed to reach significance: $F_{1,604}$=2.5, P=.11, ^{2}=.004, power=.35. In addition, no significant differences emerged across sex, $F_{1,604}$=.62, P=.43, ^{2}=.001, power=.12.

Sample Diversity

Chi-square analyses indicated that, when compared with the MTurk Master Worker sample (see Table 2), the undergraduate sample included more females (χ^2_1=31.9, P<.001), fewer individuals who were married (χ^2_4=188.4, P<.001), and, naturally, fewer individuals who had obtained a Bachelor's degree or higher educational qualification (χ^2_7=189.5, P<.001). The samples did not differ with respect to race (χ^2_6=8.6, P=.20), but the MTurk sample (mean=37.67) was considerably older than the undergraduate sample (mean=19.37; t_{598}=25.36, P<.001).

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Replicating Previous Data Trends

Several other studies have shown robust effects such that the perception that one could control disease onset would result in higher levels of perceived responsibility for disease onset, as well as higher ratings of anger and blame [37]. These findings were fully replicated within the present data. Multivariate general linear modeling revealed that participants who read scenarios in which the target acquired a disease through lifestyle choices rated the target higher in responsibility, anger, and blame (mean=3.15, 2.01, and 2.76, respectively) when compared with ratings for targets who were said to have acquired their disease through a genetic contribution (mean=1.44, 1.26, and 1.34, respectively): $F_{3, 596}$=183.77, P<.001, ^{2}=.48, power=1.0. These ratings did not differ across sample, were not influenced by the presence of an alert, nor were they influenced by the type of disease presented in the scenario (diabetes or heart disease): $Fs_{3, 596}$<1.78, Ps>.15, ^{2}<.009, power<.46.

Discussion

Study 1

We utilized MTurk to attract a very specific type of respondent; indeed, the data was gathered simply, effortlessly, and at an affordable total cost. However, with the initial discovery that nearly one-third of the responses represented duplicate IP addresses, the focus of the study was re-directed towards examining the quality of the Workers' responses.

The Quality of Our MTurk Data

The survey had been launched without restricting it from being completed by two or more people at the same IP address. The justifications for this decision were as follows: (1) If more than one individual with diabetes resided at a particular household, we wanted the survey to be open to all members of the household, and (2) This was a 25-min survey paying only US $0.25.

With this in mind, lying about having diabetes for US $0.25 did not seem to be an advantageous decision. With respect to subversive activities, Berinsky et al use the same logic to suggest that "given the relatively low pay rate of our studies and the availability of other paid work, we do not believe our work is likely to encourage such behavior" [19]. Yet the sheer number of individuals who entered our study using duplicate IP addresses was unexpected, and, in retrospect, naïve. Because these IP addresses were presented within seconds of one another, the most plausible explanation is that these were Workers attempting to get past the qualifications page to receive compensation. It is essential that researchers properly utilize controls to protect against repeated access from a single IP address.

In addition, this particular study paid only US $0.25 for a lengthy survey. It is possible that this amount of money is not sufficient for participants to invest conscientiously in the work [39]. The survey description, however, included the appropriate time estimate for completion. Workers had the opportunity to simply avoid the survey given the explicit expectations, but some may have chosen, instead, to complete the work with low quality. High pay, however, may not mitigate these concerns because Chandler and Paolacci provide evidence that participants were even more likely to try to fraudulently enter a high-paying study (US $1.00) than a low-paying study (US $0.25) [40].

Another red flag was the extremely quick, virtually inhuman survey completion times. Maniaci and Rogge report that, in some types of studies, respondents demonstrating extraordinarily fast reaction times are simply and easily—and routinely—excluded from analyses [31]. In our case, that would be advisable because some of our responses were most likely responses from automated form-filling bots that have been programmed to complete Internet surveys. For example, in our study, 12 respondents logged response times of less than 60 s on a survey that had been pretested at 25 min. Moreover, our research team could not reproduce these speeds even when we tried, even by simply clicking each page without reading any portion of it. As a result of our experience, we believe it is essential for researchers to report survey completion time data as a perfunctory part of the publication process. In addition, adding a "CAPTCHA" would also be a recommended practice because it protects against bots by generating tests that humans, but not computer programs, can accomplish.

The subsample of 252 was comprised of participants we could not exclude from the sample for *not* being conscientious; however, it did not allow us to conclude that they *were* conscientious in their responses. Nor did it allow us to conclude that they were actually diagnosed with diabetes, despite their answers on the initial qualifications page. For example, some research suggests that the use of qualifications pages at the beginning of a survey is not optimal to study design. Chandler and Paolacci provide evidence that explicitly prescreening conditions can substantially increase fraudulent reports in an attempt to meet study qualifications [40]. The authors believe that the prescreen practice may lend researchers to be overly confident that the respondent is honestly reporting a particular characteristic or condition (eg, race or diabetes). These data are disturbing given that the basis for the interpretation of entire projects can rest on the supposition that a respondent possesses certain specific characteristics [25]. Chandler and Paolacci contend that these types of responses "create an obvious validity problem and may lead to erroneous conclusions about the population of interest" [40].

Instead, Chandler and Paolacci propose a pre-screen survey. Those individuals who acknowledge particular characteristics important to the study design in the initial pre-screen survey could then be invited back to the actual survey. Notably, Chandler and Paolacci believe that this could have the added benefit of enabling the recruitment of a more diverse pool of respondents [40].

Nonetheless, we must openly acknowledge that recommending that we must restrict duplicate IP addresses, that we cannot be confident that participants will be honest when answering qualification questions, that we should not use obvious screens, or that we must cross a particular threshold of monetary payments to get high-quality data affirms an underlying assumption that a substantial portion of MTurk Workers cannot

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be trusted to produce honest, high-quality data. Ipeirotis provides evidence that the majority of US MTurk Workers do not participate because the tasks are fun [41]; instead, 12% use it as a primary source of income, and money earned on MTurk is "...at least relevant to the vast majority of MTurk Workers" [17].

The Diversity of Our MTurk Data

Participant diversity was essential to the conduct of the present study. If we limit our attention to the 252 respondents that could not, a priori, be excluded from consideration, we find that the demographic composition is roughly similar to that reported in other MTurk samples. We report that 60.7% (153/252) were female, whereas Berinsky et al found that 60.1% were female [19]. Berinsky et al reported a mean age of 32.3 years, whereas our sample averaged nearly 39 years. A large portion of our sample reported being married (47.2%; 119/252). Berinsky et al reported that large percentages of MTurk Workers report never having been married and that they currently rent the home they are living in; however, we would also expect to see that trend in a college student sample.

With respect to the self-report of race or ethnicity, 83.5% of the Berinsky et al sample was white [19], whereas 68.3% (172/252) of our sample identified as Non-Hispanic white. The samples were comparable with respect to the proportion of Hispanic individuals, but our sample reported more than twice as many African Americans as Berinsky et al (9.9% vs 4.4%).

Ultimately, as we continue to applaud MTurk for its ability to secure a diverse sample, it is important to make a clear distinction between whether a sample is more diverse than some standard (eg, a college student population or adult convenience sample) and whether it meets the criteria for what would constitute a diverse sample in and of itself. For example, Behrend et al report a significant chi-square difference between their MTurk and undergraduate samples in terms of ethnicity [21]. Rather than being actually more diverse, one interpretation might be that the crowdsourced sample appears instead to be differently diverse, with more Hispanics but fewer African-Americans. The authors highlight that both samples are, nonetheless, predominantly Caucasian (82.20% and 79.78%, respectively). Likewise, in the current sample, we ultimately obtained data on only 77 individuals across several racial categories. We certainly did not meet any reasonable standard for what would constitute a truly diverse sample.

Summary

As problematic as these data were, they highlighted a very important question: Are there other researchers out there who have made similar mistakes? This could suggest two important potential outcomes: (1) Perhaps those Web-based responses made it through the publication process, or (2) Perhaps there are a lot of "file drawer" research studies out there that have quietly produced poor quality Web-based data, which is a methodological issue that needs to be openly discussed, debated, and formally addressed. This effort prompted the question: How can we *know* if our data is of sufficiently high quality unless we methodically test for it?

Study 2

Clearly, as indicated in Study 1, if one is not vigilant with survey design and Web-based parameter settings, the results can be disastrous. Our second survey was specifically designed to test a means by which to increase the likelihood of conscientious behavior, to provide a way to detect cheating if it occurred, and ultimately, to encourage the purposeful reporting of such information by researchers during the journal review process. There are a number of techniques that help in keeping unconscientious responders out of surveys. For example, MTurk provides the opportunity to set high approval ratings and restrict samples to individuals who have completed a large number of successful HITs. Our first study was restricted to individuals who had a 90% approval rating or better, while our second study was restricted to elite Master Workers with an approval rating of at least 95%. Restricting to Master Workers, however, severely limits the pool numbers and, by its very nature, would likely result in a more homogenous group; this technique would further limit generalizability. Thus, some researchers simply use a 95% or greater approval rating, without the application of the Master Worker designation [40].

However, one must consider the accuracy and utility of approval ratings. Approval ratings must be used carefully. If you approve a Worker's submission, the Worker gets paid. If you reject the Worker's submission, payment is not made. Given Institutional Review Board protocols for conducting research with human subjects, it is likely that approval ratings are artificially inflated by some social science research projects. For example, it is quite common for research participants to be told that they may choose to skip questions they feel uncomfortable answering. At the same time, it would then be unethical for a researcher to reject a Worker's submission for not being complete. While this may be irrelevant to individuals using MTurk for "work," this is particularly tricky if you are conducting research on a sensitive health topic. The way around this, of course, is to present a consent form that fully and clearly articulates that (1) the Worker must answer every question in order to receive compensation and (2) a person will not receive compensation unless he or she answers each question adequately. It is likely that this practice could discourage respondents from participation. In support of the idea that approval ratings may be inflated, Kumar initially suggested using Workers with an approval rating greater than 95%, but less than one year later had increased his recommendation to greater than 98% [42].

Alternatively, one could improve data quality by improving conscientious responding *during* the administration. With this in mind, we empirically tested whether an alert would improve conscientious behavior. Not only did our alert have no impact on conscientious responding, the effect size was functionally zero. This outcome is potentially the byproduct of a ceiling effect of our highly conscientious sample; nonetheless, the present data suggest that an alert may not be the answer.

Finally, one can work to assure data quality *after the fact* by including traps to test for conscientious responding. We found that, although MTurk Master Workers were more likely to fail traps than the undergraduate sample, overall trap failure rates were remarkably low. We do not want to lose sight of what we

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believe to be exceptional performance on our survey by emphasizing that there were only 60 trap failures in a context where the potential number of trap failures could have exceeded 16,000. And, in fact, we were able to fully replicate an established finding in psychosocial health research.

One can also examine how long it took the respondents to complete the survey in comparison to a pre-testing standard [43]. One could exclude the responses from all participants who exceed three standard deviations from the mean completion time, as was done in the present study. However, speed is not a singularly effective determinant of unconscientious responders. Those who are unconscientious "speeders" could potentially manipulate their overall response time simply by spending some amount of time idling. Respondents could also be exposed to distractions such as phone calls or text messages that would affect response time. In addition, Clifford and Jerit provide evidence that respondent motives can significantly affect response time, which makes it difficult to determine the meaning that should be attached to response time [29]. Their data revealed a positive correlation between cheating and response time; students who were self-reported cheaters spent longer answering questions. Thus, unreasonably fast speeds could reflect a respondent not paying attention, while unreasonably slow speeds could be consistent with the idea that cheating was a function of searching outside sources for a "correct" answer to a knowledge question. Our study also showed that we can expect MTurk respondents to be significantly faster in completing a Web-based survey. This is likely due to their extensive experience with this medium. It certainly is a difficult balancing act when considering response time, given that faster speeds in an MTurk respondent result in financial gain.

Perhaps comprehensive examples for trap measures ought to be developed for researchers to implement in their Web-based surveys. For example, a trap question might ask the participant to select the word "cat" from a list of response options. In this case, it is not an attention check because the participant could continue to subsequent questions even if they answer incorrectly, but the researcher would know that the participant had not read the question carefully. However, even this recommendation that trap questions be routinely utilized within surveys may not necessarily assure conscientious responses. MTurk users are sophisticated and would quickly become aware of any specific trap questions that were recommended [25]. In fact, MTurk blogs exist where MTurk users routinely compare information about HITs; in this community, word can spread quickly. Most importantly, our embedded traps were specifically designed to camouflage within the cover story of our research. These questions were not salient, and this continues to be a very desirable design feature. Because this was a study, in part, about trap questions, a total of 26 potential traps were included. While we do not suggest that there is a need for that many trap questions in subsequent studies, we would suggest that at least some trap questions be included in every survey, and that they be fully and carefully camouflaged during the survey design phase.

When a survey response is flagged as being of poor quality, the data analysts must decide whether to keep or delete the data. Measuring response accuracy ultimately leads to a discussion on what to do with the data after poor-quality responses have been identified. Casler et al suggest that "...with thoughtful and creative manipulation checks in place, researchers usually can discard participants who have not taken the task seriously or who had insufficient skills to complete it correctly" [44]. This is not a universally accepted proposition as Chandler et al contend that researchers are overzealous when excluding participants [45]. Moreover, Oppenheimer et al, as well as Berinsky et al offer an interesting perspective by suggesting that removing inattentive performers skews the sample by removing a certain type of person [46,47]. For example, if people who are more educated pay more attention and pass more screens, then the resultant sample will be biased in favor of more educated respondents, potentially influencing validity. Thus, the paring down of a sample by discarding "certain" participants would seem to be a very slippery slope. Who, exactly, should be deleted, and how many participants can be deleted for viable use of a dataset? We do not pretend to offer a definitive solution, but we do believe that at least a reporting of this information should be a perfunctory part of the review process.

Limitations

Sample Diversity

We started this investigation with an attempt to achieve sample diversity. Compared to the MTurk sample, the undergraduate sample included more females, fewer individuals who were married, and, naturally, fewer individuals who had obtained a Bachelor's degree or higher. The samples did not differ with respect to race. Overall, out of the 616 total participants recruited over a span of 15 weeks, only 121 self-reported a race other than Non-Hispanic white.

To mitigate health disparities, it is essential to study diverse samples. Some researchers suggest that one way to increase diversity representation in Web-based samples is to screen a large pool of MTurk Workers and then select a subset of participants who match desired sample characteristics [19]. Because of issues associated with access to computers and the Internet, however, this method will still ignore those of lower socioeconomic status that we often want as participants in health research. While MTurk samples may be ideal for work and specific types of research questions, these samples may not impact our ability to make a meaningful contribution to understanding how to reduce health disparities.

In essence, it does not appear, in any rendition, that our diversity goals were met. While published reports laud MTurk for its ability to foster a diverse sample, our studies highlight that while the sample could potentially be more diverse than a standard college student sample, our efforts did not lend themselves to meeting the criteria for what would constitute a diverse sample in and of itself. Our two studies provide support for continuing a meaningful mutualistic environment and presence in, for example, community centers and churches. Ultimately, improving open access to a wide range of study participants and funding cost-effective and cooperative efforts for a variety of health-relevant studies are ways to mitigate health disparities.

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Recommendations

Above all, our recommendation is not to be complacent. With respect to diversity, it is imperative to find ways to expand minority recruitment efforts even in an Internet environment. With respect to data quality, we suggest that every posted survey include traps. Attention checks alone are not sufficient—they would serve as reminders during the survey administration, but would not assist in assessing the quality of the resultant responses. Notably, some researchers suggest that questions with factual answers should be avoided in the survey design phase, arguing that participants may be more likely to use the Internet to search for correct answers [32]. However, routinely avoiding factual answers would be a costly mistake because, by definition, we would be unable to *ever* assess the quality of the resultant data. Ultimately, in any self-report format, it is difficult to be certain that your participants have been conscientious in their responses. This is particularly the case with Web-based surveys, where a certain degree of trust is implicit in every administration. Of course, the same criticism would be made about any self-report measure, even if the participant is in the same room with the researcher.

Conclusions

Published studies in the health domain are rapidly appearing that utilize MTurk participants. Some report the qualifications that were imposed on the participants during data collection or the quality control checks that were applied to the resultant data [48,49]. Others present insufficient detail or no information at all [50,51]. As a result, the reader does not know whether sufficient standards were applied and not reported, or not applied at all. Because some researchers have clearly experienced successful data collection on MTurk, while others report disastrous results, Kees et al recently identified that one essential area of research is the continued investigation of the types and magnitude of cheating behavior occurring on Web-based platforms [24]. These studies can contribute to this dialogue, and they alternately provide evidence of disaster and success. As a result of our experience, however, we would strongly suggest that standards be in place for publishing the results of Web-based surveys of health-relevant data, as an expanded version of the CHERRIES Checklist [52]. These standards should protect against publication of surveys that do not include suitable quality assurance tests built into the survey design, distribution, and analysis. We would recommend that specific information be reported, including the settings for the hosting platform, any filters that were applied, as well as the specific qualifications of the Worker. How much incentive was provided? And how did participants respond to embedded trap questions? It is essential that we create strict protocols for reporting quality checks of all data collected through Web-based research. Health-relevant research, in particular, cannot risk conclusions built on faulty data, and this should not be a file-drawer problem. We must scrutinize Web-based methodological techniques as we would any other paradigm.

Conflicts of Interest

None declared.

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Abbreviations

AMT: Amazon Mechanical Turk
HIT: Human Intelligence Task
IP: Internet Protocol
MTurk: Amazon Mechanical Turk
NSSE: National Survey of Student Engagement

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Viewpoint

Addressing Disparities in Diabetes Management Through Novel Approaches to Encourage Technology Adoption and Use

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Abstract

Type 2 diabetes (T2D) is one of the nation's leading drivers of disability and health care utilization, with elevated prevalence among individuals with lower education, income, and racial/ethnic minorities. Health information technology (HIT) holds vast potential for helping patients, providers, and payers to address T2D and the skyrocketing rates of chronic illness and associated health care costs. Patient portals to electronic health records (EHRs) serve as a gateway to consumer use of HIT. We found that disparities in portal use portend growing T2D disparities. Little progress has been made in addressing identified barriers to technology adoption, especially among populations with elevated risk of T2D. Patients often lack digital literacy skills and continuous connectivity and fear loss of the relationship with providers. Providers may experience structural disincentives to promoting patient use of HIT and apply hidden biases that inhibit portal use. Health care systems often provide inadequate training to patients and providers in use of HIT, and lack resources devoted to obtaining and optimizing use of data generated by HIT. Lastly, technology-related barriers include inadequate consideration of user perspectives, lack of evidence for patient-focused apps, and lack of features to enable providers and health care systems to readily obtain aggregate data to improve care and facilitate research. After discussing these barriers in detail, we propose possible solutions and areas where further research is needed to ensure that individuals and health care systems obtain the full benefit of the nation's planned $38 billion HIT investment. A digital inclusion framework sheds new light on barriers posed for patients with social health inequalities. We have determined that partnerships with community organizations focused on digital inclusion could help health systems explore and study new approaches, such as universal screening and referral of patients for digital skills, health literacy, and Internet connectivity.

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KEYWORDS

diabetes; chronic illness; vulnerable populations; digital divide; community health workers; healthcare disparities; patient portals; patient engagement; meaningful use; health literacy

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Introduction

The Promise of Health Information Technology for Type 2 Diabetes Management

More than 29 million adults have type 2 diabetes (T2D), with prevalence elevated among Hispanics (12.8%), blacks (13.2%), and individuals with less than a high school education (13.6%) versus some college (7.8%) and whites (7.6%) [1]. Medication, diet, and physical activity can limit the health consequences of T2D [2,3], but recommended targets for blood sugar, lipids, and blood pressure control are met by only about one-half of those affected [4].

Responding to federal financial incentives [5,6], physicians rapidly adopted electronic health records (EHRs) between 2009 and 2015, making portals available for 65% of patients to view their records [7]. Serving as persuasive technology [8], portals offer significant potential for improving medical management of chronic diseases. Portals also open the door to telehealth and to remote monitoring of data from connected devices such as glucose monitors [9]. Remote glucose monitoring saves California Medicaid $939 yearly per diabetic patient. Nearly every state Medicaid program now covers some telehealth and about one-half reimburse for remote monitoring [10]. Barriers to technology adoption among populations facing social health inequalities (SHIs) [11], however, are not being addressed and research is not keeping pace.

Digital Inclusion Perspective on Health Information Technology

MetroHealth System in Cleveland, Ohio, was the nation's first public hospital to adopt EHRs (1999-2002) [12]. In 2015, MetroHealth received a national award for improving care while returning nearly $8 million on its health information technology (HIT) investment [13]. Nevertheless, similar to adoption rates reported elsewhere [14-16], only 29.1% (70,835/243,248) of MetroHealth adult patients have logged in to their portal accounts. Use lags for blacks (23.4%) and Hispanics (23.8%) and for those without commercial insurance (39.3%) [17]. Many patient barriers to portal adoption [18] are also associated with the digital divide.

Based on engagement with the digital inclusion movement, we offer this Viewpoint to illuminate HIT adoption barriers faced by those with reduced digital skills and health literacy and those who lack always-on smartphones and ample data plans. Digital inclusion refers to "the activities necessary to ensure that all individuals and communities, including the most disadvantaged, have access to and use of information and communication technologies" [19]. We suggest new approaches to addressing HIT-related disparities in hopes of defying the inverse care law [20].

Findings

Patient-Related Barriers to Health Information Technology Adoption

Some leading barriers to adoption among patients include inadequate Internet access, digital skills, and eHealth literacy and concerns about diminution of the relationship with the provider. General technology adoption among SHI populations is a prerequisite for HIT adoption. Differences in residential access to broadband explained 68% of portal use variation among MetroHealth patients [17]. Lack of computer skills and Internet access have been identified by others as barriers to portal use [21-24].

Nationally, census data show that home broadband Internet subscriptions are considerably less prevalent among seniors (67.0%), blacks (69.7%), Hispanics (74.5%), and those with annual income less than $20,000 (48.8%) compared with all households (80.8%) [25]. Smartphone adoption is growing rapidly but gaps remain for those over 65 years (47.1%), with less than high school (50.9%) and high school (62.8%) education, with a disability (51.4%), and living in poverty (60.2%) compared with 74.8% ownership for all individuals age 15 years and older. Ownership among Hispanics (75.8%) slightly exceeds that for whites (74.6%); blacks lag only slightly (70.3%) [26].

Smartphone access to portals is new and not widespread [17,27], but apps are sometimes easier to use than Web-based services. However, mobile Internet is generally slower and more expensive than fixed broadband. Dependency on smartphones for Internet is now seen among 13.9% to 18.5% of SHI groups versus 7.9% of all adults [26]. About half of smartphone-dependent individuals report needing to disconnect service at times [28]. Among low-income mobile broadband subscribers, 30% exceed their data caps every month, resulting in service interruption (21%), slowed speeds (24%), or costly fees (27%) [29]. Data disruptions are especially problematic for enabling patients to address underlying social determinants of health in light of Internet-based job applications, government benefits management, coursework requirements, and the like. Computers offer large screens and keyboards that are easier for typing and searching. Fixed broadband connections are typically fast, secure, and include ample data. However, 59% of nonusers cite cost as the leading barrier to adoption [30]. Having both mobile and fixed connectivity optimizes convenience and productivity but is an unaffordable luxury to many.

Cellular phones (smart or not) are replacing landlines, especially among adults living in poverty, those younger than 44 years, and Hispanics. Cost-related cellular service interruptions are particularly disruptive to mobile-only households. Portals provide a vital connection with health care providers for those in a state of "dependable instability" of mobile communications [31].

Some evidence shows benefits from home monitoring of glucose, blood pressure, and weight [32]. However, only 20% of invited participants agreed to join a study in England of telehealth with regular transmission of physiologic information; concerns about operating the technology were an important barrier [33].

A systematic review of adherence-focused mobile apps found improvements in diabetes-specific clinical outcomes in 11 of 26 randomized trials [34]. Use of health-related smartphone apps is prevalent although user characteristics are inconsistent across surveys [35,36]. Portal adoption is strongly predicted by

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eHealth literacy [16,37,38], the ability to obtain and use health information from digital devices [39,40]. More common among those age 65 years and older, blacks and Hispanics, and individuals with low income and education [41], lower health literacy is associated with requiring more assistance and time to perform standard portal tasks [42].

MetroHealth patients had small differences by race or type of insurance in viewing lab results but larger differences using functions that required composition such as requesting advice and responding to messages. Patients were less likely to send messages if black, Hispanic, not commercially insured, less educated, or with less access to broadband [17]. SHI disparities in messaging frequency have also been reported [15,16].

Diabetic patients [43] and black and Latino portal nonusers [44] revealed in surveys and focus groups fears that portals would undermine relationships with providers or reduce valued human contact. Others reported fears about portal use invoking government surveillance and deportation [45].

Provider- and Health Care System–Related Barriers to Health Information Technology Adoption

Providers may encounter structural disincentives or act on biases that inhibit patient use of HIT. Provider endorsement is important for portal adoption among diabetic [21] and other patients [16]. However, providers may withhold portal promotion fearing income loss from reduced clinical visits [46,47] or lacking time [34] or compensation [45] for responding to messages.

About 40% of adult MetroHealth patients had established portal accounts by 2015 [13], but only 29.1% (70,835/243,248) had ever logged in [17]. This gap has been reported elsewhere [14,48,49], perhaps reflecting an observation from a safety net facility study: "The assumption built into the [Meaningful Use] metric is that providing patients with instructions is sufficient to convert them into active portal users. Therefore, outreach strategies often emphasized enrolling as many patients as possible" [45].

Provider bias in recommending portals has received little attention. According to results of a national survey, the odds of a provider offering portal access were only 0.59 for blacks (CI 0.42-0.84) versus whites and 0.47 for Hispanics (CI 0.32-0.68) versus non-Hispanics [50]. Similar findings were reported among federally qualified health center patients [22].

Portal recommendations may reflect provider assumptions about whether patients have digital skills or value connectivity. Reminiscent of historic discriminatory lending practices [51], Callahan and the National Digital Inclusion Alliance recently documented "digital redlining" by the predominant Internet Service Provider in Cleveland, who "withheld fiber-enhanced broadband improvements" from areas with high concentrations of black and low-income residents [52]. This pattern was also reported for the entire state of California [53]. Thus, patients facing SHIs may lack the option of home broadband at any price.

Among nearly 50,000 patients with T2D seen at health systems participating in the Better Health Partnership regional health quality improvement collaborative (for which Bolen serves as the Director of Cardiovascular Disease Programs), careful analysis of aggregate EHR data led to improvements and reduced disparities in care and outcomes [54]. Yet health care systems may lack resources that enable optimal use of the EHR for such purposes or for direct patient engagement. Expanded portal use could generate data that would add value to EHR data, especially when typologies of portal usage patterns are applied [55].

Technology Barriers

HIT developers have been long criticized for lack of user-friendly design [56,57]. Usability issues were the main reason for nonuse of HIT among low-income racial and ethnic minorities [58]. Little has been written about how health systems support patient use of portals, suggesting that little help is being offered. Portal research study publications usually note that instruction was provided by clinicians or research assistants; such individuals are unlikely to have expertise in digital skills training. Password management and recovery is challenging for those with lower digital literacy [43] and "even for extremely experienced users with a high degree of savvy regarding new technologies" [58]. Safety net patients who were regular Internet users had difficulty registering for the Diabetes Prevention Program mobile app because they "rarely checked email and some participants did not have email accounts, requiring help to set up new ones." Patients with fewer computer skills had fundamental difficulties navigating an online form, such as knowing how to enter a Web address or skip a question [59]. Patients reliant on public Wi-Fi or shared phones are especially concerned about account security [43,60].

Much consumer-focused HIT, including patient portals, has been introduced with limited evidence of effectiveness. Regarding diabetes-specific outcomes, a 2014 review found consistent improvements in hemoglobin A_{1c} levels but not in other biomarkers [61]. In another study, individuals randomized to use wearable activity trackers and a Web interface to monitor diet lost *less* weight than those in the control arm [62]. Nonetheless, some evidence shows that with heavy utilization portals can have an impact on SHI populations [63,64].

Solutions

Low-cost smartphones, Internet access programs, and free digital skills training are now widely available [65], offering an unprecedented opportunity to address key portal use barriers. Four actions to reduce SHIs through eHealth have been suggested: promote universal access to eHealth technology, consider patient literacy level, consider cultural factors, and engage populations at risk of SHIs with eHealth design [11]. We offer additional suggestions for expanding HIT adoption.

The MetroHealth Patient Centered Media Lab team is testing having physicians issue prescriptions for portal adoption and offering training for the portal smartphone app. Elsewhere, a portal opt-out approach enabled community health centers to reduce racial disparities in repeat portal use [66]. To go even further, we suggest screening all patients for digital skills (with a checklist, hands-on demo, or free online tools) [67,68]; health

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literacy (with a single question) [69,70]; and connectivity (using standard survey questions) [30,71,72]. Or patients could simply be asked about their interest in low-cost desktop, tablet, and mobile equipment and broadband or mobile data and referred to local partners for assistance. The Centers for Medicare and Medicaid Services funded the United Way of Greater Cleveland and several other communities to screen patients for certain barriers to health such as lack of funds for transportation and utilities and refer them to community organizations for support [73,74]. Screening for Internet access and then referring clients to community partners for skills training and connectivity would be a valuable augmentation to this new initiative.

As part of a national program [75,76], Callahan engaged community organizations in several cities (from 2010 to 2012) to equip, train, and connect 21,000 low-income residents who lacked computers or home Internet. Training and connectivity support were transformative for many [77,78], and we are now referring patients to that initiative's Cleveland-area partners for skills training and connectivity support. Patients may be eligible for free or reduced-cost equipment and service through federal, state (including Medicaid), and commercial programs [65,79,80]. (Plans with unlimited data are especially valuable versus ones with low data caps [29]). Similar partnerships are underway in just a few other cities [81-85]. However, integration of clinical and community systems is now seen as essential for treating obesity and related chronic diseases [86]. Community Reinvestment Act funds invested by local banks in communities to redress the legacy of discriminatory lending from the 1930s to the 1970s could be leveraged to expand broadband access and skills training [87].

Consumer-focused software should not require instruction. However, between digital skill and health literacy gaps and technology shortcomings, portal training is essential for increased adoption, reduced disparities, and increased impact on health. Instruction time will vary from 15 minutes among eHealth literate individuals [83,88,89] to many hours for patients with such conditions as serious mental illness [90]. Portal training could be tailored based on digital skill and health literacy assessments; options include on-line, tutor-facilitated, individual, and group classes [82]. Portal training should use evidence- or theory-based techniques geared to the pivotal moments in the learning progression, from fear to mastery [91].

Tieu [42] identifies 5 key portal functions on which patients should be trained: logging in, viewing visit summaries, viewing prescribed health education information, viewing test results, and looking up information in a connected online library. Those with low numeracy may need assistance interpreting laboratory results [92]. Dictation and autocomplete [60] plus template messages could help with tasks requiring composition. Portal training should address concerns around authentication and password management, data security, loss of the personal relationship with the provider, and fear of deportation [45] as expressed by persons with SHIs.

In preparation for expanding referrals of patients to the portal, we are training community health workers to perform digital skills assessments and some portal training; others are using technology navigators for similar purposes [48]. Clinical and digital skills training content should be provided by individuals with the relevant expertise. Family caregivers represent a largely untapped resource to help patients bridge digital skill and connectivity gaps, albeit raising privacy concerns [93].

Discussion

Further Research and Development

To accelerate health improvement and reduced disparities through HIT, better technology and intervention studies are needed. Extracting the full value from rich EHR and portal data requires dedicated, trained staff [94]. Their jobs could be made much easier if software makers included tools for such purposes.

Mobile access could increase portal use, but there has been little uptake at our own or other institutions [17,27]. Portal instructions and health information should be presented at patients' reading level, with ready access to more detailed or simplified information. Movies, illustrations, and graphs are especially useful for those with lower literacy or language barriers [18]. Portal adoption interventions must be developed and tested. The Network of Digital Evidence in Health (NODE Health) is applying evidence-based medicine rigor to address the current void in much digital health technology [95]. As a NODE Health consortium member, Sheon seeks to ensure [96] that overlooked SHI perspectives [97] are considered in assessment of digital health efficacy [98].

Patient input to technology development benefits both underserved and advantaged patients [58]. Inclusion of technology novices is especially important for usability testing [57]. One project paid "citizen scientists" for helping to create a diabetes mobile app [99]; SHI patients may need such funds to participate. For patient convenience, treatment recommendations that are shared among comorbidities, such as physical activity for T2D and depression, could be addressed in a single app or portal feature [57]. In the Patient Centered Media Lab, Perzynski [100] engages patients in designing and deploying HIT apps such as an augmented reality exercise game to prevent T2D. Perzynski and Shick [101] have created a single-click app that displays social and environmental determinants of health specific to a patient's residential address plus links to community support to address these issues.

Finally, mobile phone ownership is almost universal in the United States with disparities nearly closed [102]. Short message service (text) messaging improves insulin titration [103] and medication adherence for chronic diseases [104]. Text messages require only a cellular phone and do not require a data plan and should thus be considered for interventions.

Conclusion

A digital inclusion lens reveals digital skill and connectivity barriers that must be addressed to avoid widening T2D disparities. Health care systems should partner with local digital inclusion advocates to screen and help patients obtain low-cost Internet service, equipment, and basic digital skills training. These are essential for portal training to be efficient and effective. Portal training should be informed by those with expertise in digital skills and health literacy acquisition. Paraprofessionals such as community health workers could be

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trained accordingly to assume some of these responsibilities at a relatively low cost. Research on the cost effectiveness and impact of these novel approaches should lead to support for broad dissemination, if not insurance reimbursement.

Acknowledgments

Shari Bolen wrote the first draft of the manuscript with other authors contributing equally. Amy Sheon led a major revision and took over as the lead author. The other authors contributed equally to the revision.

Conflicts of Interest

Dr Sheon is the founder and CEO of Public Health Innovations, LLC, advising clients on using innovation to improve public or population health. Mr Callahan is an employee or paid consultant for organizations which advocate, facilitate, or provide digital skills training, training in use of patient portals, and support for low-income households to attain Internet connectivity. Philanthropic support for these activities may be affected by matters discussed in the manuscript. Dr Perzynski is cofounder of Global Health Metrics, LLC, a company that produces health risk assessment software, and created HealthStead.org. Callahan, Sheon, and Perzynski volunteer as President, Secretary, and Member of the Board of Connect Your Community Institute, a nonprofit organization promoting digital inclusion in northeast Ohio.

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Abbreviations

eHealth: electronic health
EHR: electronic health record
HIT: health information technology
NODE Health: Network for Digital Evidence in Health
SHI: social health inequalities
T2D: type 2 diabetes

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Review

Functionality, Implementation, Impact, and the Role of Health Literacy in Mobile Phone Apps for Gestational Diabetes: Scoping Review

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Abstract

Background: The increasing ownership of mobile phones and advances in hardware and software position these devices as cost-effective personalized tools for health promotion and management among women with gestational diabetes mellitus (GDM). Numerous mobile phone apps are available online; however, to our knowledge, no review has documented how these apps are developed and evaluated in relation to GDM.

Objective: The objective of our review was to answer the following 2 research questions: (1) What is known from the existing literature about the availability, functionality, and effectiveness of mobile phone apps on GDM prevention and management? (2) What is the role of health literacy in these apps?

Methods: We searched 7 relevant electronic databases for original research documents using terms related to mobile phone apps, GDM, and health literacy. We thematically categorized selected articles using a framework adapted from Arksey and O'Malley.

Results: We included 12 articles related to 7 apps or systems in the final analysis. We classified articles around 2 themes: (1) description of the development, feasibility, or usability of the apps or systems, and (2) trial protocols. The degree of personalization varied among the apps for GDM, and decision support systems can be used to generate time-efficient personalized feedback for both patients and health care providers. Health literacy was considered during the development or measured as an outcome by some apps.

Conclusions: There is a limited body of research on mobile phone apps in relation to GDM prevention and management. Mobile phone apps can provide time- and cost-efficient personalized interventions for GDM. Several randomized controlled trials have been launched recently to evaluate the effectiveness of the apps. Consideration of health literacy should be improved when developing features of the apps.

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KEYWORDS

gestational diabetes; mobile app; health literacy; smartphone; scoping review

Introduction

Gestational diabetes mellitus (GDM) is diagnosed in the second or third trimester of pregnancy and is differentiated from type 1 (T1DM) and type 2 diabetes mellitus (T2DM) [1]. GDM affects 5.8% to 12.9% of women worldwide [2] and 9.2% of women in the United States on average [3]. Women with GDM are more likely than nondiabetic women to experience cesarean

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delivery, preeclampsia, and T2DM after delivery, and babies of GDM mothers have a higher risk of macrosomia, shoulder dystocia, birth injuries, hypoglycemia, and hyperbilirubinemia compared with those of nondiabetic mothers [4-6].

Epidemiologic studies have shown that modifiable risk factors such as prepregnancy body weight, recreational physical activity before and during pregnancy, and dietary patterns before pregnancy may be related to GDM risk [7]. GDM prevention efforts related to weight control and healthy lifestyle can potentially decrease risks of adverse outcomes for mothers and their children [8,9]. For up to 85% of women who already have a diagnosis of GDM, lifestyle changes may be sufficient to manage the disease, while oral metformin or insulin therapy might be needed for others [10]. Women with mild GDM who received dietary intervention, self-monitoring of blood glucose (BG), and insulin therapy had significantly lower risks of macrosomia (5.9% vs 14.3%, $P<.001$), shoulder dystocia, cesarean delivery (26.9% vs 33.8%, $P=.02$), and preeclampsia or gestational hypertension (8.6% vs 13.6, $P=.01$) than those who received standard care in a randomized controlled trial (RCT) of 958 women [11].

Mobile phones have portability, constant Internet connectivity, and increasing capacity to run complex apps, which makes them ideal tools in health services to collect personal information, provide personalized intervention, and potentially save time and cost as compared with standard health care [12,13]. Mobile phone apps are showing a positive impact on T1DM and T2DM self-management in the past two decades [14]. As self-management is critical for all diabetes patients, women with GDM may be highly motivated to adopt GDM self-management regimens, since they are concerned with possible complications of the disease affecting their baby [15,16]. Health-conscious pregnant women are likely to view apps and social media sites as a means to improve and monitor their pregnancy, their personal health, and their child's development and health [17]. Although GDM apps are widely available on online app stores, few published articles have described these apps, and we know of no review of mobile phone apps for GDM being published to date.

Being diabetic during pregnancy is challenging and can create high levels of stress and anxiety. Women with GDM need to access information about the disease, make adjustments to their lifestyle habits, learn to monitor their BG, and potentially learn to administer insulin or other medication in a very short period—usually 12 to 16 weeks from diagnosis to delivery [18]. There is evidence to suggest that health literacy (defined as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions [19]) is specifically associated with diabetes management. Indeed, T2DM patients with lower health literacy levels have less diabetes-related knowledge [20] and are less engaged in mobile- and Web-delivered self-care interventions [21]. Furthermore, more engagement with these interventions is correlated with better glycemic control [21]. Among women whose pregnancies were complicated with diabetes (pregestational diabetes or GDM), health literacy was associated with patient-provider communication and risks that may cause adverse pregnancy outcomes, such as not taking a folic acid supplement [22,23]. Health literacy levels also confound the delivery of care from providers to GDM patients, especially among women from a disadvantaged background. Low literacy has been shown to have a significantly negative impact on women's understanding of GDM information and their ability to engage in a dialogue with health providers about their care. Low literacy also increases the communication challenges for diabetes educators who are working with these women [24]. Level of knowledge about GDM is significantly associated with glycemic control [25]. Literacy-appropriate and culturally appropriate educational messages should be developed and delivered to improve the health of patients and lessen the burden for their providers [24]. Mobile phone apps can be a useful educational strategy for GDM women with low health literacy due to the apps' flexibility of providing tailored information [26]. However, to our knowledge, the health literacy feature of mobile phone apps targeting women with GDM has not been evaluated.

Our objective was to review the literature on mobile phone apps designed for women who have or are at risk for developing GDM, and to describe the development, functionality, implementation, and impact of these apps. A secondary objective was to summarize the health literacy-related features of the apps described in the identified articles.

Methods

Research on mobile phone apps and GDM is relatively new; therefore, we conducted this scoping review as a first step to examine the availability of literature in this area. Scoping reviews are different from systematic reviews in that they answer broader research questions, and studies in various designs instead of a few predefined designs such as RCT and cohort can be relevant to the research questions; in addition, the quality of the studies is not evaluated [27]. We followed Arksey and O'Malley's 5-stage scoping review framework [27] to (1) identify the research questions, (2) identify relevant studies, (3) select studies, (4) chart the data, and (5) collate, summarize, and report the results.

Stage 1: Identifying the Research Questions

The research questions addressed in this review were as follows: (1) What is known from the existing literature about the availability, functionality, and effectiveness of mobile phone apps on GDM prevention and management? (2) What is the role of health literacy in these apps?

Stage 2: Identifying Relevant Studies

We selected 7 databases in consultation with a reference librarian: PubMed, Cochrane Library, Web of Science, CINAHL Complete, Communication & Mass Media Complete, Inspec, and Google Scholar. We identified articles by conducting searches using a combination of 2 sets of keywords: (1) gestational diabetes and (2) mobile, app, digital, technology, mHealth, wearable, wireless, smartphone, cell phone, telemedicine, or telecare. The combination of the first 2 sets of keywords and a third keyword, literacy, was searched in all 7 databases to identify extra articles. To retrieve the most relevant results, titles and abstracts were searched in PubMed; title,

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abstract, and keywords were searched for in Cochrane Library; topics were searched for in Web of Science; and abstracts were searched in CINAHL Complete, Communication & Mass Media Complete, and Inspec. The Google Scholar search was based on title. We also conducted a backward search of references of all articles that met the inclusion criteria.

Stage 3: Selecting the Studies

We retrieved articles for further analysis according to the following inclusion criteria: the targeted study population had to be women with GDM or women who were at risk of GDM; we considered overweight and obese women to be at risk for developing GDM. Studies had to describe a mobile phone app, and the mobile phone app had to focus on health promotion or disease prevention, or both. Exclusion criteria were studies focused solely on women with T1DM or T2DM. We excluded studies if mobile devices were used only to communicate between patients and health care providers (for data transmission, short messages, talk, or counseling). Other exclusion criteria were reviews or editorials, studies not in English, and studies for which the full text was not available.

According to these criteria, we selected the articles by title, abstracts, and then full text. Figure 1 presents the flow diagram of the search strategy. The initial searches were carried out in July 2016 and were not limited by date. The same searches were performed again in April 2017 to identify newly published studies.

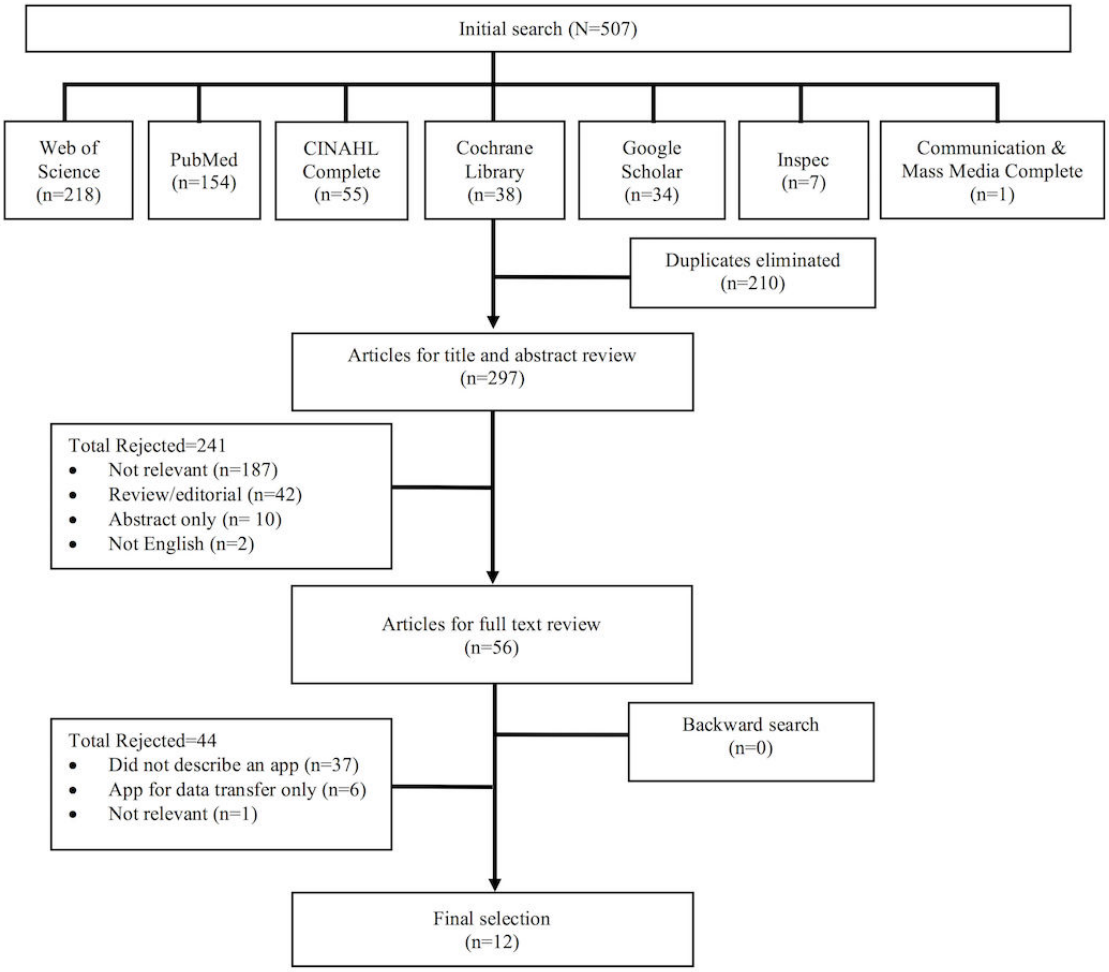
Stage 4: Charting the Data

After a full-text review, we classified studies into 2 categories based on the following content: (1) description of the development, feasibility, or usability of the apps or systems, and (2) trial protocols. To answer the research questions, we created a data charting form in Excel for Mac Version 15.25.1 (Microsoft Corporation) with the following elements: authors, year of publication, country of the study, category of the study, features of the app, behavioral theories, personalization features of the app, health literacy-related features, study design, sample characteristics, usability, feasibility, intervention components, and outcome measures.

Stage 5: Collating, Summarizing, and Reporting the Results

We used information from the data charting form to summarize the overall number of studies, years of publication, characteristics of the study populations, countries where studies were conducted, and the focus and purpose of the studies. We report results of the review as categories and elements identified in stage 4 to answer the research questions, make comparisons among the studies, and identify research gaps.

Figure 1. Flow diagram of the search strategy.



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Results

A total of 507 articles from the 7 databases matched the initial search criteria using a combination of the keyword gestational diabetes and app-related keywords. The addition of a third keyword, literacy, did not yield additional results. Removing duplicates resulted in 297 articles for title and abstract review. We excluded 241 articles after the abstract review for the following reasons: not relevant (n=187), review or editorial (n=42), abstract only (n=10), and not in English (n=2). We reviewed the full text of the remaining 56 articles, which resulted in the elimination of 44 articles for the following reasons: did not describe an app (n=37), the app was used only to transfer data (n=6), and not relevant (n=1). We included a total of 12 articles in the final analysis (Figure 1).

Characteristics of the Studies

The final 12 articles were published between 2014 and 2017 and were conducted in 7 countries: Switzerland, Spain, Norway, the United Kingdom, South Korea, Ireland, and Malaysia. Among the 12 articles, 7 described the development and feasibility or usability of the app or system [28-34]; 4 proposed RCT protocols using an app or system [35-38]; and 1 described the development of an app [16]. A total of 7 distinct systems or projects containing an app were described in the 12 articles.

Development, Usability, and Feasibility of Apps and Systems

Table 1 summarizes specific features of the apps and systems. Table 2 summarizes the results from development, usability, and feasibility studies.

Garcia-Saez et al described the development of a telemedicine system called MobiGuide [16]. This system used a decision support system (DSS) to generate personalized feedback for GDM management based on an expert-approved GDM guideline and patients' data. MobiGuide includes a body area network, which provides real-time monitoring of biosignals such as BG by a Bluetooth-enabled glucometer, blood pressure by a blood pressure monitor, and activity level by an accelerometer within the smartphone. The MobiGuide system generates advice directly to both patients and health care providers. For the patients, advice regarding therapy, monitoring, and clinical assessment was generated based on their compliance with the therapy prescribed by the doctors to reinforce their behaviors. For the doctors, recommendations for changing diet and exercise, or insulin prescriptions, were generated based on patients' compliance and BG control. In the feasibility test of the MobiGuide system, 20 women with GDM were initially instructed to measure their BG (4 times/day), ketonuria (once/day, manually entered), blood pressure (twice/week), and weight (once/week). One participant dropped out after 1 week. Recommendations were modified based on patients' control and compliance. For example, good glycemic control could switch the BG measurement recommendation from 4 time per day to twice per week with 4 measures per day. Patients had high compliance (proportion of performed to recommended numbers of measurements) for BG (0.87±0.11), ketonuria (0.98±0.03), and blood pressure (0.82±0.24). When compared with the data of a historical cohort of 247 GDM patients, MobiGuide users had significantly better compliance to follow at least 4 BG measurements on indicated days (1.01±0.10 vs 0.87±0.28; P=.03) and better blood pressure control (98.6/64.7 vs 119.3/72.8 mmHg; P<.001). All 19 patients who completed the study received the message "High BG (2 abnormal per week). Did you eat more than you should?" The compliance rate (number who responded to the questions) was 0.31. Other recommendations related to ketonuria were generated to fewer patents (1-4 patients) with 0 to 1 compliance. Most of the users (12/17, 71%) thought the system improved their confidence in GDM management, 15/17 (88%) thought it did not complicate their lives, 12/17 (71%) liked the system's ability to adapt to their daily life and context change, and 16/17 (94%) would recommend it to other patients. All 6 clinicians thought the system helped them to identify treatment priorities, 5/6 (83%) agreed the system increased patient safety, and 4/6 (67%) thought the system made it easier to manage patients [34].

As part of the expert personal health system (PHS) developed by Bromuri et al, an Android smartphone was given to GDM women to input their BG measures once they read it from the glucometer that they were provided [28]. Autonomous software entities, or agents, were programmed based on the American Academy of Family Physicians' monitoring rules [39] to serve as the "experts." The PHS was able to monitor BG readings and generate text-based alerts of hypoglycemic and hyperglycemic events to the caretaker (nurses, dietitians, doctors) on a Web interface. For example, if 2 BG values were less than 3 mmol/L within 1 hour, a hypoglycemia warning would be generated. With the automated alerts, caretakers were able to initiate an in-person or phone-based consultation with the patient based on the BG measures that triggered the alerts. An RCT was conducted with 24 GDM women to compare effects between a control group (standard care, n=12) and an intervention group (n=12) using the PHS in addition to standard care [28]. All women were asked to record their BG values 6 times a day for 2 to 4 months: fasting, postprandial breakfast, preprandial lunch, postprandial lunch, preprandial dinner, and postprandial dinner. The intervention group recorded significantly more BG measurements than the control group (235±86 vs 135±80; P<.001). Women in the intervention group had overall better BG control (5.4 vs 5.7 mmol/L or 98 vs 102.4 mg/dL; P<.001) than the control group. Among the 6 daily BG measurements, 4 were significantly better controlled in the intervention group (all 4 P<.001). In the intervention group, all patients rated the smartphone app easy to use and were satisfied with the care provided by the system. Caregivers in this study considered the system appropriate for GDM management. Although the time needed for patients' consultation remained the same, the caregivers thought the PHS was more time efficient because they were able to focus on the hyperglycemic or hypoglycemic events based on the alerts instead of going through patients' BG records manually. In addition, consultations could be initiated within 1 to 3 days with the PHS instead of 1 to 3 weeks with the standard care after the hyperglycemic or hypoglycemic events. The PHS system also allowed for the possibility of daily consultation on patients' BG readings.

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Table 1. Characteristics of the 7 apps and systems.

Author, year, reference	Country	App and technology characteristics	Theory and theoretical constructs	Personalization	Health literacy-related features
Garcia-Saez, 2014 [16]	Spain	MobiGuide (app) Patients' data automatically collected by body area network or manually entered in app; decision support system generates feedback to patients and clinicians based on clinical guidelines.	Reminders and advice generated to reinforce behaviors.	Patients' compliance, BG[a] control, personal information, and preferred time of receiving reminders used to generate personalized reminders.	N/A[b]
Bromuri, 2016 [28]	Switzerland	PHS[c] (app and Web) Patient's side: Android app collects BG values, medication data, and symptoms. Caregiver's side: a Web app, existing medical knowledge designed to provide alerts about the glycemic values to caregivers.	N/A	Alerts based on patients' BG control.	BG data visualization.
Garnweidner-Holme, 2015 [29]	Norway	Pregnant + (app) Auto transfers BG levels; gives immediate feedback on BG levels; provides information about healthy eating and PA[d]; prints BG records at their clinics; provides general information about GDM[e].	Health belief model used to develop content.	Culturally tailored dietary recommendations; information tailored to preference and prepregnancy PA level.	Content checked against Suitability Assessment of Materials and Kreuter's message checklist to improve text and layout. A diabetes lexicon was used to explain medical jargon. BG data visualization.
Jo, 2016 [32]	South Korea	App generates common recommendations applicable to all GDM patients and tailored recommendations based on algorithms linking patients' data and clinical guidelines.	N/A	Tailored recommendations based on BG, diet, PA, ketone, and weight.	N/A
Mackillop, 2014 [33]	United Kingdom	GDm-Health (system) Automatically uploads BGs from glucometer to app through Bluetooth and then to server; health care professionals have remote access; 2-way communication between women and health care professionals.	N/A	Alerts generated by the system to health care providers based on frequency and reading of BG.	BG data visualization.
Kennelly, 2016 [36]	Ireland	Pears (app) Provides list of daily PA and behavioral tips, and a database of low glycemic index recipes.	Control theory: SMART[f] goals; social cognitive theory: barriers to change	Dietary advice and PA goals set at in-person education session with nutritionist or dietitian and obstetrician.	N/A
Skau, 2016 [38]	Malaysia	Jom Mama eHealth platform (app and Web) App incorporates personal goal setting, progress tracking, and general information on healthy lifestyles. A Web-based backend interface can be accessed by CHPs[g].	Goal setting with CHPs and in the app, motivational interviewing techniques adopted by CHPs.	Personalized goal setting and follow-up with CHPs. The app provides interactive options allowing users to select lifestyle challenges.	Change in health literacy is a secondary end point.

[a]BG: blood glucose.

[b]N/A: not applicable.

[c]PHS: personal health system.

[d]PA: physical activity.

[e]GDM: gestational diabetes mellitus.

[f]SMART: specific, measurable, achievable, relevant, and time specific.

[g]CHP: community health promoter.

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Table 2. Summary of usability and feasibility studies and RCT[a] protocols.

Author, year, reference	Country	App or system name	Focus and study design	Target audience and sample	Key results and outcome variables
Peleg, 2017 [34]	Spain	MobiGuide	Feasibility Quasi-experimental	Intervention: GDM[b] patients (n=20) Control: historical cohort GDM patients (n=247) Duration: <34th gestational week to delivery (5-11 weeks)	Intervention vs control: BG[c] measurement compliance[d] (1.01±0.10 vs 0.87±0.28; *P*=.03), BP control (98.6/64.7 vs 119.3/72.8 mmHg; *P*<.001). Patient compliance[e]: BG measures (0.87±0.11), ketonuria (0.98±0.03), BP (0.82±0.24), responded to message "High BG (2 abnormal per week), did you eat more than you should?" (0.31). Patient satisfaction (rated positive): system increased confidence (12/17), liked system's adaptability to daily life (12/17), system did not complicate life (15/17); would recommend to others (16/17). Clinician satisfaction (rated positive): system helped identify priorities (6/6), increased patient safety (5/6), easier to manage patients (4/6).
Bromuri, 2016 [28]	Switzerland	PHS[f]	Development, usability, feasibility RCT	Intervention (telemedicine): GDM patients (n=12) Control (standard protocol): GDM patients (n=12) Duration: 24th-32nd gestational week to delivery (2-4 months)	Intervention vs control: number of BG measures (2749 vs 1616; *P*<.001); BG control (5.4 vs 5.7 mmol/L or 98 vs 102.4 mg/dL; *P*<.001). Intervention group satisfaction: 12/12 satisfied with the care by PHS and perceived the system easy to use. Caregiver satisfaction: perceived the system as appropriate, reduced reaction time, provided possibility of daily consultation, and saved time through automated alerts.
Garnweidner-Holme, 2015 [29]	Norway	Pregnant+	Development, usability	Women with GDM (N=22) Duration: 1-time use of the app	Perceived ease to register and control BG levels. Participants had success performing given tasks: finding information on healthy eating (10/11), physical activities (10/11), GDM (10/11), finding where to register BG levels (11/11), entering appointments for medical consultations (9/11), and finding how to register body weight (5/11).
Borgen, 2017 [35]	Norway	Pregnant+	RCT protocol (ongoing)	Women with a 2-hour OGTT[g] ≥9 mmol/L (N=230) Intervention: app + standard care Control: standard care Duration: <33rd gestational week to 3 months postpartum	BG level measured at 2-hour OGTT 3 months postpartum. Change in health behavior and knowledge about GDM, quality of life, birth weight, mode of delivery, and complications for mother and child.
Jo, 2016 [32]	South Korea		Development, usability, feasibility	Usability: GDM patients (n=5) User acceptance test: GDM patients (n=60) Duration: 1 week	Average usability score: 69.5 out of 100. User acceptance score with behavioral intention to use 5.5, intrinsic motivation score 4.3, perceived ease of use score 4.6, and perceived usefulness score 5.0, out of 7 for all measures.
Mackillop, 2014 [33]	United Kingdom	GDm-Health	Development	Beta testing phase: GDM patients (n=7) Service development phase: GDM patients (n=50) Duration: diagnosis to delivery	Women used the system for 13.1 weeks on average. 46/54 women submitted the minimum of 18 BG readings per week. 19,410/19,686 (98.6%) of BG readings were manually tagged with additional information (time of measurement and comments) by patients.
Hirst, 2015 [30]	United Kingdom	GDm-Health	Usability	See row above	Satisfaction: women were satisfied with the care (45/49), and agreed the equipment was convenient (47/49), reliable (43/49), and fit into their lifestyle (42/49).

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Author, year, reference	Country	App or system name	Focus and study design	Target audience and sample	Key results and outcome variables
Hirst, 2016 [31]	United Kingdom	GDm-Health	Feasibility	See 2 rows above	12/41 (29%) women delivered LGA[h] babies. Mother's BG (LGA vs non-LGA babies): mean BG (6.3 vs 5.6 mmol/L; *P*=.004), fasting BG (5.8 vs 5.1 mmol/L; *P*=.004), and 2-hour postprandial BG (6.9 vs 6.0 mmol/L; *P*=.001). Odds of delivering an LGA baby increased with every 1-SD increase (0.7 mmol/l) in mean BG (OR[i] 5.5, 95% CI 1.4-21.2) and mean postprandial BG (OR 6.1, 95% CI 1.6-23.4).
Mackillop, 2016 [37]	United Kingdom	GDm-Health	RCT protocol (ongoing)	N=200 pregnant women with abnormal glucose tolerance Intervention: use GDm-Health system (app), attend the clinic every 4-8 weeks Control: standard care, self-record BG diary at home, attend the clinic every 2-4 weeks Duration: 14-34 weeks to delivery	Efficacy of GDm-Health; BG control and management intensity; maternal and fetal outcomes.
Kennelly, 2016 [36]	Ireland	Pears	RCT protocol (ongoing)	N=506 pregnant women, 10-15 weeks' gestation, body mass index 25-39.9 kg/m^2 Intervention: targeted low GI[j], nutritional advice, and a daily exercise prescription (in-person education session) with a smartphone app as support, and biweekly follow-up emails Control: standard obstetric care Duration: 2nd to 3rd trimester	Incidence of GDM at 29 weeks. Gestational weight gain, maternal physical activity levels in the 3rd trimester, and GI and glycemic loading of maternal diet in the 3rd trimester.
Skau, 2016 [38]	Malaysia	Jom Mama	RCT protocol (ongoing)	N=660 newly registered married or engaged couples. Female not pregnant, diabetes-free at baseline Intervention: contact with community health promoter: 3 face-to-face meetings, 3 phone calls, communication through WhatsApp group chat, and use of the eHealth platform Control: standard care Duration: 8 months	Change in abdominal fat content. Change in body mass index, waist-to-height ratio, waist-to-hip ratio, weight, hemoglobin A_{1c}, fasting lipid profile, blood pressure, health literacy, dietary intake, physical activity and sedentary behavior, and stress level. Incidence of GDM.

[a]RCT: randomized controlled trial.

[b]GDM: gestational diabetes mellitus.

[c]BG: blood glucose.

[d]Number of days measured ≥4 BGs/number of days prescribed to measure BG.

[e]Proportion of performed/recommended measurements.

[f]PHS: personal health system.

[g]OGTT: oral glucose tolerance test.

[h]LGA: large for gestational age.

[i]OR: odds ratio.

[j]GI: glycemic index.

Pregnant+ is an app developed to monitor GDM women's BG level by Bluetooth transmission or manual input [29]. It generates immediate feedback, provides information on healthy diets based on the cultural background of the user (eg, using food items preferred in users' cultures), provides physical activity information based on level of activity, and provides general information about GDM. The content of the app was designed to emphasize patients' perceived severity of their disease, emphasize perceived benefits to treatment and management, and provide cues to action based on the health

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belief model. Although BG records cannot be transferred automatically to the health care providers due to medical data security, users can print their BG records at the clinics [29]. In a user involvement study for the Pregnant+ app, most participants were able to perform tasks related to the 4 major functions of the app; namely, finding (1) where to register BG levels (11/11, 100%), (2) information about healthy eating (10/11, 91%), (3) information about physical activities (10/11, 91%), and (4) general information about GDM (10/11, 91%) [29]. Fewer participants were able to find other functions, such as entering appointments for medical consultations (9/11, 82%) and finding how to register body weight (5/11, 45%). Users of this app believed it would make it easier for them to register and control their BG level than with standard care. They also reported favorable reviews for the features that provided real-time feedback and information about GDM, diet, and physical activity.

Jo and Park developed an app for Korean women with GDM [32]. This app generates recommendations about the risk factors of GDM, importance of GDM management, and management of BG, diet, physical activity, and body weight to patients based on their initial assessment and lifestyle data, including caloric intake and physical activity level. Algorithms using patients' data and clinical guidelines [40-42] were developed to generate individually tailored recommendations. A total of 5 GDM patients participated in the usability test of this app. The average usability score was 69.5 out of 100 as measured by a Korean version of the System Usability Scale [32]. User acceptance was measured using Wilson and Lankton's model of patients' acceptance of provider-delivered eHealth [43]. The user acceptance score with behavioral intention to use was 5.5, intrinsic motivation score was 4.3, perceived ease of use score was 4.6, and perceived usefulness score was 5.0, out of 7 for all measures.

The GDm-Health system is a real-time BG monitoring management system for women with GDM that consists of a smartphone app and a website [33]. This smartphone app allows women to automatically synchronize their BG levels from their glucose meter through Bluetooth and provides immediate feedback based on the BG readings. BG levels are sent to a central server where health care professionals can access the data on a website. Another function of this system is to allow 2-way communication where health care professionals give advice or change medication and users can request a callback from the team to address their concerns. A total of 7 women were involved in the beta test phase of the GDm-Health system, and 50 women with GDM tested the system until delivery. On average, the women used the system for 13.1 weeks, 46 of 54 (85%) submitted the minimal requirement of 18 BG readings per week, and 19,410 of 19,686 (98.6%) readings were manually tagged with additional information indicating when it was measured (pre- or postprandial) [33]. The Oxford Maternity Diabetes Treatment Satisfaction Questionnaire was developed and used to assess the acceptability of the system [30]. Overall, 45/49 (92%) women were satisfied with the care delivered by the system, and 46/49 (94%) agreed they had a good relationship with their care team. Most agreed that the equipment was convenient (47/49, 96%), reliable (43/49, 88%), and fit into their lifestyle (42/49, 86%). Birth outcome data were available for 41 women, of whom 12 (29%) delivered large for gestational age (LGA) babies. Mothers of LGA versus non-LGA babies had significantly higher mean (6.3 vs 5.6 mmol/L; *P*=.004), fasting (5.8 vs 5.1 mmol/L; *P*=.004), and 2-hour postprandial BG readings (6.9 vs 6.0 mmol/L; *P*=.001). A 1-SD increase (0.7 mmol/L) in mean BG increased the odds of delivering an LGA baby by fivefold (odds ratio 5.5, 95% CI 1.4-21.2) [31].

Randomized Controlled Trial Protocols

A total of 4 ongoing RCTs are using a mobile phone app or using an app as part of the intervention component to prevent or manage GDM [35-38]. Table 1 summarizes characteristics of the apps and Table 2 summarizes characteristics of the RCT protocols.

Mackillop et al are testing the efficacy of using the GDm-Health system compared with standard clinic care [37]. A total of 200 women with abnormal glucose tolerance between 14 and 34 weeks of gestation have been randomly assigned to 1 of 2 groups: GDm-Health system and clinic visit every 4 to 8 weeks; or normal clinic care (visit the clinic every 2 to 4 weeks). The primary outcome is BG control, as determined by mean BG readings from recruitment until delivery compared between the intervention and the control group. The secondary outcomes are compliance with the allocated BG monitoring regimen, maternal and neonatal outcomes, glycemic control using hemoglobin A_{1c} and other BG metrics, and patient attitudes toward care.

Borgen and colleagues are evaluating the efficacy of the Pregnant + app [35]. A total of 230 pregnant women with GDM who own a smartphone, understand Norwegian, Urdu, or Somali, and are before 33 weeks of gestation were recruited. Women will randomly receive either the Pregnancy+ app and standard care or standard care until 3 months postpartum. The primary outcome is glucose tolerance after the intervention, measured by 2-hour oral glucose tolerance test. Secondary outcomes are birth weight, mode of delivery and complications for mother and child, change in diet and physical activity from baseline to 36 weeks of gestation (measured by a modification of the Fit for Delivery questionnaire and the Pregnancy Physical Activity Questionnaire), and quality of life (measured by a short version of the Edinburgh Postnatal Depression Scale and by health-related quality of life during pregnancy and postpartum) [35].

Kennelly et al are conducting a pregnancy, exercise, and nutrition research study with smartphone app support (Pears) targeting low glycemic index dietary and physical activity promotion among overweight and obese pregnant women [36]. The Pears healthy lifestyle package includes a 75-minute in-person education session, biweekly emails, 2 follow-up appointments, and an app. The app provides behavior, dietary, and physical activity tips, physical activity benefits, and a database of low glycemic index recipes. Control theory and social cognitive theory were applied to set up patients' personal SMART (specific, measurable, achievable, relevant, and time-specific) goals, and to overcome personal and environmental barriers to change. The authors are randomly assigning 506 overweight or obese women between 10 and 15

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weeks' gestation to the intervention or the control arm to assess the impact of the Pears healthy lifestyle package [36]. The primary outcome is the incidence of GDM at the 29th week. Secondary outcomes will be gestational weight gain, maternal physical activity levels, and glycemic index and glycemic load of the mothers' diet in the third trimester.

Skau et al developed a behavior change intervention, Jom Mama, targeting young Malaysian couples to promote women's health prior to pregnancy [38]. This project includes 3 in-person and 3 phone communications with community health promoters, and an eHealth platform. The eHealth platform includes an app for the couples and a Web-based interface for the community health promoters. The couples can set personal goals, track their progress, and access general information on healthy lifestyles from the app. Women and spouses can select different challenges for obtaining a healthy diet (eg, avoid soft drinks), increasing their physical activity, or decreasing their sedentary behavior during the intervention period (eg, cycle for 30 minutes). Community health promoters follow the progress of the couples and interact with them during the in-person and phone communications using the information from the Web-based interface. Skau and colleagues are testing the efficacy of the Jom Mama project on preconception health promotion [38]. They are recruiting a total of 660 nulliparous women between 20 and 39 years of age who own a smartphone and are free of diabetes to randomly assign to an intervention or control group. The planned follow-up duration will be 8 months. The primary outcome is change in waist circumference. Secondary outcomes will be changes in other anthropometric (eg, body mass index, waist-to-hip ratio), biochemical measures (eg, hemoglobin A_{1c}, lipid profile), health literacy, dietary intake, physical activity, and stress level. They will also measure the incidence of GDM proposed as an outcome in women who completed the intervention and become pregnant after the trial.

Health Literacy-Related Features

Health literacy was taken into account in 2 of the 7 final apps and systems. The Pregnant+ app was the only system that incorporated user literacy level in the development phase [29]. The researchers checked the app against Kreuter's message checklist, which includes checking the content, writing, literacy, and elements of visual communication [44] and administering the Suitability Assessment of Materials instrument [45] to make sure the app was appropriate for their targeted audience. In addition, after the second stage of the user involvement study with 11 GDM patients of varying literacy levels, a diabetes wordlist was added to the app to explain medical jargon [29]. The Jom Mama intervention was designed to measure change in the level of health literacy using the European Health Literacy Survey Questionnaire (a 47-item scale covering 3 domains: health care, disease prevention, and health promotion) as one of the outcomes of the intervention [38]. PHS, Pregnant+, and GDm-Health all used a data visualization strategy to present normal and abnormal BG data in figures [28,29,33]. Although Jo and Park involved users in the development of the app, they did not mention whether the app met the health literacy level of their targeted users [32]. Mackillop et al assumed that their target users for the GDm-Health system being recruited from a large single-center tertiary referral unit in southern England would have high rates of literacy and low levels of social deprivation [37].

Discussion

Principal Results

There is a limited body of published data on the use of mobile phone apps for GDM. In this review, 12 articles focused on the development, usability, feasibility, and trial protocols of mobile phone apps or interventions including an app. DSSs were used to connect patients' data to tailored feedback for both patients and health care providers using clinical guidelines. Health literacy was considered a feature of 1 app during the development phase [29] and was measured as an outcome by another app [38].

Comparison With Prior Work

Figure 2 presents the common framework combining all the characteristics of the app or system with automated features. The findings suggest that DSSs have the capacity to generate real-time personalized feedback based on users' input and existing clinical guidelines. From the studies identified, a variety of data from the users have been collected, recorded, and saved in the app or system, or used to develop the app or system. These data include health records, biosignals collected by body area network, user preferences, culture, lifestyle data, clinical data, and personal health goals. However, not all of the information was used in the DSSs to generate output to the patients or health care providers. The information that was used most frequently was BG levels collected by body area network or entered by the users. The MobiGuide system had the highest level of personalization among all the apps and systems we identified [16]. This system feeds the DSS with historical clinical data, the personal health record, body area network sensor data, and manually entered data to generate personalized feedback. However, deciding on the right amount of advice to reinforce users' behaviors without overwhelming them can be challenging. The primary functions of the apps and systems included providing information, promoting lifestyle change, assessing and monitoring user status, and managing medication and complication with approval from providers. Also, protecting the security and privacy of patients' data is a common feature of the apps and systems. Similar to the findings of this review, in a review of commercial apps for diabetes self-management, El Gayar found that 12 of 71 (17%) had decision support capabilities and all of them were related to insulin dosage suggestions as opposed to lifestyle changes [14]. Internet-based interventions that promoted lifestyle modifications for diabetes management, were based on theory, included interactive components and personalized feedback, and provided peer support were most successful [46]. In our review, only 2 apps incorporated behavior change theories [16,29], and 2 RCTs used theories in their proposed interventions, but not specifically in their app or system [36].

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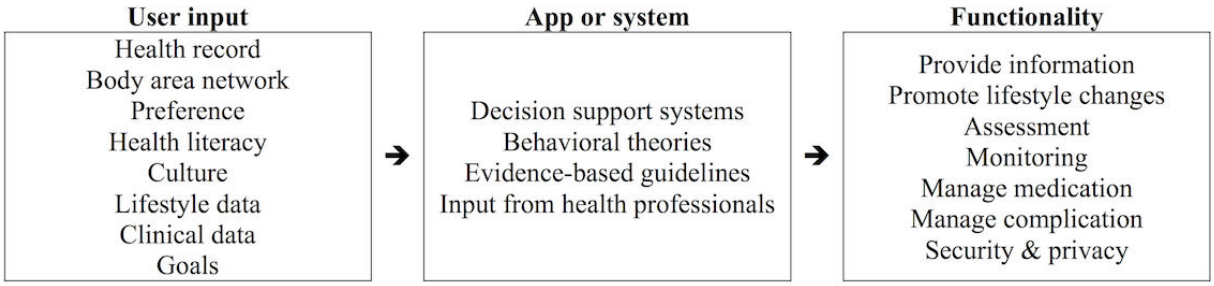
Figure 2. Framework of automated app or system.



Even if the apps provide high-quality, evidence-based content, the value is limited if the information does not adequately match and address the usability, accessibility, readability, and health literacy needs of target audiences [47]. Although users were frequently involved in usability and feasibility studies to inform the development and finalization of the app or system, their literacy level was discussed in only 2 studies. Caburnay et al analyzed the health literacy-related features of more than 100 diabetes apps with a specific focus on using plain language, displaying content clearly, organizing and simplifying the user interface, and engaging users [48]. A total of 84% of the apps employed at least one of the plain language strategies, such as using common everyday words; avoiding undefined technical or medical terms; and using active voice, action words, and present tense [48]. Involving users in the development phase and evaluating users' attitudes, knowledge, beliefs, and behavior related to health information are helpful strategies to improve usability of an app [49].

Overall, the users involved in the usability and feasibility studies found it easy to navigate the apps and systems, and were satisfied with the technology. Apps and systems have the potential to improve compliance with BG monitoring and treatment prescriptions, and improve communication between users and health care providers. El-Gayar et al categorized the technology for diabetes self-management into the Internet, cellular phones, telemedicine, and decision support techniques [50]. However, our review found that DSSs can be embedded in mobile phone apps to generate real-time feedback.

Only 1 feasibility study [28] with a sample of 24 women showed that patients who received PHS care had better BG control than did patients who received standard care. Better blood pressure control was reported in another feasibility study; however, no difference in BG control was observed [34]. Large RCTs are needed to confirm the system's impact on BG control and other clinical outcomes. In this review, we identified 3 RCT protocols: only 1 protocol, by Mackillop et al [37], evaluated the efficacy of the GDm-Health system, and the other 2 protocols evaluated complex lifestyle programs with an app as part of the intervention [36,38].

Limitations

We applied no evaluation criteria to the articles due to the nature of this scoping review. This review only searched abstract, title, and topics in most databases, which may not yield a complete pool of relevant articles. Articles published in languages other than English were not included. However, this is, to our knowledge, the first known review of mobile phone apps on GDM to provide an overview of the literature.

Conclusions

This scoping review describes the literature on mobile phone apps for GDM prevention and management. We identified and described 12 articles that discussed the design and development, usability, feasibility, and RCT protocols of GDM-related apps. Findings from this scoping review suggest that mobile phone apps have the potential to prevent GDM and improve GDM management. Future research should focus on large RCTs of the impact of these apps. In addition, health literacy levels of the potential audience should be taken into consideration when developing and evaluating the usability of apps for this audience.

Acknowledgments

Both authors contributed significantly to the conception, design, data interpretation, and analysis of the articles; participated significantly in the writing and critical revision of the manuscript; and read and approved the final manuscript, as well as all previous versions.

Conflicts of Interest

None declared.

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Abbreviations

BG: blood glucose
DSS: decision support system
GDM: Gestational diabetes mellitus
LGA: large for gestational age
PHS: personal health system
RCT: randomized controlled trial
T1DM: type 1 diabetes mellitus
T2DM: type 2 diabetes mellitus

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Original Paper

A Novel Approach to Identifying Barriers and Facilitators in Raising a Child With Type 1 Diabetes: Qualitative Analysis of Caregiver Blogs

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Abstract

Background: With rising incidence of type 1 diabetes (T1D) diagnoses among children and the high levels of distress experienced by the caregivers of these children, caregiver support is becoming increasingly important. Historically, relatively few support resources have existed. Increasing use of the Internet, and blogs in particular, has seen a growth of peer support between caregivers of children with T1D. However, little is known about the type and quality of information shared on T1D caregiver blogs. At the same time, the information on such blogs offers a new window into what challenges and successes caregivers experience in helping to manage their children's T1D.

Objective: The purpose of this study was to (1) analyze blogs of caregivers to children with T1D to better understand the challenges and successes they face in raising a child with T1D, and (2) assess the blogs for the presence of unsafe or inaccurate clinical information or advice.

Methods: An inductive thematic qualitative study was conducted of three blogs authored by caregivers of children living with T1D, which included 140 unique blog posts and 663 associated comments. Two physician investigators evaluated the blogs for presence of clinical or medical misinformation.

Results: Five major themes emerged: (1) the impact of the child's diagnosis, (2) the burden of intense self-management experienced in caring for a child with T1D, (3) caregivers' use of technology to ease their fear of hypoglycemia and impacts that device alarms associated with this technology have on caregiver burden, (4) caregivers' perceptions of frequently missed or delayed diagnosis of T1D and the frustration this causes, and (5) the resilience that caregivers develop despite the burdens they experience. Misinformation was exceedingly rare and benign when it did occur.

Conclusions: Blog analysis represents a novel approach to understand the T1D caregiver's experience. This qualitative study found many challenges that caregivers face in raising a child with T1D. Despite the many barriers caregivers face in managing their children's T1D, they find support through advocacy efforts and peer-to-peer blogging. Blogs provide a unique avenue for support, with only rare and benign findings of medical misinformation, and may be a resource that diabetes care providers can consider offering to families for support.

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KEYWORDS

type 1 diabetes; blogs; caregiver; self-management; social media; peer support; Internet

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Introduction

Type 1 diabetes (T1D) is an increasingly common chronic condition among children, with the incidence growing 3% to 5% per year since 1960, and with more rapid growth since 1990 [1]. Between 2001 and 2009, there was a 21% increase in the prevalence of T1D in people younger than 20 years [2]. Globally, 78,000 children ages 14 years and younger are diagnosed every year [3]. Having a child diagnosed with a chronic and life-threatening illness such as T1D is highly distressing to the caregiver and can lead to parental depression, acute stress, or posttraumatic stress reactions [4-7]. Higher levels of acute distress in parents predict not only parents' development of persistent mental health difficulties [8,9], but also longer-term psychological, behavioral, and general well-being outcomes among their children [10-13]. Among youth with T1D, high levels of parental distress have been associated with poorer health outcomes in both the children and the parents [14-16]. In their recent position statement regarding psychosocial care for people with diabetes, the American Diabetes Association recommended that providers include caregivers in their assessment of diabetes distress, depression, and anxiety (level B recommendation) [17].

In addition to psychosocial stressors, the burden of T1D management often falls to the child's caregiver(s), and few conditions require as much self-management as T1D. Although it is generally recommended that patients with T1D meet with their diabetes health care team quarterly, this results in but a few hours of in-person contact, leaving more than 8000 hours per year that T1D must be self-managed [18]. Caregivers to children with T1D often describe feeling isolated in managing the complex, relentless demands of this disease [19]. They face numerous challenges in adjusting to a T1D diagnosis and in managing their child's T1D care.

It is therefore important to understand the specific challenges that caregivers face and help identify novel sources of support. Despite advances in technology for the diabetes community, health care providers (HCPs) have relatively few resources to which they may refer caregivers for support. There are even fewer that are easily and rapidly accessible. Although there are examples of early evidence supporting online and mobile resources [20-23], there is comparatively less known about already widespread and publicly available resources outside of the research environment. Blogs—public online journals—have become popular in the age of social media. Blogs represent a growing online resource for caregivers to children with T1D to initiate and receive support. Many bloggers feel that by sharing their struggles and celebrating their successes, blogs help them to more effectively approach the daily self-management T1D requires [18]. A referral from a HCP to high-quality blogs might serve as a valuable tool in lessening the psychosocial burden caregivers of children with T1D carry with them, but to date there has been little data on the types or quality of information present on health care-related blogs. In addition, HCPs may be hesitant to refer caregivers to blogs for support given the lack of data on medical misinformation that may exist on blogs.

The objectives of this study were to better understand the issues faced by caregivers to children with T1D via qualitative analysis of blog content and to assess the types and quality of information found on blogs, specifically focused on identifying potential misinformation.

Methods

Sample Description and Recruitment

Three publicly available online blogs authored by caregivers to children living with T1D were analyzed to identify barriers and facilitators in their experiences caring for their children with T1D. This study was approved by the Penn State College of Medicine Institutional Review Board (STUDY00000870). Blogs were selected using a strategy described by D'Auria [24], based on a Google search for "parent blog diabetes," and validated by concurrence with the blogs' inclusion as a top blog for parents of children with diabetes. Bloggers were recruited via email and consented to allow retrospective analysis of publicly available blog entries and comments posted on their sites from June 1, 2012 to August 31, 2014. Blog posts, including comments, were imported into NVivo 10 (QSR International) [25].

Inductive Thematic Analysis

After reviewing the blogs and noting initial impressions, a codebook was developed and revised through ongoing discussions among the study team. To first establish Cohen kappa [26], the primary coders (EM, TO) each coded 10% of the dataset. Initial kappa was .920 and a subsequent recheck after additional coding yielded kappa .934. With high interrater reliability established through kappa as well as through group discussion, the primary coders then coded the remaining blog posts and comments individually. Project team meetings included biweekly coding audits. For any discrepancies found, the project team discussed the current meaning of the code and either further modified the code to reflect the correct meaning or revised the coding based on group consensus.

Coding proceeded until saturation, which was determined through a combination of three indicators: (1) use of a saturation table [27], (2) finding that no further edits to the codebook were necessary any longer (and then continuing to code an additional 10% of the sample to corroborate this), and (3) when the study team felt confident that no new themes were being uncovered.

The research team employed inductive thematic analysis [28] to construct emergent themes. The project team reviewed the dataset in multiple ways. For the codes most frequently used, the associated content was reviewed to identify emergent themes. A coding matrix was also produced to identify highly coincident codes and the content associated with them (content frequently coded simultaneously to each of two codes), and to further explore the thematic relationships between them. All members of the study team agreed on the emergent themes presented.

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Clinical Review of Blog Content for Medical Misinformation

Two physicians (TO, SO) reviewed the entire dataset to identify any occurrences of information that was clinically inaccurate, incorrect, or misleading, or content that might be construed as medical advice.

Results

Study Sample

Three online blogs were analyzed, representing 140 blog posts and 663 associated comments. All were publicly available on the Internet without registration or permission. Characteristics of the dataset are presented in Table 1. Two blogs were authored by mothers and one by a father. Represented families include both single-parent and two-parent families, as well as families with one, two, and three children with T1D. During the period of reviewed blog posts, the bloggers' children with diabetes ranged in age from 4 to 16 years.

Table 1. Participant blog characteristics.

Blog name	Caregiver role	Family characteristics	Age of children when diagnosed with T1D (gender)	Age of children at time of blog posts	Blog posts during study period	Associated comments
Candy Hearts [29]	Mother	Two-parent family	2 years (female)	9-11 years	43	164
Bleeding Finger Blog [30]	Father	Two-parent family	3 years (female)	6-8 years	47	117
			3.5 years (female)	4-6 years		
Our Diabetic Life [31]	Mother	Single-parent family	8 months (male)	14-16 years	50	382
			2.5 years (male)	8-10 years		
			5.5 years (male)	10-12 years		
Totals					140	663

Emergent Themes From Inductive Thematic Analysis

Qualitative analysis of blogs yielded five major themes about the caregivers' experiences of caring for their children with T1D.

Theme 1: Fear and Worry Are Common, Starting at the Time of Diagnosis, and Although the Fears and Worries Change in Ensuing Years, These Emotions Persist

Caregivers' blog posts described the worry they felt at the time of the diagnosis when they wondered how they would care for their newly diagnosed child:

> *But one day you were not well. Worry set in. We watched you in fear in the hospital bed.*
>
> *All the while, I sat there, wondering how I would be able to keep her alive without a team of nurses and doctors waiting just outside the door.*

Beyond the diagnosis period, fear and worry persist. There is a particular fear of hypoglycemia:

> *How do I accurately describe the worry that lays wait in my stomach when a child announces a very low number, the choking responsibility of life, and the rolodex of emergency protocols that run through my brain?*
>
> *I want you to know, when there is an extreme low, and your child is sitting with a blank look in front of you, barely able to speak...I have been there. I have felt the confusion, the panic, and the deep worry you have in your heart.*

Parents described in great detail the fear they have that their children will die of hypoglycemia, particularly at night while the child is sleeping. They refer to the emotions they face as they walk to check on their child in the middle of the night or the next morning ("the walk that never ends, the walk to check for disaster") and the feelings they experience wondering if their child is still alive ("the feeling in my throat as I lean against a bedroom door jamb, waiting for their chests to rise and fall in the morning is a terrible feeling").

Theme 2: Caregivers Experience Unrelenting Physical and Emotional Burdens Related to the Intense Management Demands of Caring for a Child with T1D

Caregivers are challenged by the heavy burden that diabetes brings to the family unit, including the sheer work involved in managing a condition that has a 24/7/365 presence. A commonly expressed pressure is the burden of "having to know what their blood sugars are" at all times. The constant attention to detail causes caregivers to become "worn down." Caregivers discussed the unrelenting presence T1D has in their lives:

> *I got up early to give her a breakfast bolus 2 hours before the start of testing with a solid 20-minute prebolus in an attempt to slow/minimize/prevent an astronomical breakfast spike with cognitive function.*
>
> *How can I lament about the laboriousness of this disease, the constant stream of numbers knocking, knocking, knocking all the livelong day, and the infuriating knowledge that there will never ever, ever be a break from this, when we can take walks by the ocean as a family?*

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> *How do I explain to you that some nights the exhaustion holds me like a straight jacket...that the nights are all encompassing, and I will my tears to fall back into my body rather than intentionally give in to the fear and exhaustion?*

Despite these efforts, diabetes can be unpredictable. Even stringent efforts to follow treatment parameters result in frequent glucose levels outside the target range: "I think one of the hardest parts is the unpredictability and no rhyme or reason—it makes it impossible to understand and comprehend, which then makes it frustrating when fixes don't [work]." This unpredictability only adds to caregivers' self-described burden of lost sleep: "While friends were boasting about weekend getaways and trying new restaurants, we were holding our breath to see if the pizza bolus from dinner would wreak havoc on a good night's sleep." They vividly described attempting to control their children's blood glucose levels at night to keep them safe: "I tested her blood sugar every 2 hours between 10pm and 6am in an attempt to catch any fluctuations that might require an intervention…" and "I know that there were many nights she lost hours and hours of sleep to make sure the kids were safe for me." This leads to frustration ("I want you to know, when your alarm goes off in the middle of the night and you want to throw your alarm clock out the window...I have been there") and the desire for a good night's sleep ("Kind of weird, a full night sleep for a birthday present, a half night with 2 hours of REM will do. A good night sleep, it has been a while, whatever a good night of sleep is").

Related to lost sleep and the desire to preserve some sleep, caregivers discussed the struggle to balance the children's glucose control with their own need for sleep, and the feeling that one must be sacrificed for the other ("Should I treat gently and wake in a couple hours to see where they are going...or...should I treat in such a way that I know they will be safe...so I can sleep") and their discomfort with this decision ("Higher numbers for my boys to ensure sleep for myself is sometimes a necessary trade off, but never a comfortable one").

Finally, caregivers discussed the persistently bothersome memories of the time around diagnosis ("Yes, I am aware it's been 9 years since her diagnosis. I still cry when I talk about it") and how the diagnosis changed life so dramatically for the family ("Life changed, abruptly, never returning close to what it was before").

Theme 3: Caregivers Use Technology to Help With Self-Management and the Fear of Hypoglycemia, and Such Technology Is Generally Seen As Quite Helpful, but Device Alarms Can Also Be Intrusive and Add to the Burden Felt by Caregivers

Caregivers described their excitement over new devices ("I realize an insulin pump may not be the most exciting toy for most of the world, but it's big stuff in this house—and many other homes, too") and how they help in decreasing the self-management burden of T1D:

> *It's kind of odd, getting excited about a medical device, but it makes a crappy disease a little easier.*
>
> *...both my daughters switched to the same insulin pump...and [continuous glucose monitor (CGM)] this last summer. This has made diabetes management, for us, a lot easier. I've publicly endorsed the [CGM] (some quality issues are there however, like buttons falling off, power port cover coming off) but it is a great tool. I love the range, it catches our daughters upstairs when they are playing or sleeping; the accuracy I find is great.*

At the same time, the device alarms were noted as intrusive: "Somewhere, a CGM alarmed, and into the story enters diabetes as the main antagonist" and "It beeps all the time."

Theme 4: Many Caregivers Are Especially Bothered by What They Perceive to Be the Frequently Missed and/or Delayed Diagnosis of T1D

There was an unusually large outpouring of comments by caregivers who recalled their child's diagnosis as initially missed and/or substantially delayed. This most frequently comes to light when news is spread online about another child recently diagnosed quite late or even after dying: "The symptoms, the physician responses, the results, and the outrage at how something could have been so easily caught, diagnosed and treated without taking our children all the way to death's door." Some caregivers recall being told that their ill child had "a virus" or "the flu" without testing being done, days or even weeks before serum or urine glucose testing was eventually ordered and led to the diagnosis of T1D. There were also strong feelings among T1D caregivers that in children less fortunate than theirs, who were only diagnosed in late (and quickly fatal) ketoacidosis, their deaths could have been prevented if the children had received glucose testing earlier in their illness. They expressed concern that "many medical professionals just don't understand how quickly [diabetic ketoacidosis] can turn life-threatening."

Theme 5: Despite the Fears and Frustrations That Caregivers Experience, They Demonstrate Resilience, Often Through Advocacy Efforts and Peer Support Through Blogs

Quite often, caregiver resilience takes the form of advocacy efforts, as there is substantial discussion in blogs of caregivers' efforts to promote public awareness, to become involved in advocacy organizations, and to encourage others to do the same. Caregivers encourage one another to "change the world" through "sharing their stories" and inspire each other to "cure this thing!" They discuss the need to make their voices heard in political, industrial, and community venues: "Think about what you want your lawmakers to know about living with type 1 diabetes" and "There are policy makers, pharma companies, news outlets, and simply neighbors in our immediate area that need to hear our collective voices." They advocate on behalf of their children, who they feel are often too young to do so themselves: "I want to make my voice heard and speak for my daughter until she can learn to speak for herself."

Support for caregivers is discussed frequently. Blogging is used to provide support to peers, to receive support from peers, and as a mechanism for processing and coping. Those who found blogs at the time of their child's diagnosis described what an

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important and highly valued source of support blogs can be: "I found your blog early in our journey and it gave me so much more than you will ever know" and "Honestly I do not know what I would have done had I not found your blog." Bloggers encouraged others to blog: "Only you can tell your story, and that story might be the one that connects with someone and makes a difference in their life." They also discussed the importance of the peer-to-peer support received through blogs: "Knowing that there are others out there going through the same things helps other people so much."

Medical Advice/Misinformation

Two physician members of the study team (TO, SO) reviewed all posts and comments during the study period to identify instances of bloggers or commenters providing information that was clinically incorrect or inaccurate, or that could be perceived as medical advice. No instances of medical misinformation were found among the 140 blog posts reviewed. In the 663 comments associated with those blog posts, two instances of possible medical misinformation or medical advice were found:

> *I have read about cats who were very good at giving alerts when a diabetic member of the family had a low blood sugar. Daisy may become very good at it too, if you give her a reward each time she does it.*

This comment was considered to be medical misinformation because it could be interpreted by a blog visitor as encouragement to try to train household pets to detect hypoglycemia, a practice that is not recommended or supported by the literature.

> *His blood sugar was 129... a bit higher than I would've ordinarily liked, but considering he was sick and had just drank some apple juice helps explain it (as did a lot of [diabetes online community] reassurance).*

This comment was considered to be medical misinformation because the commenter relied on his/her own understanding and reassurance from lay users online, rather than consulting with a HCP to interpret a glucose measurement in their child without diabetes (not their child with diabetes). This raised concern that the comment might encourage others to do the same.

Conversely, all blogs analyzed contained a general statement/disclaimer instructing readers that the blogs' content should not be considered medical advice and encouraging them to consult a HCP for any medical information. For example, the blogger from Our Diabetic Life provides the following statement:

> *I can guesstimate a bolus in lightning speed. I can check my boys' blood sugars in the wee hours in the morning, half-asleep, with only one eye open. I can do a lot of things...but one thing I can't do is be your child's endocrinologist. Everything on this blog works for our family, but might not work for yours. Funny thing diabetes, one size does not fit all. If you see some technique here that you would like to try, call your doctor, use common sense, and remember: I am not a doctor...I'm just a mother of three boys with type 1 diabetes. That is it. Mother. Not doctor. Blogger. Not doctor. Friend. Not doctor...*

Discussion

Principal Results

Blogs tell a story. They allow narrative expression of an individual's experience, which can have significant health benefits [32,33]. They allow insight into the personal, day-to-day issues faced by families living with T1D. They allow us to see their struggles and challenges as well as their successes. They also allow us to witness the interactions of peers as they provide support to one another.

Using this novel approach of blog analysis, we found that caregivers of children with T1D experience many challenges, starting from the time surrounding their child's diagnosis and continuing forward. We found that caregivers experience fear and worry at the time of their child's diagnosis, and that this fear persists, specifically surrounding hypoglycemia, especially at night. This finding is consistent with other studies of T1D caregivers conducted through more traditional means [34-37], but to our knowledge, this is the first study to specifically focus on public blog analysis as a primary means to examine such issues. Also consistent with research by Lowes et al [38,39], we found that there is some degree of chronic sorrow, with caregivers continuing to talk about their child's diagnosis on blogs, even years later. Caregivers also discuss the frustration and anger that arise from their perception that there is too often a delay or misdiagnosis surrounding the initial presentation of T1D in children.

Interestingly, there was very little discussion of glycated hemoglobin A_{1c} in the caregiver blogs studied, although glycated hemoglobin A_{1c} is often a focus of most HCPs in evaluating the overall quality of diabetes management in individuals with T1D. During blog discussions, caregivers focus more on immediate management issues, such as preventing hypoglycemia at night. Caregivers often discuss fear of nighttime hypoglycemia and even death due to nighttime hypoglycemia, but there is not much discussion about long-term diabetes complications. There are few studies focused on providing behavioral interventions to children with T1D and their parents to reduce fear of hypoglycemia [40-42], and our study supports the need for future research to target pediatric interventions to address parents' fear of hypoglycemia, perhaps through education and support.

Caregivers assume significant emotional and physical burdens in caring for their children with T1D. Although these burdens are numerous and varied, they are exemplified by prominent online discussions of lost sleep due to the unpredictability of diabetes, which is further compounded by alarms from diabetes management devices. Such devices are certainly considered helpful, but they can also be seen as intrusive as other studies have also shown [43,44].

Despite this, caregivers are resilient. They find support from one another through blogs, and they encourage each other to advocate for change regarding issues they find burdensome, including public misunderstanding of T1D and efforts to

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diagnose T1D more quickly. Although not carried out only through blogs but through other social media as well, a recent example of this is the advocacy efforts that led to various states adopting resolutions regarding awareness of and testing for T1D, including North Carolina (House Bill 20, so-called "Reegan's Rule"), California (Senate Resolution 63), and Pennsylvania (House Resolution 569), for example. Such advocacy and peer-to-peer support show great potential for the utility of blogs.

However, many HCPs may be hesitant to refer patients to online blogs for support for reasons including concern about the spread of misinformation and the lack of clinical or other professional moderation of content [45]. This in-depth analysis of 140 blog posts and 663 associated comments spanning 27 months of content revealed a distinct paucity of medical misinformation. There was also a significant degree of self-moderation among blogs. Although not moderated by clinical professionals, the blog owners typically moderate comments before publishing and are acutely aware of the potential for misusing or misinterpreting information on their blogs; all contain a prominently posted statement that their content should not be considered medical advice, encouraging parents instead to obtain medical advice only from their health care team. These findings suggest that concerns about safety of blog content and lack of moderation might be unnecessarily high. Perhaps this can help HCPs reconsider how and if to add high-quality blogs to the relatively small list of support resources they can offer to T1D caregivers.

Limitations and Strengths

One of the primary limitations of this study is one shared by virtually all research on social media: that the data are all derived from those who have chosen to express their views online, with no contribution from those who have not chosen to share. This relates to the small sample size as well; although we analyzed three blogs extensively (from among the unknowable number of T1D caregiver blogs, which likely number in the dozens or even hundreds) this is akin to conducting qualitative interviews among a small sample of individuals who represent a small fraction of the population. But balancing this are two relative strengths of the approach: (1) the inclusion of blog posts spanning a period greater than two years may allow greater depth than a typical qualitative interview of one to two hours, and (2) the inclusion of comments associated with the blog posts includes many other people in the study sample and analysis. Despite this, these findings cannot be generalized without further study, but that is an inherent and accepted characteristic of qualitative research. Another limitation is inherent to blog research itself: in contrast to more traditional qualitative methods involving personal or focus group interviews, analysis of existing blogs does not afford the opportunity to ask clarifying questions or to elaborate. The blog posts and comments must stand on their own. Although this is certainly somewhat limiting, there are significant methodological and financial benefits that are quite valuable. For example, the recruitment process is far easier, there is no scheduling involved and likewise no project costs in offering compensation to participants, and there are no transcription costs because the data are already typed by their authors. Such strengths must be balanced against the limitations of the approach. Ultimately, a combination of blog analysis and more traditional interviews may be a promising combination in approaching qualitative research. Blog analysis would reduce the time and cost associated with doing purely interview-based research, and doing some interviews in addition would afford the opportunity to pursue clarification and elaboration where that is impossible with blog analysis alone.

Conclusions/Future Directions

This study of blogs found that caregivers to children with T1D worry about hypoglycemia, especially at night, and that the time around diagnosis is life altering and scarring, which has been found in other caregiver studies not utilizing blog analysis. These corroborations lead us to suspect that this novel research approach is able to produce valid results. Beyond that, this study provides insights into caregivers' persistent emotions, the physical and emotional burdens they bear, benefits of incorporating newer technologies into diabetes management—and the new issues that also come with progress. Finally, blog use was found to be a vehicle for providing peer support and to allow peers to come together and encourage one another to advocate for issues they feel are important.

This study suggests that high-quality blogs can provide much-needed peer-to-peer support to caregivers of children with T1D, and other research is needed to verify that. Blogs could be considered as an adjunct to in-person support groups and as a venue for support in the many geographic areas that do not have easy accessibility to endocrinology offices [46,47]. If blog use is found more broadly to be a valid and safe means of support, practical methods and timing to incorporate this into practice will need to be established.

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Authors' Contributions

SO and TO conceived the study, which was developed further with EM and HS. SO was principal investigator. EM and TO were the primary coders. TO and HS performed the inductive thematic analysis. TO and SO performed clinical review of the dataset. EM developed and maintained the NVivo files. All authors contributed to manuscript preparation, with most of the writing by TO.

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Conflicts of Interest

None declared.

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Abbreviations

CGM: continuous glucose monitor
HCP: health care provider
T1D: type 1 diabetes

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Review

Digital Health for Medication Adherence in Adult Diabetes or Hypertension: An Integrative Review

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Abstract

Background: Optimal management of chronic diseases, such as type 2 diabetes and hypertension, often include prescription medications. Medication adherence (MA) is one component of self-management. Optimization through digital health—eHealth and mHealth—could enhance patient awareness and/or communication between the patient and provider.

Objective: Medication adherence is a major issue that affects 50%-60% of chronically ill adults. Digital health refers to eHealth and mHealth, collectively, and as these technologies become more accessible, remote health delivery is increasingly available as an adjunct to improve medication adherence; communicate with patients and providers; and provide education to patients, families, and communities. The objective of this integrative review was to examine the types of digital health technologies that targeted medication adherence in the adult population with diabetes or hypertension.

Methods: An integrative review was conducted using databases within EBSCOhost, PubMed, and Scopus. Eligible studies available as of September 2016 had to be written in English, had to contain digital health interventions to improve medication adherence to prescription medications in adults 18 years or older, and had to focus on diabetes or hypertension.

Results: Of the 337 located studies, 13 (3.9%) used a digital health intervention for medication adherence to prescribed medications for diabetes or hypertension and were assessed according to the Chronic Care Model.

Conclusions: The 13 studies included in this review found no conclusive evidence of improved medication adherence using digital health interventions such as interactive voice response (IVR), short message service (SMS) text messaging, telemonitoring, and interactive software technology. Among the 13 studies were digital health interventions that foster medication adherence via one-way communication to the patient or two-way communication between the patient and health care provider for adjunct medication adherence strategies. More research is needed to determine which digital health interventions are most beneficial for individuals with diabetes or hypertension.

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KEYWORDS

digital health; medication adherence; Chronic Care Model; diabetes; hypertension

Introduction

Background

The effect of chronic diseases on the health and wellness of individuals is increasing in every region of the world. The World Health Statistics 2012 report states that one in three adults worldwide has raised blood pressure and one in 10 adults has diabetes [1]. Further, diagnosis and treatment with low-cost medication has reduced mean blood pressure across populations in high-income countries and has the potential to reduce death

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and disability in low-income countries [1]. Globally, there are approximately 422 million adults with diabetes as compared to 108 million in 1980 (4.7%-8.5% in the adult population) [2]. Chronic conditions such as diabetes and hypertension contribute to an international chronic disease burden and negatively influence patient health outcomes [1,2].

Treatment of chronic conditions often includes prescription medications. Nonadherence to medication therapy can compound the increases in morbidity and mortality, and can further add to additional health care costs [3]. It is estimated that increased prescription medication adherence (MA) could save the United States US $5 billion annually in health care costs, including decreasing expensive emergency department visits and hospitalizations [4]. Medication nonadherence contributes significantly to the growing burden of disease and high costs associated with care [3,5,6].

The purpose of this integrative review is to assess the benefits of using digital health technology to improve medication adherence for diabetes and hypertension in the adult population. The following questions were asked to guide the review:

1. Does digital health technology improve medication adherence in adults with diabetes or hypertension?
2. What are benefits and barriers of medication adherence technology when implemented in adults with diabetes or hypertension?

Medication Nonadherence is a Major Problem

Medication nonadherence for individuals with chronic diseases such as diabetes and hypertension has been established as a major factor associated with negative patient outcomes [3,7]. Medication nonadherence is defined as taking less than 80% of prescribed doses, without exceeding recommended dosing [8,9]. Medication nonadherence is a complex issue with many contributing factors, which have been categorized as individual related (ie, forgetfulness and low health literacy skills) and medication related (ie, increasing dosage, increased number of medications, poor communication skills of provider, and lack of medication review by provider) [8]. The landmark World Health Organization report from 2003 stated that nonadherence to taking medications in developed countries is 50% [10], underscoring that nonadherence to prescription medication remains a significant issue, not only in the United States, but worldwide.

Measuring Medication Adherence/Nonadherence Remains Problematic

Methods to measure medication adherence fall into three categories: subjective, objective, or biochemical marker analyses. Subjective measurement is obtained by asking the patient, family member, caregiver, or physician about medication use [9]. Objective measurement is obtained by pill count, pharmacy refill information, electronic pharmacy refill data, serum drug level, or levels in the blood or urine [3,9,11]. Additionally, the use of biomedical measures is objective and accurate; however, they are expensive [11]. Technology-based methods have been introduced that provide digital health options. Whether these digital health devices improve adherence remains a topic of debate in the literature.

Health Technology to Promote Medication Adherence

Telehealth is the use of electronic information and telecommunication technologies to support clinical health care from a distance, patient and professional health education, as well as public health and health administration [12]. Additionally, telehealth includes preventive and curative health care delivered over a distance, and all forms—electronic health (eHealth), telehealth, and telemedicine—are intersected by mobile health (mHealth) [13]. A number of electronic (ie, eHealth), mobile (ie, mHealth), telehealth, and telemedicine methods have been developed to improve the delivery of health care for various conditions. eHealth refers to secure cost-effective use of information and communication technologies specific to health and health-related fields [14]. mHealth is a component of eHealth and includes mobile technologies used for dissemination of health services and information (ie, mobile phones, monitoring devices, tablets, personal digital assistants, and wireless devices) [14-16]. mHealth promotes the individual's interaction with an electronic device or technology to access or receive health information, directions, or support about health [17]. Digital health refers to eHealth and mHealth collectively [14].

In addition to facilitating communication among health care providers, these modalities can provide the opportunity for patients to receive one-way communication about health conditions and two-way communication with providers that is tailored to a health condition; this includes health data that can be transmitted as well as collected [15,16,18,19]. The diverse nature of digital health modalities as well as the evolving nature of technology provide both an opportunity and challenge for health care providers who seek to integrate technology into patient care. A plethora of data exists on the use of digital technology to assist with medication adherence [20-23]; however, further exploration is needed to determine whether these modalities improve and subsequently enhance chronic disease self-management, in particular, medication adherence in adults.

Findings from studies including digital health devices have shown improvements in self-management and adherence to treatments in many conditions such as asthma, chronic obstructive pulmonary disease, hypertension, and diabetes [24-26]. A Cochrane review of mobile phone messaging for self-management of chronic disease reported medication compliance in hypertension was 8.9% higher in the short message service (SMS) text message group versus the control group [27]. Several studies have indicated that interactive voice response (IVR) and SMS text messaging foster medication adherence through telephone-delivered diabetes education and interactive reminders can improve medication adherence in patients with diabetes [20,21,23]. Mobile communication also includes one-way and two-way text messages and weekly IVR calls to promote medication adherence for low-income racially and ethnically diverse adults with type 2 diabetes [28,29]. Additionally, telemonitoring, telehealth, and the use of a virtual classroom have been shown to enable the individual with diabetes to participate in adherence strategies [22,30]. These digital health strategies provide interactive communication that is timely and patient centered. The tailored information provided

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has the potential to improve patient outcomes through education and timely information.

Table 1. Chronic Care Model[a] components and descriptions.

Chronic Care Model components	Descriptions
Self-management support	Designed to inform the patient and family by providing training and promotion to foster self-management. The eCCM[b,c] further adds 24/7 access, convenience, reminders, and alerts.
Decision support	Emphasizes the goal to improve medical decisions for providers and patients to access current evidence-based care guidelines, reminders, and information buttons.
Clinical information systems	Collects, maintains, and utilizes patient registries; develops patient portals, Internet, mHealth, mobile phones, wearable devices, electronic health records, and personal health records.
Delivery system design	Emphasizes the importance of interdisciplinary clinical teams and collaboration between the patient and multiple providers.
Community support	Health care organization makes an effort to form powerful alliances and partnerships. The eCCM[c] further adds that eHealth education is included as a component, including eCommunity and encompassing message training, health education, technology training, numeracy, literacy, usability, and security.
Health systems	Creates an environment in which organizational efforts improve health care.

[a]The Chronic Care Model includes self-management support, decision support, clinical information systems, delivery system design, community support, and health systems as interdependent components for holistic care.

[b]eCCM: eHealth-enhanced Chronic Care Model.

[c]The eCCM further defines the role of eHealth tools and eCommunity to support holistic care.

Theoretical Framework

The Chronic Care Model (CCM) (see Table 1) is a well-established, validated framework to provide a caring approach for chronically ill individuals with a focus on increasing function and improving clinical outcomes [31].

The CCM postulates that optimal care for individuals with chronic illness requires a health system that provides the following: community support, self-management support, decision support, clinical information systems, and delivery system design [32]. Further, the eHealth-enhanced CCM (eCCM) includes the role of eHealth tools in self-management for individuals with chronic illness [31]. The eCCM is particularly tailored for assessing digital health findings as compared to the CCM, due to the inclusion of eHealth tools and strategies. This is also due to the broader definition of eCommunity to encompass a broader definition of digital health support available to include community support and education. The CCM and the eCCM are interdependent with the eCCM further defining the significance of eHealth [31].

CCM-based interventions were effective in improving clinical, behavioral, psychological/psychosocial, and diabetic knowledge outcomes, including medication adherence in patients with diabetes in research that did not utilize digital health interventions [33]. The CCM has been used as a framework for care in Malaysia and was found to improve patient outcomes [32] as well as practice-based care delivery redesign [33,34].

With developments in digital health, technology has further incorporated medication adherence strategies for chronic illnesses such as diabetes and hypertension [33-36]. These factors are interrelated, and the CCM has been implemented across many chronic conditions such as asthma, bipolar disorder, breast cancer, diabetes, hypertension, and obesity [37]. For the purpose of this integrative review, the CCM will be used to evaluate the use of digital health technology for medication adherence in diabetes or hypertension.

Methods

This integrative review adhered to the following five stages: (1) problem identification, (2) literature search, (3) data evaluation, (3) data analysis, and (5) presentation [38]. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart in Figure 1 [39] was used to depict the search results. Using a two-step strategy, a literature search was conducted to find relevant studies published from January 2006 to October 2016. Consultation with a health reference librarian aided in the refinement of search terms in the databases.

In the first step, a search strategy was developed. One reviewer (CMC) conducted the search using the following databases included within EBSCOhost to ascertain relevant studies: PubMed and Scopus. A combination of keywords and Medical Subject Headings (MeSH) terms were used as follows: “mobile health,” “mHealth,” “telemedicine,” “eHealth,” “remote consultation,” *or* “digital health” *and* “medication adherence,” “medication nonadherence,” “medication compliance,” “medication noncompliance,” *or* “medication persistence” *and* “diabetes mellitus,” “diabetes,” “type 2 diabetes,” *or* “type 2 diabetes mellitus” *and* “technology,” “websites,” *or* “apps.” Reference lists of relevant studies were hand searched. Identified citations were exported to Endnote reference management program. This strategy initially yielded 337 studies.

For inclusion in this review, peer-reviewed studies were required to report on a digital health intervention for medication adherence. Inclusion criteria included (1) English-language, peer-reviewed randomized controlled trials (RCTs) with quasi-experimental, observational, or qualitative design; (2) studies containing digital health interventions to improve

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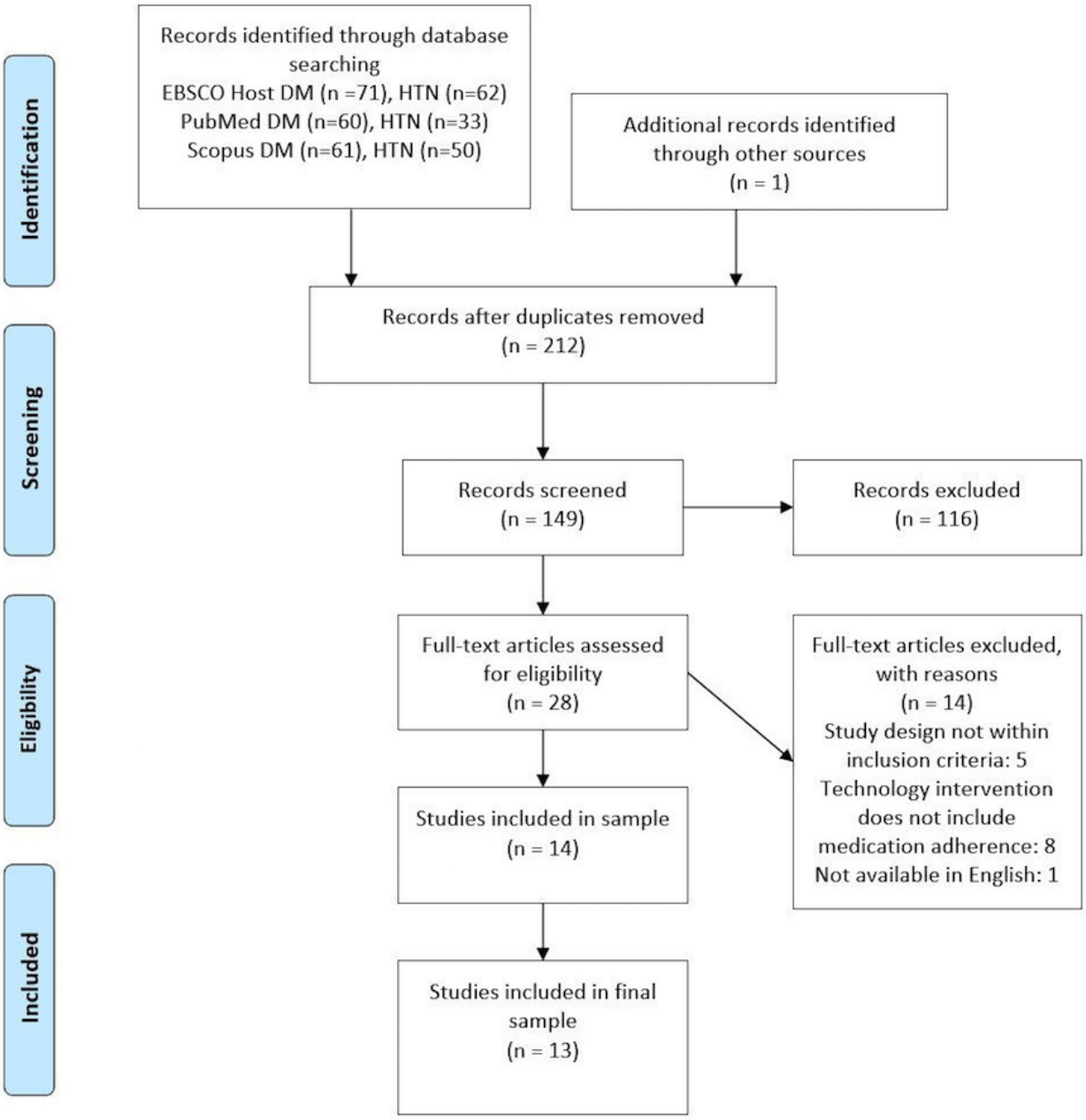
medication adherence to prescription medications in adults (ie, 18 years or older); and (3) studies focused on diabetes or hypertension. Exclusion criteria included (1) studies that did not include results of medication adherence rates or (2) pilot studies. Titles and abstracts were reviewed for relevance.

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart of studies from search to inclusion [39]. DM: diabetes; HTN: hypertension.



Results

Overview

Of the 337 studies, 13 (3.9%) [22,26,40-50] used a digital health intervention to promote medication adherence to prescribed medications for diabetes and hypertension that was summarized (see Multimedia Appendix 1) and evaluated with the Chronic Care Model (see Table 2).

Studies included nine RCTs, one quasi-experimental study, and two observational studies, one of which was a mixed-methods design. Most studies were conducted in the United States, with one study each conducted in the United Kingdom, South Africa, and South Korea.

A total of 13 studies were selected, analyzed, and organized (see Multimedia Appendix 1). Medication adherence findings for the intervention and data extraction categories, including the study objective, design, sample, intervention length, and participant age, are included in Multimedia Appendix 1. Strategies used to improve medication adherence included four primary approaches: IVR (with or without human interaction), SMS text messaging, telemonitoring and/or tailored care management, and Web-based software. The subheadings in this section consist of progressively interdependent components of

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the Chronic Care Model that influence patient-centered, evidence-based care and are designed to improve health outcomes by changing the routine delivery of care (ie, self-management support, decision support, clinical information systems, delivery system design, community support, and health systems) [37]. The reviewed studies are presented in Multimedia Appendix 1 with the intent to categorize findings based on CCM components in order to assess findings about digital health interventions for medication adherence. Table 2 provides a summary of CCM components used in each study [22,26,40-50].

Table 2. Chronic Care Model applied to studies.

Study author, year	Chronic Care Model components used in studies[a]				
	Self-management support	Decision support	Clinical information systems	Delivery system design	Community support
Aikens et al, 2014 [40]	X			X	X
Arora et al, 2014 [41]	X				
Bobrow et al, 2016 [42]	X				
Davidson et al, 2015 [43]	X	X	X		X
Edelman et al, 2015 [44]	X	X		X	X
Katalenich et al, 2015 [45]	X	X		X	
Kim et al, 2006 [46]	X		X		
Migneault et al, 2012 [48]	X	X			
Nelson et al, 2016 [47]	X				
Nundy et al, 2014 [49]	X				X
Shane-McWhorter et al, 2014 [22]			X	X	
Wakefield et al, 2011 [26]				X	
Wild et al, 2016 [50]			X	X	

[a]The health systems component was not found in the included studies.

Application of Chronic Care Model in Aim 1

Self-Management Support

The goal of *self-management support* is to inform the patient and family by providing training and health promotion to foster self-management [37]. The eCCM further adds 24/7 access, convenience, reminders, and alerts [31]. In a study conducted by Aikens and colleagues [40], a combined program of automated telemonitoring, clinician notification, and informal caregiver involvement was found to be associated with improvements in medication adherence between pretest (mean 1.20, SD 0.95) and posttest (mean 0.87, SD 0.88) using linear regression analyses. This observational, open-label trial of 301 adults aimed to identify changes in diabetes self-management and psychological distress associated with an mHealth, IVR, self-management support program [40]. Arora and colleagues [41] conducted an RCT of 128 adult patients with poorly controlled diabetes in an urban emergency department with a unidirectional, SMS text message-based mHealth intervention in English or Spanish; the RCT was called the Trial to Examine Text-based mHealth for Emergency department patients with Diabetes (TExT-MED). There was improved medication adherence among the TExT-MED group compared to the control group as measured by the Morisky Medication Adherence Scale (MMAS) (score of 4.5 to 5.4) [20]. Bobrow and colleagues [42] found that interactive SMS text messaging subsequently improved medication adherence in a group of 1372 patients treated for hypertension as indicated by prescription refill data (ie, had at least 80% of the days covered). Refill rates were higher among the information-only message group (156/248, 62.9%) and interactive message group (134/225, 59.6%) compared to the usual care group (94/190, 49.5%) [42]. Similarly, Davidson and colleagues [43] found a cellular-connected, electronic medication device that provided reminder signals and mobile phone messaging; 38 patients were reminded to take their blood pressure (BP) medications using a Bluetooth-accessible, BP monitor-improved medication adherence device in African American and Hispanic participants. Medication adherence was defined by the percent of SMS text message reminders over the past day(s) and the mean medication adherence score was 92 (SD 0.09) for all participants in the intervention group [43]. In an RCT of patients with diabetes and hypertension, Edelman and colleagues [44] found that 377 participants receiving tailored, focused behavioral content had improved medication adherence obtained by self-report. The secondary outcome of nonadherence was 52 out of 193 (26.9%) for the diabetes intervention group and 58 out of 184 (31.5%) for the control group as reported by the medication-taking scale [44]. Similarly, Katalenich and colleagues [45] found that engagement in the automated Diabetes Remote Monitoring and Management System improved medication adherence as measured by the MMAS, although the improvement was not statistically significant. The intervention group (50/98, 51%) had higher adherence (28%, 26%, and 27%) than the control group (48/98, 49%) (12%, 22%, and 20%) at baseline, 3 months, and 6 months, respectively; however, overall improvements in medication adherence self-report were not significant [45]. A

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quasi-experimental study conducted by Kim and colleagues [46] found that SMS text messaging from nurses by mobile phone or the Internet improved medication adherence in 45 patients with diabetes. Self-reported medication adherence was measured by the Summary of Diabetes Self-Care Activities (SDSCA) measure; diabetes medication-taking adherence increased 1.1 days per week at posttest as compared to pretest [46]. Recently, Nelson and colleagues [47] leveraged IVR and SMS text messaging in 80 patients with diabetes using MEssaging for Diabetes (MED) and found short-term improvements in medication adherence among adults with type 2 diabetes. Medication adherence was assessed using the SDSCA medications subscale and improved in the intervention group at 1 month (mean 6.5, SD 1.4) and 2 months (mean 6.8, SD 0.4), but did not continue to improve at 3 months (mean 6.2, SD 1.3) [47]. Likewise, an RCT conducted by Migneault and colleagues [48] found that a culturally adapted, automated telephone system used among 337 hypertensive, urban African American adults improved medication adherence slightly as measured using the MMAS (0.19 points relative to controls), which was not statistically significant. Finally, Nundy and colleagues [49] conducted a mixed-methods observational cohort study using a theory-driven, mobile phone-based intervention with 74 adults with diabetes; an automated SMS text messaging system combined with remote nursing improved medication adherence as measured by the SDSCA measure of weekly adherence and the MMAS. At both 3 and 6 months, the MMAS 4-item score (out of 4) improved (3.3, $P<.10$ and 3.4, $P<.02$, respectively) compared to baseline (2.9, $P<.10$); however, no change in weekly medication adherence was observed between 3 and 6 months (score of 4.4 and 4.4, respectively) [49]. There are positive benefits of the use of one-way and two-way digital health messages to engage patients in timely self-management to improve medication adherence. Strategies such as IVR and SMS text messaging provide evidence of improved short-term medication adherence using educational and reinforcement reminders.

Decision Support

Decision support emphasizes the goal to improve medical decisions for providers and patients to access current evidence-based care guidelines [37]. In addition, eCCM discusses reminders and info buttons [31]. Davidson and colleagues [43] discussed a "several year" iterative design process for the Smartphone Medication Adherence Stops Hypertension (SMASH) program that involved key informant interviews and focus groups with health care providers and patients to develop SMS text message reminders. Likewise, Edelman and colleagues [44] used nurses' behavior-modifying content specific to each patient's individual barriers based on evidence-based approved content. In addition, Migneault and colleagues [48] developed the Telephone-Linked-Care intervention using ethnic mapping in focus groups for hypertension. In addition, Katalenich and colleagues [45] used validated diabetes algorithms to evaluate glycemic control and adherence. Of the four studies that included decision support for medication adherence, two had statistically significant findings [43,44] while two did not have statistically significant differences between groups [45,48].

Clinical Information Systems

Clinical information systems are used to collect, maintain, and utilize information within the context of health care, such as patient registries and electronic medical records [31]. In addition, eCCM emphasizes the development of patient portals, Internet, mHealth, mobile phones, wearable devices, and patient health records [31]. Integration of secure-messaging e-visits, home monitoring with feedback, health risk appraisal with feedback, medication refills, tailored interventions, and links to community programs are possible with digital health technology. In a study by Davidson and colleagues [43] to measure medication adherence, electronic medication trays provided reminder signals and SMS text messaging reminded 38 African American and Hispanic participants to monitor BP with Bluetooth-enabled monitors; a mean of 92% (SD 0.09) of reminders were received across the 6-month trial. Additionally, an MA (medication adherence) score was averaged to calculate adherence (daily scores ranged from 0 to 1) with "fully compliant" defined as ingesting all medications within a 3-hour window. Ingesting all medications within a 6-hour window received half credit and ingesting all medications outside a 6-hour window or a missed dose received no credit. The mean MA score was 92 (SD 0.09) for all participants [43]. Additionally, the intervention group BP mean adherence was 86.2% (SD 6) (on time every 3 days) [43]. Recently, Katalenich and colleagues [45] studied health care providers who could monitor progress of their 98 patients through a Web-based secure portal; study findings revealed the intervention group (50/98, 51%) had higher MA than the control group (48/98, 49%) at each measurement time—baseline, 3 months, and 6 months. Additionally, Kim and colleagues [46] included the use of the Internet to support secure communication-based optimal diabetes recommendations, with the intervention group (33/45 completers, 73%) having an increased MA of 1.1 days per week between pretest and posttest. A study by Shane-McWhorter and colleagues [22] discussed the asynchronous involvement of a remote care monitor—usually a pharmacist—and email alerts to a medical provider if a patient has an out-of-range value via a mobile communication platform. The nonrandomized prospective observational preintervention and postintervention design of the study with 125 participants resulted in improvements in medication adherence for diabetes patients (6.2 and 6.5, respectively; $P=.09$) and hypertension patients (6.3 and 6.7, respectively; $P=.05$); however, the difference in improvement was not statistically significant for the intervention group. An RCT conducted by Wild and colleagues [50] that included 321 participants with type 2 diabetes used Bluetooth technology to transmit BP, glucose, and weight readings through a supplied modem interacting with a remote secure server manned by research nurses. Medication adherencewas reported with no significant differences between the monitored intervention group (n=160) and control group receiving usual care (n=161). MA linear regression models were performed for 270 participants: monitored group (n=139; baseline and follow-up mean 0.7, SD 0.9) and unmonitored/control group (n=131; baseline mean 1.0, SD 1.0; follow-up mean 0.8, SD 1.0). Of the four studies that included medication adherence clinical information support using digital health technology, there were no statistically significant

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findings; supportive measures, such as secure portal, Internet, or medication pill dispenser, were not discussed in the outcomes.

Delivery System Design

Delivery system design includes the importance of interdisciplinary clinical teams and collaboration between the patient and multiple providers [37]. Bluetooth-enabled devices and the use of chat, voice, and video communication allow the health care team to provide many of the elements of a traditional office visit. The use of innovative technology affords a low-cost, flexible means to supplement formal health care. Aikens and colleagues [40] found that automated telemonitoring clinician notification provided the clinician with actionable feedback through faxed updates about patient-reported health and self-care problems including MA. Aikens and colleagues [40] identified significant pre-post improvement in MA (mean MMAS score 1.20, SD 0.95 and mean MMAS score 0.87, SD 0.88, respectively; $P<.001$). Additionally, Edelman and colleagues [44] reported that a nurse-led diabetes and hypertension behavior modification intervention, Tailored Case Management for Diabetes and Hypertension (TEACH-DM), communicated patient results to providers with statistically insignificant differences between groups as follows: 26.9% from the diabetes intervention group and 31.5% from the diabetes control group were nonadherent (medication-taking scale); 43.0% from the hypertension intervention group and 42.9% from the hypertension control group were nonadherent [44]. Similarly, providers in the Diabetes Remote Monitoring and Management System study could monitor the progress of their patients through a Web-based portal [45]. Overall improvements in medication adherence self-report were not statistically significant [45]. Shane-McWhorter and colleagues [22] used remote telemonitoring for patients with uncontrolled diabetes and/or hypertension from four rural and primary clinics and one stroke center with improvement in medication adherence for diabetes and hypertension, although improvements were not statistically significant ($P=.09$ and $P=.05$, respectively). Wakefield and colleagues [26] used a home telemonitoring device and home care management in patients with comorbid diabetes and hypertension. Medication adherence improved over time for all three groups—high intensity, low intensity, and usual care—but there were no differences among the three groups [26]. Lastly, Wild and colleagues [50] included supported telemonitoring intervention involving self-measurement and transmission to a secure website with no significant differences identified between groups in medication adherence. Of the six studies that included MA delivery system design, one reported statistically significant improvement [40]. The conflicting results from these studies suggest that more research is needed to determine which groups might benefit from digital health strategies.

Community Support/eHealth Education

Community support links the patient to local resources and provides an opportunity for organizational leaders to establish new relationships and expand [37]. In the eCCM model, *eHealth education* is included as a component of eCommunity and encompasses message training, health education, technology training, numeracy, literacy, usability, and security [31]. Two studies in this review included culturally attuned messages to improve medication adherence [43,48]. Additionally, two studies found a positive correlation between social support and medication adherence [40,49]. One study addressed health literacy, but did not find a significant correlation to medication adherence [44].

Health Systems

The health care system creates an environment in which organization efforts improve care [37]. No studies included organization of health care and health systems.

Benefits and Barriers of Medication Adherence by Digital Health Technology in Aim 2

The second aim of this review was to determine the benefits and barriers of MA technology studied in adults with diabetes or hypertension. Overall, the strongest benefit of digital health technologies to measure medication adherence involve patient engagement in diabetes and hypertension self-management through either one-way or two-way interactive reminders or educational information. Some reminders were culturally adapted [43,48] as well as tailored to the population of interest [40,44,47]. In addition, patient-reported data (ie, medication-taking behaviors, blood glucose, blood pressure, and weight) could be shared with health care providers through interactive communication platforms using SMS text messages, Bluetooth-enabled devices, or the Internet.

The primary barriers of digital health technologies for measurement of MA included the iterative nature of tailored message development, which involved input from focus groups, health care providers, and patients [40,43,44,47], as well as staffing the interactive application [22,26,46,50]. While there were varying costs, there were also ongoing expenses of maintaining a communication platform and/or personnel. The included studies discussed the expense of maintaining telemonitoring infrastructure [50], personnel [22,26], Web-based software [47,48], and electronic medication trays [43].

Discussion

Improvement of Medication Adherence Using Digital Health Technology

The first aim of this review was to determine if digital health technologies improve medication adherence in adults with diabetes or hypertension. Of the 13 studies included in this review, there was no conclusive demonstration of improved medication adherence using digital health interventions such as IVR, SMS text messaging, telemonitoring and remote monitoring, and interactive software technology. However, in some studies the benefits of digital health technology were short term or close to statistically significant [47]; for example, benefits improved but were not statistically significant [22] or there were benefits in both the intervention and control groups [26].

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Table 3. Benefits and barriers of digital health technology for medication adherence.

Study author, year	Digital health technology	Benefits	Barriers
Aikens et al, 2014 [40]	IVR[a]-tailored text messages; clinician notification	Interactive, tailored SMS[b] text messages; clinician notification	Development of tailored SMS text messages
Arora et al, 2014 [41]	Daily SMS text messages in English or Spanish	Frequent reminders, available in English or Spanish	One-way reminders
Bobrow et al, 2016 [42]	SMS text messaging	SMS text message reminders by mobile phone	Use of refill data; availability of medications
Davidson et al, 2015 [43]	Electronic medication trays: reminder signals; reminder SMS text messages	Culturally sensitive	Expense of electronic medication trays
Edelman et al, 2015 [44]	TEACH-DM[c]: call from nurse; tailored SMS text messages; diabetes- and hypertension-focused content versus nontailored, noninteractive information	Tailored SMS text messages	Development of tailored SMS text messages
Katalenich et al, 2015 [45]	SMS text messages or phone call reminders to use automated system; no interaction unless severely high or low glucose	SMS text message reminders by mobile phone	No interaction unless severely high or low glucose
Kim et al, 2006 [46]	SMS text messages and Internet education	Medication reminders and education	Nurse SMS text message expense
Migneault et al, 2012 [48]	Automated, multi-behavior intervention or education-only control	Culturally adapted reminders and education	Expense of computer-based, interactive counseling system; development of tailored SMS text messages
Nelson et al, 2016 [47]	SMS text messages/IVR: deliver and tailor text messages and voice communications to promote MA[d]	Tailored SMS text messages and IVRs	Expense of communication platform; development of tailored SMS text messages
Nundy et al, 2014 [49]	Web-based software reminders and texted-back responses to questions	Interactive (text-back), mobile-based, educational messages and reminders	Expense of Web-based software
Shane-McWhorter et al, 2014 [22]	Telemonitoring with asynchronous measurements transmitted from the patient to a remote care coordinator: pharmacist or certified diabetes educator	Self-management; patient data entered for clinician review	Expense of remote care coordinator
Wakefield et al, 2011 [26]	Closed surveillance via home telehealth device and nurse care management	Self-management; patient data entered for clinician review	Expense of nurse care management
Wild et al, 2016 [50]	Supported telemonitoring intervention involved self-measurement and transmission to a secure website; review by family practice clinicians	Clinician notification	Expense of telemonitoring infrastructure and password-protected server

[a]IVR: interactive voice response.

[b]SMS: short message service.

[c]TEACH-DM: Tailored Case Management for Diabetes and Hypertension.

[d]MA: medication adherence.

While studies demonstrated improved v [40,41], there was no consistent evidence of sustained adherence. Notably, nine studies were 6 months or less in duration. In five studies, there was improvement in medication adherence, but the difference in medication adherence was not statistically significant between the intervention and control groups [22,26,44,48,50].

Different psychometric instruments informed adherence measurement across populations. Medication adherence self-report was the primary method, with MMAS being the most commonly used psychometric instrument, either as the sole measure or in conjunction with another measure such as a self-report questionnaire [40,41,45,48-50]. The MMAS is a well-validated and reliable psychometric instrument to measure medication adherence in populations [51]. Although all 13 studies measured medication adherence, there was a lack of a consistent measure among studies to assess medication adherence, which may partially account for mixed findings of significance in the study interventions.

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This review illustrates that digital health interventions hold promise for improving short-term medication adherence for diabetes and hypertension, including IVR, SMS text messaging, telemonitoring, and Web-based software. Nevertheless, despite the growing interest in the use of various digital health technologies, there is limited evidence of efficacy of such interventions for enhancing long-term medication adherence among adults with diabetes or hypertension. Thus, there are still areas in which to learn about medication adherence digital health interventions, such as long-term outcomes, cost-effectiveness, and impact of patient age, ethnicity, and socioeconomic status. Digital health technologies are a promising option. Digital health technologies have improved medication adherence and self-care for some patients with chronic obstructive pulmonary disease [52], coronary artery disease [53], and heart failure [54,55]. More research is needed in adult populations with chronic illnesses and for longer study durations than 6 months using evidence-based, common assessment strategies; these will determine which patients and demographic groups can benefit from digital health interventions for medication adherence. Table 3 provides a summary of the benefits and barriers of the included studies.

Chronic Care Model

This review included MA interventions categorized according to the Chronic Care Model. In addition, health care providers could use the CCM to provide a blueprint to support care that is evidence based, population based, and patient centered [56] in order to improve digital health intervention-driven outcomes. While the CCM guided this integrative review, other theoretical models could be considered to review digital health technology interventions, such as the Theory of Planned Change or the Technology Acceptance Model. Additionally, the eCCM should be further used and evaluated for validation in chronically ill populations. Other theoretical models could be used or created to assess digital health for individuals with different comfort levels with technology. For example, the Senior Technology Acceptance Model has been developed to assess older adults' comfort with technology in Hong Kong [57].

Limitations

There are opportunities to pursue a better understanding of medication adherence and to measure the impact on clinical practice. Currently, there is no consensus about methods to assess medication adherence, which makes it difficult to compare adherence rates across studies. The most frequently used method for assessing adherence is self-report, a subjective assessment of adherence; while cost-effective, self-report is often not as reliable as objective measurements, such as serum drug level or pill count [9]. Additionally, there were studies that addressed treatment adherence or self-management that did not meet the inclusion criteria for this integrative review because MA outcomes were not addressed as a study outcome or medication adherence outcome was not reported.

Conclusions

This integrative review was conducted to examine the types of digital health technologies that have targeted medication adherence in the adult population, aged 18 years and older. Digital health included a number of technologies to foster medication adherence, including IVR, SMS text messaging, telehealth, and Web-based software. In some chronically ill populations, the digital health technology interventions that were reviewed fostered v via one-way communication to the patient or two-way communication between the patient and health care provider [43,48]. Two-way communication occurred through patient timely reporting of monitored results, such as blood glucose and BP to the health care provider to receive feedback about care [40]. Digital health technologies were found to be diverse and the populations studied varied in size, ethnicity, and age range. There remains ample opportunity to enhance patient and provider communication via digital technology as new mobile and electronic media emerge, especially in populations increasingly familiar with mobile phones, tablets, and other mobile communication devices.

Relevance to Practice and Research

Nonadherence by adults is a significant public health problem and there are opportunities to better understand the role of digital health interventions for this population [3]. Digital health interventions provide cost-effective strategies as an adjunct to medication adherence management [43,49]. Future interventions should address the use of digital health interventions for medication adherence using evidence-based systematic frameworks to ensure this technology provides high-quality alternatives. This is a prominent area for future research considering the availability of technology among adults globally. Moreover, study findings suggest that digital health interventions can improve short-term medication adherence. Digital health interventions could help reduce health disparities related to nonadherence in chronically ill populations, such as those with diabetes and hypertension, where these interventions are used in combination with other treatments for those seeking to improve medication adherence. These modalities need further exploration among younger and much older populations and over longer durations to document sustainability of medication adherence.

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Conflicts of Interest

None declared.

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Multimedia Appendix 1

Summary of studies included.

[PDF File (Adobe PDF File), 466KB - diabetes_v2i2e20_app1.pdf]

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Abbreviations

BP: blood pressure
CCM: Chronic Care Model
eCCM: eHealth-enhanced Chronic Care Model
eHealth: electronic health
IVR: interactive voice response
MA: medication adherence
MED: MEssaging for Diabetes
MeSH: Medical Subject Headings
mHealth: mobile health
MMAS: Morisky Medication Adherence Scale
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial
SDSCA: Summary of Diabetes Self-Care Activities

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SMASH: Smartphone Medication Adherence Stops Hypertension
SMS: short message service
TEACH-DM: Tailored Case Management for Diabetes and Hypertension
TExT-MED: Trial to Examine Text-based mHealth for Emergency department patients with Diabetes

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Original Paper

A Fully Automated Conversational Artificial Intelligence for Weight Loss: Longitudinal Observational Study Among Overweight and Obese Adults

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Abstract

Background: Type 2 diabetes is the most expensive chronic disease in the United States. Two-thirds of US adults have prediabetes or are overweight and at risk for type 2 diabetes. Intensive in-person behavioral counseling can help patients lose weight and make healthy behavior changes to improve their health outcomes. However, with the shortage of health care providers and associated costs, such programs do not adequately service all patients who could benefit. The health care system needs effective and cost-effective interventions that can lead to positive health outcomes as scale. This study investigated the ability of conversational artificial intelligence (AI), in the form of a standalone, fully automated text-based mobile coaching service, to promote weight loss and other health behaviors related to diabetes prevention. This study also measured user acceptability of AI coaches as alternatives to live health care professionals.

Objective: The objective of this study was to evaluate weight loss, changes in meal quality, and app acceptability among users of the Lark Weight Loss Health Coach AI (HCAI), with the overarching goal of increasing access to compassionate health care via mobile health. Lessons learned in this study can be applied when planning future clinical trials to evaluate HCAI and when designing AI to promote weight loss, healthy behavior change, and prevention and self-management of chronic diseases.

Methods: This was a longitudinal observational study among overweight and obese (body mass index ≥25) participants who used HCAI, which encourages weight loss and healthy diet choices through elements of cognitive behavioral therapy. Weight loss, meal quality, physical activity, and sleep data were collected through user input and, for sleep and physical activity, partly through automatic detection by the user's mobile phone. User engagement was assessed by duration and amount of app use. A 4-question in-app user trust survey assessed app usability and acceptability.

Results: Data were analyzed for participants (N=70) who met engagement standards set forth by the Centers for Disease Control and Prevention criteria for Diabetes Prevention Program, a clinically proven weight loss program focused on preventing diabetes. Weight loss (standard error of the mean) was 2.38% (0.69%) of baseline weight. The average duration of app use was 15 (SD 1.0) weeks, and users averaged 103 sessions each. Predictors of weight loss included duration of AI use, number of counseling sessions, and number of meals logged. Percentage of healthy meals increased by 31%. The in-app user trust survey had a 100% response rate and positive results, with a satisfaction score of 87 out of 100 and net promoter score of 47.

Conclusions: This study showed that use of an AI health coach is associated with weight loss comparable to in-person lifestyle interventions. It can also encourage behavior changes and have high user acceptability. Research into AI and its application in telemedicine should be pursued, with clinical trials investigating effects on weight, health behaviors, and user engagement and acceptability.

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KEYWORDS

obesity; artificial intelligence; self efficacy; weight loss; prediabetes; smartphone; diabetes; compassion; mobile health; text messaging

Introduction

The Burden of Type 2 Diabetes

An estimated 30.3 million Americans, or 9.4% of the US population, have type 2 diabetes (T2D). Another 84.1 million, or 33.9% of the adult US population, has prediabetes and is at risk for developing T2D [1]. The estimated cost of diabetes in 2012 was US $245 billion [2]. Another estimated cost is an extra annual per-patient cost of US $4217 [3]. It is the country's most expensive chronic disease [4], the seventh-leading cause of death in the United States, and a risk factor for complications and cardiovascular disease [2].

The T2D burden is largely attributable to modifiable risk factors [5]. Each 1 kg decrease in excess body weight lowers T2D risk by 16% among individuals with prediabetes [6]. Modest weight loss among overweight individuals also improves glycemic control [7-10]. Other modifiable risk factors for T2D include diet quality, sleep [11], and physical activity [12]. Diets rich in fruit, vegetables [13-15], low-fat dairy products, polyunsaturated fatty acids, nuts, dietary fiber, and whole grains [16], and diets lower in red and processed meat, refined grains, and sugar-sweetened beverages can lower T2D risk [17,18]. Still, two-thirds of American adults are overweight or obese [19]. Consumption of nutrient-dense foods, such as vegetables, fruits, whole grains, seafood, and low-fat dairy products is low while consumption of solid fats and added sugars is high [20]. Nearly 4 out of 5 adults fail to meet physical activity recommendations for aerobic and strength training exercise [21].

Lack of Health Care System Resources

Lifestyle modification programs can lead to weight loss and reduction of diabetes risk [22], but they are difficult to maintain on one's own [23], and health care resources are limited [24]. The Association of American Medical Colleges projects shortfalls of both primary care physicians and endocrinologists by 2030 [25]. Both providers and patients report lack of time [26]. Patients also perceive a lack of provider compassion, including components such as sensitivity, caring, and understanding [27], despite both the Health and Medicine Division, formerly the Institute of Medicine, and the American Diabetes Association recognizing the significance of patient-centered care [28,29].

Economic resources in the health care system are inadequate for preventive measures such as weight loss and other behavioral changes. Diabetes with complications is among the most expensive condition billed to Medicare [27], and most of the T2D expenditures in the United States are for intensive treatments such as hospital inpatient care (43%), prescription medications to treat complications (18%), and nursing/residential facility stays (8%) [2].

The Role of Artificial Intelligence in Compassionate Diabetes Care

Significant progress has been made in leveraging technology to increase efficiency and improve health outcomes, including in chronic disease self-management [30]. For example, mobile apps have been used for patient monitoring, health service support, treatment, diagnosis, health promotion, and disease prevention [31], and to support weight and diabetes management and glycemic control [32-35]. However, while technology has improved health care efficiency, such as in the use of electronic health records [36], it has not been widely used to increase compassionate patient-centered care in direct patient interactions despite evidence that empathy and patient-centered care result in better health outcomes [37]. Technology such as artificial intelligence (AI) can help fulfill this need in T2D prevention by promoting healthy lifestyle changes. By utilizing AI that is compassionate and effective, these programs can reduce the need for in-person appointments and direct patient-provider interaction, providing much-needed scalability to relieve pressure on limited health care resources.

As AI and mobile health technology provide a platform to make health behavior coaching programs more accessible to patients, they can also enable the scaling up of empathy and compassion. It can be designed to be compassionate based on characteristics defined in the literature, such as being one-on-one, individualized, and responsive to patients, and having "empathy plus sympathy" [38]. Scalable technologies such as conversational AI can have a notable impact on T2D prevention and management, in which sustained patient self-efficacy and behavior change greatly affect health outcomes.

The Lark Health Coach Artificial Intelligence Mobile Phone App

The Lark Health Coach AI (HCAI) mobile phone app was designed with goals of achieving healthy behavior change among at-risk users and introducing compassionate care in health care systems to allow patients access to infinitely scalable healthy behavior change coaching and support.

Lark's AI health coaches mimic health professionals' empathetic health counseling through casual conversations using empathetic text-based communication and other interactive elements. Lark has a variety of products focusing on chronic conditions including obesity and diabetes. In this study, we looked at Lark's Weight Loss HCAI, which is a product focused on promoting weight loss and other diabetes-preventing and diabetes-managing behaviors such as achieving and/or maintaining healthy sleep duration [11], choosing foods and beverages categorized as "healthy," and setting and achieving daily and weekly activity goals. Portions of the HCAI use content and methods based on the Diabetes Prevention Program (DPP) curriculum, which has been shown to lead to weight loss [39].

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The HCAI aims to increase compassion in health care according to the definition of compassion: "the feeling that arises in witnessing another's suffering and that motivates a subsequent desire to help" [40]. The AI witnesses user suffering or positive feelings through user-provided feedback about their struggles, such as not losing weight or feeling ill, or accomplishments, such as eating a healthy meal. It shows a "subsequent desire to help" through conversations around the event or feeling. The conversations deliver messages that provide both strategic help (eg, "A pastry here and there won't hurt you/But next time experiment with which healthier alternatives you also find yummy and satisfying"), as well as emotional support (eg, "know that when it comes to weight loss, ups and downs are typical").

To promote sustainable behavior change and increased self-efficacy, the AI incorporates interactive elements of cognitive behavioral therapy (CBT) such as reflection, legitimization, respect, support, and partnership [24]. Conversations with patients are triggered by and responsive to real-time data gathered automatically from sensors on phones or integrated devices such as wearables, or by patient-provided information, such as dietary consumption. Features intended to improve the user experience include the continuous and unlimited availability of the app, as well as responsiveness to user input. Users can initiate conversations with their health coach any time and receive immediate feedback. The health coach responds to users' specific input, such as food and beverage consumption, weight, or sleep duration, with relevant content such as praise, educational material, or reflection.

Study Overview and Aims

Because of the shortcomings in traditional health care delivery channels to help patients achieve healthy lifestyle changes for lowering T2D risk, and the potential for mobile technologies to provide effective and compassionate interventions, there is a role for conversational AI to provide highly scalable health coaching to effect positive change in behaviors known to lower T2D risk. This study's objectives were to (1) investigate conversational AI use and relationships with weight loss and meal healthiness, and (2) investigate user engagement and acceptability of the HCAI. We hypothesized that AI users would lose weight and improve meal healthiness.

Methods

Study Design

Recruitment

This was a retrospective study among 239 overweight and obese (body mass index [BMI] of at least 25 kg/m^2) adults at one of six primary care offices in Nevada and southern California who were within a provider network that had partnered with Lark for this trial. Patients' primary care physicians offered the HCAI free of charge to patients meeting the BMI requirement. Additional selection criteria were use of Android or iOS mobile phones and not being previous or current Lark app users. Patients who agreed to use the app had a link to install the app sent to their mobile device during the office visit. No further physician support was provided to patients. Initial use of the app took place from July 2016 to January 2017.

Ethics

Michigan State University's Institutional Review Board (IRB) determined that this study was not classified as human subject research and therefore did not require IRB approval.

Lark Health Coach Artificial Intelligence Mobile Phone App

Health Coach Development and User Setup and Experience

Lark (Lark Technologies) HCAI has been available for Android and Apple mobile phones since 2015. The HCAI provides weight loss coaching through modules with lessons on topics such as self-monitoring, goal-setting, and action planning, plus unlimited text-based quick counseling sessions to help users achieve behavior change goals. Users can complete the modules within 16 weeks, or they can take longer if they repeat lessons or avoid logging into the app for a week or more. The HCAI learns about users and provides personalized content. Additional human-like coaching aspects include guiding dialogues with users and leading users through goal-setting modules for weight loss and food choices.

When setting up the app, users are asked to enter age, gender, weight, and height, and are guided through content to set a goal weight. Users can choose their goal weight but are discouraged from selecting a goal weight that would put them at an underweight BMI (≤18.5 kg/m^2). The HCAI prompts users to enter their weight weekly and to enter meals and snacks. They can also enter their weight measurements and diet consumption anytime (Figure 1). Users receive feedback immediately after data entry and in daily and weekly update conversations. Users can log in to the app and initiate conversations at any time. Conversations are designed to look like standard text message conversations (Figures 2-5).

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Figure 1. User weight progress dashboard, where users can enter weight (left two panels) and see a chart of weight change since starting the program (right panel).

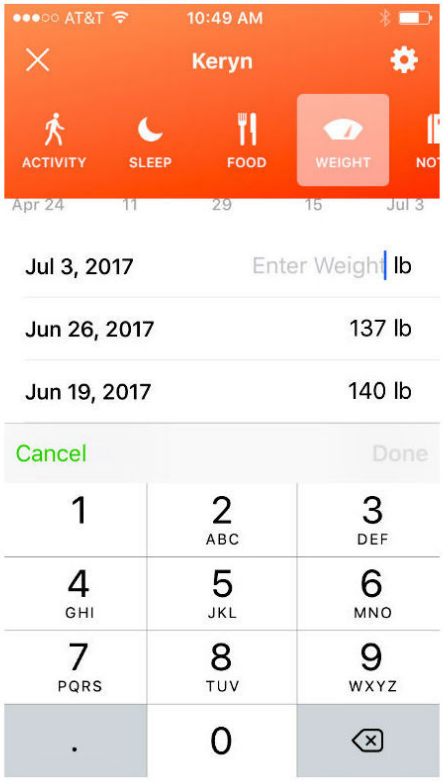

Figure 2. Sample portion of a conversation with the AI promoting healthy behavior change through compassion and cognitive behavioral therapy strategies including in-the-moment responsiveness, responsiveness to user input, and reflection.

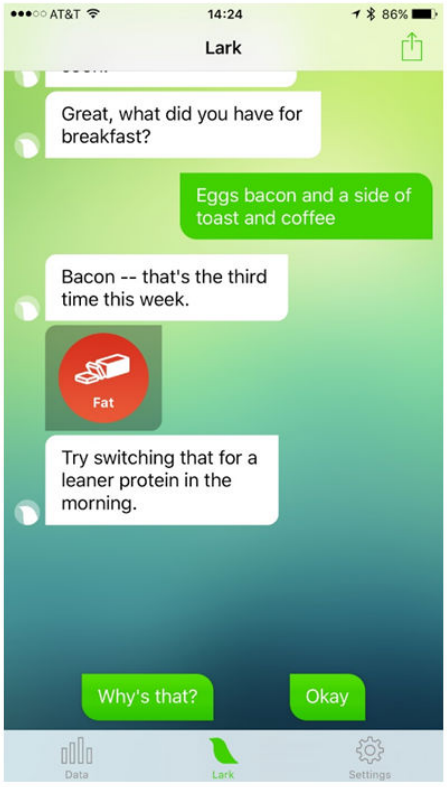

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Figure 3. Sample conversations about goal weight and user weight loss.

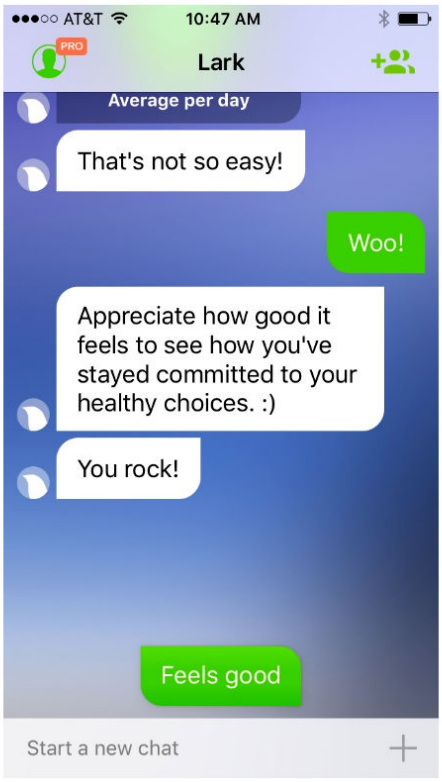

Figure 4. Sample conversations following user-logged meals.

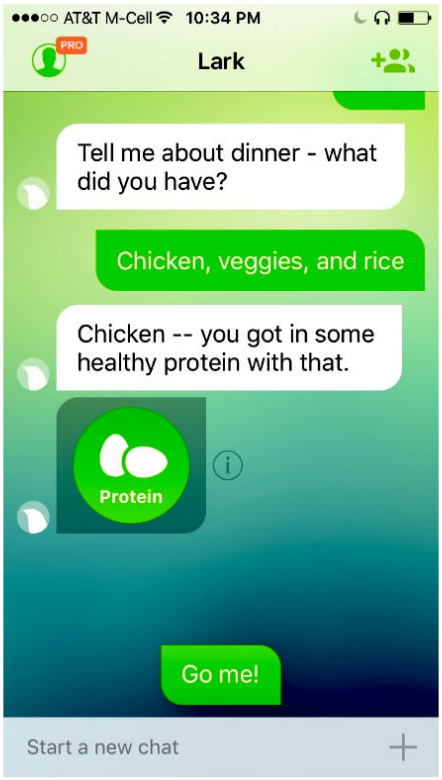

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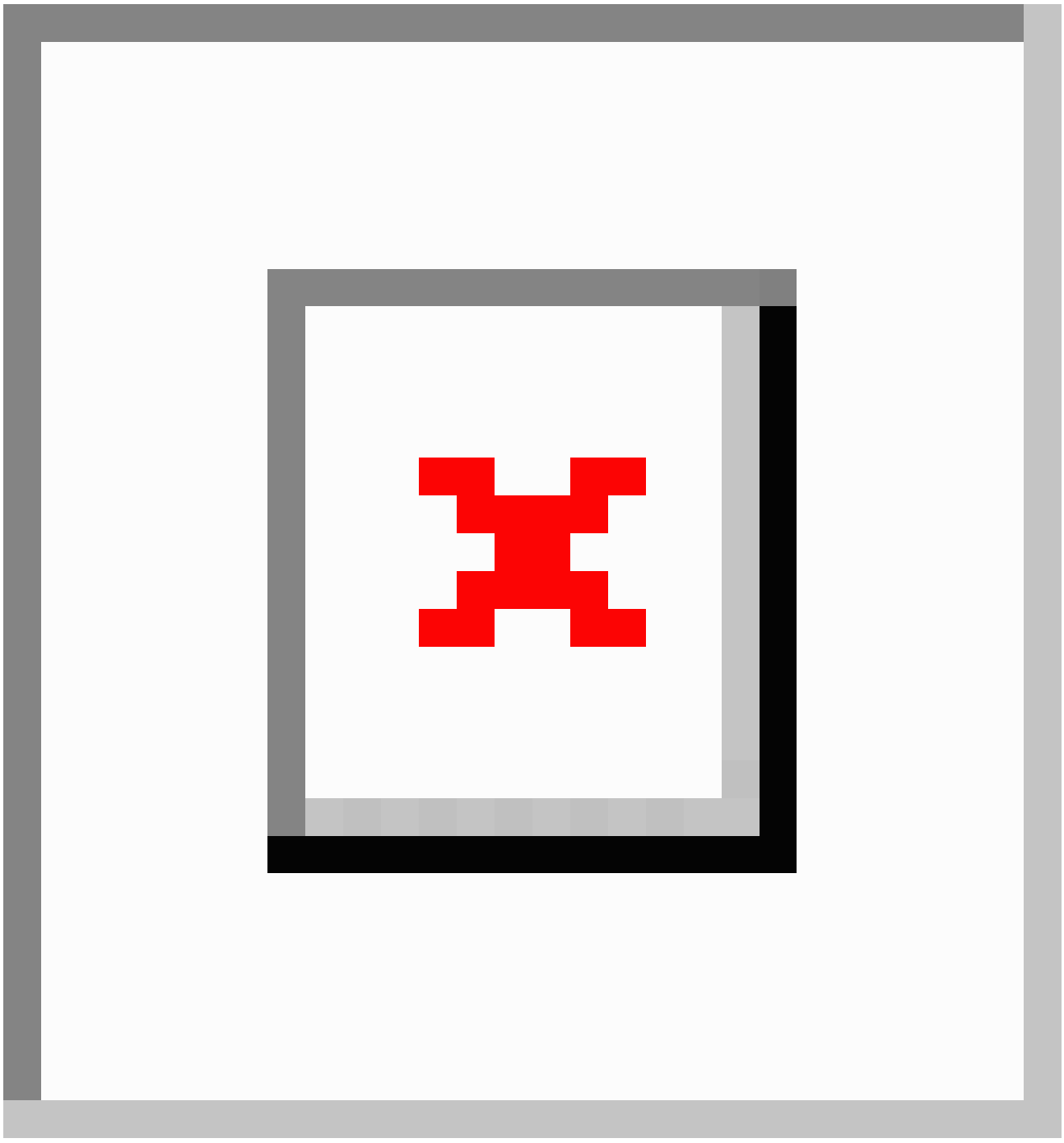
Figure 5. Conversation following user-logged bout of physical activity (1 hour, 26-minute run) praising the user for the run, informing the user (left panel) that the run is a good strategy for increasing overall activity, and (center and right panels) comparing the user's total current activity for the day (green line) to the user's daily average on weekend days since starting the program (white dashed line).



Outcome Evaluation

Weight Loss

Each user's weight loss was calculated as the difference between the final recorded weight and the baseline weight. The primary outcome in this study was percent weight change.

Meal Quality

The HCAI classified individual foods and beverages as "healthy" if they promote weight control based on literature, or they were nutrient-dense or have predominantly nutrient-dense components (eg, vegetables, whole grains, fruit, nuts, lean proteins, and mixed foods such as vegetarian burgers and Greek salad); "unhealthy" if associated with weight gain based on literature and/or contain many empty calories [20] (eg, fried foods, sweets, sugar-sweetened beverages, and fatty red and processed meats); or "neutral" if not classified as "healthy" or "unhealthy" (eg, corn, which is high in nutrients such as dietary fiber and potassium, but higher in starch and calories than many other vegetables). Meals were recorded as "healthy" if they contained at least one healthy food and no unhealthy foods, and "unhealthy" if they contained at least one unhealthy and no healthy foods.

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Percent healthy and unhealthy meals at baseline were calculated by dividing the total number of healthy and unhealthy, respectively, meals logged by the total number of meals logged (including healthy, unhealthy, and neither) during the first week of logging. Final percent healthy and unhealthy meals were calculated based on the final week that users logged meals.

User Engagement

Duration of AI use was measured by the time, in weeks, between a user's first and final use of the app. The number of conversations each user had with the app was also recorded.

Artificial Intelligence Acceptability and User Satisfaction

User satisfaction was assessed by an in-app user trust survey with four questions measuring (1) overall satisfaction, (2) net promoter score (NPS), (3) disappointment if HCAI were not o ered, and (4) self-reported health improvement (Table 1). The satisfaction score (SS; Question 1) was the percentage that rated satisfaction as 6-10. Question 2 was used to calculate NPS by subtracting the percentage of detractors (score 0-6) from the percentage of promoters (score 9-10), as described by Krol et al [41]. The disappointment score (DS; Question 3) was the percentage that rated disappointment if the HCAI were not offered as 6-10. Health outcome score (HOS) was percentage of users responding that their health was "Much better than before" or "Somewhat better than before." The SS, DS, and HOS were developed directly with the provider network.

Table 1. User trust survey to determine patient SS, NPS, DS, and HOS.

Measurement	Question text
SS	How would you rate your overall satisfaction with the Lark Weight Loss Program (where 10 is Very Satisfied and 0 is Very Dissatisfied)?
NPS	How likely are you to recommend the Lark Weight Loss Program to others (where 10 is Extremely Likely and 0 is Extremely Unlikely)?
DS	If the need were to arise again in the future, how disappointed would you be if the Lark Weight Loss Program was not available to you (where 10 is Extremely Disappointed and 0 is Not at all disappointed)?
HOS	As a result of the help you received from the Lark Weight Loss Program, would you say your health is (Much better than before, Somewhat better than before, Neither better nor worse, Somewhat worse, Much worse than before)?

Statistical Analysis

Dataset

Data points were user-entered values for age, gender, height, weight, dietary intake, with self-reported anthropometric data [42,43] and Web-reported diet intake previously validated [44,45]. As shown in Figure 6, participants installed the app and provided their height and baseline weight. An additional 81 additional participants had downloaded the app, making an initial total of 239, but they failed to provide initial height and/or weight data. Data from another 76 participants were eliminated from analysis for failing to record a second weight, making it impossible to determine weight change from baseline. Consistent with guidelines used to evaluate DPP outcomes [46], 13 of the remaining 83 users were recorded as "inactive" due to failure to record conversations with the HCAI in at least 4 separate weeks, leaving data from 70 participants available for analysis.

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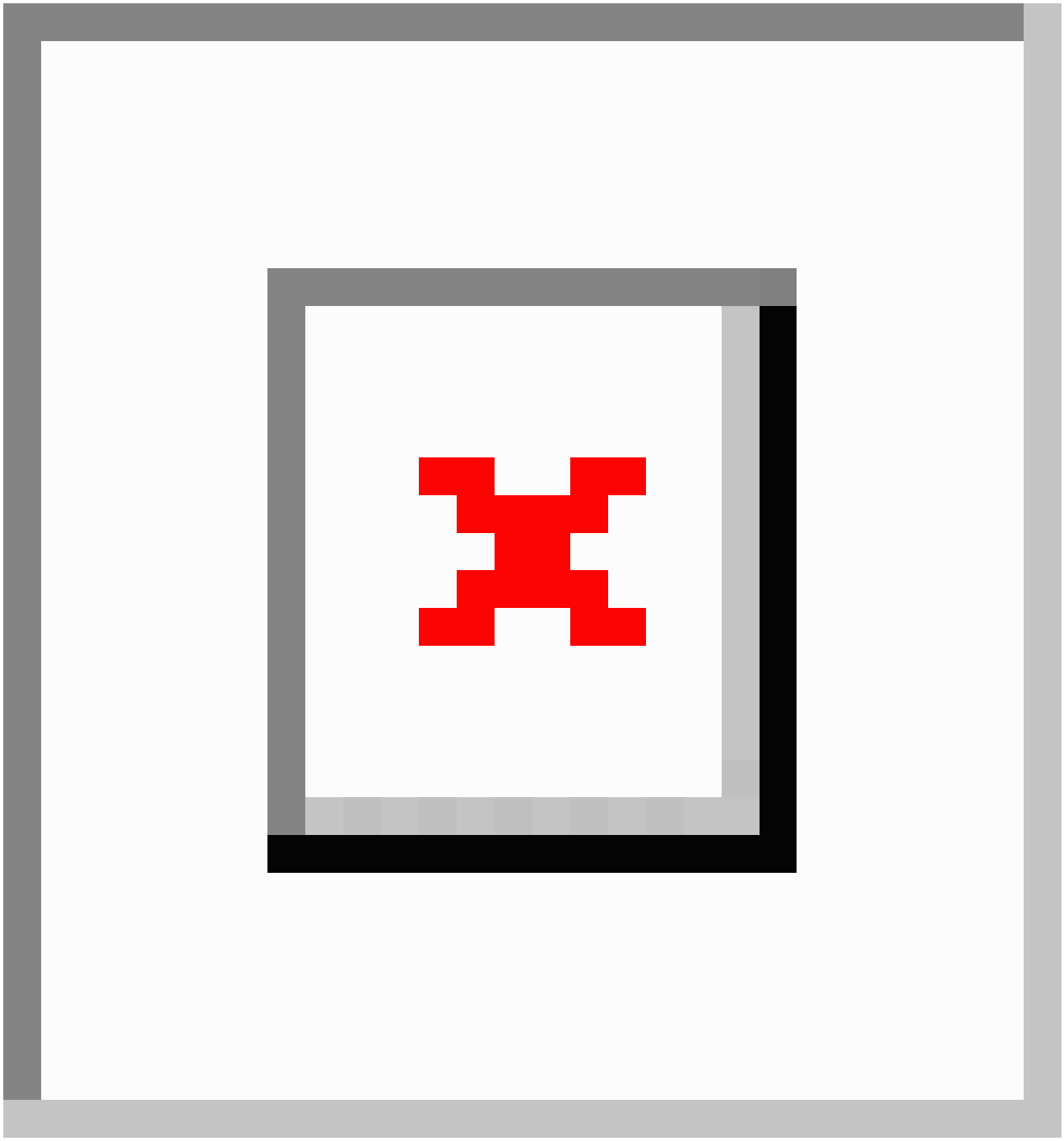
Figure 6. Participant selection flow. “Active” users recorded conversations with the HCAI in at least 4 separate weeks.



Missing Data

The age variable had 27 missing values, so ages were imputed according to accepted methods [47]. Only instances where the variable age had missing values were imputations applied and outliers removed. There was no significant difference between the new and existing variables for age.

Data Analysis

We examined associations between percent weight loss and a set of selected independent variables using univariate and multivariate analyses. Variables determined to be statistically significant at an alpha of .2 in the univariate analysis were selected in multivariate analyses to control for the effects of other variables. Variables were also assessed for collinearity using variance inflation factor. Generalized regression was used to quantify the independent association between selected covariates and percent change in weight. We applied a weighting factor consisting of the number of entries made per user to normalize the associations. All statistical analyses were conducted using JMP Pro, Version 13.1.0. SAS Institute Inc.

Results

User Statistics

Participant baseline characteristics are presented in Table 2. Users were 74.5% (35/47) female with average age 47 years. Baseline weight was 98.0 kg (SD 3.16) and BMI was 37.0 kg/m^2 (SD 1.40). Standard error of the mean (SEM) is included.

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Weight Loss, Meal Quality, User Engagement, and Artificial Intelligence Acceptability and User Satisfaction

Users averaged 103 sessions each over the course of 15.0 weeks, where a session constituted a discrete text-based conversational interaction between the user and the HCAI. Users averaged 2.4 kg or 2.4% weight loss (Table 3), and 75.7% (53/70) of users lost weight in the program. The percentage of healthy meals increased by 31% (from 51% [414/808] of total meals logged at baseline to 67% [22/33] at 21 weeks), and the percentage of unhealthy meals decreased by 54% (from 14% [117/808] to 6% [2/33]). User height, baseline weight, number of conversations with the HCAI, total number of meals logged, and numbers of healthy and unhealthy meals were associated with weight loss (P<.25) (Table 4). The number of conversations a participant had with the HCAI was also associated with weight loss when combined with duration of use. The total number of meals logged was a significant predictor of weight loss, while the number of unhealthy meals logged was a significant predictor of weight gain. Gender was statistically significant but not included in the multivariate model due to small sample size. Number of healthy meals logged was removed to avoid collinearity with number of meals logged. The variance inflation factor between these variables was greater than 10 [48].

Table 2. Baseline characteristics of app users (N=70)[a].

Variables	Mean (SEM)	95% CI	Range
Age, years	46.9 (1.89)	43.1 to 50.7	18 to 76
Height, cm	163 (1.41)	161 to 167	135 to 188
Baseline weight, kg	98.0 (3.16)	91.7 to 104	55 to 219
Baseline BMI, kg/m^2	37.0 (1.40)	34.1 to 39.9	24 to 95

[a]Eight lower outliers were replaced with 1.5 sigma of smallest height value without outliers.

Table 3. Weight change and HCAI use (N=70).

Variable	Mean (SEM)	95% CI	Range
Final weight, kg	95.7 (3.20)	89.3 to 102	54 to 220
Final BMI, kg/m^2	36.0 (1.44)	33.2 to 38.9	24 to 95
Weight change, kg	-2.40 (0.82)	-4.03 to -0.77	-54 to 5
Weight change, %	-2.38 (2.4/98) (0.69)	-3.75 to -1.00	4 to 44
Duration of AI use in weeks	15.0 (1.0)	13.1 to 17.0	4 to 33
Number of conversations with AI	103 (13.8)	75.0 to 130	5 to 824
Number of weight entries	6.1 (0.6)	5.0 to 7.3	2 to 32
Number of meals logged	68 (8.5)	49.8 to 84.7	0 to 351
Healthy meals logged, %[a]	59% (40.2/68) (5.71)	28.9 to 51.7	0 to 247
Unhealthy meals logged, %[b]	11% (7.54/68) (1.16)	5.24 to 9.85	0 to 53

[a]Eight lower outliers were replaced with 1.5 sigma of smallest height value without outliers.

[b]The percent of healthy plus unhealthy meals does not total 100% because some meals were categorized as neither healthy nor unhealthy.

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Table 4. Factors correlated with weight loss.

Variable	Univariate linear regression[a] β (95% CI)	*P*	Multivariate generalized regression[a] β (95% CI)	*P*
Gender[b]	1.52 (-0.30 to 3.34)	.10		
Age, years	0.02 (-0.021 to 0.056)	.365	0.082 (0.075 to 0.09)	<.001
-0.002 (-0.003 to -0.002)<.001Duration of AI use, weeks	0.004 (-0.115 to 0.123)	.948	-0.058 (-0.078 to -0.037)	<.001
Height, cm	0.03 (-0.02 to 0.077)	.244	0.044 (0.035 to 0.053)	<.001
Duration of AI use in weeks x number of conversations				
Baseline weight, kg	0.02 (-0.01 to 0.036)	.187	-0.008 (-0.012 to -0.004)	<.001
Number of conversations with the AI	-0.008 (-0.013 to -0.004)	<.001	-0.002 (-0.004 to 0.001)	.144
Number of meals logged	-0.012 (-0.020 to -0.004)	<.01	-0.035 (-0.039 to -0.031)	<.001
Healthy meals logged	-0.018 (-0.030 to -0.007)	<.01		
Unhealthy meals logged	-0.055 (-0.114 to 0.005)	.072	0.088 (0.068 to 0.107)	<.001

[a]Regression weighted by number of entries per user.

[b]Male-Female difference assessed using the Tukey-Kramer honestly significant difference test.

Table 5. User trust survey results.

Question	Mean	Standard deviation	Calculated scores
SS (n=70)	7.9	2.1	87[b]
NPS (n=76)	8.3	2.3	47[c]
DS (n=70)	6.7	3.2	68[d]
HOS[a] (n=57)	NA	NA	60[e]

[a]The HOS was assessed and calculated from a rating scale (“Much worse,” “Somewhat worse,” “Exactly the same,” “Somewhat better,” and “Much better”), so mean and standard deviation could not be calculated.

[b]Percentage of users who rated satisfaction as 6-10 on a scale of 0-10.

[c]Percentage of detractors (score 0-6) subtracted from the percentage of promoters (score 9-10) [43].

[d]Percentage who rated disappointment if the HCAI were not offered as 6-10.

[e]Percentage of users who responded their health was “Much better than before” or “Somewhat better than before.”

The number of meals logged was significantly correlated with number of conversations. For every additional conversation, users logged approximately 0.6 additional meals (R^2=0.9, P<.01). The most number of average meals (33% [22.4/68]) were logged when users were in Module 2.

Artificial Intelligence Acceptability and User Satisfaction

The in-app user trust survey had a 100% response rate. The average scores for Questions 1 (satisfaction in program), 3 (disappointment if not offered), and 4 (health outcome) were 7.9, 8.3, and 6.73, respectively. The average SS, NPS, DS, and HOS scores were 87, 47, 68, and 60, respectively (Table 5).

Discussion

Principal Results

This study showed that users of a conversational AI can lose a magnitude of weight comparable to that achieved with lifestyle change programs with live components among individuals with high diabetes risk. This suggests a value in investigating the potential for patients to use AI to effectively drive positive changes in lifestyle behaviors associated with preventing the development of diabetes. In this study, use of the HCAI was associated with average weight loss of 2.4 kg or 2.4%, which is comparable to a loss of 2.32 kg reported in a meta-analysis of 22 lifestyle intervention studies among individuals with risk factors for diabetes [49]. In the SCALE trial, average weight loss was 2.8 kg (2.6% of body weight) among participants in the lifestyle plus placebo group, who received weekly individual or group dietary and exercise counseling [50].

A separate review examined the results of trials of Web-based interventions for weight loss among adults [51]. The average weight loss among participants who completed the respective interventions in the studies highlighted in this review ranges from 1.3%-9.2% of starting weight; the range is 1.3%-3.8% when excluding the three most effective weight loss interventions, which all included human components. These

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values are comparable to the amount of weight loss (2.3% of baseline) observed in our study, although unlike in our study, most of the studies include human components in their interventions.

The weight loss achieved in this study has further implications for public health when considering the Finnish National Diabetes Prevention Program, a community-based program with one-on-one counseling visits or group sessions covering topics such as weight loss, diet quality, and exercise. Despite the in-person component of the program, average weight loss among 919 participants was 1.2%, which is less than the weight loss recorded in our study without an in-person component or the costs associated with it [52].

Also of note is that most users registered for HCAI between August and October 2016, so a significant proportion of program participation and associated weight loss occurred over the holiday season. This is a time when 51% of annual weight gain is estimated to occur. About half of adults gain 1% of body weight [53], and 14% of overweight and obese individuals gain at least 2.3 kg more than normal weight [54,55].

The amount of weight loss in this study may be clinically significant for diabetes risk. Weight loss of 1 kg can lower diabetes risk by 16% [6], and another study found that losing 5 kg is associated with a 50% decrease in risk [7]. Losing as little as 5% of excess body weight improves insulin sensitivity [56]. Even preventing weight gain is important, since gains of 5-7.9 kg and at least 8 kg body weight raise relative risk by 1.9 and 2.7, respectively [7].

The HCAI users recorded improvements in dietary patterns, as percentage of healthy meals logged increased by 31% and unhealthy meals decreased by 54%. This shift in meal quality indicated increased consumption of healthy food compared to unhealthy foods. The result is another potential decrease in diabetes risk, since even small shifts in diet composition can have significant impacts on diabetes risk [57,58].

This study also showed that conversational AI delivered via mobile phone app can have high acceptability among users. The NPS was 47, compared to the health industry average of 18, with the industry leader, Kaiser Permanente, achieving a score of 43 [59]. User satisfaction was 87%.

Comparison With Prior Work

Previous studies have investigated the effectiveness of Web-based programs and found mixed results. A recent systematic review of systematic reviews concluded that Web-based programs had consistently better results than no program but were sometimes less effective than traditional, in-person weight control programs [60]. The magnitude of weight loss reported in this study is comparable to that found in other studies reporting weight loss among mobile phone app users. For example, 77.9% of users reported weight loss while using a health and fitness mobile phone app with weight, food, and physical activity tracking features [61]. Another study investigated the effects of a mobile phone based health coach on weight loss and health behaviors among overweight or obese young adults [62]. Those who were assigned to the intervention group lost an average of 1.8 kg compared to a gain of 0.3 kg among those in the control group. Notably, in contrast to our study, this study included an in-person counseling session at baseline for both groups, with the intervention group receiving a second 40-minute session at baseline.

To be able to accurately claim to be an option for increasing lifestyle change program access to patients, an AI lifestyle coach must achieve health outcomes comparable to those of traditional in-person programs, while being less costly. The weight loss of 2.4% observed in this study is comparable to the 2.3% weight loss reported in a Centers for Disease Control and Prevention Web-based lifestyle modification DPP program among individuals at risk for diabetes [49]. When comparing our study's results to those of the original DPP study, the 2.4% weight loss was greater than the 2.1% in the metformin group, which had a 31% lower incidence of diabetes during follow-up [63]. The intensive lifestyle modification group in that study had a 5.6 kg weight loss and 58% lower incidence of diabetes, but they received 16 one-on-one lessons in the first 24 weeks, with additional one-on-one and group sessions after that. In contrast, our intervention required no live assistance in setting up or using the health coach.

This is only an early study, but it is important to determine which components of the health coaching app may have contributed to weight loss among users. While the app included logging and tracking features, the program also included health coaching that included educational components and behavior change support based on CBT. A previous study [64] found no extra weight loss, compared to a control group, among users of a popular calorie-counting app with weight tracking and physical activity logging but without health coaching. This implies that the health coaching aspects of the HCAI app may have had a significant impact on weight loss.

The AI was found to have high acceptability among users, which can improve retention in weight loss programs [65]. Previous studies have documented the acceptability of telehealth interventions for weight management. For example, one study among overweight participants found that amount of weight loss and program satisfaction was as high in a telehealth program as in a traditional program, and furthermore, participants rated the telehealth program as more convenient [66].

Limitations

A study limitation was its lack of control group for direct comparison. However, it can be assumed that without a weight loss intervention, a control group would not lose weight and might gain weight since the average annual weight gain among American adults is 0.5-1 kg [67]. Another limitation was that weight loss and dietary intake were self-reported, although evidence suggests these data can be considered sufficiently valid [42,43,46]. Counterbalancing these limitations of the current dietary assessment method is user ability to avoid the potential for memory bias, as could be a concern when conducting weekly or other periodic in-person diet assessments. Reporting dietary intake via self-entry into the HCAI rather than to a live person also avoids biases stemming from social desirability, which are a common source of inaccuracies in dietary assessment [68]. Since the HCAI both guided participants on food and beverage choices and assessed participants' meal quality, it is also

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possible that participants modified their food choices based on app feedback or deliberately misreported dietary intake to record "healthy" meals. Inaccuracies in self-reported weight can be avoided in the future as the HCAI incorporates the use of cellular weight scales so user weights are automatically recorded.

The scarcity of demographic information collected from users could be seen as a limitation of the study, since it is unknown which subpopulations would be likely to achieve similar results if they were to use the app in the future. However, the fact that the average participant lost weight despite lack of screening based on demographics suggests a wider applicability of the app in weight loss interventions.

Because this study was observational and not experimental, another limitation was its inability to determine causality. Participants who had at least one conversation with the HCAI in at least 4 different weeks lost 2.4% of baseline body weight on average, but it was not determined whether app use caused weight loss, or whether weight loss was caused by lifestyle changes resulting from app use or from other causes, or whether weight loss resulted from another cause that was not investigated in this study. Furthermore, because participants were not screened based on weight loss intentions, nor asked follow-up questions regarding behaviors related to weight loss, it is possible that some weight loss could have resulted from causes unrelated to HCAI use or lifestyle changes encouraged by the HCAI. It is conceivable, for example, that participants took weight loss medications or underwent bariatric surgery during the study period. Future research should include an experimental study that includes data collection surrounding possible confounding or other factors related to weight loss.

The AI automatically tracked physical activity according to any motion detected by mobile phone sensors, and users could log their activity manually. Inaccuracies could result if users completed physical activity bouts without carrying their phones (ie, activity was not automatically detected and recorded) and users neglected to manually input these bouts, or if users double-logged physical activity; that is, if their workout was detected and recorded automatically and they separately entered it manually. Similarly, sleep duration was detected and recorded automatically, but users could add, modify, or delete data.

Another limitation was the potential for incomplete or incorrect classification of foods and therefore meals. This could be due to missing foods in the Lark food database or to incorrect classification of foods as healthy, unhealthy, or neutral when users entered ambiguous foods (eg, "chicken salad" could comprise mayonnaise and chicken and be "unhealthy" or comprise chicken and lettuce and be "healthy").

Applicability in Chronic Disease Management

The cost of chronic diseases comprises 75% of health care costs in the United States [69], but risk reduction is possible through lifestyle changes. Primary care support is limited, and supplementation is needed. One study found a median primary care visit length of 15.7 minutes, which included covering a median of 6 topics. Typical length spent on each topic was 5 minutes for the longest topic, and 1.1 minutes for the others [70]. These figures suggest that mHealth technology, such as conversational AI in mobile phone apps, could fulfill a need by complementing in-person health care providers in supporting behavior change. This is supported by the results of a systematic review that concluded that telemedicine interventions for chronic disease management can lead to improved health outcomes and lower costs of care and have high user acceptability [71]. Table 6 compares selected characteristics of in-person coaching and HCAI.

Table 6. Comparison of selected characteristics of in-person coaching and health coach artificial intelligence.

Characteristic	In-Person Coaching	HCAI
Number and frequency of coaching sessions	Sessions can be limited to a certain number per day, week, or program.	Sessions are unlimited.
Need to schedule appointments	Appointments for coaching sessions may be required.	Users can initiate coaching sessions without an appointment.
Coaching availability	Coaching may be available only during set hours	Coaching is available anytime: day, night, or weekends.
Cost of coaching	Insurers, healthcare providers, and/or patients must pay salaries and/or per-session costs of health coaches.	There is no salary or additional per-session cost associated with HCAI.
Patient level of comfort	Live coaches can be intimidating.	Patients can identify personal challenges without fear of shame or judgement by the HCAI

The HCAI could potentially improve access to weight loss behavior change interventions. Telemedicine interventions, including those using mobile phones as a means of delivery, can be effective in reaching underserved populations, such as isolated rural communities and inner-city communities without sufficient providers compared to the number of patients [72]. Telemedicine interventions also have the built-in advantage of potentially being lower in cost than in-person or even remote appointments with live providers. The cost of labor associated with health care is estimated to be US $24 per visit to a primary care provider [73], while there is no additional cost per interaction with the HCAI. Patients installed and used the HCAI on their own after receiving the link, and the health coaching sessions did not require any time commitment from providers.

Conclusions

Compassionate Care for Weight Loss and Behavior Change

The HCAI was designed to promote weight loss and healthy lifestyle behaviors in a compassionate experience using conversational AI. It included elements of CBT interventions with in-the-moment responses based on user input including

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user-initiated conversations about feelings and accomplishments, and user-entered behaviors including weight, food consumption, and physical activity. The HCAI takes a holistic approach, providing both strategic suggestions and emotional support, and aiming to make users feel valued. For example, it responds to a challenge, such as guilt over overeating, by providing an idea about how to approach the situation in the future ("Just let this feeling give you insight/Into how you might want to do things differently next time") and reminding users of their worthiness ("You are a wonderful and worthy human being, deserving of the best treatment you can give yourself"). The HCAI design also considers the challenge of long-term maintenance of weight loss, since an estimated 80% of those who lose at least 10% of weight loss for at least a year eventually experience regain [69]. To promote long-term weight loss, this health coach supports self-efficacy, healthy behaviors such as regular weigh-ins and increased physical activity, and a multidisciplinary approach, which is linked to better success [74].

Future Work

As seen in this study, technology for fully automated health coaching AI is available for real-life applications. Results from this study showed that participants lost weight while using the HCAI, which implies a potential for the HCAI to aid patients and providers in losing excess weight and improving health behaviors. The study also demonstrated the ease of use of the app, since participants received no assistance in installing or using the app, and its engagement and acceptability among overweight and obese participants (Table 5).

Additional work is underway or being planned to further investigate health coaching AI and its roles in chronic disease management. Health coach AI apps similar to the weight loss focused HCAI in this study have been developed and are being used for prediabetes management and for diabetes prevention and management. A version for managing pre-hypertension is also under development.

Current work includes a randomized controlled trial to investigate effects of the AI on aspects of chronic disease management including weight control, diet quality, medication adherence, and home blood pressure monitoring among individuals with pre-hypertension. Another planned study is a retrospective study among individuals with prediabetes who use a version of the health coach that is a DPP. Outcomes include weight loss and self-efficacy.

This study demonstrates AI's potential to provide compassionate care that is associated with weight loss, increased healthy lifestyle behaviors, and user trust that can reduce diabetes risk.

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Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
BMI: body mass index
CBT: cognitive behavioral therapy
DPP: Diabetes Prevention Program
DS: disappointment score
HCAI: Lark Health Coach Artificial Intelligence
HOS: health outcome score
NPS: net promoter score
SS: patient satisfaction score
T2D: type 2 diabetes mellitus

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