JMIR Diabetes

Emerging Technologies, Medical Devices, Apps, Sensors, and Informatics to Help People with Diabetes
Volume 6 (2021), Issue 3 ISSN 2371-4379 Editors-in-Chief: Ricardo Correa, MD, EdD; Sheyu Li, MD

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Original Paper

Abbreviated Dietary Self-monitoring for Type 2 Diabetes Management: Mixed Methods Feasibility Study

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Abstract

Background: Type 2 diabetes mellitus (T2D) can be managed through diet and lifestyle changes. The American Diabetes Association acknowledges that knowing what and when to eat is the most challenging aspect of diabetes management. Although current recommendations for self-monitoring of diet and glucose levels aim to improve glycemic stability among people with T2D, tracking all intake is burdensome and unsustainable. Thus, dietary self-monitoring approaches that are equally effective but are less burdensome should be explored.

Objective: This study aims to examine the feasibility of an abbreviated dietary self-monitoring approach in patients with T2D, in which only carbohydrate-containing foods are recorded in a diet tracker.

Methods: We used a mixed methods approach to quantitatively and qualitatively assess general and diet-related diabetes knowledge and the acceptability of reporting only carbohydrate-containing foods in 30 men and women with T2D.

Results: The mean Diabetes Knowledge Test score was 83.9% (SD 14.2%). Only 20% (6/30) of participants correctly categorized 5 commonly consumed carbohydrate-containing foods and 5 noncarbohydrate-containing foods. The mean perceived difficulty of reporting only carbohydrate-containing foods was 5.3 on a 10-point scale. Approximately half of the participants (16/30, 53%) preferred to record all foods. A lack of knowledge about carbohydrate-containing foods was the primary cited barrier to acceptability (12/30, 40%).

Conclusions: Abbreviated dietary self-monitoring in which only carbohydrate-containing foods are reported is likely not feasible because of limited carbohydrate-specific knowledge and a preference of most participants to report all foods. Other approaches to reduce the burden of dietary self-monitoring for people with T2D that do not rely on food-specific knowledge could be more feasible.

(JMIR Diabetes 2021;6(3):e28930) doi:10.2196/28930

KEYWORDS

diabetes mellitus, type 2; diet, diabetic; feasibility studies; diet records; dietary carbohydrates

Introduction

Background

Approximately 34.2 million people in the United States have diabetes, and type 2 diabetes mellitus (T2D) constitutes 90%-95% of these cases [1]. T2D is a unique disease that can be managed through diet and lifestyle changes. Even in advanced stages of T2D that necessitate antidiabetic drugs or insulin, diet and lifestyle changes make an important contribution to glycemic stability [2]. However, according to the American Diabetes Association, knowing what and when to eat is the most challenging aspect of diabetes management [3]. Research shows that among people with T2D, who are under the impression that they are following a *diabetes diet*, only 32.6% successfully meet dietary recommendations [4]. One of the most frequently used behavior change techniques that have been shown to be effective in producing positive clinical outcomes for individuals with T2D is the *self-monitoring of behavior* [5]. Specifically, self-monitoring of diet and glucose levels can assist people with T2D to better manage their glucose levels through the improvement of multiple behavior change constructs, including goal setting, knowledge, and self-efficacy [6]. However, current self-monitoring strategies require the individual to record everything one consumes, which can be burdensome and unsustainable, and may inhibit dietary behavior change [7].

The feasibility and utility of less burdensome approaches for tracking one's diet need to be explored to promote behavioral changes through self-monitoring. Several diet tracking approaches are currently being explored to reduce the burden of dietary self-monitoring (eg, commercial diet tracking apps and image-assisted and image-based diet tracking) [8]. However, most of these approaches require all foods to be tracked. Although this may be appropriate and expected by users interested in calorie tracking, it may not be necessary for other health promotion efforts, including the dietary self-management of T2D. As opposed to total caloric intake, the main concern for people with T2D is carbohydrate intake. When an individual without diabetes consumes carbohydrate-containing foods and beverages, the carbohydrates are broken down in the body to form glucose, and insulin is secreted by pancreatic β cells to aid the entry of glucose into the liver, muscle cells, and fat cells. In patients with T2D, the same carbohydrate breakdown process occurs, and insulin is secreted; however, the cells are resistant to insulin, causing inhibition of glucose entry into the cell, and therefore, glucose stays in the bloodstream. Due to this, a decline in insulin production occurs, and eventually, pancreatic β cells can fail, leading to a further increase in blood glucose levels. Instead of having individuals with T2D track all dietary intake, one plausible approach would be to reduce the intensity of dietary self-monitoring by tracking only carbohydrate-containing foods. This approach is consistent with historical diabetes-focused medical nutrition therapy and diabetes self-management education and support paradigms (eg, carbohydrate counting and exchange-based meal planning) promoted by the American Diabetes Association, as well as newer recommendations that encourage individualized guidance on self-monitoring of carbohydrate intake [9]. Support for the effectiveness of abbreviated dietary self-monitoring approaches comes from other areas of health promotion. A recent systematic review (Raber et al, unpublished data, 2021) showed that, even in weight loss studies where tracking all food intake would be expected, less intensive dietary self-monitoring was similarly effective as tracking all food intake. Specifically, findings showed significantly greater weight losses in the intervention groups than in the control groups in 63% of the studies where participants monitored all food intake and in 67% of the studies where participants used an abbreviated dietary self-monitoring approach (eg, tracking only certain types of foods or meals). Despite recommendations to self-monitor carbohydrate intake, there is a paucity of research examining the feasibility and effectiveness of abbreviated dietary self-monitoring approaches in the management of T2D.

Objectives

This study aims to conduct a preliminary examination of the feasibility of a plausible abbreviated dietary self-monitoring approach for the management of T2D, in which only carbohydrate-containing foods are recorded in a diet tracker. We hypothesized that this less intensive dietary self-monitoring approach would be feasible if people with T2D (1) have general diabetes knowledge and diabetes-related nutrition knowledge and (2) find this approach acceptable based on the ease of use and a preference over recording all foods.

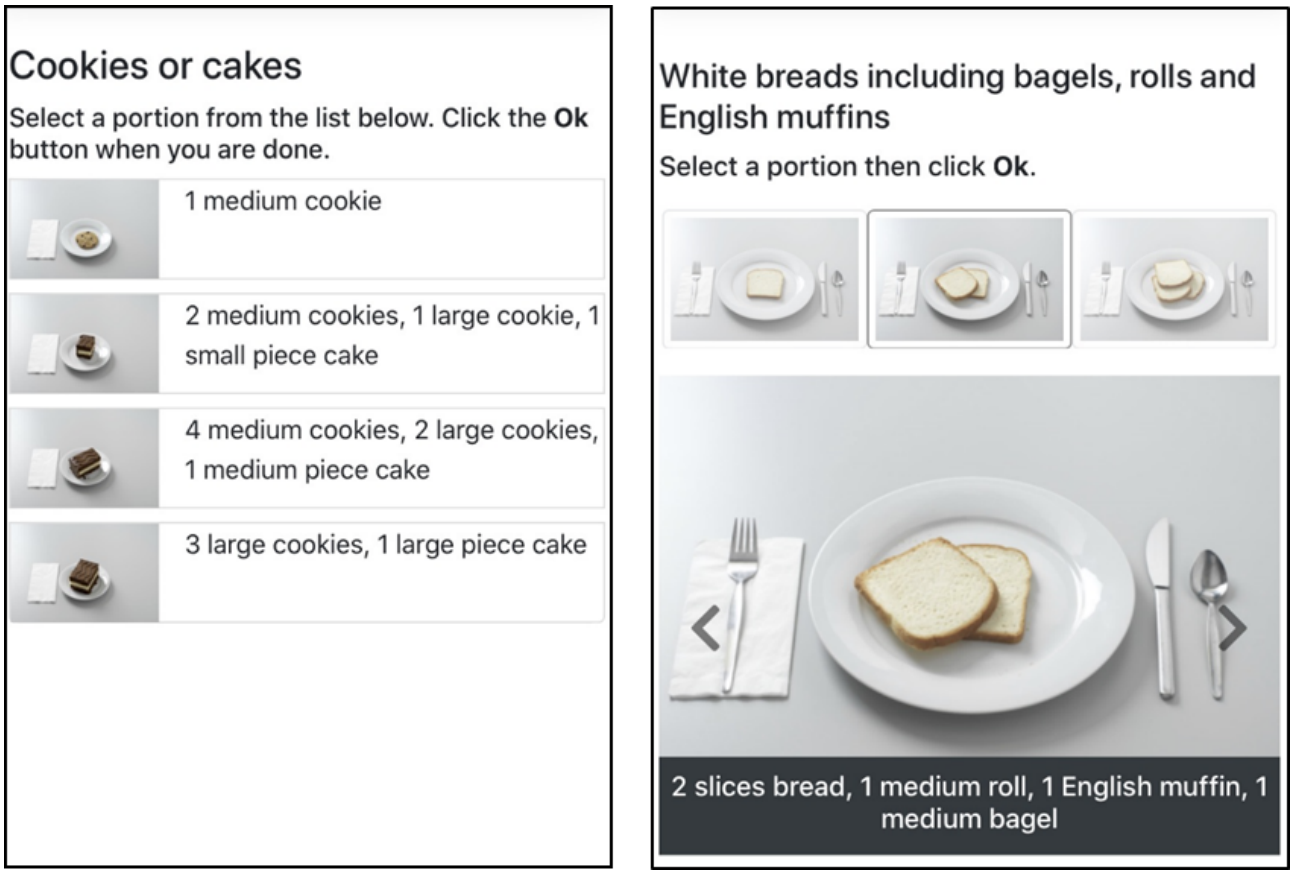
Methods

Study Design

This study is a secondary analysis of data collected in phase I of the project mDGS (mobile dietary guidance system). Project mDGS aims to develop an mDGS that assists people with diabetes self-management. The objective of phase I of project mDGS is to evaluate the usability of three functional prototypes of the food entry interface and two functional prototypes of the portion size estimation interface designed for the mDGS mobile app. The methods for food entry were selected from previously validated mobile-based research tools [6,10,11]. These methods include the following: (1) text entry, where the user enters a food description to search for a specific food; (2) tree structure, where the user works through a hierarchical tree structure based on food groups and subgroups (ie, grains-bread-whole grain) to find and select a specific food; and (3) food group, where the user is directed through a food list by designated food groups as performed by food frequency questionnaires. The methods for portion size selection depicted in Figure 1 include a portion list and a carousel [11]. A full set of smaller food portion images is displayed using the *portion list* method. The user then selects one picture to expand for better viewing. The *carousel* type of portion size estimation displays images for the user to select from by swiping left or right. Other options for diet tracking have been developed, including voice-based searching or barcode scanning; however, these methods were not tested because their utility is limited or not well validated in research. The primary results from the evaluation were used to inform the final design specifications for the mDGS app. Here, we describe the secondary findings of the evaluation. Specifically, this secondary analysis examines the qualitative and quantitative

data collected to assess the feasibility of using mDGS to record the intake of only carbohydrate-containing foods compared with that of all foods. Project mDGS was reviewed and approved by the University of Arizona Human Subjects Protection Program. All enrolled participants provided informed consent in either written or electronic form.

Figure 1. Portion size estimation methods: portion list (left) and carousel (right).



Study Recruitment

Participants were recruited using in-person (pre–COVID-19 pandemic) and remote (during the pandemic) methods. The in-person recruitment methods included flyers placed in a primary care clinic, attendance at a community health fair, and an information table staffed by research personnel in the lobby of the university-affiliated diabetes clinic. The in-person recruitment method yielded 4 enrolled participants. In March 2020, all recruitment efforts were conducted remotely using ResearchMatch following institutional guidance to cease in-person research. A total of 487 emails were sent to ResearchMatch volunteers with T2D, with 57 people indicating interest in the study. One additional participant was recruited via a standing contact form on the department website, and another participant was recruited via word of mouth. Of the 59 interested people, 18 (31%) did not respond to further contact attempts, and 5 (8%) did not attend their scheduled data collection sessions. Furthermore, 5% (3/59) of interested people declined because of time constraints (n=1), security concerns regarding the virtual platform (n=1), and mention of needing a social security number for tax reporting purposes related to participant compensation in the consent form (n=1). One potential participant was not enrolled because the recruitment goal was already met.

Interested participants were screened using an eligibility questionnaire. Eligible individuals were those aged at least 18 years, had been diagnosed with T2D for at least 6 months, were fluent in English, familiar with the use and functionality of mobile apps (ie, using a mobile app at least once per week), and willing to use a health-related mobile app in the future. Exclusion criteria were unwillingness to use a mobile app for T2D management, inability to attend an in-person or virtual data collection session, and the use of a mobile app less than once a week. Statistics on comorbid conditions were not collected for this study. One interested person was excluded because of a lack of mobile app use. In total, 31 participants enrolled and participated in the data collection interview; however, 1 participant experienced technical difficulties during the data collection process, resulting in substantial missing data. This participant was excluded from the analyses, resulting in an analytical sample of N=30.

Data Collection Procedures

Eligible individuals were scheduled for 1-hour interview sessions. For in-person meetings, the sessions began with informed consent procedures and the completion of quantitative surveys on demographics, medication use, mobile technology use, personal experience with diabetes, and general diabetes knowledge. Remote data collection sessions were similar, except that participants provided consent and completed questionnaires on REDCap (Research Electronic Data Capture), and interview

sessions were conducted on the Health Insurance Portability and Accountability Act–compliant Zoom for Health platform (Zoom Video Communications). The study staff obtained permission to audio record the interviews. All interview sessions consisted of guiding participants to access a functional version of the web-based mDGS mobile app and to trial each of the three prototyped food entry interfaces and the two portion size interfaces by entering sample meals (breakfast, lunch, and dinner) consisting of typically consumed foods in standard US portion sizes into the app. All meals included foods that were high and low in glycemic index and had a moderate-to-high glycemic load (glycemic load>15). The order in which participants tested the food entry and portion size selection interfaces was randomized to omit the effect of order on the evaluation. The research staff asked evaluation questions designed to assess the acceptance and utility of each interface. In addition, participants were asked, using qualitative and quantitative methods, for their opinions on the mDGS concept and their thoughts on the future directions for the app. As the parent study was focused on the functional usability of the mDGS diet tracker, no additional context for using the app was provided (ie, time frame for recording intake). For this study, only data specific to questions on general diabetes knowledge and diabetes-related nutrition knowledge and the acceptability of reporting only carbohydrate-containing foods versus all foods were analyzed. The related measures are described in the following sections.

Measures of Diabetes Knowledge

General diabetes knowledge and diabetes-related nutrition knowledge were assessed using the brief Diabetes Knowledge Test developed by the Michigan Diabetes Research Training Center [12]. Of the 23 knowledge test items, only the first 14 (61%) items, which were nonspecific to insulin use, were included. The general test component's reliability is demonstrated by a coefficient α of .77, and its face validity is supported by the consistency observed in four separate analyses [12]. Diabetes-related nutrition knowledge was computed from the 5 items specific to nutrition in a manner similar to that of a previous study [13]. The Diabetes Knowledge Test was not completed by the first 4 study participants, as it was added to the study when the protocols were modified for remote data collection.

Diabetes-related nutrition knowledge specific to identifying carbohydrate-containing foods was additionally assessed using a study-specific task similar to that used in previous research [14]. Participants were asked to categorize 10 commonly consumed food items as containing or not containing carbohydrates (≤5 g). A random-ordered list of 5 carbohydrate-containing and 5 noncarbohydrate-containing foods was provided to all participants. The 5 carbohydrate-containing foods were coffee with cream and sugar, a turkey sandwich, strawberries, hash browns, and orange juice. The 5 noncarbohydrate-containing foods were steak, bacon, eggs, unsweetened green tea, and steamed broccoli. Participants were instructed to check all food items that they considered to contain carbohydrates.

Measures of Acceptability

As part of the interview, acceptability was assessed quantitatively on a 10-point Likert scale as the perceived difficulty of reporting only carbohydrate-containing foods, and their preference for reporting only carbohydrate-containing foods versus all foods was recorded qualitatively. Participants were also asked to provide reasons for their answers. Preference for reporting dietary intake was assessed by the following question: "Would you be interested in using a diet tracker that focused only on foods and beverages that interfere with good diabetes management vs. a diet tracker that requires you to enter ALL the foods and beverages you eat?" All interviews were recorded and transcribed. Furthermore, 2 trained research staff independently coded the transcribed interviews by identifying the themes in participant responses. A third researcher reviewed the coding and resolved any discrepancies before the analysis. Quantitative reports of acceptability were completed by averaging the reported scores on a 10-point Likert scale. Qualitative analyses were completed manually by quantifying the number of participants who stated they would prefer to enter all foods, just carbohydrate-containing foods, or had mixed opinions based on the question presented above. The label *mixed opinions* was provided to individuals if they preferred to start tracking one way and then switch to the other or if they wanted both options to be available. The reasons for perceived difficulty were categorized based on similar responses and quantified.

Statistical Analysis

Descriptive statistics were used to characterize study participants. Tabulated and qualitative data are presented as frequencies. Quantitative data are summarized as means, SDs, and ranges.

Results

Sample Characteristics

In total, 30 participants completed the study. The participants were predominantly female (18/30, 60%), non-Hispanic (27/30, 90%), and White (25/30, 83%). They ranged in age from 28 to 78 years with a mean age of 58.6 years (SD 11.9) and represented each of the 5 regions of the United States. Most reported having T2D for 6-10 years (12/30, 40%), followed by 0.5-5 years (7/30, 23%), and 11-15 years (7/30, 23%). Nearly all participants (27/30, 90%) reported having had prior T2D education (Table 1).

Table 1. Participant characteristics and Diabetes Knowledge Test scores (N=30).

Variable	Statistic
Age (years), mean (SD)	58.6 (12.1)
Sex (female), n (%)	18 (60)
Ethnicity (non-Hispanic), n (%)	27 (90)
Race, n (%)	
White	25 (83)
Black or African American	3 (10)
Pacific Islander	1 (3)
Declined to answer	1 (3)
Years with T2D[a], n (%)	
0.5-5	7 (23)
6-10	12 (40)
11-15	7 (23)
16-20	2 (7)
>20	2 (7)
Prior T2D education (yes), n (%)	27 (90)
Diabetes Knowledge Test[b]	
Test score, mean (SD)	83.4 (14.2)
Participants with test score>65%, n (%)	22 (88)
Diabetes-related nutrition knowledge score[b,c], mean (SD)	82.7 (20.1)

[a]T2D: type 2 diabetes.

[b]Five participants did not complete the Diabetes Knowledge Test.

[c]Diabetes-related nutrition knowledge was computed from the items on the Diabetes Knowledge Test specific to nutrition (ie, items 1, 2, 3, 4, 7, and 12).

Measures of Diabetes Knowledge

The mean score of the participants in the Diabetes Knowledge Test was 83.9% (SD 14.2%; range 16.7%-100%), and the mean score of the diet-related Diabetes Knowledge Test questions was 82.7% (SD 20.1%; range 16.7%-100%). The median score of the carbohydrate-containing foods knowledge task was 80% (range 40%-100%), reflecting an average of 8 correctly categorized foods. Only 20% (6/30) participants correctly categorized all 10 foods. The carbohydrate-containing foods most incorrectly classified by participants were strawberries (11/30, 37%), coffee with cream and sugar (10/30, 30%), orange juice (10/30, 30%), and steamed broccoli (7/30, 23%).

Measures of Acceptability

The first measure of acceptability of recording only carbohydrate-containing foods versus all foods with the mDGS app was *perceived difficulty*. In the quantitative analysis, the mean perceived difficulty of recording only carbohydrate-containing foods was 5.3 (SD 2.5; range 1-10; 1=not difficult at all and 10=very difficult). From the qualitative analysis, the most cited reasons for greater perceived difficulty were not knowing what foods contain carbohydrates (20/30, 67%), the acknowledgment that certain foods may vary in carbohydrate content by brand (3/30, 10%), and the acknowledgment that not all carbohydrates are *bad* (2/30, 7%). One participant who reported not knowing what foods contain carbohydrates stated as follows:

> *...sometimes you think that certain things do not contain carbs because when you think of carbs, you think of (at least I do) of bread, pasta, rice, beans. You think of those things as carbs, so there might be other things that contain carbs that I don't know right away, so I may say that just reporting things [containing carbs] would be difficult because I don't know exactly what does not contain carbs.*

Another participant, who reported not knowing what foods contain carbohydrates, stated the following:

> *I'm not sure which has carbs, and which don't sometimes. Isn't practically every food have a little bit of carb or something? I don't know.*

Regarding the variability in carbohydrate content of certain foods, one participant stated the following:

> *Like a sugar free candy is fine with carbs, but umm you can find some sugar free sweet of some kind, but it doesn't mean that it is umm, it will say 'doesn't impact sugar' like these net carb things like Atkins sweets. But it doesn't mean that, and it'll say, 'does*

> *not contain sugar or will not impact carbs, does not impact calories' and so you have to report it typically on these kinds of apps, and that's the tedium.*

Regarding the relative quality of some carbohydrate-containing foods, another participant stated the following:

> *Well, some are very obvious, but others like the strawberries or the broccoli, you know they have some carbs, but we don't necessarily know. I mean, most people probably wouldn't think of strawberries having carbs.*

A second qualitative measure of acceptability was the reported preference for recording carbohydrate-containing foods only or all foods. Approximately half (16/30, 53%) of the participants reported a preference for recording all foods over recording carbohydrate-containing foods only, 30% (9/30) reported a preference for recording carbohydrate-containing foods only, and 17% (5/30) wanted to have both options. The top-cited reasons for preferring to record all foods over only carbohydrate-containing foods were being unknowledgeable about what foods contain carbohydrates (12/30, 40%) and wanting additional dietary feedback related to diabetes management (8/30, 27%; eg, calorie tracking for weight loss). Regarding the lack of knowledge about what foods contain carbohydrates, one participant stated the following:

> *I mean I think it would feel easy, but I'd probably be wrong. Before I did this little exercise today, I would've probably labeled bacon as a carb because it can be fatty...I confuse fat with carbs.*

Another participant wanted to record all foods because it was easier not to have to think about which foods were carbohydrate-containing and stated:

> *Probably it would be all the foods because you know, you do things sometimes automatically and don't think about it.*

A participant who was interested in receiving additional dietary feedback on the total caloric intake stated as follows:

> *I need to enter everything in there...so I can know where I'm at you know. It's like, okay, they tell you you can have so many calories a day. Well, if I overused all of them, I want to know. I need to have something telling me that, and it's only going to happen if I enter everything in.*

Another participant interested in receiving additional dietary feedback, who was less confident about his diabetes-related nutrition knowledge, stated the following:

> *I want to know how much protein I'm eating and how much fat I'm eating too. But that could be my ignorance about diabetes. I haven't educated myself nor has a dietitian given me the overview picture of what every food group does to my blood sugar. So, I just think I need to enter all foods.*

Later, this participant said he wanted to report all foods because he was also focused on weight loss:

> *My point was I had to lose weight, so I was being coached in being a diabetic within the context of having to lose weight.*

All 9 participants who reported a preference for recording carbohydrate-containing foods only versus all foods cited that recording carbohydrate-containing foods only would reduce the burden associated with reporting all foods. One participant stated as follows:

> *If you report everything...that is where the tedium comes in, where you're trying to count every little, tiny, nit-picky thing.*

Another participant, when offered the option of recording carbohydrate-containing foods only, stated the following:

> *...that would make my life a lot easier. That is with managing diabetes, not necessarily for weight loss. But for managing diabetes, yes.*

Finally, among those who wanted both options (5/30, 17%), 4 participants noted the educational benefits of first recording all foods for some time until they were confident in their ability to record only carbohydrate-containing foods, with one participant stating:

> *I can probably do the one with everything first and learn a little more and then if I felt confident and, like, I was ready to do the just the one.*

Another participant, who first wanted to start by recording all foods and then move to recording carbohydrate-containing foods only, specifically noted the burden of having to record all foods:

> *...Recording everything could be too cumbersome. But if you could figure out what is helping you versus what isn't helping you that way, you know what I mean, [mDGS could] be a program you can use. The problem is when you get too involved with trying to put too many details in your diet and trying to watch everything it becomes overwhelming.*

The last participant with a mixed opinion thought that having the option to enter all foods or only carbohydrate-containing foods would be beneficial to users who may have goals in addition to diabetes management. This participant stated as follows:

> *I think the app should be set up in such a way that you can have multiple objectives. And if your objective is to monitor your diet and learn to eat better portion sizes and stuff like that, then all foods. If you're just worried about the diabetes type of questions, then just the carb-containing foods. But I think that should be something that somebody can decide for themselves. Those options can easily be in the same app.*

Discussion

Principal Findings

This study aimed to examine the feasibility of an abbreviated dietary self-monitoring approach in which only carbohydrate-containing foods are recorded in a mobile diet

tracker. We hypothesized that this approach would be feasible if people with T2D (1) had diabetes-related nutrition knowledge to report only carbohydrate-containing foods and (2) found the approach acceptable based on the ease of use and a preference for this approach over recording all foods. However, our results did not support the feasibility of this specific approach. First, we found that diabetes-related nutrition knowledge was highly variable among participants, with proportionally few participants being able to classify 10 commonly consumed foods as containing versus not containing carbohydrates (≤5 grams). Second, we found that approximately half of the participants reported a preference for recording all foods versus carbohydrate-containing foods, with most participants citing a lack of knowledge about carbohydrate-containing foods as the primary barrier to acceptability.

Despite observing seemingly adequate mean levels of general diabetes knowledge and diabetes-related nutrition knowledge in this study, we observed an insufficient knowledge base on carbohydrate-containing foods that would be necessary for the proposed abbreviated dietary self-monitoring approach. Participants in this study had relatively good general diabetes knowledge compared with other studies of people diagnosed with T2D for a similar duration. Hashim et al [15] reported a mean Diabetes Knowledge Test score of 55%, and Almalki et al [16], who also used the Diabetes Knowledge Test, showed that only 21.6% of participants had good diabetes knowledge (defined as scoring >65%). However, in the studies by Hashim et al [15] and Almalki et al [16], it is unclear whether participants had received diabetes education, which may explain the higher mean diabetes knowledge scores observed in this study, where 90% (27/30) of participants reported having had diabetes education. Among a similarly educated sample of people with T2D, Breen et al [13] reported that diabetes-related nutrition knowledge was modest based on average scores of 60% on the diet subsection of the Audit of Diabetes Knowledge Questionnaire. These results are consistent with our findings and further support that diabetes-related nutrition knowledge is suboptimal, even among those who have had diabetes education.

Another important finding was that, regardless of diabetes-related nutrition knowledge, half (14/30, 47%) of the study sample expressed a preference for reporting carbohydrate-containing foods only or moving between reporting carbohydrate-containing foods and all foods, based on their health behavior goals (eg, glucose stability or weight loss) or as they gained confidence in identifying carbohydrate-containing foods. With regard to diet tracking for weight loss, there may be expectations that tracking total caloric intake is necessary for successful weight loss despite previously reviewed evidence (Raber et al, unpublished data, 2021, [17]) reporting that abbreviated dietary self-monitoring and other behavioral weight loss strategies (eg, daily self-weighing) are similarly, if not more, effective. On the basis of this supporting literature and the findings of this study, the feasibility and efficacy of other abbreviated dietary self-monitoring approaches should be explored. One plausible approach, which would minimize the reliance on diabetes-related nutrition knowledge, is to provide a (personalized) list of commonly consumed carbohydrate-containing foods and have users select only those that they have consumed, an approach similar to ecological momentary diet assessment approaches [8].

Strengths and Limitations

A strength of this study is that we used both quantitative and qualitative data collection approaches to obtain enriched data on the feasibility of the proposed, abbreviated dietary self-monitoring approach. In addition, recruitment was remote, which led to a geographically diverse sample and the ability to better generalize our results. Finally, participants were provided context for reporting dietary intake in the parent study (eg, evaluating mobile diet tracker prototypes), which might have enhanced their consideration of the stated options for reporting. One of the limitations of this study was that this was a secondary analysis of data collected as part of the evaluation of a mobile diet tracker prototype; therefore, methods were not designed to assess the efficacy of abbreviated dietary self-monitoring. In addition, the sample was small and predominantly White; however, those enrolled were almost equally represented men and women and were diverse in terms of age and duration of diabetes diagnosis. The sample only consisted of participants who were familiar with the use and functionality of mobile apps in general, which may have skewed preference for use; however, this sample was selected to reflect those who may actually consider using an app for diet tracking. Food insecurity and other social determinants of health were not assessed, both of which could affect general diabetes and diabetes-related nutrition knowledge; however, 90% (27/30) of participants had received diabetes education, which implies that our participants had adequate access to resources. Future work to develop the mDGS app will need to address this limitation by assessing participants for food insecurity or other social determinants of health before study participation and data extraction to determine if this has an impact on study results. Although we only asked a few questions regarding diabetes-related nutrition knowledge, to our knowledge, this is one of the few studies that used a simple but effective carbohydrate-containing food knowledge task to assess knowledge about carbohydrate-containing foods. Finally, our sample performed comparatively better on the Diabetes Knowledge Test than the populations sampled in the previously cited studies, which could have biased our findings. However, the inclusion of the carbohydrate-containing foods knowledge task, which highlighted a discrepancy between general diabetes knowledge and diabetes-related nutrition knowledge in our population, and the inclusion of qualitative and quantitative measures of food reporting preference strengthened our conclusions.

Conclusions

Our findings suggest that this abbreviated dietary self-monitoring approach may not be feasible, particularly for those with limited knowledge of carbohydrate-containing foods. Despite these findings, this study adds to the paucity of literature that explores options for less intensive dietary self-monitoring for the management of T2D. On the basis of a review (Raber et al, unpublished data, 2021) supporting the efficacy of less intensive dietary self-monitoring in other areas of health promotion, these findings do not rule out the potential efficacy

of abbreviated dietary self-monitoring approaches for T2D management altogether. It is important to acknowledge that nearly half of the participants in this study, regardless of their diabetes-related nutrition knowledge, reacted positively to only having to record carbohydrate-containing foods, which is consistent with published reports [4] on the burden of dietary self-monitoring. Furthermore, removing the barrier of limited diabetes knowledge could significantly shift the preference for and feasibility of abbreviated dietary self-monitoring for the management of diabetes. Collectively, these findings suggest that offering users a choice to record all foods versus record only carbohydrate-containing food or identifying other abbreviated dietary self-management approaches that rely less on diabetes-related nutrition knowledge could be an effective diabetes self-management strategy.

Acknowledgments

The authors would like to thank the study participants for their contributions to project mDGS and acknowledge the Border Latino and American Indian Summer Exposure to Research and the Arizona Area Health Education Centers Program. Project mDGS was funded by the National Institutes of Health Small Business Innovation Research Phase I grant (R43DK121665).

Conflicts of Interest

RW is a majority stockholder of Viocare, Inc.

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Abbreviations

mDGS: mobile dietary guidance system
REDCap: Research Electronic Data Capture
T2D: type 2 diabetes mellitus

Edited by K Mizokami-Stout, D Griauzde; submitted 18.03.21; peer-reviewed by K Rawlings, Y Zheng; comments to author 05.05.21; revised version received 02.06.21; accepted 25.06.21; published 12.08.21.

Please cite as:
Richardson KM, Cota Aguirre G, Weiss R, Cinar A, Liao Y, Marano K, Bedoya AR, Schembre S
Abbreviated Dietary Self-monitoring for Type 2 Diabetes Management: Mixed Methods Feasibility Study
JMIR Diabetes 2021;6(3):e28930
URL: https://diabetes.jmir.org/2021/3/e28930
doi:10.2196/28930
PMID:34387551

Original Paper

Challenges and Lessons Learned From a Telehealth Community Paramedicine Program for the Prevention of Hypoglycemia: Pre-Post Pilot Feasibility Study

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Abstract

Background: Prevention through Intervention is a community paramedicine program developed by Birmingham Fire and Rescue Services in Alabama. This program aims to reduce dependency on emergency medical services (EMS) for nonemergency-related events through education and to lower the frequency of emergency calls in underserved populations. A telehealth intervention with an emphasis on hypoglycemia was implemented to (1) tailor the intervention to meet the educational needs of participants and (2) facilitate follow-ups. A pre-post pilot feasibility evaluation of the telehealth intervention was conducted.

Objective: This paper describes the results of the feasibility evaluation, implementation challenges, and the lessons learned about the deployment of a hypoglycemia prevention program in an underserved area and its evaluation.

Methods: This single-arm pretest-posttest intervention included (1) an initial in-person visit (week 1), (2) 3 weekly telecoaching calls (weeks 2-4), (3) 1 biweekly call (week 6), and (4) a final in-person visit (week 8) for collecting posttest data from individuals who called EMS due to hypoglycemic events. In-person visits included educational sessions conducted by EMS personnel. Participants' education included tailored content related to hypoglycemia. Weekly telecoaching calls focused on hypoglycemia symptom monitoring and education reinforcement via a telehealth dashboard. The primary measures focused on feasibility measures, and exploratory measures focused on the fear of hypoglycemia, self-efficacy, and a knowledge of diabetes.

Results: A total of 40 participants participated in the intervention. However, the study was marred with high attrition. The various factors behind the low retention rate were discussed. There was a decreasing trend in all three subdomains of the fear of hypoglycemia from pretest to posttest. There was also a significant increase in participants' self-efficacy in hypoglycemia self-management (P=.03).

Conclusions: This study shows preliminary and promising results for a community-based intervention specifically for hypoglycemia. However, the socioeconomic setting in which the intervention was delivered may have resulted in high dropout rates and low attendance during the intervention, which are considerations for future telehealth studies.

Trial Registration: ClinicalTrials.gov NCT03665870; https://clinicaltrials.gov/ct2/show/NCT03665870

(JMIR Diabetes 2021;6(3):e26941) doi:10.2196/26941

KEYWORDS

hypoglycemia; telehealth; community paramedicine; diabetes; self-efficacy

Introduction

Hypoglycemia is a common but potentially avoidable health problem that can be a barrier to achieving good glycemic control. Hypoglycemia is indicated by abnormally low blood glucose concentrations (usually <70 mg/dl) and can result from physical exercise, certain diets, the misuse of drugs, endocrine disorders, and renal insufficiency [1,2]. However, antidiabetic agents, which increase insulin production and exogenous insulin levels, are the most common causes of hypoglycemia [3,4]. Although mild episodes of hypoglycemia occur 0.8 to 2 times per week in people with type 1 diabetes and people with insulin-treated type 2 diabetes, severe hypoglycemia rates range from 1.4 to 1.7 episodes per year. Except for some severe events, the majority of hypoglycemic episodes can be prevented and easily treated at home by following simple guidelines [2,5]. If it is not treated, hypoglycemia can have deleterious effects on people's quality of life [6], mortality, and morbidity [7,8]. The unpleasant aspects of hypoglycemia may result in severe anxiety and the fear of hypoglycemia (FH) in people with diabetes. The FH is associated with the frequency of past hypoglycemic episodes and can promote compensatory behaviors, such as reducing insulin dosages to avoid hypoglycemia. This can be a major barrier to achieving glycemic control for people with diabetes [9-11]. In the prevention of hypoglycemia, sociocultural health literacy and the economic status of the population are critical components that necessitate the education of health care practitioners and patients—a key factor in the provision of care [12].

Inadequate health literacy is common among vulnerable populations. It is independently associated with poor glycemic control and an increased incidence of hypoglycemia (59%) in patients with diabetes [13,14]. It is also linked to the higher use of health care services, which costs the US economy between US $106 billion and US $238 billion annually [15]. The residents of the area served by our community paramedicine program belong to the lowest quartile of health literacy scores [16]. The initiation of the community paramedicine program offers an opportunity to improve care management and health literacy for patients with hypoglycemia. However, although studies on community education programs have reported successful outcomes [17-19], these studies mainly depend on the skill and knowledge of select individuals and have not resulted in the sustained integration of hypoglycemia interventions into regular practice.

As a model of mobile integrated health care programs, community paramedicine is an evolving community-based health care design that ultimately aims to increase access to basic paramedic services by integrating the services of multiple disciplines [20-22]. Through partnerships with local emergency medical services (EMS) and other health care services, mobile integrated health care–based community paramedicine programs deploy trained paramedics to help patients with complex chronic conditions at home. By visiting frequent users of the 911 system, these programs reduce the number of unnecessary emergency department transports and the number of nonemergency phone calls, thereby improving care management through patient education, advocacy, and navigation [23,24]. Fire departments receive thousands of "essentially preventable" medical emergency calls related to chronic conditions, including hypoglycemia [25-27].

A community paramedicine program, Prevention through Intervention, was initiated by the Birmingham Fire and Rescue Department in Alabama. This community paramedicine program attempts to expand access to health services for underserved rural populations who lack consistent primary care or preventive services and therefore frequently seek nonurgent care. The program involves educational home visits that are conducted by 1 paramedic who is assigned full-time to the program and provides services such as wellness and medication checks, safety assessments, and services for connecting people to primary care when such care is needed. This study was conducted as part of the Prevention through Intervention program. This study aimed to use telehealth to facilitate the tailoring of a telehealth intervention to meet the precise educational needs of participants, enable follow-ups, and perform a preliminary pilot feasibility and acceptability evaluation of the program.

Methods

Study Design

A single-arm pretest-posttest intervention group was used to test various outcomes (see *Measures* section). Due to our community partner expressing ethical concerns about including a control group without an intervention, it was not possible to establish an untreated control group. Therefore, a pretest-posttest design was chosen. This was also recommended by our community partner—the Fire and Rescue Department (ie, where this study was conducted). A total of 40 people enrolled in this study.

Participant Eligibility, Recruitment, and Enrollment

The home of the community paramedicine program, which was where this study was conducted, receives about 1000 hypoglycemia-related EMS calls on an annual basis. All patients who called 911 due to hypoglycemia-related events were screened based on the following inclusion criteria: (1) residents in the service area of the fire district, (2) individuals aged ≥18 years, (3) individuals receiving intravenous 50% dextrose (intravenous treatment for hypoglycemia provided by EMS personnel), and (4) individuals who are not enrolled in any diabetes-related educational programs. All successfully screened participants were provided with an informed consent form. Participants were only enrolled in this study after they provided consent. Any resident who met the first 3 inclusion criteria based on EMS records (prescreening) was contacted via telephone by EMS personnel to assess their interest in participating in this study. If they were interested and were successfully screened for the last inclusion criterion, the resident was scheduled for an in-person consenting and baseline data collection session. This was done sequentially until 40 participants were enrolled in this study.

Unlike paramedics, emergency medical technicians in fire departments are not allowed to administer glucagon in prehospital settings [28]. They usually respond to hypoglycemic events by using intravenous 50% dextrose. Therefore, we did

not include glucagon administration as part of the inclusion criteria.

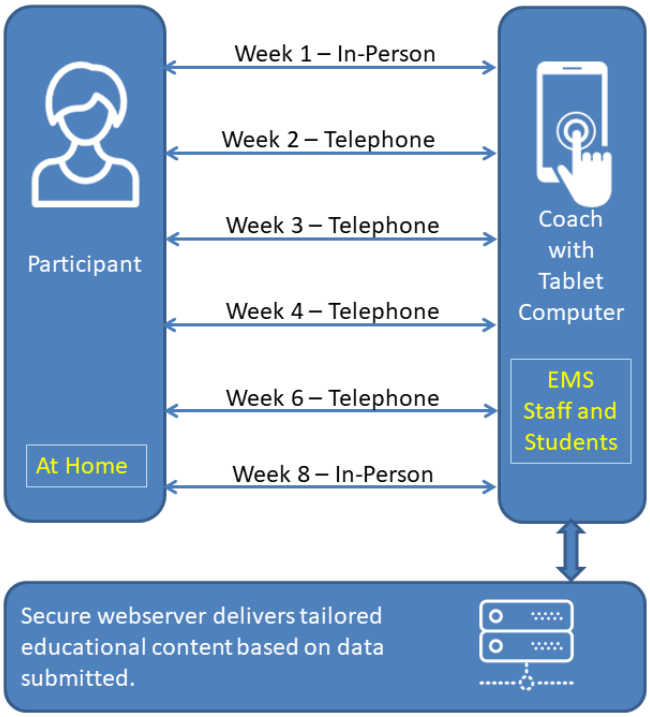
Intervention

The intervention included an initial in-person visit (week 1), which was followed by 3 weekly telecoaching calls (weeks 2-4), 1 biweekly call (week 6), and a final in-person visit in week 8 to perform posttest data collection (Figure 1). Anecdotal evidence from our community partner and related literature [29] indicated that having a lack of blood sugar and other vital sign monitoring devices and not visiting primary care physicians (to reevaluate prescriptions) often contributed to hypoglycemia episodes. To encounter these scenarios, health and wellness kits that included blood glucose meters, a blood pressure monitor, and oral dextrose gels were provided as an incentive to the participants.

During weeks 1 and 6 of this study, EMS personnel visited the homes of the recruited participants. During the week 1 visit, the EMS personnel used tablet computers to educate the participants. Their education involved the retrieval of tailored multimedia content, which was shown as a part of the verbal education provided on topics related to hypoglycemia. Based on an assessment of participants' diabetes literacy, numeracy [30], and knowledge [31], appropriately tailored content that matched participants' needs from the Diabetes Literacy and Numeracy Education Toolkit (DLNET) was provided by the telehealth platform. The DLNET is a comprehensive platform that was designed to facilitate diabetes education for patients with diabetes, especially for those with low health literacy. The DLNET provides 24 interactive modules that consist of diabetes care topics, such as blood glucose monitoring, exercise, and dietary instructions.

Student volunteers and EMS personnel used a telehealth dashboard, which was designed for this study, to coach and monitor participants over the phone during weeks 2, 3, 4, and 6. These calls focused on the active monitoring of hypoglycemia-related symptoms and the reinforcement of any education that participants received during week 1.

Figure 1. Study intervention design. EMS: emergency medical services.

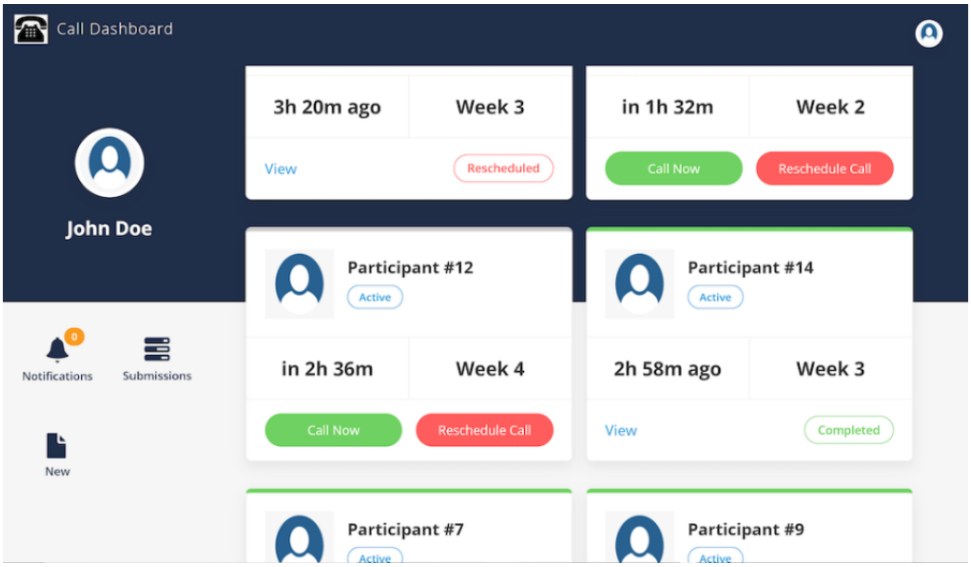


Telehealth Platform

The telehealth platform was built by repurposing, refining, and customizing a proven technical infrastructure that is currently being used by multiple projects (Figure 2). The platform used an Apache server (Apache Software Foundation) that runs a CakePHP back end that is connected to an Angular/Ionic framework–based front end. This enabled the telehealth platform to be delivered as both a web application and a hybrid mobile app with very minimal changes.

The telehealth dashboard automatically scheduled all of the recurring coaching calls for times that were convenient to the participants and in line with the intervention protocol. The community paramedicine personnel received alerts when it was time to call a participant and were able to mark the success or failure of completing the calls. When the calls were not successful, the calls could be rescheduled. It was also possible to perform weekly data collection and take notes during calls.

Figure 2. Telehealth dashboard.



Measures

Primary Measures

The primary focus of this study was evaluating the feasibility of recruitment, intervention delivery, retention, and data collection.

Exploratory Outcome Measures

One of the most important impacts of hypoglycemia is noncompliance with diabetes treatment due to the FH. This was measured by using the Hypoglycemia Scale: FH-15 questionnaire, which includes 15 items (5-point Likert scale) [32]. The response options were 1 (never), 2 (almost never), 3 (sometimes), 4 (almost always), and 5 (every day). A total score of ≥28 indicated that participants had an FH.

Self-efficacy in hypoglycemia self-management was assessed with the Perceived Diabetes Self-Management Scale (PDSMS) [33]. The questionnaire includes 8 items that are rated on a Likert 5-point scale (1=‘‘Strongly Disagree’’; 5=‘‘Strongly Agree’’). Higher scores represent higher levels of self-efficacy of hypoglycemia.

The Spoken Knowledge in Low Literacy Diabetes (SKILLD) [31] scale was used to assess participants’ diabetes knowledge. This 10-item questionnaire includes diabetes self-care–related questions, such as questions about glucose management and lifestyle modifications, for evaluating diabetes knowledge.

Data Collection

All data pertaining to the exploratory measures were collected during the in-person visits conducted in week 1 and week 8 of this study. The data were directly entered into the tablet computer that was carried by the EMS personnel.

Statistical Analysis

Participant attrition, session attendance, and overall instrument completion were recorded and analyzed by using descriptive statistics. We tested the pre-post exploratory measures by using simple parametric tests (one-tailed Student *t* test) after testing the normality of the data obtained. All statistical analyses were conducted by using SAS 9.4 (SAS Institute), and statistical significance was set at $P<.05$.

Results

Summary of Results

The findings from this study fell into 2 categories. First, we focused on the feasibility-related aspects of this study. Second, we focused on the exploratory outcomes. The lessons learned and challenges in implementing this study are presented in the *Discussion* section.

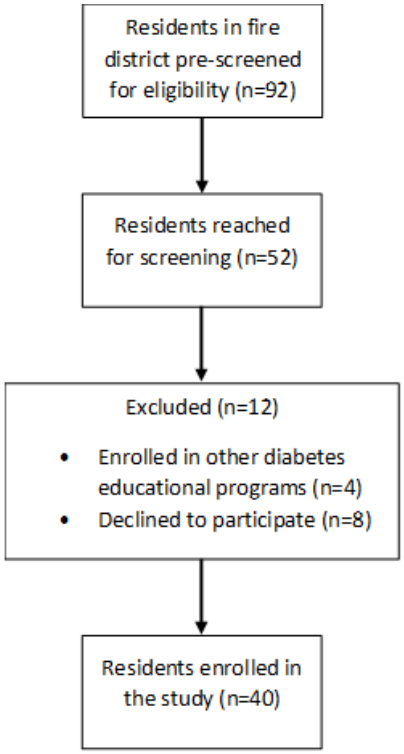
A total of 40 participants enrolled in this study. The mean age of participants was 67.13 years. The average age of males (n=18) was 69.33 years, and the average age of females (n=22) was 65.32 years.

Feasibility Metrics

Recruitment

For recruitment, we relied on EMS personnel to review EMS records and screen participants. Of the 92 people who were identified (prescreened) in a 6-month period, we were able to contact 52 (57%). Of the 52 people contacted, 40 (77%) fully qualified for and agreed to participate in this study (Figure 3).

Figure 3. Participant enrollment flowchart.



Intervention Delivery and Retention

The first step of the intervention was an in-person visit, which was by the EMS personnel, to the participants' homes. This session focused on obtaining consent, collecting baseline data, and educating participants. All 40 people who agreed to participate in this study made it through this session. However, as shown in Table 1, in the subsequent weeks that involved intervention sessions that were delivered over the telephone, we experienced a constant reduction in the number of people reached. For the final visit, which was again conducted in person, only 13 people were reachable.

Table 1. The number of participants who were reached via telephone.

Time point	Participants, n (%)
Week 2	25 (62)
Week 3	15 (37)
Week 4	13 (32)
Week 6	9 (22)

Data Collection

The pretest and posttest data were collected with the tablet computers that were provided to the EMS personnel during the in-person visits. The outcome assessment measures were embedded in the telehealth dashboard. This resulted in no missing or incomplete data, and little to no cleanup was required during the data analysis phase.

Exploratory Measures

The FH

The FH survey results revealed a decreasing trend in the overall average scores for all three subdomains—the average scores for fear (mean 13.78, SD 6.3 vs mean 9.38, SD 1.19), avoidance (mean 8.19, SD 4.42 vs mean 6.08, SD 4.37), and interference (mean 10.97, SD 5 vs mean 7.92, SD 1.55). The sum of the scores in the pretest scale was 32.95. This decreased to 23.38 after the intervention. However, no significant decrease in posttest scale scores was identified (P=.90).

Self-efficacy

The one-tailed paired t test analysis revealed that the intervention resulted in significant improvements in participants' self-efficacy in hypoglycemia self-management. Among the 13 participants who completed both the pre- and postsurvey, the average total PDSMS score significantly increased (mean 6, SD 8.59; P=.03). According to the results, the participants appeared to have significantly more confidence in the topic "No matter how hard I try, managing my diabetes doesn't turn out the way I would like" and tended to exhibit an increase in scores for the "I am able to manage things related to my diabetes as well as most other people" topic. The scores for these topics increased by an average of 1.3 points (SD 1.11; P<.001) and 1 point (SD 1.73; P=.06), respectively.

Knowledge of Diabetes

The SKILLD survey results also showed improvements in participants' knowledge of the complications of diabetes. The mean difference between the pre- and postsurvey scores was 0.5 (SD 0.65; *P*=.01). Although not significant, improvements in knowledge regarding symptoms of hypoglycemia (*P*=.33) and in normal hemoglobin A_{1c} levels (*P*=.27) were seen in the posttest scores.

Discussion

Study Overview

To our knowledge, this is the first study to conduct a community paramedicine and mobile integrated health care intervention [34] with a specific focus on hypoglycemia by using a telehealth platform. Working with a community partner enabled us to establish a smooth enrollment process for the intervention. However, the low retention rate was an important problem during intervention delivery and data collection. These should be explored in the context of this study to better understand and interpret the intervention outcomes.

Factors That Lead to Low Retention

Residents of the area that was served by this project belong to the lowest quartile of health literacy scores [16]. Although we included 40 participants, relatively high dropout rates and low attendance rates were observed due to the participants' low economic and educational statuses. As noted by our community health partner, most residents do not have a permanent phone number and use pay-as-you-go phones. Although participants were available for the baseline visit in week 1, they were not reachable for the final visit in week 8 for scheduling an in-person appointment. Tracking the participants via telephone was, by itself, challenging, and the lack of a permanent phone number made the process even more complicated. The results of this study show early promise, despite the challenging environment of the intervention. However, repeating this study in other socioeconomic settings or neighborhoods is needed to evaluate the intervention for its fullest potential. Additionally, other strategies for improving patient outreach and retention are needed to test this type of intervention.

Study Personnel

This study helped us learn about several other aspects about the involvement of EMS personnel in community paramedicine programs. During our intervention, we experienced some challenges with completing the in-person visits. Due to safety concerns, EMS personnel carried out the visits at their convenience. Relying on EMS personnel hindered the collection of the data and the completion of this study. Additionally, because of the nature of this pilot study, we were unable to have exclusive staff join the EMS personnel during the in-person visits. Moreover, the EMS staff in this study changed several times during the intervention due to organizational reasons. Future studies should consider including exclusive staff to ensure protocol fidelity. Another solution is employing the temporarily injured employees of fire departments. Employees who are unable to actively return to fieldwork are often available in fire stations and are best suited for telehealth calls. Future research should consider using protocols for including injured EMS personnel who could actively participate as health coaches in studies.

Importance of Trust

Another valuable insight we learned from this intervention was about the impact that EMS personnel's attire had on the participants' confidence and trust. We observed that wearing a professional uniform favorably influenced participants' trust and confidence in the paramedics. Participants also expressed the most confidence when the same EMS personnel attended to their emergency medical needs. Future studies that try to evaluate community paramedicine or telehealth need to ensure that such factors of trust are considered in the intervention design.

We designed a telehealth dashboard that the EMS personnel in this study could use to coach and monitor participants with hypoglycemia over the phone. At the end of the 8-week intervention period, nonsignificant improvements were found across various knowledge domains and subdomains (fear: *P*=.74; avoidance: *P*=.60; interference: *P*=.88) of the FH. The intervention resulted in significant improvements in participants' self-efficacy in hypoglycemia self-management and improved their knowledge of the complications of diabetes, which was measured by using the SKILLD scale. The lack of significant FH-related results might have been due to the very low completion rate (retention), as only 13 out of the 40 participants had posttest data. To interpret the results of this study in the right context, the challenges faced and the lessons learned during this study must be considered.

Although hypoglycemia can usually be safely and cost-effectively treated by paramedics, EMS protocols have been developed independently. This has led to variations in protocol content and formats, which can result in varying standards of care. However, the clinical practices of paramedics and emergency care protocols should be evidence-based and reflect common standards of care, formats, and content [35]. A standardized protocol can be easily accessed through a telehealth platform and can be used to provide guidance and education to patients. Therefore, by using a platform with evidence-based content and a standardized protocol, our study established an example of a telehealth-supported community service that can equally benefit people in need.

Limitations

Although we wanted to conduct a randomized feasibility study, the establishment of an untreated control group was not accepted by our community partner due to ethical concerns. Therefore, we chose a pre-post study design. Future studies should consider using designs that involve either simple randomization (by individuals) trials or cluster randomization (by fire districts) trials to understand our intervention's broader impacts. Although this pilot study was limited to a sample size of 40, future studies should also consider having larger sample sizes. Given the high attrition and the challenging socioeconomic settings in which this study was conducted, the findings of this study cannot be generalized. Similar studies should be conducted across areas with different socioeconomic populations. Finally, we offered

health kits that were comprised of blood glucose test kits, blood pressure cuffs, and dextrose gels. However, it should be noted that these kits could have had a confounding effect on the outcomes of this study, as there is evidence suggesting that the mere presence of self-monitoring equipment can influence diabetes-related outcomes [29].

Conclusions

Our study shows early promising results for a community-based hypoglycemia prevention intervention. However, our pilot study has several limitations. We comprehensively presented the challenges we faced and the lessons we learned throughout this study, and these should be considered when designing future studies.

Acknowledgments

This project was funded by the University of Alabama at Birmingham Center for the Study of Community Health—a member of the Prevention Research Centers Network—and was supported by the Centers for Disease Control and Prevention Cooperative Agreement (award number: U48/DP006404) and the University of Alabama at Birmingham Diabetes Research Center (award number: P30DK079626) of the National Institute of Diabetes and Digestive and Kidney Diseases.

Authors' Contributions

MT was the principal investigator and conducted all aspects of the research. AGZ and EE helped prepare the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

DLNET: Diabetes Literacy and Numeracy Education Toolkit
EMS: emergency medical services
FH: fear of hypoglycemia
PDSMS: Perceived Diabetes Self-Management Scale
SKILLD: Spoken Knowledge in Low Literacy Diabetes

Edited by D Griauzde, K Mizokami-Stout; submitted 04.01.21; peer-reviewed by YK Lin, K Fitzner; comments to author 30.01.21; revised version received 26.03.21; accepted 17.06.21; published 03.08.21.

Please cite as:
Thirumalai M, Zengul AG, Evans E
Challenges and Lessons Learned From a Telehealth Community Paramedicine Program for the Prevention of Hypoglycemia: Pre-Post Pilot Feasibility Study
JMIR Diabetes 2021;6(3):e26941
URL: https://diabetes.jmir.org/2021/3/e26941
doi:10.2196/26941
PMID:34342593

Original Paper

A Personalized Mobile Health Program for Type 2 Diabetes During the COVID-19 Pandemic: Single-Group Pre–Post Study

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Abstract

Background: With increasing type 2 diabetes prevalence, there is a need for effective programs that support diabetes management and improve type 2 diabetes outcomes. Mobile health (mHealth) interventions have shown promising results. With advances in wearable sensors and improved integration, mHealth programs could become more accessible and personalized.

Objective: The study aimed to evaluate the feasibility, acceptability, and effectiveness of a personalized mHealth-anchored intervention program in improving glycemic control and enhancing care experience in diabetes management. The program was coincidentally implemented during the national-level lockdown for COVID-19 in Singapore, allowing for a timely study of the use of mHealth for chronic disease management.

Methods: Patients with type 2 diabetes or prediabetes were enrolled from the Singapore Armed Forces and offered a 3-month intervention program in addition to the usual care they received. The program was standardized to include (1) in-person initial consultation with a clinical dietitian; (2) in-person review with a diabetes specialist doctor; (3) 1 continuous glucose monitoring device; (4) access to the mobile app for dietary intake and physical activity tracking, and communication via messaging with the dietitian and doctor; and (5) context-sensitive digital health coaching over the mobile app. Medical support was rendered to the patients on an as-needed basis when they required advice on adjustment of medications. Measurements of weight, height, and glycated hemoglobin A_{1c} (HbA_{1c}) were conducted at 2 in-person visits at the start and end of the program. At the end of the program, patients were asked to complete a short acceptability feedback survey to understand the motivation for joining the program, their satisfaction, and suggestions for improvement.

Results: Over a 4-week recruitment period, 130 individuals were screened, the enrollment target of 30 patients was met, and 21 patients completed the program and were included in the final analyses; 9 patients were lost to follow-up (full data were not available for the final analyses). There were no differences in the baseline characteristics between patients who were included and excluded from the final analyses (age category: P=.23; gender: P=.21; ethnicity: P>.99; diabetes status category: P=.52, medication adjustment category: P=.65; HbA_{1c} category: P=.69; BMI: P>.99). The 21 patients who completed the study rated a mean of 9.0 out of 10 on the Likert scale for both satisfaction questions. For the Yes-No question on benefit of the program, all of the patients selected “Yes.” Mean HbA_{1c} decreased from 7.6% to 7.0% (P=.004). There were no severe hypoglycemia events

(glucose level <3.0 mmol/L) reported. Mean weight decreased from 76.8 kg to 73.9 kg (P<.001), a mean decrease of 3.5% from baseline weight. Mean BMI decreased from 27.8 kg/m^2 to 26.7 kg/m^2 (P<.001).

Conclusions: The personalized mHealth program was feasible, acceptable, and produced significant reductions in HbA_{1c} (P=.004) and body weight (P<.001) in individuals with type 2 diabetes. Such mHealth programs could overcome challenges posed to chronic disease management by COVID-19, including disruptions to in-person health care access.

(JMIR Diabetes 2021;6(3):e25820) doi:10.2196/25820

KEYWORDS

type 2 diabetes; prediabetic state; text messaging; mobile applications; glycated hemoglobin A; HbA1c; blood glucose; body mass index; mHealth; COVID-19; diabetes; intervention; self-management; chronic disease; outcome

Introduction

Close to half a billion people in the world live with type 2 diabetes, and this prevalence is expected to increase by 25% by 2030 [1]. An estimated 430,000 (14.4% prevalence) Singapore residents aged 21 years and older had type 2 diabetes in 2015, and it has been estimated that the number will grow to 820,000 in the year 2035 (22.7% prevalence), assuming no change to the current landscape [2]. In addition, an estimated 560,000 (18.6% prevalence) Singapore residents in 2015 have prediabetes, of whom an estimated 490,000 (16.2% prevalence) were undetected. Type 2 diabetes has been identified as a chronic disease whose patients persistently incur high health care costs [3]. Effective scalable prevention measures are thus urgently needed to prevent and better manage type 2 diabetes to reduce its burden.

Lifestyle and behavior modification interventions for the prevention and management of type 2 diabetes have been shown to be effective in reducing risk of disease progression [4,5]. Executed well, lifestyle and behavior modification intervention programs can even have long-term sustained beneficial effects in decreased diabetes incidence and associated complications [6]. Such programs have traditionally been structured with a high frequency of in-person group-based sessions over a long duration (at least 6 months) [4,5]. Such programs can require a sizeable multidisciplinary professional team to run, which is costly [7,8], thereby limiting the scalability and sustainability of such interventions.

Simultaneously, many of these traditional lifestyle and behavior modification intervention programs have been found to have low participation rates [4] and high attrition [9]. Reasons for dropping out from such intervention programs include conflict between work schedules and center's hours of operation, distance to center, forgetfulness, lack of familiarity with the center and services, and apathy toward diabetes education [10]. Potential solutions to these barriers include running the program in the community [11,12], with reduced intensity [13], and leveraging mobile health (mHealth) interventions [14].

The use of mHealth for lifestyle and behavior modification interventions capitalizes on easily rolled out technologies to make communication and self-management education components easily accessible and independent of location. Over the years, mHealth interventions have progressed from using phone calls, text messages, and internet websites to, more recently, smartphone apps. The use of mHealth interventions for chronic disease care and management has been well-received with high acceptability and engagement [15-17]. In the care and management of type 2 diabetes, mHealth interventions have been successful in achieving improvements in clinical outcomes [18,19]. The use of adaptable feedback on behaviors with tailored messaging in mHealth interventions further allows for personalization according to the needs and preferences of patients [20,21]. Such a patient-centered approach of mHealth interventions could improve motivation in patients to make lifestyle and behavioral modifications and to sustain the changes made [22,23].

The use of wearable sensors in mHealth interventions provides real-time tracking and monitoring in patients with type 2 diabetes. Self-monitoring of blood glucose level, either by finger-stick or continuous glucose monitoring (CGM) technology, has been shown to be useful in helping patients improve their diabetes control [24-27]. Blood glucose data logged in mHealth apps can be consolidated with app-recorded diet and physical activity data and have been found to help facilitate self-care in patients at risk of or with type 2 diabetes [28,29]. Drawing on advancements in technology, integration of various successful features could bring about synergistic improvements in mHealth interventions for the management of type 2 diabetes.

Given the increasing burden and cost of uncontrolled type 2 diabetes and related complications, there is a great urgency for scalable and effective solutions that reduce such a burden and cost [30,31]. In response to this need, a personalized mHealth-anchored intervention program was designed and implemented in patients with type 2 diabetes or prediabetes. This study aimed to evaluate the effectiveness and feasibility of this personalized mHealth program in improving glycemic control and enhancing care experience in diabetes management.

Methods

Site and Population

The program was conducted in Singapore, a city-state in tropical Southeast Asia with a population of 5.64 million people [32]. The patients were recruited from the Singapore Armed Forces in collaboration with their Headquarters Medical Corps. The Singapore Armed Forces provides primary health care services within military camps for its full-time service personnel and conscripts and a range of risk-based health screening programs for personnel in older age ranges. These older personnel with

chronic health conditions are also free to obtain care from the national health care system outside of the Singapore Armed Forces.

The patients were recruited from active full-time service personnel and conscripts. Invitation to participate in the program was conducted by the Singapore Armed Forces' Headquarters Medical Corps through a series of intranet publicity advertisements posted over 4 weeks in February 2020. Interested patients were screened by the Headquarters Medical Corps and were enrolled into the program if they were interested and met the eligibility criteria (of having type 2 diabetes or prediabetes). The patients were deemed to have (1) type 2 diabetes, if they had glycated hemoglobin (HbA_{1c}) ≥6.5% in the past 1 year or if they were on medication for type 2 diabetes, or (2) prediabetes, if they had an HbA_{1c} level in the range 5.7% to 6.4% in the past year, and they were not taking any medications for type 2 diabetes. The enrollment target was set at 30 individuals, which was deemed to be sufficient to assess the feasibility and acceptability of such an intervention in a pilot program [33,34].

Intervention Program

The Singapore Armed Forces' Headquarters Medical Corps worked with NOVI Health, a health care technology start-up based in Singapore, to provide their proprietary mHealth program to the enrolled population.

All eligible patients were offered the 3-month intervention program in addition to the usual care that they received for their type 2 diabetes or prediabetes (Figure 1). The program was standardized to include the following components: (1) in-person initial consultation with a clinical dietitian that served as a health coach, (2) in-person review with a diabetes specialist doctor, (3) 1 Abbott Freestyle Libre CGM device that provided monitoring in the first 2 weeks, (4) access to the mobile app that allowed dietary intake and physical activity tracking and communication via text messaging with the dietitian and doctor, and (5) context-sensitive digital health coaching provided by the dietitian over the mobile app (Figure 2).

Figure 1. Intervention program timeline and protocol. *Recruitment with a series of publicity advertisements on the Singapore Armed Forces' intranet. ^Glycated hemoglobin level (HbA_{1c}) was measured if there was no valid reading within the prior 3 months.

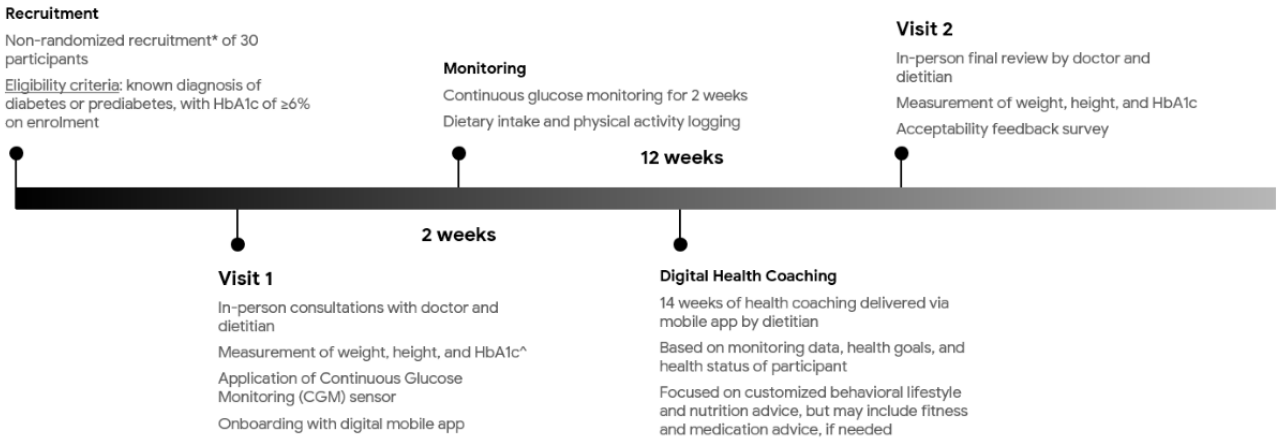
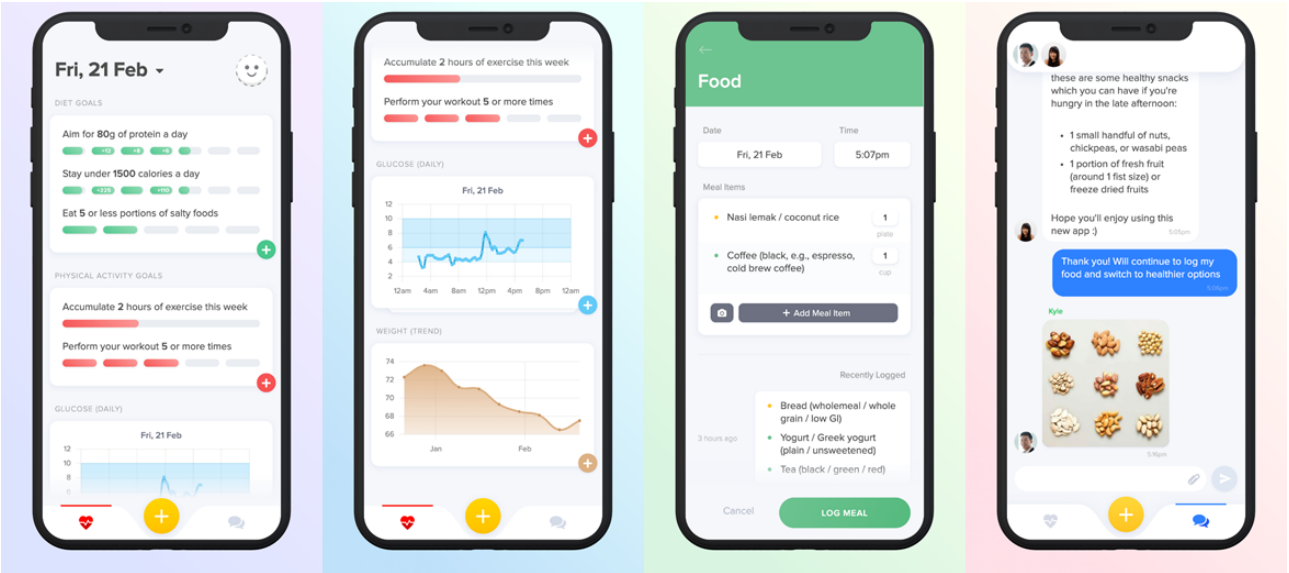


Figure 2. Screenshots of mobile app dashboard with diet and physical activity goals, real-time continuous glucose monitoring data, dietary intake and physical activity logs, and personalized recommendations delivered through the messaging function in the mobile app.



In the first in-person visit to the clinic (Visit 1), the patients had a consultation with the dietitian to set their health goals and discuss behavioral lifestyle changes that could be made. The patients also had a consultation with the diabetes specialist doctor, which allowed for the review of comorbidities and medication regime. The patients were also provided with 1 CGM device and were guided on how to use the device for glucose monitoring and how to provide the care team with access to their real-time CGM data.

In the subsequent 3 months after Visit 1, the patients were free-living and used the mobile app to log their dietary intake and physical activity. The dietitian and doctor were able to view the CGM, dietary intake, and physical activity data together with available information on the patients' health status (information on HbA_{1c}, comorbidities, and medication regime). This allowed them to deliver timely personalized recommendations through the messaging function of the mobile app. The health coaching via the mobile app was led by the clinical dietitian, with input from the fitness coaches provided when needed, and with medical oversight from the reviewing diabetes specialist doctor. Medical support via the mobile app was also provided to the patients on an as-needed basis (if they experienced hypoglycemia requiring medication adjustments or if they required advice on the adjustment of medications, etc). After 3 months, the patients returned to the clinic for their second in-person visit (Visit 2) to meet with the diabetes specialist doctor and dietitian for final review.

Patient recruitment for the program started in February 2020 and the program ran from March 2020 to June 2020. The recruitment period and the first month of the intervention program corresponded with a worsening COVID-19 situation in Singapore through the months of February and March 2020. This culminated in a national-level lockdown, which started on April 7, 2020 and ended on June 1, 2020, coinciding with the second and third months of the intervention program. The 2 in-person visits to the clinic (Visits 1 and 2) happened to have been scheduled in the periods before and after the lockdown in Singapore and were, therefore, not impacted.

Outcome Measurements

Measurements of weight, height, and HbA_{1c} were conducted at Visits 1 and 2. Weight and height were measured by a trained nurse, using a Surgico Healthweigh machine. At the end of the program at Visit 2, the patients were asked to complete a short acceptability feedback survey to understand the motivation for joining the program, their satisfaction, and suggestions for improvement. The question on motivation, "What was your primary motivation for signing up for this program?" had 4 options: "1. Wanted to get my diabetes under control, 2. Wanted to get dietary advice for my diabetes, 3. Wanted to lose weight, 4. Was asked to participate by HQMC." There were 2 satisfaction questions rated on a 10-point Likert scale, "How satisfied were you with the program?" and "How likely are you to recommend this program to your colleague?" A fourth question "Do you think that other servicemen would benefit from this program?" was a Yes-No question asking the patients on whether the program would be beneficial to others.

Data Analysis

Patients were considered to have completed the study and included in the final outcomes analyses if they had completed the full 14 weeks of the intervention program, with weight, height, and HbA_{1c} measurements at baseline (Visit 1) and at completion of the program (Visit 2). Means were calculated for continuous baseline characteristic variables. Due to nonnormality of data, the Wilcoxon signed rank test was used to compare means between those who completed the study and those that were lost to follow-up and excluded. Proportions were calculated for baseline characteristics that were categorical variables. The Fisher exact test was used if counts were less than 5 to compare distributions of those who completed the study and those who were lost to follow-up and excluded.

The final analyses of main outcomes of interest for acceptability and effectiveness were limited to only the those who completed the study. For the outcomes of HbA_{1c}, weight, and BMI, the patients were further split for subgroup analyses: (1) by baseline HbA_{1c} ≤7% or >7%, and (2) by baseline BMI<27.5 kg/m^2 (normal and overweight) or ≥27.5 kg/m^2 (obese). The HbA_{1c} cut-off was selected based on the HbA_{1c} threshold set by major clinical guidelines for what is considered good diabetes control [35-37], and the BMI threshold was selected based on what is considered obese in the Asian population [38]. Due to nonnormality of data, the Wilcoxon signed rank test was used for the paired comparisons of the main outcomes at Visit 1 and Visit 2, with significance level set at α=.05. Analyses were conducted in R (version 3.6.1). Means and standard deviations of the main outcomes are presented, along with *P* values, where applicable. Calculation of type II beta errors were also conducted for the main outcomes of interest using G*Power (version 3.1.9.4), for a 2-tailed test according to a Laplace parent distribution and α=.05. Beta errors >.2 are indicated.

Ethics Approval

This study was conducted as part of a program evaluation. The data collected were presented at the Singapore Armed Forces' Joint Medical Committee for Research and approved for exemption from full review at the Institutional Review Board.

Results

Baseline Characteristics

Over the 4-weeks recruitment period in February 2020, there were 130 individuals screened, of whom 30 met eligibility criteria and were interested in participating in the program. Of the 30 enrolled patients, 7 were lost to follow-up, and 2 had completed the program but did not have complete measurements from Visit 2. As such, 21 patients were included in the final outcome analyses. There were no significant differences in any of the baseline characteristics (age category: *P*=.23; gender: *P*=.21; ethnicity: *P*>.99; diabetes status category: *P*=.52, medication adjustment category: *P*=.65; HbA_{1c} category: *P*=.69; BMI: *P*>.99) between the patients who were excluded and those who were included in the final outcome analyses (Table 1). The majority of the patients were male. The majority of the patients had diabetes; the patients who had diabetes were all on glucose

lowering medication upon enrollment into the program. While there were patients who were on insulin therapy upon entry into the program, no patient started insulin during the program. There were 5 patients who had their medication adjusted. One patient's insulin dosage was reduced, 2 patients had their medication (sulfonylurea) switched to another oral antihyperglycemic medication to reduce hypoglycemic risk, and 2 patients had 1 oral antihyperglycemic medication added to their existing regime. Approximately two-thirds of the patients had baseline HbA_{1c} >7%, and approximately half had BMIs that placed them in the obese category.

Table 1. Baseline characteristics of all enrolled patients, patients lost to follow-up, and patients who completed the program and were included in the final analyses.

Characteristics	All recruited (n=30)	Lost to follow-up (n=9)	Completed (n=21)	*P* value
Age (years), mean (range)	49.1 (21-64)	43.7 (21-61)	51.4 (32-64)	.054
Age, n (%)				.23
<50 years	17 (57)	7 (78)	10 (48)	
≥50 years	13 (43)	2 (22)	11 (52)	
Gender, n (%)				.21
Female	9 (30)	1 (11)	8 (38)	
Male	21 (70)	8 (89)	13 (62)	
Ethnicity, n (%)				>.99
Chinese	24 (80)	8 (89)	16 (76)	
Malay	1 (3)	0 (0)	1 (5)	
Indian/Pakistani	5 (17)	1 (11)	4 (19.0)	
Diabetes status, n (%)				.52
Prediabetes	2 (7)	1 (11)	1 (5)	
Type 2 diabetes	28 (93)	8 (89)	20 (95)	
Medication adjustments, n (%)				.65
Adjusted	8 (27)	3 (33)	5 (24)	
Not adjusted	22 (73)	6 (67)	16 (76)	
Baseline HbA_{1c}[a] (%), mean	7.7	7.9	7.6	>.99
Baseline HbA_{1c} category, n (%)				.69
≤7%	11 (37)	4 (44)	7 (33)	
>7%	19 (63)	5 (56)	14 (67)	
Baseline BMI[b] (kg/m^2), mean	27.9	28.2	27.8	.96
Baseline BMI category, n (%)				>.99
<27.5 kg/m^2	15 (50)	4 (44)	11 (52)	
≥27.5 kg/m^2	15 (50)	5 (56)	10 (48)	
Baseline weight (kg), mean	77.7	79.7	76.8	.82

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

[b]BMI: body mass index.

Acceptability Feedback

For the multiple-choice question on motivation, 48% of patients (10/21) selected "Wanted to get my diabetes under control," 19% of patients (4/21) selected "Wanted to get dietary advice for my diabetes," 3 (14% of patients (3/21) patients selected "Wanted to lose weight," and 19% of patients (4/21) selected "Was asked to participate by HQMC." The patients rated a mean of 9.0 out of 10 on the Likert scale for both satisfaction questions. For the Yes-No question on the benefit of the program, all patients selected "Yes."

Effectiveness Outcomes

For all 21 who completed the study, mean HbA_{1c} decreased from 7.6% to 7.0% (*P*=.004) (Table 2). Mean weight had decreased from 76.8 kg to 73.9 kg (*P*<.001), which was a mean decrease of 3.5% (SD 3.2%) from baseline. Mean BMI had decreased from 27.8 kg/m^2 to 26.7 kg/m^2 (*P*<.001).

Table 2. Comparison of HbA_{1c}, weight, and BMI at Visit 1 and Visit 2 for all patients who completed the study.

Outcome	Visit 1, mean (SD)	Visit 2, mean (SD)	*P* value
HbA_{1c}[a] (%)	7.6 (1.1)	7.0 (0.8)	.004
Weight (kg)	76.8 (15.6)	73.9 (13.8)	<.001
BMI[b] (kg/m^2)	27.8 (5.4)	26.7 (4.8)	<.001

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

[b]BMI: body mass index.

Subgroup Analyses by Baseline HbA_{1c} Category

For patients who had baseline HbA_{1c} ≤7%, there was no statistically significant change in HbA_{1c} upon completion of the 3-month intervention program (*P*=.67), but the beta error was found to be >.2 (Table 3). However, mean weight decreased from 75.0 kg to 73.0 kg (*P*=.02; mean decrease 3.9%, SD 3.7%). Mean BMI decreased from 26.8 kg/m^2 to 26.1 kg/m^2 (*P*=.02). For the patients who had baseline HbA_{1c} >7%, mean HbA_{1c} decreased from 8.1% to 7.2% (*P*=.005). Mean weight also decreased from 77.8 kg to 74.3 kg (*P*=.006), which was a mean decrease of 2.5% (SD 1.8%) from the baseline weight. Mean BMI decreased from 28.3 kg/m^2 to 27.1 kg/m^2 (*P*=.006).

Table 3. Comparison of Visit 1 and Visit 2 characteristics for patients who had baseline HbA_{1c} ≤7% or >7%.

Outcome	Baseline HbA_{1c} ≤7% (n=7)			Baseline HbA_{1c} >7% (n=14)		
	Visit 1, mean (SD)	Visit 2, mean (SD)	*P* value	Visit 1, mean (SD)	Visit 2, mean (SD)	*P* value
HbA_{1c}[a] (%)	6.7 (0.3)	6.6 (0.6)	.67[b]	8.1 (1.0)	7.2 (0.8)	.005
Weight (kg)	75.0 (13.5)	73.0 (12.2)	.02	77.8 (16.9)	74.3 (14.9)	.006
BMI[c] (kg/m^2)	26.8 (5.1)	26.1 (4.8)	.02	28.3 (5.7)	27.1 (4.9)	.006

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

[b]Type II beta error >.2.

[c]BMI: body mass index.

Subgroup Analyses by Baseline BMI Category

There were no statistically significant changes in HbA_{1c}, weight, or BMI for patients who were in the normal and overweight BMI category, after the intervention in Visit 2, but beta errors were found to be >.2 (Table 4). For the patients who were in the obese BMI category, mean HbA_{1c} decreased from 7.6% to 6.8% (*P*=.006). Mean weight also decreased from 89.3 kg to 84.1 kg (*P*=.002, mean decrease 5.9%, SD 2.2%). Mean BMI decreased from 32.5 kg/m^2 to 30.6 kg/m^2 (*P*=.002).

Table 4. Comparison of Visit 1 and Visit 2 characteristics for patients who had baseline BMI <27.5 kg/m^2 (normal and overweight) or ≥27.5 kg/m^2 (obese).

Outcome	Normal and overweight (n=11)			Obese (n=10)		
	Visit 1, mean (SD)	Visit 2, mean (SD)	*P* value	Visit 1, mean (SD)	Visit 2, mean (SD)	*P* value
HbA_{1c}[a] (%)	7.7 (1.3)	7.3 (0.9)	.14[b]	7.6 (0.9)	6.8 (0.6)	.006
Weight (kg)	65.5 (8.7)	64.6 (8.1)	.07[b]	89.3 (11.1)	84.1 (11.2)	.002
BMI[c] (kg/m^2)	23.5 (2.1)	23.2 (2.03)	.07[b]	32.5 (3.6)	30.6 (3.7)	.002

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

[b]Type II beta error >.2.

[c]BMI: body mass index.

Complications

During the study, the patients had no hospitalization episodes for any diabetes-related complications. There were no severe hypoglycemia (glucose level <3 mmol/L) events observed or reported.

Discussion

General

This study evaluated a real-world personalized mHealth-anchored intervention program for feasibility, acceptability, and effectiveness for diabetes management. The program garnered a lot of interest and the enrollment target was

met fairly quickly (in less than a month). The program was implemented as planned in spite of the disruptions from COVID-19. The program also received high patient ratings of satisfaction and perceived benefit from participation in the program. The patients achieved a significant reduction in HbA_{1c} in 3 months, ending the program with an average HbA_{1c} of 7%. Reduction of HbA_{1c} levels to ≤7% is consistent with the glycemic target set by most clinical guidelines [35,36] and has been shown to reduce microvascular [39-43] and macrovascular [44] complications in individuals with type 2 diabetes. Patients in the study also achieved weight loss over 3 months that met the clinically significant threshold of 3% [45,46]. Such reductions have been observed to lead to improvements in cardiovascular risk factors such as glycemic control, systolic and diastolic blood pressure, as well as with respect to low-density lipoprotein and high-density lipoprotein cholesterol levels [47].

The improvements observed were achieved in patients who had known type 2 diabetes and prediabetes and who were receiving usual care and on existing medications. This suggests that there could be a role for a personalized mHealth program for patients with diabetes, even those receiving usual medical care for their diabetes. Such a program could improve control of diabetes and further reduce the risk of microvascular and macrovascular complications. In the subgroups of patients with glycemic and BMI measures above the ideal range, the impact of the personalized mHealth program was even greater. These results were not unexpected as the patients with starting HbA_{1c} and weight values that were further from target were likely to have more room for improvement. The mHealth program could benefit most individuals with diabetes; targeting the program at individuals with higher HbA_{1c} or higher BMI would yield greater improvements in both HbA_{1c} and BMI.

Diabetes Management Programs

Traditionally, diabetes management programs that supplement usual care for individuals with diabetes have focused on enhancing support and education, improving nutrition, and increasing physical activity with a structured curriculum-based approach [4]. Such intervention programs are usually conducted in-person and have been shown to be effective in improving glycemic control. In the Look AHEAD trial [48], intensive lifestyle intervention components involved group and individual meetings to achieve and maintain weight loss through decreased caloric intake and increased physical activity. The trial achieved an HbA_{1c} reduction of 0.7% and weight loss of 8.6% over 1 year [48]. In recent years, mHealth lifestyle intervention programs have emerged, bringing convenience and accessibility to individuals with diabetes, achieving HbA_{1c} reductions of approximately 0.3% to 0.5% [18,19,49-51] and insignificant changes in weight loss [19,49,51].

The personalized mHealth program in this study combined health coach-led personalized lifestyle intervention with medical support by a specialist doctor, the use of CGM, and integrated delivery through a mobile app. The medical support allowed for medication adjustments where beneficial, for example, optimizing the timing of administration of the medication to more effectively suit the lifestyle patterns of the patient. However, it is important to note that, in this study, there were no major adjustments of medications, such as initiating patients on insulin, that could have confounded the improvements observed. This is in contrast to another feasibility study with the same mHealth components, in which it was not possible to determine if improvements were due to intensification of medical therapy or from the other components of the intervention program [52].

The mobile app and CGM allowed the real-time tracking of diet, physical activity, and glucose, for interventions that were highly personalized, context sensitive, and delivered in a timely manner. Visualization of their own data, coupled with remote monitoring and actionable insights from trusted experts through the mobile app to make sense of that data, could enable the patients to appreciate the impact of their behaviors on their own health parameters. This could have further empowered and reinforced the user to implement behaviors that improve their health on a continuous, real-time basis in between clinic visits, with a low risk of adverse events such as hypoglycemia. The integrated solution incorporating medical support, CGM, and lifestyle care delivery through a mobile app likely accounted for the intervention in this study achieving results comparable to those reported in other diabetes lifestyle intervention programs, in a far shorter period of 3 months.

Based on the responses from the survey at the end of the program, patients found this personalized mHealth program to be beneficial in improving their diabetes control. Patients also reported that they were satisfied with the personalized mHealth program. These results suggested that patients found value in the mHealth program and were also receptive to the program. As there was no glycemic threshold effect, participation in a personalized mHealth program could be recommended to most individuals with diabetes or prediabetes, with the understanding that greater clinical improvement is seen with poorer starting glycemic control.

COVID-19 and Implications on Chronic Disease Management

This program was conducted against the backdrop of a worsening COVID-19 pandemic, which saw Singapore undergo a national-level lockdown, termed *circuit breaker*, from April 7, 2020 to June 1, 2020. This coincided with the mHealth-anchored digital coaching phase of the program. During this period, there were widespread closures, of premises such as nonessential workplaces, schools, exercise and recreational facilities, and places of worship, along with the prohibition of all social gatherings [53]. Essential services in health care, transport, cleaning, food services, and supply chains remained open, but on a reduced capacity basis. This had several implications on the health and diabetes control of the patients.

With the closure of sports facilities, many of the patients who performed their physical activity in these locations were unable to continue doing so. Closure of workplaces and recreational facilities, as well as banning of social gatherings, meant that patients left their homes less and commuted less, resulting in lower physical activity levels [54]. The stress of being under lockdown may also have increased the consumption of

ultra-processed food, which can be detrimental to diabetes control. While it is too early to assess the impact of the lockdown on diabetes control, experts anticipate a negative impact on weight as well as glycemic control [55,56].

During the circuit breaker period, the patients also had greater difficulty accessing health care. Many of the patients had their regular reviews with their primary care physicians postponed. Some of the patients in critical operational roles were confined to military camps, with some reporting difficulties getting refills of certain medications from their external health care providers, and in some instances, difficulties in communicating via the mobile app due to certain camp security restrictions. These health care access issues would have negatively impacted the patients' diabetes care and control during this period.

The patients in this study experienced clinically significant improvements in their glycemic control (P=.004), weight (P<.001), and BMI (P<.001). This was in spite of the anticipated worsening of weight and glycemic control due to decreased physical activity, poorer diet, and lack of access to health care due to a national-level lockdown [54-56]. This highlights the role that a diabetes solution with an mHealth component can play in improving the management of chronic diseases, such as type 2 diabetes, especially during periods where there are barriers to accessing health care in person.

Strengths and Limitations

This study evaluated a real-world context-sensitive mHealth-anchored intervention program with free-living patients. The program also coincidentally began during the start of the COVID-19 pandemic, with the bulk of the encounters occurring during the national-level lockdown in Singapore. This allowed for a timely study of the use of mHealth for chronic disease management just as the world needed to move toward embracing more digital solutions to limit in-person interactions.

A limitation of this study was that the program was conducted only with military personnel, which could have been expanded to include other professions so that the results could be more generalizable. However, the focus on military personnel could inform specific occupational policy changes to improve chronic disease prevention and management for active military personnel [57] and could reduce productivity lost among active personnel [58].

Another limitation was that the study consisted of a single intervention arm with no control group. Without a control group, there is a possibility that patients not undergoing the same program might still experience the same improvements with usual care during the same time period. However, this study demonstrated the feasibility of the program and also provided pilot data that can pave the way for future studies. Further explorations could be done on the improvements of the personalized mHealth program intervention and its various components.

Close to one-third of the patients had dropped out of the program. However, this was not higher than expected for a 3-month program, and we did not observe any systemic differences between the patients who completed the program compared to those who dropped out analyses (age category: P=.23; gender: P=.21; ethnicity: P>.99; diabetes status category: P=.52, medication adjustment category: P=.65; HbA_{1c} category: P=.69; BMI: P>.99). In spite of the small sample size, there was sufficient power for differences to be detected in the main analyses. However, there was insufficient power for a few of the subgroup analyses (beta errors were found to be >.2).

The patients were also only followed-up for 3 months until the end of the program; therefore, long-term effects of the program are unknown. This is a limitation commonly found in the review of other mHealth interventions [18,49,51], but there have been some promising indications of positive long-term outcomes [59]. This warrants additional follow-up investigations in future studies to explore whether effects are sustained after the program has ended, and whether some components could be implemented periodically in a cost-effective way to maintain the improvements achieved.

Conclusion

The personalized mHealth-anchored intervention program demonstrated feasibility and acceptability and was able to produce significant reductions in HbA_{1c} (P=.004) and body weight (P<.001) in individuals with type 2 diabetes, in addition to usual care. The results also suggested that a program with a strong mHealth component could overcome challenges posed by COVID-19 to chronic disease management, including disruptions to in-person health care access. Further investigation is warranted to test the persistence of the results and the use of such digital therapeutics as a scalable solution to address the burden of diabetes.

Acknowledgments

The intervention program was a contracted health service paid for by the Singapore Armed Forces. Funding for the publication of this manuscript was provided by the Singapore Ministry of Health's National Medical Research Council Centre Grant Programme (grant number NMRC/CG/C026/2017_NUHS) for SPHERiC (the Singapore Population Health Improvement Centre). We would like to acknowledge senior dietitian Ruth Ho and staff nurse Liu Qing for their contributions to the delivery of the intervention program, as well as Nabilah Rahman for providing statistical advice.

Authors' Contributions

KTXQ, SAT, TCH, and CT were responsible for the design of the intervention program. TCH and JT assisted with recruitment of patients for the program and operational aspects of the implementation of the program. IYHA was responsible for data analysis.

IYHA and KTXQ wrote the first draft of the manuscript. All authors provided input, edited, and approved the final draft of this paper.

Conflicts of Interest

KTXQ, JT, and SAT are cofounders and shareholders of NOVI Health. IYHA, CT, TCH, and JWMK declare no conflicts of interest.

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Abbreviations

BMI: body mass index
CGM: continuous glucose monitoring
HbA_{1c}: glycated hemoglobin A_{1c}
mHealth: mobile health

Edited by D Griauzde; submitted 01.12.20; peer-reviewed by M Khadra, C Sahin; comments to author 13.01.21; revised version received 14.04.21; accepted 06.06.21; published 09.07.21.

Please cite as:
Ang IYH, Tan KXQ, Tan C, Tan CH, Kwek JWM, Tay J, Toh SA
A Personalized Mobile Health Program for Type 2 Diabetes During the COVID-19 Pandemic: Single-Group Pre–Post Study
JMIR Diabetes 2021;6(3):e25820
URL: https://diabetes.jmir.org/2021/3/e25820
doi:10.2196/25820
PMID:34111018

Original Paper

Health Internet Technology for Chronic Conditions: Review of Diabetes Management Apps

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Abstract

Background: Mobile health (mHealth) smartphone apps have shown promise in the self-management of chronic disease. In today's oversaturated health app market, selection criteria that consumers are employing to choose mHealth apps for disease self-management are of paramount importance. App quality is critical in monitoring disease controls but is often linked to consumer popularity rather than clinical recommendations of effectiveness in disease management. Management of key disease variances can be performed through these apps to increase patient engagement in disease self-management. This paper provides a comprehensive review of features found in mHealth apps frequently used in the self- management of diabetes.

Objective: The purpose of this study was to review features of frequently used and high consumer-rated mHealth apps used in the self-management of diabetes. This study aimed to highlight key features of consumer-favored mHealth apps used in the self-management of diabetes.

Methods: A 2-fold approach was adopted involving the Apple iOS store and the Google search engine. The primary search was conducted on the Apple iOS store using the term "diabetes apps" (device used: Apple iPad). The top 5 most frequently used mHealth apps were identified and rated by the number of consumer reviews, app ratings, and the presence of key diabetes management features, such as dietary blood glucose, A_{1C}, insulin, physical activity, and prescription medication. A subsequent Google search was conducted using the search term "best Apple diabetes apps." The top 3 search results—"Healthline," "Everyday Health," and "Diabetes Apps–American Diabetes Association"—were explored.

Results: In total, 12 mHealth apps were reviewed due to their appearing across 4 evaluated sources. Only 1 health app—Glucose Buddy Diabetes Tracker—appeared as the most frequently used within the Apple iOS store and across the other 3 sources. The OneTouch Reveal app ranked first on the list in the iOS store with 39,000 consumer reviews and a rating of 4.7 out of 5.0 stars but only appeared in 1 of the other 3 sources. Blood glucose tracking was present across all apps, but other disease management features varied in type with at least 3 of the 5 key features being present across the 12 reviewed apps. Subscription cost and integration needs were present in the apps which could impact consumers' decision to select apps. Although mobile app preference was assessed and defined by the number of consumer reviews and star ratings, there were no scientific standards used in the selection and ranking of the health apps within this study.

Conclusions: mHealth apps have shown promise in chronic disease management, but a surge in development of these nonregulated health solutions points to a need for regulation, standardization, and quality control. A governing body of health IT professionals, clinicians, policymakers, payors, and patients could be beneficial in defining health app standards for effective chronic disease management. Variabilities in features, cost, and other aspects of management could be reduced by regulatory uniformity, which would increase patient engagement and improve disease outcomes.

(JMIR Diabetes 2021;6(3):e17431) doi:10.2196/17431

KEYWORDS

chronic disease; diabetes; blood glucose; diabetes management; mHealth disease apps; diabetes apps; best Apple diabetes apps

Introduction

Background

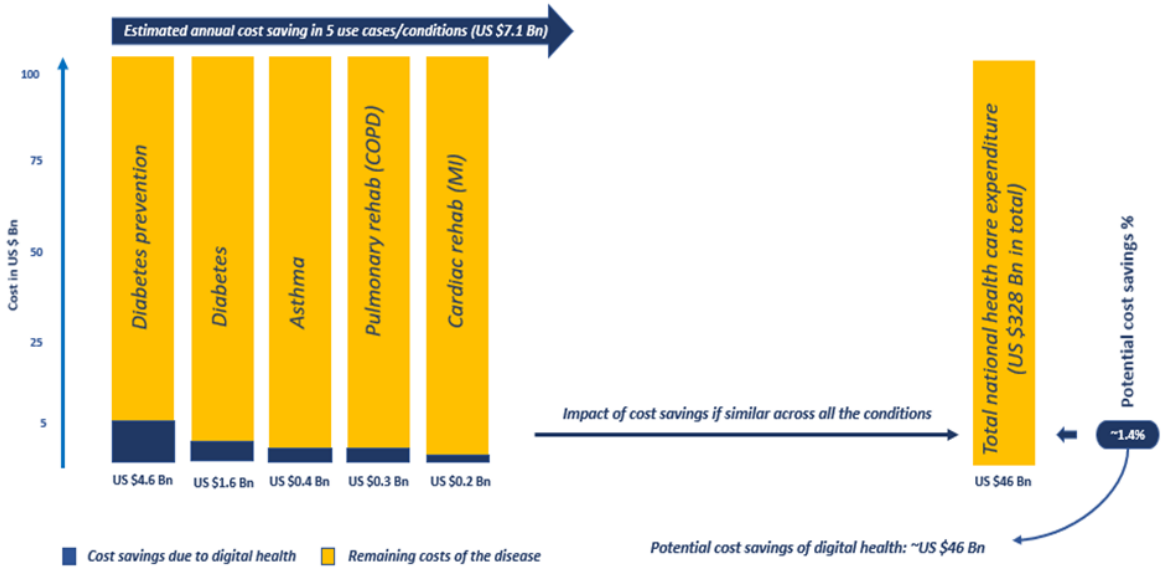
Health information technology (HIT) has been touted as a solution for prolonged management of chronic diseases, such as diabetes, and their associated lifestyle fluctuations in diet, exercise, and prescription medication. Remote monitoring of diabetes through mobile health (mHealth) apps is one of the early management mediators of the disease and has increased in use throughout recent years [1]. Over 3500 apps and counting have been designed and tailored specifically for chronic conditions [2]. Many of these apps include mobile developments aimed at effectively addressing disease management through increased patient self-management to reduce associated health care costs. The effective application of information technology in chronic disease management holds the potential to significantly impact health care outcomes through facilitated treatment adherence which integrates both compliance and modifiable health behaviors (ie, diet and exercise) [3]. Improving adherence through the use of HIT has become a critical focus within the health care industry to improve patient outcomes and reduce associated health care costs. Due to the need for continuous monitoring and long-term care of chronic disease sufferers, early HIT advancements, such as telehealth and telemonitoring, have been employed to reinforce patient adherence to chronic disease controls [4]. HIT solutions have continued to evolve as mHealth technologies have become popular platforms for delivery of at-home care and have developed new capabilities that enable patients to self-manage chronic conditions.

Health-related smartphone apps provide a "platform for the delivery of self-management interventions that are highly adaptable, have low healthcare expenditure costs, and remain easily accessible" for patient use [4]. Some platform features enable patients to self-measure blood glucose levels, log diet and healthy eating habits, track physical activities, enhance medication adherence, monitor insulin dosages, and receive real-time feedback on critical monitoring elements of a regimen management plan prescribed by a physician [1]. Condition management apps are on the rise and "now account for 40% of all digital health apps" with notable focus on disease-specific management apps [5]. The 5 areas of focus are chronic conditions that include mental health, diabetes, heart and circulatory conditions, nervous system disorders, and musculoskeletal conditions, 2 of which are leading causes of death in the United States (Table 1) [5]. A study by The IQVIA Institute for Human Data Science further reported that "clinical benefits across a broad array of conditions resulting from digital health application usage estimates a potential 1.4% savings in US national healthcare expenditures—equating to approximately $46 billion in total annual cost savings" (Figure 1) [5]. Currently, "there are over 300,000 health applications available in the market that address a variety of user needs from weight loss to management of chronic conditions, with diabetes being the most commonly targeted condition" [6].

Table 1. Disease-specific app by therapy area according to the IQVIA Institute for Human Data Science [5].

Therapy area	Proportion (%)
Mental health	28
Diabetes	16
Heart	11
Musculoskeletal system	7
Nervous system	7
Respiratory system	5
Cancer	5
Pain	4
Eyes and ears	4
Digestive system	4
Skin and tissue	3
Endocrine	3
Kidney disease	1
Hematology	1
Other	1

Figure 1. Potential annual cost savings with the use of digital health apps [5]. Bn: billion; COPD: chronic obstructive pulmonary disease; MI: myocardial infarction. (Adopted from Aitken et al, IQVIA, 2017.)



Within the last decade, mobile phone usage has substantially increased with approximately three-quarters of the US population owning mobile phones [7]. This has contributed to an increase in mobile access across patients with chronic conditions like diabetes. Mobile HIT tools and platforms use 4 main categories to promote adherence strategies for chronically ill patients: (1) SMS text messaging, (2) smartphone apps or software, (3) smartphones coupled with a wireless or Bluetooth compatible device, and (4) specific medical instruments connected to a smartphone via a cord [4]. Of these platforms, SMS text messaging has been reported to be the most commonly used by physicians and care providers, accounting for 40% of mobile HIT usage for appointment and medication reminders, patient education delivery, and the monitoring of symptoms through real-time data collection [4,8]. As HIT mobile solutions become more accessible for chronic disease patients, mHealth app designs aim to specifically accommodate this population.

Mobile Management of Diabetes

A chronic disease is "defined broadly as a condition that lasts one year or more and requires ongoing medical attention, limits activities of daily living or both" [9]. The prevalence of chronic disease is continually rising in the United States and has moved far beyond the bar of epidemic concern, as 60% of adults in the United States have at least 1 chronic disease and 40% have 2 or more of these conditions [9]. Generally incurable but often treatable, chronic diseases contribute to the nation's astounding $3.3 trillion annual health care costs and present heavy burdens on the nation's health care spending [9]. Chronic diseases directly affect the economy, overall health care budgets, and employee productivity while also highlighting the urgent need for interdisciplinary solutions with long-term sustainability [10].

The top 3 chronic illnesses with the highest economic impact on United States health care systems are heart (cardiovascular) disease, cancer, and diabetes [9]. The cumulative aggregate of the 3 diseases constitutes a significant portion of the "nation's annual health care expenditures" costing the "US health care system and employers $237 billion every year" in care and management [9,10]. Diabetes, or diabetes mellitus, is one of the leading causes of chronic disease deaths in America, with an estimated 30 million individuals diagnosed with the disease and another 80 million deemed to be prediabetic, which is the precursor to type 2 diabetes [9]. The disease is one of the most prevalent noncommunicable diseases, yet it is one of the costliest in terms of care and long-term management. The cost of long-term management of diabetes has contributed to heightened clinical interest in mobile, self-management solutions aimed at curtailing prolonged disease management costs and improving patient prognosis.

Diabetes presents in varying forms—type 1, type 2, and gestational—and disease development is attributed to insufficient production or use of insulin in the body leaving an excess of glucose in the bloodstream to be used as energy [11]. Type 1 diabetes is defined as an immune system attack on the cells that make insulin in the pancreas [11]. Alternatively, type 2 diabetes is typically diagnosed if the body does not sufficiently make or use insulin [11]. Both forms could present at any stage of life due to the body's inability to manufacture or use insulin as intended [11]. Type 1 diabetes is most common among children, adolescents, and young adults but is treatable and manageable through the daily intake of insulin by those diagnosed with the disease [11,12]. Type 2 diabetes is most prevalent among adults and affects 90% of those with a diabetes diagnosis [12]. Gestational diabetes presents during pregnancy in women and is a fair indicator that type 2 diabetes might develop later in life if gestationally diagnosed while pregnant [11,12]. Healthy maintenance of blood glucose levels is key to diabetes management. The incorporation of modifiable lifestyle changes is often recommended to improve disease outcomes and offset future costs in long-term management for those with the type 2 disease [12].

Diet

Diet is a major contributor of the leading forms of chronic disease in the United States and is often the primary risk factor of focus when chronic disease management is addressed. Many studies reiterate the direct correlation between poor dietary habits and chronic disease, yet 93.3 million US adults are obese and "about half of all-American adults—117 million individuals—have one or more preventable chronic diseases; many of which are related to poor quality eating patterns and physical inactivity" [13,14]. mHealth technologies have been used in recent years to track dietary glucose levels. In diabetes patients, the implementation of food tracking technologies has contributed to fewer occurrences of glycemic episodes leading to diabetic coma [15]. Mobile apps proven to assist in glucose monitoring are One Drop and DiabetesConnect, which are available from Apple iOS and Android app stores. These apps are used to track dietary intake but are not free of charge [16]. The One Drop app can sync data with insulin pumps, is Bluetooth accessible, and allows for access to support groups to strengthen disease management outreach and outcomes [16]. DiabetesConnect provides the user with access to downloadable and printable activity reports to be shared with their health care provider to enhance the clinical management experience [16]. Many diabetic individuals have also been found to employ the use of mHealth apps to assist with efficient tracking of blood glucose dietary intake, which is a prime clinical concern of a diabetes management regimen [16].

Exercise

Another vital lifestyle factor that significantly influences the risk of developing type 2 diabetes is exercise [17]. Research consistently indicates that "physical inactivity is a primary cause to a myriad of chronic conditions/diseases" [18] and that "physical activity improves glycemic control and reduces the risk of cardiovascular disease and mortality in patients with type 2 diabetes" [17]. As a result, cardiovascular fitness is essential for the successful management of blood glucose levels, and research has shown that physical activity helps "reduce the risk of type 2 diabetes by approximately 50%" [17]. The Apple iOS Health App is an option for patients looking to track all exercise activities, including activity duration, stationary activities, measurements, and energy. With the availability of mHealth technology tools such as the Apple iOS Health App, awareness of physical activity levels can be effectively monitored and tailored to meet prescribed exercise regimens. The future points to mHealth apps that can "use embedded technology to showcase advanced uses of a smartphone to help in the prevention and management of chronic disorders such as type 2 diabetes" [19]. Indeed, the ability to monitor physical activity from handheld health devices or mHealth apps strengthens the capacity of patient disease self-management.

Prescription Medication

An effective diabetes management program rests heavily on prescription medication adherence in addition to healthy diet and exercise. In fact, it is so crucial to diabetic management and control that it could prove fatal for patients who do not comply. "Direct health care costs associated with nonadherence" to prescription medication treatment plans "have grown to approximately $100-$300 billion of US health care dollars spent annually" [8]. The American Association of Clinical Endocrinologists /American College of Endocrinology and the American Diabetes Association support a "stepwise, progressive approach to pharmacotherapy" [20] in diabetes management. This specific type of pharmacotherapy refers to glycemic control, which is commonly associated with the use of metformin, a medication that inhibits the production of glucose in the blood [20]. With the introduction of monitoring health apps, such as Glucose Buddy Tracker, medications can be administered in a timely manner at the onset of irregular blood glucose levels [21] to prevent emergency room visits caused by delayed response. The Glucose Buddy Tracker app provides a monitoring log with alerts to check blood sugar levels in addition to prescription reminders and A_{1C} results [21]. To enhance management plans, these logs retain numerical and medication data that are transmitted to a primary physician of choice at no cost [21]. Lifestyle modification plans have become vital in the fight against rising chronic disease incidences, and the use of quality mHealth apps have shown favorable results towards increasing patient empowerment in the self-management of chronic diseases such as diabetes.

Methods

A 2-fold approach was adopted involving the Apple iOS store and the Google search engine. A primary search for mobile diabetes apps was conducted on an Apple iPad (Apple Inc) within the Apple iOS store using the search term "diabetes apps." The search rendered 179 results across the educational, recipe, and health and fitness sectors, most of which were excluded from this study. We identified and explored the top 5 most frequently used apps for features key to diabetes management: blood glucose A_{1C}, insulin, physical activity, and prescription medication, along with app cost and other descriptive details. The most frequently used apps were considered to be those that had the highest number of consumer app reviews and the highest app rating on a 1 to 5-star Likert scale. The rationale behind searching within the Apple iOS store was entirely dependent on the iOS share (the percentage of people using iOS). A careful analysis of the market share and percentage of the population in the United States that use iOS revealed that approximately 62% use iOS and 38% use Android platforms; therefore, this study focused on data available in the Apple iOS store [22]. Although future research can expand to include other mobile operating system platforms, the intent of the present study was to capture patterns in mobile diabetes app use from a majority standpoint. The comments section under Table 2 captures the integration requirements and iOS-based apps.

A subsequent Google search was conducted using the search term "best Apple diabetes apps" to assess whether the selected Apple iOS apps would appear as the most frequently used across other online diabetes sources. We explored the first 3 diabetes search results—Healthline, Everyday Health, and Diabetes Apps–American Diabetes Association—and examined the 5 most frequently used apps across these sources against the same Apple iOS review criterion. In total, 12 unique apps that

appeared across sources were examined. A blend of iOS users and Google search was deemed fit for this study owing to the percentage of people accessing or using these platforms to search for diabetes apps. The details of the app features are summarized in Table 2. Finally, a literature search was conducted using PubMed and National Center for Biotechnology Information (NCBI) databases, as well as Centers for Disease Control and Prevention (CDC), JMIR, and mHealth sources, to identify the means of furthering the efficacy and impact of mHealth apps in the self-management of diabetes.

Results

The 5 most frequently used Apple iOS diabetes apps with the highest consumer ratings were OneTouch Reveal, Glucose Buddy Diabetes Tracker, Glucose Blood Sugar Tracker, One Drop, and Dario Blood Glucose Tracker (#1-#5, respectively, Table 2). All 5 mHealth apps provide feature capabilities that track blood glucose, and only 4 (#1-#4) include the additional ability to monitor A_{1C} and insulin levels. Two of the five apps (#4 and #5) enable physical activity tracking without the need to integrate with other health apps. Three of these mobile apps (#2-#4) provide prescription medication management abilities. Although significantly lower in customer reviews, the One Drop app was the only inclusive app to incorporate diabetes self-management capabilities for all assessed variances. Additional feature details such as cost, clinical recognition, data usability, integration compatibilities, and language were also recorded.

OneTouch Reveal had the highest number of consumer reviews at 39,000 within the Apple iOS store and received a rating of 4.7 stars out of 5.0 on likeability, offering only blood glucose, A_{1C}, and insulin tracking features. This app is free of cost, available in 13 languages, and has physician summary report capabilities for 14, 30, or 90 days. It requires integration with Apple Health for physical activity tracking. The Glucose Buddy Diabetes Tracker has been descriptively ranked as the #1 diabetes app for more than the 10 years within the Apple iOS store but ranked second in consumer reviews with 13,000. Despite its US $3.99 app fee or US $14.99 to US $59.99 premium subscription options, consumers granted the app a higher rating than the OneTouch Reveal1 app, giving it a 4.8-star rating for disease management abilities. The Glucose Buddy Diabetes Tracker features support blood glucose, A_{1C}, insulin, and prescription medication tracking while also requiring integration with Apple Health or other comparable fitness apps to track physical activities. This app is available in 30 languages and enables tracked data to be exported into PDF or Microsoft Excel files for physician evaluation purposes.

The One Drop app singularly offers collective tracking abilities of blood glucose, A_{1C}, insulin, physical activity, and prescription medication within the app. Being free, available in 10 languages, and recognized across 15 peer-reviewed studies, One Drop only generated 10,000 consumer reviews and a lower rating of 4.5 stars in comparison to the other apps reviewed. Apple iOS users appeared less interested in the Dario Blood Glucose Tracker despite being the only app to meet the US Food and Drug Administration accuracy guidance standards, as it only brought in 8400 consumer reviews among its users compared to the 10,000 or more for the other 4 apps reviewed. This app did, however, receive the highest usability rating, receiving 4.9 stars out of 5.0 for its blood glucose, insulin, and nonintegration requirement in tracking physical activities. It is also free of charge, available in 30 languages, and enables on-demand data sharing of the monitored outcomes to be used for medical purposes.

The subsequent Google search for the “best Apple diabetes apps” returned Healthline, Everyday Health, and American Diabetes Association as the first 3 online source options. Healthline and Everyday Health are not scientific-based sources but are part of the Healthline Media brand whose health-related websites “reach more than 81 million people in the Unites States every month” [23]. The assessment of Apple’s iOS frequently used apps across other diabetes sources indicated the strong need to establish regulatory standards of mHealth apps. The Glucose Buddy Diabetes Tracker was the only app among the 3 online sources to appear as one of the leading Apple iOS apps for diabetes self-management. The app ranked first in frequent use within the Everyday Health and American Diabetes Association sources but second within Healthline and the Apple iOS store. The OneTouch Reveal app also had a shift in ratings, appearing first and highest in consumer reviews in the iOS store and Healthline online source. Other apps worth mentioning due to having chief diabetes tracking features include mySugar Diabetes Tracker Log (3500 reviews), Diabetes:M (518 reviews), Glooko (312 reviews), and Health2Sync (126 reviews).

Table 2. List of the top 5 diabetes self-management mobile apps by source.

App name by source	Rating	Number of reviewers	Price (US $)	Functions (a[a], b[b], c[c], d[d], e[e])	Comments
Source 1: Apple iOS store					
1. *OneTouchReveal*[f]	4.7	39,000	0	a,b,c,d	Apple Health integration needed
2. *GlucoseBuddyDiabetesTracker*	4.8	13,000	3.99[g]	a,b,c,d,e	Other fitness integration
3. Glucose Blood Sugar Tracker	4.7	11,000	0	a,b,c,d,e	Health kit integration
4. One Drop	4.5	10,000	0	a,b,c,d,e	
5. Dario Blood Glucose Tracker	4.9	8400	0	a,c,d	
Source 2: Healthline–Best Diabetes Apps					
6. *OneTouchReveal*	4.7	39,000	0	a,b,c,d	Apple Health integration needed
7. *GlucoseBuddyDiabetesTracker*	4.8	13,000	3.99[g]	a,b,c,d,e	Other fitness integration needed
8. *mySugar-DiabetesTrackerLog*	4.7	3500	3.99[g]	a,b,c,d,e	Apple Health integration needed
9. *Diabetes:M*	4.6	518	0	a,b,c,d	Apple Health integration needed
10. *Health2Sync*	4.7	126	0	a,b,c,d,e	Apple Health integration needed
Source 3: Everyday Health					
11. *GlucoseBuddyDiabetesTracker*	4.8	13,000	3.99[g]	a,b,c,d,e	Other fitness integration needed
12. *mySugar–DiabetesTrackerLog*	4.7	3500	0	a,b,c,d,e	Apple Health integration needed
13. Diabetes Tracker by MyNetDiary	4.6	802	9.99[g]	a,b,c,d,e	Optional other fitness integration needed
14. *Diabetes:M*	4.6	518	0	a,b,c,d	Apple Health integration needed
15. *Health2Sync*	4.7	126	0	a,b,d,e	Apple Health integration needed
Source 4: Diabetes Apps–American Diabetes Association					
16. *GlucoseBuddyDiabetesTracker*	4.8	13,000	3.99[g]	a,b,c,d,e	Other fitness integration needed
17. *mySugar–DiabetesTrackerLog*	4.7	3500	0	a,b,c,d,e	Apple Health integration needed
18. Glooko	4.7	312	0	a,c,d,e	Apple Health integration needed
19. Diabetes Pal	3.3	25	0	a,b,c,d,e	
20. OnTrack Diabetes	2.3	4	0	a,b	

[a]a: dietary blood glucose.

[b]b: dietary.

[c]c: insulin.

[d]d: physical activity.

[e]e: Rx medicine.

[f]App names in italics indicated the most popular apps by source.

[g]Subscription offered.

Discussion

Principal Findings

Many studies point to mHealth apps as crucial weapons in the battle to find sustainable solutions to long-term chronic disease management. Not only can the use of these compact health solutions increase disease self-management abilities among chronic sufferers but consistent use of quality mHealth apps can also positively impact disease care and treatment and mitigate emergency room visits leading to long-term hospital stays.

Features key to the existence of a well-rounded diabetes management program were included and assessed in this study: blood glucose A_{1C}, insulin, physical activity, and prescription medication. All 5 Apple iOS apps had blood glucose tracking capabilities, while the presence of the other assessed features varied by app. The Glucose Buddy Diabetes Tracker was the only app among all 3 of the online sources to appear as one of the leading Apple iOS apps for diabetes self-management.

Instead of using clinical standards to evaluate the quality and capabilities of mHealth apps, we evaluated apps based on consumer rankings and popular use. The most frequently used apps were considered to be those with the highest number of consumer apps reviews and the highest app rating on a 1 to 5-point Likert scale. mHealth apps collect vital health data that can be manipulated in various forms and be shared with attending physicians to strengthen disease-management plans for diabetes and other chronic health conditions alike.

Challenges and Limitations

Although there are reports of the positive impact associated with the use of diabetes-related mHealth apps, there are several challenges and limitations—namely, patient demographics, smartphone accessibility, and privacy concerns—that continue to hinder increased use among patients with chronic health issues. In addition, over the course of 1 year, mHealth app downloads dropped drastically from more than 35% in 2015 to roughly 7% in 2016 [24]. This drop can be attributed to hidden costs, high data entry burden, loss of interest, and security and privacy concerns [24]. Data input frequency and users' adherence to the time lines (as mentioned in the app) are factors that continue to be a challenge in this space. Maintaining data integration among various input parameters to generate a unified view and monitor the user's condition while ensuring a high level of security remains another challenge in this space. The confidentiality of the patient information and adherence to HIPAA (Health Insurance Portability and Accountability Act) guidelines where applicable is another challenge. There is a definite need for a governing body to oversee and regulate the data transmission methods when the information is shared over the web. Even if the information is shared with a primary care physician or a provider, critical security touch points and monitoring will enhance patient outcomes.

Sociodemographics

When assessing patient demographics as it relates to diabetes management, patient's age and race play a crucial role in deciding whether mHealth apps should be implemented to fit the patients' overall needs. For instance, according to a 2015 study, individuals who were found more likely to use mHealth or iOS apps were younger, more educated, of Latino or Hispanic ethnicity, earning higher incomes, and classified as obese by their BMI [25]. When it comes to smartphone use, younger populations are often highly proficient with and adaptable to smartphones [21]. In contrast, older adults might find the use of app-based mobile technologies to be challenging for diabetes management [21]. Regarding race and its role in the adoption of mHealth apps, evidence has shown that people of minority racial or ethnic groups and those that have lower health literacy use mHealth apps less when compared to individuals of nonminority racial or ethnic groups and to individuals that report higher health literacy, respectively [26]. Higher educational level and annual income tend to affect the adoption of these apps given the technological demand required of the user [27]. Consequently, the need for educational assistance of those with lower education and income levels is strongly needed to promote the benefits of diabetes self-management.

Cost

The cost of technology alone has proven to be another challenge to mobile app usability. In order to take advantage of mHealth apps in the self-management of chronic disease, patients must first have the financial means to purchase a smartphone in which access to these solutions is housed. The latest version of popular smartphones using the Apple iOS operating system without a wireless service contract can cost from US $500 to US $700 per device [21]. In addition to the cost of the device, some iOS apps have associated costs as reported in Table 2. Research has shown that apps requiring payment for use compared with free apps are more likely to integrate health-literate design strategies, such as using plain language, clearly labeling links to app features, and providing effortless consumer usability functions [28]. Patients considered to be of low socioeconomic status are more likely to have low health literacy [26]. The cost of paid apps may not be affordable for patients with low health literacy, restricting them by default to using free apps and struggling with their limited features.

Privacy

Privacy has become a concern as indicated by numerous reports of recent security breaches in the hospital industry, by the potential lack of access to information during power failures, and by computer server malfunctions [29]. As of December 27, 2018, the Department of Health and Human Services Office for Civil Rights received notifications of 351 data breaches of 500 or more health care records, and this number continues to rise [23]. Health data security and privacy concerns play a huge role in the lack of patients' acceptance of mHealth apps [24]. With app developers presenting such an array of app options to consumers, the safety and effectiveness of patient information cannot be ensured.

Conclusions

Given the severity of the nation's chronic health epidemics, continued efforts are extremely necessary to find innovative solutions for improving the cost efficiency and sustainability of chronic care. mHealth apps continue to provide invaluable

health solutions towards strengthening patient empowerment through the use of mobile disease self-management platforms. Mobile apps such as Apple iOS One Touch Reveal and Glucose Buddy Diabetes Tracker were shown to be popular, in frequent use, and ranked highly among Apple consumers and other diabetes online sources. However, mobile app choices are ultimately based on the users' preferences and needs for effective disease management.

As the prevalence of diabetes and other chronic disease becomes more widespread, research should continue to expound upon the uses of mHealth technologies as solutions that increase disease self-management and improve health outcomes for sufferers of chronic disease. Many studies have pointed to the benefits of mobile management and self-oversight of chronic disease care, but usability must actively capture the attention of the end user to be effective. At this time, there remains no clear evidence explaining why patient adherence has remained low in diabetic patients compared to other chronic diseases [30].

mHealth apps have shown promise in the management of chronic disease, but the recent surge in the development of these digital health solutions demonstrates a growing need for a governing body that is knowledgeable of HIT, clinicians, policy makers, and patients in order to better define standards for effective chronic disease management. Variability in app features, cost, and tracking abilities could be reduced by regulatory uniformity, thereby increasing both self-care participation and improving diabetes outcomes.

Conflicts of Interest

None declared.

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Abbreviations

CDC: Centers for Disease Control and Prevention
HIPAA: Health Insurance Portability and Accountability Act
HIT: health information technology
mHealth: mobile health
NCBI: National Center for Biotechnology Information

Edited by G Eysenbach; submitted 11.12.19; peer-reviewed by K Smith, J Harris, D Tao, P Durneva; comments to author 26.10.20; revised version received 31.03.21; accepted 02.06.21; published 31.08.21.

Please cite as:
Sneha S, Thalla S, Rischie I, Shahriar H
Health Internet Technology for Chronic Conditions: Review of Diabetes Management Apps
JMIR Diabetes 2021;6(3):e17431
URL: https://diabetes.jmir.org/2021/3/e17431
doi:10.2196/17431
PMID:34463627

Review

Effects of Telemetric Interventions on Maternal and Fetal or Neonatal Outcomes in Gestational Diabetes: Systematic Meta-Review

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Abstract

Background: In 2019, 1 of 6 births was affected by gestational diabetes mellitus (GDM) globally. GDM results in adverse maternal, fetal, and neonatal outcomes in the short and long term, such as pregnancy and birth complications, type 2 diabetes, metabolic syndrome, and cardiovascular disease. In the context of "transgenerational programming," diabetes mellitus during pregnancy can contribute to "programming" errors and long-term consequences for the child. Therefore, early therapy strategies are required to improve the clinical management of GDM. The interest in digital therapy approaches, such as telemetry, has increased because they are promising, innovative, and sustainable.

Objective: This study aimed to assess the current evidence regarding the clinical effectiveness of telemetric interventions in the management of GDM, addressing maternal glycemic control, scheduled and unscheduled visits, satisfaction, diabetes self-efficacy, compliance, maternal complications in pregnancy and childbirth, as well as fetal and neonatal outcomes.

Methods: Medline via PubMed, Web of Science Core Collection, Embase, Cochrane Library, and CINAHL databases were systematically searched from January 2008 to April 2020. We included randomized controlled trials, systematic reviews, meta-analyses, and clinical trials in English and German. Study quality was assessed using "A MeaSurement Tool to Assess systematic Reviews" and "Effective Public Health Practice Project."

Results: Our search identified 1116 unique studies. Finally, we included 11 suitable studies (including a total of 563 patients and 2779 patient cases): 4 systematic reviews or meta-analyses (1 of high quality and 3 of moderate quality), 6 randomized controlled trials (2 of high quality and 4 of moderate quality), and 1 low-quality nonrandomized controlled trial. We classified 4 "asynchronous interventions" and 3 "asynchronous and real-time interventions." Our findings indicate that telemetric therapy clearly improves glycemic control and effectively reduces glycated hemoglobin A_{1c} levels. Furthermore, in 1 study, telemetry proved to be a significant predictor for a better glycemic control (hazard ratio=1.71, 95% CI 1.11-2.65; P=.02), significantly fewer insulin titrations were required (P=.04), and glycemic control was achieved earlier. Telemetric therapy significantly reduced scheduled and unscheduled clinic visits effectively, and women were highly satisfied with the treatment (P<.05). From fetal and neonatal short-term outcomes, some improving tendencies in favor of telemetry were determined. No long-term outcomes were detected.

Conclusions: Telemetric interventions clearly improved glycemic control, notably glycated hemoglobin A_{1c} levels, and reduced scheduled and unscheduled clinic visits effectively, which reinforces this digital approach in the treatment of GDM.

(JMIR Diabetes 2021;6(3):e24284) doi:10.2196/24284

KEYWORDS

digital health; eHealth; gestational diabetes; systematic meta-review; telemedicine; telemetry; telemonitoring

Introduction

In 2019, 1 of 6 births was affected by gestational diabetes mellitus (GDM), according to the International Diabetes Federation [1]. Overall, some form of hyperglycemia was detected in approximately 16% of live births [1]. GDM is a major clinical health problem, with a lack of common global guidelines [2]. The reported cases of GDM have drastically increased worldwide [2]. According to the International Diabetes Federation in 2019, the prevalence of GDM ranged from 7.5% in Middle East and North Africa, 9.6% in Africa, 12.5% in Western Pacific countries, 13.5% in South and Central America, 16.3% in Europe, and 20.8% in North America and the Caribbean to 27.0% in South-East Asia, excluding countries with no estimates [3].

GDM is diagnosed in the second or third trimester of pregnancy and not overt diabetes prior to gestation [4]. The condition results in various adverse pregnancy outcomes [1]. For example, women with GDM have an increased risk of developing type 2 diabetes mellitus, metabolic syndrome, and coronary heart disease in the long term. Short-term consequences such as premature birth and pre-eclampsia can also occur [2,4,5]. According to the American Diabetes Association, there are also short-term consequences for the child, such as fetal anomalies, fetal demise, macrosomia, neonatal hypoglycemia, and hyperbilirubinemia as well as long-term consequences, such as an increased risk of obesity, hypertension, and type 2 diabetes in later life [4].

Influences during the pre- and perinatal period, among other factors, play a decisive role for health and illness in the course of later life [5]. Transgenerational programming ("fetal programming"), a perturbation during critical development phases (prenatal), can lead to a "programming error" in organ functions and metabolic regulation, on the basis of which diseases such as impaired glucose intolerance, non–insulin-dependent diabetes, hypertension, obesity, and cardiovascular disease, can develop in adulthood [5]. Diabetes during pregnancy can contribute to such programming errors and to long-term consequences for the child [5]. In this context, early therapy strategies are required to improve the clinical management of GDM effectively. GDM is limited in time; therefore, paltry time is available to detect and treat the condition [2]. As part of the clinical management of GDM, the American Diabetes Association recommends self-monitoring of fasting and postprandial blood glucose to accomplish metabolic control as well as lifestyle management, including physical activity, weight management, and medical nutrition treatment [2].

However, telemetric interventions provide new digital options to enhance clinical outcomes in GDM therapy. Interest in digital solutions such as telemetry is increasing because they are innovative and sustainable approaches. In telemetric interventions, patient data are collected remotely and transmitted via telecommunication systems to a health care provider [6]. Telematics, the science of telecommunication and informatics, was developed in the 1970s [7]. Over the years and with the advancement of technology, various digital concepts developed and expanded, such as telemedicine, eHealth, mHealth, and digital health [7]. Other reviews and meta-analyses reported positive outcomes of telemetry in GDM management [8,9]. However, evidence of the clinical effectiveness of telemetric interventions in GDM management is still lacking.

In this systematic meta-review, we aimed to assess evidence regarding the clinical effectiveness of telemetric interventions in the management of GDM to improve maternal, fetal, and neonatal short- and long-term outcomes to counteract transgenerational programming. We focused on the communication and interaction between health care professionals and patients and included different studies including randomized controlled trials (RCTs), systematic reviews (SRs), meta-analyses (MAs), and clinical trials.

Methods

Information Sources and Search Strategy

The systematic meta-review was based on the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [10]. We performed a comprehensive systematic search in different databases including Medline via PubMed, Web of Science Core Collection, Embase, Cochrane Library, and CINAHL. We selected the following keywords from the Medical Subject Headings and Embase subject headings databases and additionally searched them as title and abstract terms: "gestational diabetes," "pregnancy diabetes mellitus," "telemetry," "telemonitoring," and "telemedicine." The search strategy in the databases is explained in Multimedia Appendix 1.

Eligibility Criteria

The systematic literature search was limited to publications from January 2008 to April 2020, which target the clinical management of GDM. The telemetric interventions involved monitoring, including data transmission to health care providers and appropriate feedback to patients diagnosed with GDM (eg, web-based technologies, telephone calls, and video consultations). Furthermore, we included peer-reviewed studies in English and German and those with the following designs: RCTs, SRs, MAs, and clinical trials, including qualitative and quantitative studies.

We excluded studies that provided pooled data with other types of diabetes mellitus or with other digital applications and apps; those focused on the prevention, screening, or diagnosis of GDM; and those that described only the technologies. Furthermore, we excluded smartphone or mobile app–based interventions. Because of the different nature of these technologies, we examined them separately in another study.

Study Selection

First, we conducted an extensive literature search that included patients with type 1 diabetes mellitus, type 2 diabetes mellitus, and GDM. After the elimination of duplicates, screening of titles and abstracts, appraisal of studies with full-text access for eligibility, and additional scrutiny of reference lists to identify further studies, we finally selected suitable studies that focused on GDM for this systematic meta-review. The study selection process is described in Multimedia Appendix 2.

Data Extraction

The following data were extracted from the included studies: publication year, intervention duration, sample sizes, location, outcomes, key results, significant statistics, and conclusions.

Data Synthesis and Analysis

For the synthesis and analysis of data from the included studies, we developed and applied a scheme that classified the interventions in accordance with the technologies they used. We generated 4 categories of interventions, based on the technologies used for communication between health care professionals and patients: (1) interventions with "real-time video communication," including synchronous face-to-face communication using videoconferencing; (2) those with "real-time audio communication," including synchronous contact through telephone calls; (3) those with "asynchronous communication," including interaction via email, SMS text messaging, server or home gateway, and web-based platforms; and (4) those that combined "asynchronous and real-time communication." In addition to this classification according to our scheme, we structured the studies by their designs and outcomes.

We also added up the number of participants, first including the number of unique patients with GDM in the clinical trials (excluding SRs and MAs) and then the number of patient cases based on outcomes wherein a patient has been accounted for multiple times (including SRs and MAs).

Assessment of Risk of Bias

We assessed study quality by using 2 different tools because of variations in the design of the included studies. We used the valid and reliable instrument "A MeaSurement Tool to Assess systematic Reviews" [11] for evaluating SRs and MAs and "Effective Public Health Practice Project" [12] for appraising RCTs and non-RCTs. Both instruments classify the methodological quality ranging between "high" (or "strong"), "moderate," and "weak" (or "low").

Results

Study Selection and Characteristics

The extended literature search yielded 1647 studies, of which 1116 unique studies were screened on the basis of the defined eligibility criteria. After an additional search of reference lists, we identified 189 studies, of which 23 focused on type 1 diabetes mellitus, 99 on type 2 diabetes mellitus, 51 on mixed populations (type 1 and type 2 diabetes mellitus), and 11 on GDM. Finally, we selected 11 suitable studies on GDM in this systematic meta-review. Of them, 4 were SRs and MAs, 6 RCTs, and 1 was a non-RCT. Particularly among RCTs and non-RCTs (n=7), most of them were carried out in Europe (n=5, 51.1%) and 1 each in the United States, Canada, and Australia. Baseline characteristics of the studies are provided in Table 1, and a detailed description of the studies is provided in Multimedia Appendix 3.

Using the instruments, "A MeaSurement Tool to Assess systematic Reviews" and "Effective Public Health Practice Project," we evaluated 3 studies (1 SR or MA and 2 RCTs) as being of high quality, 7 studies (3 SRs or MAs and 4 RCTs) of moderate quality, and 1 non-RCT of low quality. An overview of the quality assessments is provided in Multimedia Appendix 4.

Generally, the included studies involved 563 individual patients and 2779 patient cases. Owing to the high heterogeneity of the telemetric interventions, the SRs and MAs were not classified in accordance with their types of intervention. We identified 4 "asynchronous interventions" (web-based systems) and 3 "asynchronous and real-time interventions" (web-based systems and telephone communication). No studies were recognized for the previously defined categories "real-time audio interventions" and "real-time video interventions."

Table 1. Baseline characteristics of the included studies (N=11).

Characteristics	Studies, n (%)
All studies	
Study design	
Systematic review or meta-analysis	4 (36.4)
Randomized controlled trial	6 (54.6)
Non-randomized controlled trial	1 (9.0)
Year	
2008-2011	2 (18.2)
2012-2014	1 (9.0)
2015-2017	5 (45.5)
2018-2020	3 (27.3)
Studies excluding systematic reviews and meta-analyses (n=7)	
Location	
United States	1 (14.3)
Canada	1 (14.3)
Europe	4 (51.1)
Australia	1 (14.3)
Intervention	
Asynchronous	4 (51.1)
Asynchronous and real-time	3 (42.9)

Synthesis of Results

A summary of the effects of maternal, fetal, and neonatal outcomes of each study is allocated in Multimedia Appendix 5.

Maternal Glycemic Control

Glycated hemoglobin A_{1c} (HbA_{1c}) values (4 studies). In total, the studies presented clear improvements in HbA_{1c} values through telemetric interventions. Ming et al [9] (moderate quality [MQ]) indicated an obvious significant reduction of –1.14% (mean difference [MD]) (95% CI –0.25 to 0.04; *P*=.01) in HbA_{1c} values among 196 patients in the intervention groups compared to the control groups (220 patients). Similarly, Rasekaba et al [8] (MQ) reported a clear enhancement (MD=–0.18%; 95% CI –0.50 to 0.14; *P*=.27) (144 patients). In contrast, Pérez-Ferre et al [13] (HQ) reported a minor deterioration in both groups (<5.8% among all women), and Given et al [14] (MQ) noted slightly lower HbA_{1c} values in the control group than in the intervention group. Both contrasting studies did not report *P* values and had comparatively smaller sample sizes (97 and 47 patients, respectively). In addition, Given et al [14] reported that slow and unreliable data transmissions (especially because of poor mobile reception in rural households that could not use a landline) affected the use of the telemetric system.

Insulin dose (1 study). In general, Rasebaka et al [15] (MQ) reported that the use of telemetric approaches had positive effects on the insulin dose. The treatment group (61 patients) required significantly fewer median insulin titrations (4, IQR 13) than the control group (34 patients; 13, IQR 25; *P*=.04). Furthermore, optimal glycemic control was achieved among the intervention subjects (maximum dose of insulin) significantly quicker than among the control subjects (4.3 weeks vs 7.6 weeks; *P*<.001). Telemetry proved to be a significant predictor of better glycemic control (hazard ratio 1.71, 95% CI 1.11-2.65; *P*=.02).

Gestational weeks at insulinitation (1 study). Pérez-Ferre et al [10] (HQ) reported explicitly earlier insulinitation in the intervention group (n=17) at 27.73 (SD 3.13) gestational weeks than in the control subjects (n=9) at 28.22 (SD 3.80) gestational weeks (*P*=.73).

Maternal Scheduled and Unscheduled Visits

Face-to-face visits (6 studies). Almost all studies (83.3%) reported that the number of face-to-face clinic visits decreased explicitly. Pérez-Ferre et al [10,13] (HQ), Lemelin et al [16] (low quality [LQ]), and Caballero-Ruiz et al [17] (MQ) outlined large significant reductions ranging between 56.00% and 88.56% (*P*=.002 [10], *P*<.03 [13], *P*<.001 [16], and *P*<.01 [17]). Pérez-Ferre et al [13] reported an even greater reduction in insulin-treated patients (62% overall and 82% in insulin-treated patients; *P*<.03). Only 1 study [15] (MQ) reported the same number of visits in the intervention and control groups.

Unscheduled visits (3 studies). Overall, most studies described substantially fewer unscheduled visits in the treatment groups. Rasekaba et al [8] (MQ) and Pérez-Ferre et al [10] (HQ) outlined significantly fewer unscheduled clinic visits (*P*=.03), with

Rasekaba et al (SR and MA) [8] referring to the study by Pérez-Ferre et al [10]. Pérez-Ferre et al [10] reported even fewer visits in the subgroup of insulin-treated patients (intervention: 0.50, SD 0.73 vs control: 2.89, SD 1.05; *P*<.001).

Obstetrical emergency visits (1 study). Lemelin et al [16] (LQ; 161 patients) revealed significantly (*P*=.014) and noticeably fewer patients with ≥1 visit to the obstetrical emergency clinic in the intervention group (2.0%, SD 2.3%) compared to the control group (3.0%, SD 3.0%).

Maternal Satisfaction and Diabetes Self-Efficacy

Satisfaction (4 studies). In general, all studies delineated that the intervention groups were highly satisfied. Fantinelli et al [18] (MQ) and Lemelin et al [16] (LQ) reported significantly higher satisfaction in the intervention groups (*P*<.001 [18] and *P*=.03 [16]). Lemelin et al [16] refers to the satisfaction with educational support. Given et al [14] (MQ) and Caballero-Ruiz et al [17] (MQ) consistently noted high satisfaction with the telemetric support (without significant statistics reported).

Diabetes self-efficacy (2 studies). In total, both MQ reviews by Rasebaka et al [8] and Fantinelli et al [18] revealed higher scores in diabetes self-efficacy in the telemedical group than in the control group, but both referred to the same included study with significantly higher scores in 2 subscales (*P*=.039 vs *P*=.036).

Compliance (3 studies). Generally, the participants in the intervention groups were more compliant. Fantinelli et al [18] (MQ) examined several studies with a total of 401 patients and concluded that the intervention groups were more compliant (no significant statistics reported). According to Homko et al [19] (MQ), who examined an internet-based system with automated reminders, the integration of reminders significantly improved patients' compliance in comparison with a previously conducted study without reminders (data sets transmitted: 17.4, SD 16.9 in the previous study to 35.6, SD 32.3 in this study; *P*<.01). In the study by Caballero-Ruiz et al [17] (MQ), slightly more blood glucose measurements were transferred in the treatment group (n=147.017) than in the control group (n=141.562) (*P*<.05).

Maternal Complications in Pregnancy

Pregnancy-induced hypertension (4 studies). In general, 2 of 4 studies (MQ and LQ) reported an explicitly lower number of women with pregnancy-induced hypertension in groups receiving the telemetric intervention (1.3% in the intervention group vs 2.5% in the control group; *P*=.23 [16]; 0.0% in the intervention group vs 3.9% in the control group, significant statistics not reported [14]). In contrast, the HQ study by Pérez-Ferre et al [13] indicated more cases in the intervention group (4.1% int eh intervention group vs 0.0% in the control group; *P*=.50), but with a smaller sample size (n=97) than the other 2 trials (n=208). In addition, Raman et al [20] (HQ) calculated a risk ratio (RR) of 1.49 (95% CI 0.69-3.20) (n=275).

Pre-eclampsia (4 studies). One of the studies reported a clearly lower number of women diagnosed with pre-eclampsia in the intervention group (Given et al [14] [MQ]: 0.0% in the intervention group vs 3.9% in the control group; *P* value not available). In the other studies, the number of pre-eclampsia cases is either the same in both groups or in favor of the control group (Raman et al [20] [HQ]: RR 1.49, 95% CI 0.69-3.20 based on 4 RCTs; Lemelin et al [16] [LQ]: no cases in both groups; Homko et al [19] [MQ]: *P*=.07). In addition, Raman et al [20] noticed a very low quality of the examined 4 RCTs.

Maternal Complications in Childbirth

Caesarean section rate (7 studies). Three (42.86%) MQ and LQ studies demonstrated positive tendencies in favor of the intervention group, but overall no significant effects were found [13,15-17,19,20]: Rasekaba et al 2015 [8] (MQ; 228 patients; odds ratio 0.48, 95% CI 0.10-2.35), Raman et al [20] (HQ; 5 RCTs with 478 patients; RR 1.05, 95% CI 0.72-1.53), Rasekaba et al [15] (MQ; *P*=.20), Pérez-Ferre et al [13] (HQ; *P*=.43), Lemelin et al [16] (LQ; *P*=.07), and Homko et al [19] (HQ; *P*=.30). Raman et al reported a very low quality of the 5 RCTs used to calculate the RR.

Preterm delivery (<37 weeks; 4 studies). In 2 of 4 MQ studies, the number of preterm deliveries in the intervention group was distinctively lower (0% in the intervention group vs 8% in the control group; no *P* value reported [14]; 5.6% in the intervention group vs 13.2% in the control group; *P*=.30 [19]). With this outcome, it is striking that these 2 studies are assigned to the category "asynchronous and real-time communication," whereas the 2 HQ and LQ studies with "asynchronous communication" had slightly more cases of premature birth in the intervention group (2.1% in the intervention group vs 2.0% in the control group; *P*=0.50; 3.8% in the intervention group vs 0.0% in the control group; *P*=0.08).

Other complications (3 studies). With the outcomes "induction of labor" (Raman et al [20] [HQ], RR 1.06, 95% CI 0.63-1.77), "umbilical cord pathology" (Pérez-Ferre et al [13] [HQ], *P*=.50), "abruptio placentae" (Pérez-Ferre et al [13] [HQ], *P*=.50), and "chorioamnionitis" (Homko et al [19] [MQ], *P*>.99), the respective HQ and MQ studies were able to determine a very slightly positive trend in favor of the control group, with small sample sizes.

Fetal Short-term Outcomes

In the outcomes, "loss of fetal well-being" (Pérez-Ferre et al [13] [HQ], 6.1% in the intervention group vs 8.3% in the control group; *P*=.50) and "intrauterine death" (Given et al [14] [MQ], 0.0% in the intervention group vs 3.9% in the control group; significant statistics not reported), small positive tendencies in favor of the intervention groups were predominantly found.

Neonatal Short-term Outcomes

Large for gestational age (LGA) (3 studies). In total, the study with "asynchronous communication" showed positive tendencies in favor of the intervention group, whereas the trial with "asynchronous and real-time communication" outlined a higher number of LGA cases in the intervention group (Pérez-Ferre et al [13] [HQ], 6.1% in the intervention group vs 8.3% in the control group; *P*=.50; Homko et al [19] [MQ], 25% in the intervention group vs 18.4% in the control group; *P*=.70). In addition, Raman et al [20] (HQ) reported an RR of 1.41 (95% CI 0.76-2.64; 228 patients) with very LQ evidence.

Macrosomia (ie, birth weight of ≥4000 g) (4 studies). Overall, only 1 RCT [16] (LQ) reported a lower rate of macrosomia in the intervention group, whereas the other studies indicated either slightly lower rates in the control group or similar rates (Rasekaba et al [8] [MQ]; *P*<.05; Rasekaba et al [15] [MQ]; *P*>.99; Lemelin et al [16] [LQ]; *P*>.99; Given et al [14] [MQ]; significant statistics not reported).

Birth weight (6 studies). In 2 of 3 studies with "asynchronous communication," birth weight was slightly lower in the intervention group (Rasekaba et al [15] [MQ]; *P*>.99; Lemelin et al [16] [LQ]; *P*=.61), whereas in the 2 studies with "asynchronous and real-time communication," birth weight was rather higher in the intervention group than in the control group (Homko et al. 2012 [19] [MQ]; *P*=.30; Given et al [14] [MQ]; significant statistics not reported).

Respiratory distress syndrome (3 studies). Primarily, positive effects were obtained through telemetry. Homko et al [19] and Given et al [14] noted that GDM occurred less in the intervention groups (Homko et al [19] [MQ], 5.6% in the intervention group vs 13.2% in the control group; *P*=.40; Given et al [14] [MQ], 4.0% in the intervention group vs 15.0% in the control group; *P* value not reported).

Shoulder dystocia (3 studies). Pérez-Ferre et al [13] (HQ) noted positive effects in favor of the treatment group (*P*=.50), whereas Lemelin et al [16] (LQ) reported 0.0% of positive effects in the control group and 2.5% in the intervention group (*P*=.25). In the study by Given et al [14] (MQ), no cases were detected in either group.

Admission neonatal intensive care unit (2 studies). The results displayed that distinctly fewer neonates had to be admitted to the intensive care unit in the intervention group than in the control group (Given et al [14] [MQ], 36% in the treatment group vs 45% in the control group; significant statistics not reported; Homko et al [19] [MQ], 11.0% in the intervention group vs 18.4% in the control group; *P*=.60).

Treatment Management Outcomes

Time saving and cost (n=4 studies). Primarily, telemetric interventions were explicitly associated with both time and cost savings. For example, Caballero-Ruiz et al [17] (MQ) demonstrated a significantly shorter visit duration in the intervention group (6.752 minutes vs 15.000 minutes; *P*<.01) and Lemelin et al [16] (LQ) calculated significant cost savings of 16% (Can $167.75 per patient; *P*=.003).

Types of Intervention

Overall, the number of studies identified was very small, and there was usually not a sufficient number of studies in both outcome classifications to be able to compare them appropriately. With the outcomes "preterm delivery," "large for gestational age," and "birth weight," a direct comparison of the intervention types was possible. With regard to the outcomes LGA and birth weight, positive tendencies in favor of telemetry were observed in the studies with "asynchronous communication." The number of preterm deliveries was lower in interventions with "asynchronous and real-time communication."

Discussion

Principal Findings

In general, telemetric therapy clearly improved glycemic control, decreased the number of scheduled and unscheduled visits effectively, and some fetal and neonatal short-term outcomes indicated improved tendencies in favor of telemetry.

The findings indicate that telemetric therapy clearly improves glycemic control and effectively reduces HbA_{1c} values in women with GDM, as revealed through MQ studies. In an MQ study by Rasekaba et al [15], patients with telemetric support required significantly less insulin titrations and were therefore probably more closely metabolically adapted. They also required substantially less insulin $dose_{max}$ units (7 units less than control subjects). Given the impact of insulin on early childhood development, this is a major finding. Telemetry also proved to be a significant predictor of better glycemic control (hazard ratio 1.71, 95% CI 1.11-2.65; *P*=.02). Furthermore, glycemic control was achieved significantly faster (4.3 weeks vs 7.6 weeks) through telemetric support, which favors a lower complication rate in the mother and child.

In addition, telemetric-supported therapy markedly reduced scheduled and unscheduled clinic visits significantly in 3 HQ, 2 MQ, and 1 LQ studies. The reduction in face-to-face clinic visits can be particularly advantageous for employed pregnant women. Less unscheduled consultations in the treatment group indicate that these women could feel secure and be better managed. This observation is reflected by the outcomes of high satisfaction of women with the telemetric applications. Despite the small sample sizes, less unscheduled consultations in insulin-treated patients indicates that this special subgroup, which usually needs closer monitoring, was probably less afraid of hypoglycemia and probably felt more secure with the treatment. However, positive tendencies were also observed with respect to higher compliance through telemetry, as revealed through MQ studies.

Early strategies are required to enhance the clinical management of GDM effectively because GDM can contribute to "programming errors" and to long-term consequences for the child. Our results indicate that telemetry, as a supportive therapy, clearly improves therapeutic safety and glycemic control among women with GDM and thus leads to a positive impact on transgenerational programming ("fetal programming"). Therefore, telemetric approaches effectively improve the clinical management of GDM and therefore contribute to a reduction in "programming errors" for the child. Unfortunately, no findings on long-term outcomes, including these diseases and other consequences, are available.

Raman et al [20] reported that the included RCTs for risk ratio calculation for these outcomes had a very low quality. Furthermore, with respect to the caesarean section rate, few MQ studies showed positive tendencies in favor of the intervention group, while more studies reported a lower rate in the control groups. This might be explained by the fact that closer supervision of the intervention group during telemetry could lead to immediate medical intervention if necessary; for

example, a caesarean section. In contrast, in the less closely monitored control group, reactions may be less rapid and therefore caesarean section rates may be lower.

Regarding the fetal short-term outcomes, loss of fetal well-being, and intrauterine death, minor positive tendencies in favor of telemetric support were reported in 1 HQ and 1 MQ studies. However, owing to very small sample sizes, these outcomes should be investigated further.

Regarding the neonatal short-term outcome LGA, positive tendencies in favor of telemetric interventions were reported in the HQ study with "asynchronous communication." The birth weight tended to be lower in telemetric interventions with "asynchronous communication" (1 HQ, 1 MQ, and 1 LQ studies). The number of preterm deliveries (<37 weeks of gestation) was clearly lower in interventions with combined "asynchronous and real-time communication," as revealed in MQ studies. Other neonatal complications were markedly lesser with telemetric support, such as respiratory distress syndrome and the admission of neonates to the intensive care unit, but only in individual MQ studies with small sample sizes.

Additionally, telemetric-supported therapy seems to be cost-effective and time-saving. Since there are only a few investigations (MQ and LQ) in this regard, further studies are needed to assess the economic impact.

In general, only a few studies were available for our comparative analysis of the types of intervention. Based on the studies we included, a clear improvement in clinical effectiveness was observed through telemetric-supported interventions. With regard to the outcomes LGA and birth weight, positive tendencies were observed upon using "asynchronous communication" and with respect to preterm deliveries, there was a clearly positive effect of using "combined communication" ("asynchronous and real-time"). Further comparative studies are urgently required, since the type of telemetric intervention might also influence interventional effects and clinical effectiveness. Therefore, telemetric interventions have to be analyzed differently in accordance with their various technological methodologies.

Strengths and Limitations

One of the strengths of this systematic meta-review is our development and application of a unique classification system for the telemetric technologies used in diabetes management. We allocate an in-depth review by incorporating different study designs. Furthermore, we have considered a wide range of outcomes in our systematic meta-review. With our differentiated and detailed analysis based on outcomes, intervention types, study quality, and sample sizes, our study provides substantiated findings.

Given the limitations, different national guidelines worldwide as well as the resulting different threshold values for the diagnosis of GDM affect the comparability of these studies. With different screening methods and definitions of GDM, participants may not be precisely comparable. Although telemetric interventions are critical among pregnant women, only a small number of studies have focused on this field.

Furthermore, HbA_{1c} is of limited value as a metric for evaluating glucose control in GDM, but the studies included in this systematic meta-review focused on HbA_{1c} levels and did not provide sufficient information on mean postprandial and fasting glycemia.

Comparison With Prior Studies

Our results regarding the reduction in HbA_{1c} values through telemetric-supported therapy are concurrent with those of Ming et al [9], who analyzed telemedicine technologies for diabetes mellitus in pregnancy, examined the subgroup of women with GDM, and reported a significant reduction in HbA_{1c} levels with an MD of –1.14% (95% CI 0.25-0.04). Rasekaba et al [8] investigated 3 RCTs and also concluded that glycemic control indicated an improving trend in favor of telemetric interventions. The authors outlined the advantages of telemetric systems in the reduction of face-to-face and unscheduled clinic consultations, which is consistent with our results. With respect to maternal and fetal or neonatal complications, Rasebaka et al [8] (3 studies) and Raman et al [20] (5 relevant studies) indicated in their meta-analyses that the complication rates in telemetric interventions and control groups (usual care) were similar. However, in our systematic meta-review, we could identify minor positive trends with regard to fetal and neonatal outcomes.

Conclusions

In conclusion, our findings indicate clear improvement in glycemic control, particularly an improvement in HbA_{1c} values, through telemetric therapy. Rasekaba et al [15], reported that significantly less insulin titrations were required, glycemic control was achieved significantly earlier, and telemetry was determined as a significant predictor for a better glycemic control. Since the needs for scheduled and unscheduled clinic visits obviously declined significantly, women probably felt more secure and supervised during telemetric-supported GDM therapy. In addition, the women seemed to be highly satisfied with the telemetric therapy. This systematic meta-review shows that telemetric-supported therapy markedly improves glycemic control among women with GDM and thus leads to a positive impact on transgenerational programming ("fetal programming"). Regarding fetal and neonatal short-term outcomes, some improving tendencies in favor of telemetric interventions were detected. These positive effects could only be achieved through telemetry itself, which reinforces this new digital approach in the treatment of GDM.

Telemetric interventions tend to save costs and time, but further studies are needed to determine the economic impact of this digital approach. We could not identify any publications for our categories of "real-time video communication" and "real-time audio communication." Since the type of intervention, namely the technologies used, might also influence clinical effectiveness, the effects of different intervention types should be investigated in more detail in future studies. Furthermore, studies are still needed to consider the long-term outcomes of these interventions.

Acknowledgments

This paper describes study number EB 440/4-1 conducted by the German Research Foundation (Deutsche Forschungsgemeinschaft). Therefore, we would like to thank the Deutsche Forschungsgemeinschaft for the strong support for this study.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search terms and strategy in the databases.
[DOCX File , 19 KB - diabetes_v6i3e24284_app1.docx]

Multimedia Appendix 2
PRISMA flowchart (adapted from Moher et al 2009).
[DOCX File , 39 KB - diabetes_v6i3e24284_app2.docx]

Multimedia Appendix 3
Characteristics of the included studies (n=11).
[DOCX File , 50 KB - diabetes_v6i3e24284_app3.docx]

Multimedia Appendix 4
Quality assessments.
[DOCX File , 24 KB - diabetes_v6i3e24284_app4.docx]

Multimedia Appendix 5
Effects on maternal, fetal and neonatal outcomes.
[DOCX File , 30 KB - diabetes_v6i3e24284_app5.docx]

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Abbreviations

GDM: gestational diabetes mellitus
HbA$_{1c}$: glycated hemoglobin A$_{1c}$
HQ: high quality
LGA: large for gestational age
MA: meta-analysis
MD: mean difference
MQ: moderate quality
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial
RR: risk ratio
SR: systematic review

Edited by G Eysenbach; submitted 12.09.20; peer-reviewed by M Rigla, R De Carvalho, E van der Velde; comments to author 16.11.20; revised version received 25.11.20; accepted 15.04.21; published 27.08.21.

Please cite as:
Eberle C, Stichling S
Effects of Telemetric Interventions on Maternal and Fetal or Neonatal Outcomes in Gestational Diabetes: Systematic Meta-Review
JMIR Diabetes 2021;6(3):e24284
URL: https://diabetes.jmir.org/2021/3/e24284
doi:10.2196/24284
PMID:34448717

Original Paper

Evaluation of the Low Carb Program Digital Intervention for the Self-Management of Type 2 Diabetes and Prediabetes in an NHS England General Practice: Single-Arm Prospective Study

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Abstract

Background: Type 2 diabetes mellitus has serious health consequences, including blindness, amputation, and stroke. Researchers and clinicians are increasingly in agreement that type 2 diabetes may be effectively treated with a carbohydrate-reduced diet. Digital apps are increasingly used as an adjunct to traditional health care provisions to support remote self-management of long-term health conditions.

Objective: Our objective was to evaluate the real-world 12-month outcomes of patients prescribed the Low Carb Program digital health intervention at a primary care National Health Service (NHS) site. The Low Carb Program is a nutritionally focused, 12-session, digitally delivered, educational behavior change intervention for glycemic control and weight loss for adults with prediabetes and type 2 diabetes. The program educates and supports sustainable dietary changes focused on carbohydrate restriction by utilizing behavior change techniques, including goal setting, peer support, and behavioral self-monitoring, as well as personalized downloadable resources, including recipes and meal plans tailored to ethnicity, weekly shopping budget, and dietary preferences.

Methods: This study evaluated the real-world outcomes of patients recruited to the Low Carb Program at an NHS general practice in Southport, United Kingdom. All of the NHS patients recruited to the program were diagnosed with type 2 diabetes or prediabetes and were given access to the program at no cost. A total of 45 participants, with a mean age of 54.8 years (SD 13.2), were included in the study. Women made up 42% (19/45) of the sample. The mean hemoglobin A_{1c} (HbA_{1c}) of the sample was 56.7 mmol/mol (SD 16.95) and the mean body weight was 89.4 kg (SD 13.8).

Results: Of the 45 study participants recruited to the program, all of them (100%) activated their accounts and 37 (82%) individuals reported outcomes at 12 months. All 45 (100%) patients completed at least 40% of the lessons and 32 (71%) individuals completed more than nine out of 12 core lessons of the program. Glycemic control and weight loss improved, particularly for participants who completed more than nine core lessons in the program over 12 months. The mean HbA_{1c} went from 58.8 mmol/mol at baseline to 54.0 mmol/mol, representing a mean reduction of 4.78 mmol/mol (SD 4.60; t_{31}=5.87; P<.001). Results showed an average total body weight reduction of 4.17%, with an average weight reduction of 3.85 kg (SD 2.49; t_{31}=9.27; P<.001) at the 12-month follow-up point.

Conclusions: A digital app prescribed to adults with type 2 diabetes and prediabetes in a primary care setting supporting a transition to a low-carbohydrate diet has been shown to be effective in improving glycemic control and enabling weight loss. Further research to understand more about factors affecting engagement with the app and further positive health implications would be valuable.

(JMIR Diabetes 2021;6(3):e25751) doi:10.2196/25751

KEYWORDS

Low Carb Program; low carbohydrate; diabetes; type 2 diabetes intervention; diabetes prevention; self-management; behavior change; prediabetes

Introduction

Background

Type 2 diabetes is a costly, chronic noncommunicable disease expected to affect 552 million people globally by 2030 [1]. The National Health Service (NHS) spends around £8.8 billion (US $11.1 billion) annually on the treatment of type 2 diabetes, with 80% spent on complications [2]. Globally, the burden of type 2 diabetes is estimated to exceed US $1.3 trillion [3]. In the developed world, individuals living with diabetes are managed by primary care teams, with medical consultation visits averaging less than 3 hours a year. Individuals are essentially on their own most of the time [4]. Because of this enormous gap between appointments, diabetes care is primarily dependent on personal self-management, which, if not performed, increases the risk of premature death, blindness, amputation, and kidney failure [5]. In reality, type 2 diabetes self-management is neither easy nor simple and requires time as well as numeracy and literacy skills [6].

As with many noncommunicable diseases, lifestyle is one of the main causes of prediabetes and type 2 diabetes, and improvements in parameters such as dietary composition, physical activity, and sedentary lifestyle are determinants for reducing the frequency of this type of pathology. Obesity is considered to be the cause of up to 80% of type 2 diabetes cases [7].

Losing weight can provide significant health benefits and losing excess body weight contributes to reduction in the risk of type 2 diabetes, heart disease, osteoarthritis, and sleep apnea [8]. In addition, the maintenance of good blood glucose control has benefits to patients, with every 1% (6.2 mmol/mol) reduction in hemoglobin A_{1c} (HbA_{1c}) contributing to a 43% reduction in the risk of amputation, 14% reduction in risk of myocardial infarction, and 37% reduction in risk of microvascular complications [9]. Poor diabetes control is also associated with a higher risk of COVID-19 complications [10].

The benefits of a low-carbohydrate diet (<130 g of carbohydrate per day) on weight and type 2 diabetes management are increasingly recognized. Recent meta-analyses comparing the effects of low-carbohydrate and low-fat diets found a significantly greater reduction in body weight for the low-carbohydrate group [11,12]. Several low-carbohydrate randomized controlled trials focusing on people with type 2 diabetes mellitus reported similar findings, with significant reductions in weight and BMI at 6 months [12].

Systematic reviews of low-carbohydrate diets (defined as <130 g of carbohydrate per day) and very low–carbohydrate (or ketogenic) diets (defined as <30 g of carbohydrate per day) in obesity generally show either *no superiority* (ie, the low-carbohydrate diet had the same impact on weight and other markers as other diets, such as low-fat and calorie-controlled diets) or a *benefit* compared to other diets [13]. A meta-analysis found that low- and very low–carbohydrate diets led to greater weight loss than following a low-fat diet and concluded that a very low–carbohydrate diet may be an alternative tool that can used against obesity [14]. A recent systematic review and meta-analysis of published and unpublished randomized trial data evaluating low-carbohydrate diets (<130 g/day or <26% of a 2000 kcal/day diet) and very low–carbohydrate diets (<10% calories from carbohydrates) for at least 12 weeks in adults with type 2 diabetes found that on the basis of moderate- to low-certainty evidence, patients adhering to a low-carbohydrate diet for 6 months may experience remission of type 2 diabetes without adverse consequences [15].

Integrating digital technology into primary care can increase access to care, improve patient outcomes, and decrease costs. Digital technology, including smartphone apps, has the potential to augment and extend the reach of health services through self-management support impacting lifestyle behaviors [16]. Use of smartphone apps has been demonstrated to improve glycemic outcomes in people with type 1 and type 2 diabetes [17]. Although there is evidence to the contrary, of the 23 studies analyzed in the systematic review published by Schoeppe et al on the efficacy of apps in improving lifestyle, smartphones were only seen to have a favorable impact on food habits in five studies and resulted in increased physical activity in nine studies [18]. Even though recent systematic reviews have concluded that internet and mobile interventions can improve lifestyle behaviors, most studies had no more than 3 to 6 months of follow-up, which emphasizes the need for research in long-term interventions [19].

Researchers and clinicians are increasingly in agreement that type 2 diabetes may be effectively treated with a carbohydrate-reduced diet [20,21]. Interventions providing low-carbohydrate or very low–carbohydrate programs have been clinically demonstrated to support improvements in weight, blood glucose, and demedication [22-26]. Long-term studies of low-carbohydrate dietary approaches to treat type 2 diabetes and obesity, however, are limited, particularly among those that are delivered and supported remotely [23,24].

The Low Carb Program

The Low Carb Program is a digitally delivered, structured, digital health intervention for adults with type 2 diabetes, prediabetes, and obesity. The app, which is NHS Apps Library–approved, is available on the web, mobile devices, smart watches, smart speakers, and smart assistants [26,27].

User data are used to personalize the experience that members receive, to improve patient engagement through individualization of the participant's experience [28]. During registration, patients are instructed to select a health goal and input their current health status and demographics, including age, gender, ethnicity, and dietary preferences, all of which are used to personalize the participant's experience of the platform. Participants are given access to therapeutic nutrition education modules. Education is personalized to the user's health status,

age, ethnicity, and dietary preferences. A new module is available each week over the course of 12 weeks. Lessons are taught through videos, written content, or podcasts of varying lengths (approximately 3 to 12 minutes long). The modules are designed to help participants gradually reduce their total carbohydrate intake to less than 130 grams per day. Much of the content of the Low Carb Program is focused on the reduction of processed and ultraprocessed foods as well as foods that are high in sugar and refined carbohydrates. The program supports users to sustainably replace starchy foods, such as potatoes or rice, with green leafy vegetables, healthy fats, and some protein. Participants are encouraged to select foods that are minimally processed, and the program emphasizes home cooking and food preparation. The program syllabus is provided in Table 1 and screenshots of the program are provided in Multimedia Appendix 1.

Table 1. Core syllabus of the Low Carb Program.

Lesson no.	Topic	Objective
1	Welcome to the type 2 diabetes program	Safety notes and alerts to medications that require the health care professional team's assistance Benefits of a reduced carbohydrate diet for people with type 2 diabetes Welcome from Dr David Unwin and reference to patient's golden opportunity for change
2	Type 2 diabetes and diet	Factors that affect blood glucose levels Encouragement to engage with their health care providers
3	Controlling portion sizes	Introducing visual methods for interpreting portion size
4	Real vs processed foods	Identifying and eliminating refined and processed food
5	Healthy and unhealthy fats	Discussion of fat types and making appropriate choices depending on goals
6	Vegetables	Demonstrating the carbohydrate content of vegetables and cooking methods
7	Fruit	Reviewing the amount of sugar and starch in fruits and vegetables
8	Snacks and desserts	Examining low-carbohydrate snack, dessert, and drink options
9	Drinks	Tips on alcohol and eating-out options
10	Eating out and takeaways	Managing eating on the go and when traveling Making healthier takeaway and food choices
11	Practical ways to eat fewer carbohydrates	Practical tips for reducing carbohydrate intake further Safety information—highlighting medications that require health care practitioner assistance
12	Intermittent fasting	Introducing the principles of reducing the eating window using the 16:8 model

The program, which is NHS-approved, encourages participants to make behavior changes based on "action points" or behavior change goals at the end of each education module, based loosely on Dr Unwin's own in-clinic program [29].

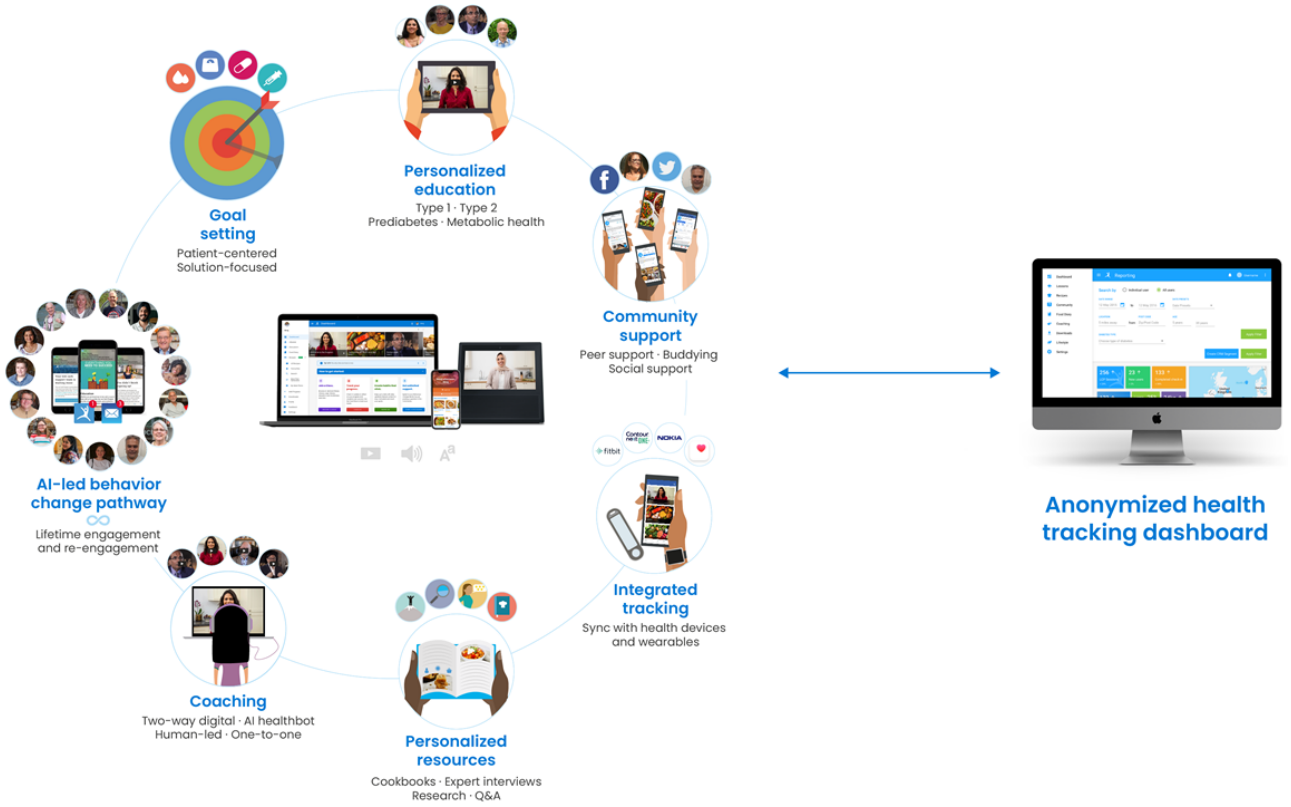
In the Low Carb Program tailored for individuals with type 2 diabetes, the first 2 weeks of the program contain an explanation of the physiology of type 2 diabetes and the role of diet, including a description of how a low-carbohydrate diet can help manage postprandial blood glucose levels and weight. The subsequent modules explore strategies to reduce dietary sources of sugar, in particular high-starch foods, such as bread, pasta, and rice. Participants are encouraged to make portion control and carbohydrate-restriction decisions based on visual plate representations. In place of carbohydrate-rich foods, an increased intake of green vegetables, low–glycemic index fruits (eg, blueberries, strawberries, and raspberries), and fats (eg, from olive oil, butter, eggs, nuts, and full-fat dairy) are advocated. The program stresses the importance of regular contact with the participants' health care providers for adjustments in medications in weeks 1, 2, and 12. Weeks 11 and 12, which concentrate on sustaining a lower-carbohydrate lifestyle, were co-designed with clinicians and patients after collecting feedback from 5000 patient users of the Low Carb Program.

Participants' health goals are supported with behavior change resources that are available to download, including information sheets, meal plans, a recipe library, and suggested food substitution ideas, all tailored to the user's preferences. Users are matched within the platform to a digital buddy and are given access to a peer-support forum available 24 hours a day. The platform also includes digital tools for submitting self-monitoring data on a number of different variables, including blood glucose levels, blood pressure, mood, sleep, food intake, and body weight. Participants can self-report and connect wearables to the platform. Previous research has found that these self-reported health outcomes can be quite close to data within medical records [21,22]. Behavior change is maintained through continual engagement, new modules, and nudges to track health outcomes and interact with the support community. Automated feedback and nudges are provided to users, based on their use of the program, through emails and native in-app push notifications, and participants are notified when the next week's module is available. Examples of personalized patient journeys in the Low Carb Program are shown in Multimedia Appendix 2. The platform requests that users check in on their weight and HbA_{1c} goals at regular intervals set by the user, defaulted to 12 months, to ensure that users feel in control of their learning at their own pace. Family

members and carers can sign up on behalf of vulnerable or elderly patients, share credential-based access to the platform, and impute data on the patient's behalf.

The key elements that make up the Low Carb Program are grounded in the COM-B (Capability-Opportunity-Motivation Behavior) model of behavior change; the elements implement evidence-based behavior change techniques that are shown to be effective in digital platforms for behavior change interventions that support weight loss, increase physical activity, and improve self-efficacy of chronic disease management [28]. The platform was designed in full compliance with the NICE (National Institute for Health and Care Excellence) guideline NG183 [30]. See Figure 1 for an overview of the Low Carb Program architecture.

Figure 1. Architecture of the Low Carb Program digital health platform. AI: artificial intelligence.



The platform has demonstrated clinical outcomes in patients with type 2 diabetes. Of 1000 patients followed for a year, participants with type 2 diabetes who completed the program reported an average of 7% loss in body weight and 1.2% or 13 mmol/mol HbA_{1c} reduction; in addition, 54% of patients eliminated or reduced medication. A total of 26% of patients who completed the program reported being in type 2 diabetes remission at 1 year [26].

Objectives

This real-world study was conducted to evaluate the effectiveness of the digitally delivered Low Carb Program intervention at 12 months on the maintenance of glycemic control for NHS-recruited patients at Norwood Surgery in Southport, United Kingdom. We hypothesized that the use of the Low Carb Program would support the following improvements: better glycemic control, as measured by HbA_{1c}, and weight loss.

Methods

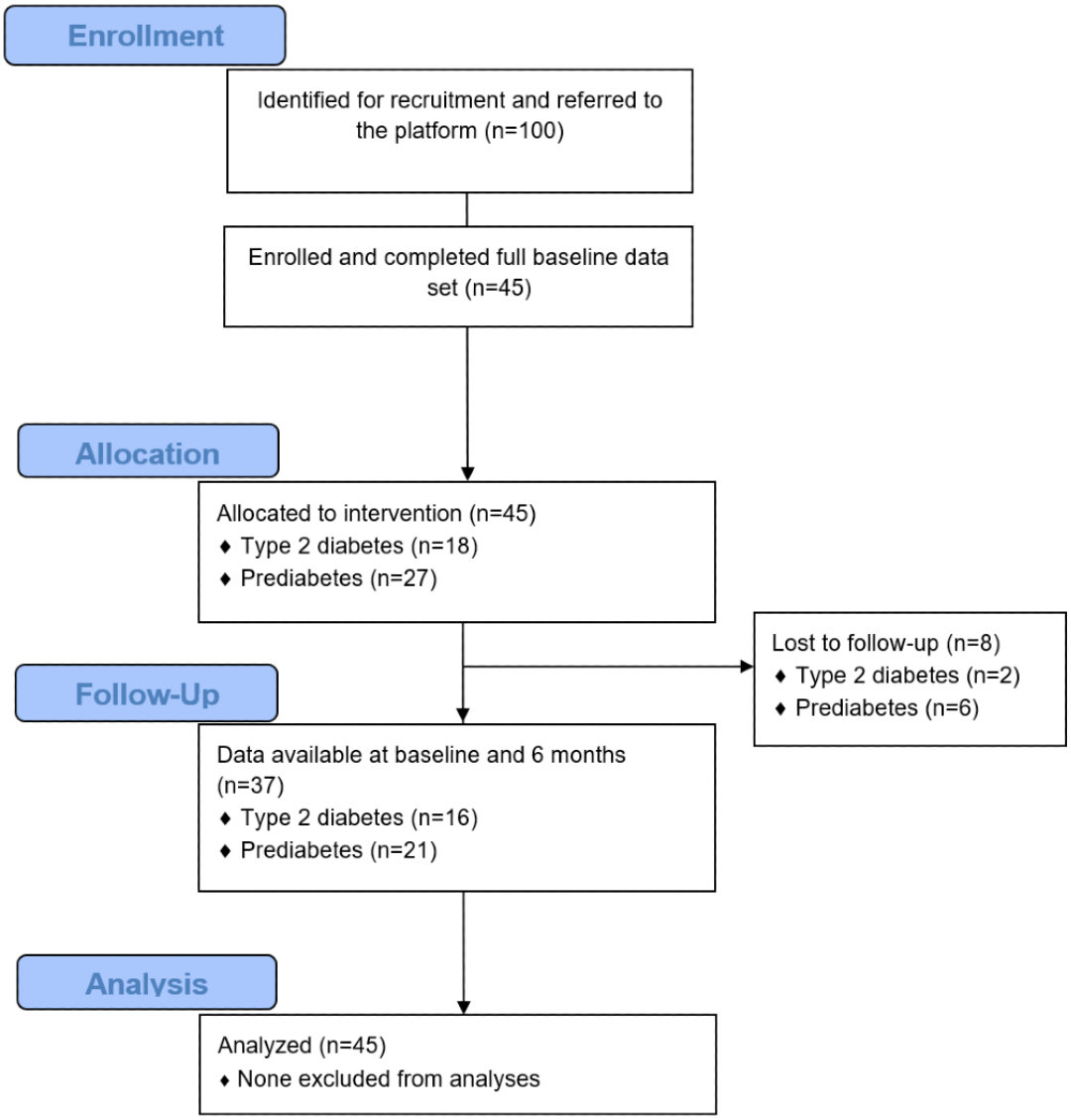
Research Design

We used a single-arm pre-post intervention study design. Participants were not paid for their participation and were given access to the program for free. Participants provided informed consent regarding their anonymized data being used for analysis and publication.

Participant Recruitment

Participants were recruited from an NHS primary care setting—Norwood Surgery in Southport, United Kingdom—between April 19, 2018, and August 19, 2019. Patients aged 18 years or older with a confirmed diagnosis of type 2 diabetes or prediabetes who presented for any reason during the recruitment window were eligible for signposting if the consulting health care professional felt it was appropriate. See Figure 2 for a CONSORT (Consolidated Standards of Reporting Trials) flow diagram.

Figure 2. CONSORT (Consolidated Standards of Reporting Trials) diagram for participant inclusion in the study.



Patients who accepted signposting were given a Low Carb Program referral card, which was redeemed on the app or website. To have a broad applicability to a nonclinical trial setting, the only de facto exclusion criterion was the inability to understand English. A total of 100 referral cards were provided to the NHS general practice in Southport. A total of 45 participants signed up and all were followed for 12 months. The characteristics of the 55 participants who declined the referral card were not recorded.

Measures

At baseline, participants recruited to the Low Carb Program input their type of diabetes, year of diagnosis, most recent HbA_{1c} test result and date, age, gender, socioeconomic status based on household income, and presence of comorbid chronic illnesses at sign-up. At 12 months, participants were again asked to report on their current HbA_{1c} level and weight.

Statistical Analyses

Analyses were performed using SPSS, version 22.0 (IBM Corp). We examined the differences in characteristics from baseline to 12-month follow-up using paired *t* tests. The primary outcome was change in weight and HbA_{1c} level. For participants who did not report their outcomes at 12 months, we ran an intention-to-treat analysis assuming no change (ie, last observation carried forward).

An a priori power analysis using G*Power 3.1 (Heinrich Heine Universität) indicated that a total sample size of 27 would be sufficient to detect a medium effect size (d=0.5) with 80% power to test the difference between two dependent means using a one-tailed test and an α of .05. Thus, our proposed sample size of 45 will be more than adequate for detecting a decrease between pre- and posttest outcomes in a paired-samples *t* test.

Results

Participant Characteristics

At baseline, the mean HbA_{1c} level was 56.7 mmol/mol (SD 16.95; range 42.1-96.7), the mean weight was 89.4 kg (SD 13.8; range 70-135), and the mean age was 54.8 years (SD 13.2). More than half of the participants were male (26/45, 58%), 87% (39/45) were White, all were from the United Kingdom. See Table 2 for full baseline characteristics of the 45 participants.

Table 2. Participant characteristics at baseline.

Characteristic	Pooled (N=45)	Type 2 diabetes: HbA_{1c}[a] ≥48 mmol/mol (n=18)	Prediabetes: HbA_{1c} <48 mmol/mol (n=27)
Age (years), mean (SD)	54.85 (13.22)	58.36 (12.46)	52.42 (13.43)
HbA_{1c} (%), mean (SD)	7.34 (1.55)	8.86 (1.46)	6.319 (0.14)
Weight (kg), mean (SD)	89.44 (13.81)	93.53 (17.91)	88.72 (6.69)
Gender, n (%)			
Male	26 (58)	14 (78)	12 (44)
Female	19 (42)	4 (22)	15 (56)
Ethnicity, n (%)			
White	39 (87)	15 (83)	24 (89)
Indian, Pakistani, Bangladeshi, or Arabic	5 (11)	2 (11)	3 (11)
Chinese, Japanese, or other East Asian	1 (2)	1 (6)	0 (0)
Employment, n (%)[b]			
Full-time employment	21 (47)	9 (50)	12 (44)
Part-time employment	7 (16)	1 (6)	6 (22)
Retired	11 (24)	5 (28)	6 (22)
Self-employed	4 (9)	3 (17)	1 (4)
Unemployed	2 (4)	0 (0)	2 (7)

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

[b]Some percentages do not add up to 100 due to rounding.

Engagement Outcomes

Of the 45 study participants recruited to the program, 37 (82%) individuals reported outcomes at 12 months, all 45 (100%) completed at least 40% of the lessons, 32 (71%) individuals completed more than nine lessons, and 29 (64%) completed all 12 core lessons of the program. Of the 45 participants, 8 (18%) did not report health outcomes but reported engagement outcomes (ie, remained engaged with the platform, which is defined as logging in within the prior 30 days).

Retention

Of the 45 baseline participants who activated their referral, 37 (82%) reported outcomes at 12 months. For the remaining 8 people (18%) lost to follow-up, the last recorded data point was carried forward to maintain a conservative real-world evaluation.

Of the 8 people lost to follow-up, 75% (6/8) were diagnosed with prediabetes and 25% (2/8) were diagnosed with type 2 diabetes; 88% (7/8) were Caucasian and 13% (1/8) were Arab; 50% (4/8) were female; and 75% (6/8) were in full-time employment, 13% (1/8) were in part-time employment, and 13% (1/8) were retired. See Table 3 for a breakdown of characteristics.

Table 3. Participant characteristics of those lost to follow-up.

Characteristic	Pooled (n=8)	Type 2 diabetes: HbA_{1c}[a] ≥48 mmol/mol (n=2)	Prediabetes HbA_{1c} <48 mmol/mol (n=6)
Age (years), mean (SD)	47.3 (11.2)	49.4 (1.4)	46.6 (13.1)
HbA_{1c} (%), mean (SD)	6.57 (0.56)	7.45 (0.1)	6.28 (0.14)
Weight (kg), mean (SD)	84.76 (10.14)	90.0 (0.0)	83.02 (11.37)
Gender, n (%)			
Male	4 (50)	2 (100)	2 (33)
Female	4 (50)	0 (0)	4 (67)
Ethnicity, n (%)[b]			
White	7 (88)	2 (100)	5 (83)
Indian, Pakistani, Bangladeshi, or Arabic	1 (13)	0 (0)	1 (17)
Chinese, Japanese, or other East Asian	0 (0)	0 (0)	0 (0)
Employment, n (%)[b]			
Full-time employment	6 (75)	2 (100)	4 (67)
Part-time employment	1 (13)	0 (0)	1 (17)
Retired	1 (13)	0 (0)	1 (17)
Self-employed	0 (0)	0 (0)	0 (0)
Unemployed	0 (0)	0 (0)	0 (0)

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

[b]Some percentages do not add up to 100 due to rounding.

Health Outcomes

HbA_{1c}

Participants showed a statistically significant mean reduction in HbA_{1c} of 3.89 mmol/mol (SD 4.32; t_{44}=6.03; *P*<.001). Participants who completed more than nine lessons of the program showed a larger reduction in HbA_{1c} of 4.8 mmol/mol (t_{31}=5.87; *P*<.001). This is equivalent to a 7.62% mean reduction in HbA_{1c}. One participant registered an HbA_{1c} increase of 6.5 mmol/mol at 12 months.

Participants with type 2 diabetes who were recruited to the Low Carb Program showed a statistically significant change in HbA_{1c} from baseline (mean 73.35 mmol/mol, SD 15.84) to 12-month follow-up (mean 67.2 mmol/mol, SD 13.59), equivalent to a mean reduction of 6.2 mmol/mol (SD 5.75; t_{17}=4.56; *P*<.001). Participants who completed more than nine lessons of the program showed a statistically significant decrease in HbA_{1c} from baseline (mean 75.7 mmol/mol, SD 14.9) to 12-month follow-up (mean 68.7 mmol/mol, SD 12.8), a mean reduction in HbA_{1c} of 7.01 mmol/mol (SD 6.06; t_{13}=4.33; *P*<.001). This is equivalent to an 8.81% mean reduction in HbA_{1c}.

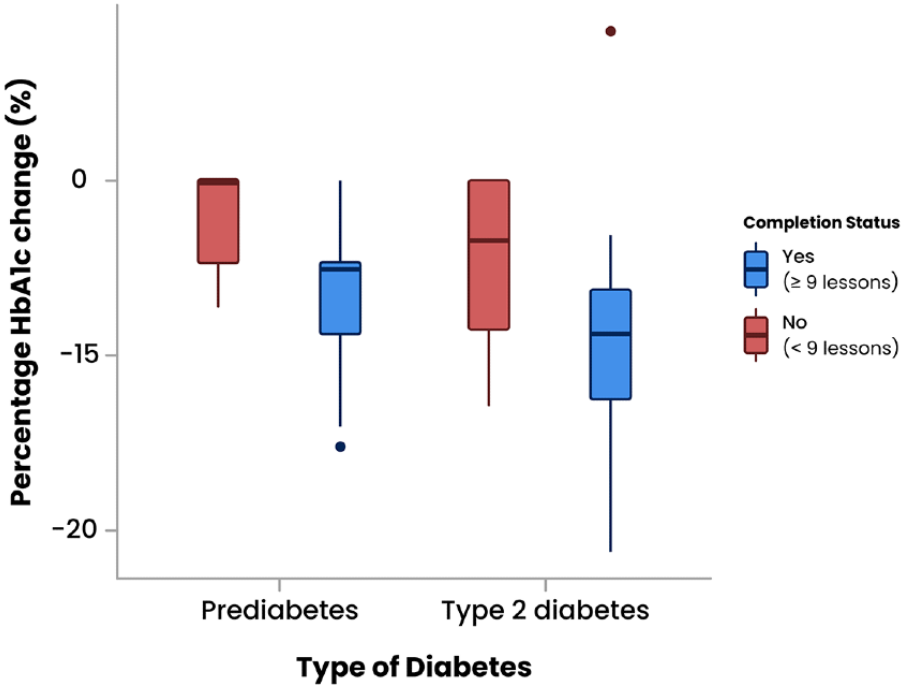
Participants with prediabetes who were recruited to the Low Carb Program showed a statistically significant mean reduction in HbA_{1c} of 2.35 mmol/mol (SD 1.96; t_{26}=6.25; *P*<.001). Those participants who completed more than nine of the lessons did even better, reporting a mean HbA_{1c} reduction of 3.04 mmol/mol (SD 1.82) at 12 months (t_{17}=7.11; *P*<.001). Results are presented in Table 4 and Figure 3.

Table 4. Change in HbA_{1c}[a] from baseline to 12-month follow-up by intervention completion.

Participants	Baseline HbA_{1c} (mmol/mol), mean (SD)	12-month HbA_{1c} (mmol/mol) mean (SD)	12-month HbA_{1c} change (mmol/mol), mean (SD)	12-month HbA_{1c} change (%), mean (SD)	*P* value
Pooled (all participants)					
All participants (N=45)	56.68 (16.95)	52.80 (14.68)	3.89 (4.32)	6.28 (5.49)	<.001
Completers (n=32)	58.8 (18.00)	54.0 (15.7)	4.78 (4.6)	7.62 (5.40)	<.001
Noncompleters (n=13)	51.5 (13.23)	49.8 (12.01)	1.69 (2.53)	3.3 (4.31)	.03
Type 2 diabetes (HbA_{1c} ≥48 mmol/mol)					
All participants (n=18)	73.35 (15.84)	67.20 (13.59)	6.19 (5.75)	7.96 (6.67)	<.001
Completers (n=14)	75.7 (14.9)	68.7 (12.8)	7.01 (6.06)	8.81 (6.77)	<.001
Noncompleters (n=4)	65.1 (18.41)	61.8 (17.10)	3.13 (0.95)	4.99 (6.22)	.18
Prediabetes (HbA_{1c} <48 mmol/mol)					
All participants (n=27)	45.56 (1.49)	43.21 (2.39)	2.35 (1.96)	5.16 (4.31)	<.001
Completers (n=18)	45.60 (1.43)	42.56 (2.38)	3.04 (1.82)	6.69 (4.01)	<.001
Noncompleters (n=9)	45.48 (1.68)	44.51 (1.95)	0.97 (1.49)	2.11 (3.24)	.09

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

Figure 3. Percentage change in hemoglobin A_{1c} (HbA_{1c}) from baseline to 12-month follow-up by intervention completion for prediabetes and type 2 diabetes patient groups. The boxes represent the IQRs, the lines within the boxes represent medians, and the circles represent outliers.



Weight

On average, participants showed a statistically significant reduction in weight, from an average of 89.44 kg (SD 13.81) at baseline to 86.67 kg (SD 13.05) at 12 months, with a mean body weight reduction of 2.77 kg (SD 2.62; t_{44}=7.09; *P*<.001), equivalent to a mean total body weight reduction of 3.01% (SD 2.8). One participant registered weight gain of 1.1% body weight over the 12 months.

Participants who completed more than nine modules of the program (32/45, 71%) had an average starting weight of 91.5 kg (SD 15.12) and showed a statistically significant mean body weight reduction of 3.85 kg (SD 2.35; t_{31}=9.27; *P*<.001), equivalent to a mean total body weight reduction of 4.17% (SD 2.49).

Participants with type 2 diabetes had an average starting weight of 93.53 kg (SD 17.91) that dropped to an average of 90.83 kg (SD 16.84) at 12-month follow-up, which is a statistically significant mean reduction of 2.70 kg (SD 2.21; t_{17}=5.17; *P*<.001). Completers reduced their weight by an average of 3.54 kg (SD 1.7; t_{17}=5.17; *P*<.001), equivalent to a mean body weight change of –3.66% (SD 2.8).

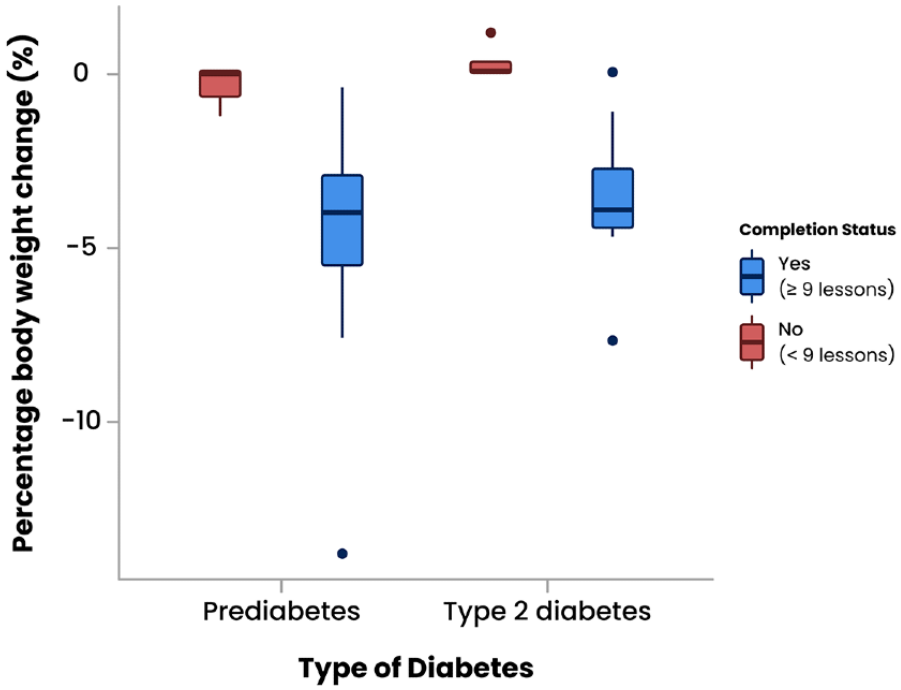
Participants with prediabetes started the program with a mean weight of 86.72 kg (SD 9.68) and reported an average weight loss of 2.82 kg (SD 2.90; t_{26}=5.05; *P*<.001), equivalent to a mean body weight decrease of 3.16% (SD 3.11). Participants with prediabetes who completed more than nine lessons of the program demonstrated a greater statistically significant change in mean body weight of 4.08 kg (SD 2.77; t_{17}=6.25; *P*<.001), equivalent to a mean reduction in overall body weight of 4.57% (SD 2.88). Results are presented in Table 5 and Figure 4.

Table 5. Change in weight from baseline to 12-month follow-up by intervention completion.

Participants	Baseline weight (kg), mean (SD)	12-month weight (kg), mean (SD)	12-month weight change (kg), mean (SD)	12-month weight change (%), mean (SD)	*P* value
Pooled (all participants)					
All participants (N=45)	89.44 (13.81)	86.67 (13.05)	2.77 (2.62)	3.01 (2.80)	<.001
Completers (n=32)	91.5 (15.12)	87.7 (14.5)	3.85 (2.35)	4.17 (2.49)	<.001
Noncompleters (n=13)	84.4 (8.50)	84.2 (8.58)	0.12 (0.51)	0.1 (0.6)	.40
Type 2 diabetes (HbA_{1c}[a] ≥48 mmol/mol)					
All participants (n=18)	93.53 (17.91)	90.83 (16.84)	2.70 (2.21)	2.78 (2.34)	<.001
Completers (n=14)	95.5 (19.68)	92.0 (18.8)	3.54 (1.70)	3.66 (1.83)	<.001
Noncompleters (n=4)	86.5 (7.0)	86.8 (7.18)	0.25 (0.5)	0.28 (0.5)	.39
Prediabetes (HbA_{1c} <48 mmol/mol)					
All participants (n=27)	86.72 (9.68)	83.90 (9.10)	2.82 (2.90)	3.16 (3.11)	<.001
Completers (n=18)	88.37 (9.69)	84.29 (9.25)	4.08 (2.77)	4.57 (2.88)	<.001
Noncompleters (n=9)	83.41 (9.31)	83.12 (9.29)	0.29 (0.45)	0.34 (0.54)	.09

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

Figure 4. Percentage change in body weight from baseline to 12-month follow-up by intervention completion for prediabetes and type 2 diabetes patient groups. Boxes represent the IQRs, the lines within the boxes represent medians, and the circles represent outliers.



Adverse Events

There were no reported adverse events related to the intervention or that resulted in discontinuation, including no reported episodes of severe hypoglycemia.

Discussion

Principal Findings

This study demonstrated that signposting patients with type 2 diabetes or prediabetes to the Low Carb Program as part of

routine general practice care can promote weight loss and improve glycemic control. With minimal implementation and support, this light-touch intervention was able to augment primary care workflows and demonstrated high uptake, adherence (ie, completion), and retention (ie, engagement within prior 30 days) of 45%, 64%, and 82%, respectively. There was a low dropout rate (8/45, 18%) at 12 months, which demonstrates high engagement in the platform.

For patients who completed at least nine of the program's 12 core modules, average weight loss was 3.85 kg compared to 0.12 kg for noncompleters. The percentage of individuals who lost at least 5% of their body weight was 16% (7/45). The majority of participants registered weight loss (37/45, 82%) and 1 person gained weight (1/45, 2%). Similarly, patients who completed the program reduced their HbA_{1c} by 4.78 mmol/mol compared to 1.69 mmol/mol for those who did not complete the program. This study shows that participants who completed the intervention achieved significant weight loss and HbA_{1c} reduction at 12-month follow-up (Tables 4 and 5).

Strengths and Limitations

This was not a randomized controlled trial, so we cannot compare the 12-month results to a control or standard-of-care group. Therefore, the results of our trial should be interpreted cautiously because this small study used convenience sampling, an open-label single-arm design, and pre-post self-reported outcomes.

However, similar to other studies on the Low Carb Program, these results support previous research that demonstrated weight loss and improved glycemic control from use of the intervention in adults diagnosed with type 2 diabetes and prediabetes [25,31,32]. This study showed high engagement and retention. Evidence suggests that digital solutions that are personalized to the user and have clinical endorsement may positively affect participant engagement [33,34]. Repeated in a larger practice, this research could have a significant impact.

One of the limitations of the research was that patients who were offered access to the Low Carb Program but chose not to accept it or did not complete the sign-up were not tracked or followed up. Although beyond the scope of this study, further research should explore reasons for signposting refusal. Another limitation was the self-reported nature of the data, as only data from Bluetooth-enabled weighing scales and self-input were collected. However, it has been shown that self-reported health outcomes are similar to actual values [35,36]. Although beyond the scope of this feasibility study, future research should extract HbA_{1c}, weight, and medication data directly from general practice record systems rather than rely on patients' self-report of this data.

Those who completed the program lost more weight than those who did not. Previous research has shown that participant motivation affects continuing intervention adherence and, as such, introduces a self-selection bias to the data, as participants who continue to adhere are more likely to have lost weight [37].

Another limitation is lack of specific feature usage data. Without feature usage data, investigating differences in outcomes or engagement with specific features of the program was not possible.

Comparison With Prior Work

Findings from this study are comparable to other similar interventions. The platform has been shown to have a high engagement rate and to be noninferior to other in-person or online interventions [38-40]. Given the brief intervention that was provided, we were able to achieve high uptake within the context of general practice and primary care. Typically, other interventions require staff resources and time.

HeLP-Diabetes (Healthy Living for People with type 2 Diabetes), an online type 2 diabetes self-management tool, reported a lower uptake, engagement, and completion rate. HeLP-Diabetes required staff to identify eligible patients and recruited patients through consultations and text messages [41]. A total of 23% of patients engaged past the first HeLP-Diabetes module, and 9.4% of patients completed the program.

The program mirrors outcomes for intensive diabetes interventions, such as Virta, which combines coaching and teleconsultation and reported an 83.2% retention rate at 1 year [42]. Noom, a diabetes prevention program in the United States, showed a similar engagement rate of 77.6% at 1 year [43].

A large nonrandomized trial of an online diabetes prevention program that provided digital education, a live e-coach, and virtual groups in North America showed similar weight loss at 12 months (4.0 kg) [44] to our study. GlycoLeap, a Singaporean mobile lifestyle management program reported a mean weight loss of 2.0 kg at 12-week follow-up (mean –2.0 kg, SD 1.6; $P<.001$) [45]. An evaluation of Time2Focus, a self-guided app for diabetes education in North America, showed a lower mean HbA_{1c} reduction at follow-up (mean –0.39 mmol/mol; $\beta=.06$; $P=.78$) [46].

This research suggests that similar to digital interventions such as HeLP-Diabetes, the mode of delivery is acceptable to both providers and patients [47]. With the growing burden of type 2 diabetes, prescribing digital health interventions to encourage behavior change can enable health care providers to support patients remotely, at scale, and enables health care providers to focus on high-risk or high-priority patients.

Conclusions

The majority of participants who registered for the intervention lost weight and improved glycemic control. Although our study design does not support causal conclusions, this real-world evaluation suggests that the intervention can be a useful adjunct for lifestyle self-management for adults with type 2 diabetes and prediabetes. Further research should explore the impact on larger groups of patients, explore the acceptability of intervention features, and refine engagement strategies to maximize uptake, completion rates, and patient outcomes.

Acknowledgments

We thank the Low Carb Program community who have been helping one another on their low-carbohydrate journeys.

Conflicts of Interest

CS is employed by DDM Health, which runs the Low Carb Program. DU is an unpaid medical adviser to DDM Health.

Multimedia Appendix 1
Screenshots of the Low Carb Program multi-platform app on the web, a mobile phone, a smart watch, and a smart speaker.
[PNG File , 241 KB - diabetes_v6i3e25751_app1.png]

Multimedia Appendix 2
Examples of personalized patient journeys in the Low Carb Program.
[PDF File (Adobe PDF File), 119 KB - diabetes_v6i3e25751_app2.pdf]

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Abbreviations

COM-B: Capability-Opportunity-Motivation Behavior
CONSORT: Consolidated Standards of Reporting Trials
HbA_{1c}: hemoglobin A_{1c}
HeLP-Diabetes: Healthy Living for People with type 2 Diabetes
NHS: National Health Service
NICE: National Institute for Health and Care Excellence

Edited by D Griauzde; submitted 23.11.20; peer-reviewed by R Schwarzer, Y Bartlett; comments to author 23.03.21; revised version received 07.05.21; accepted 20.06.21; published 09.09.21.

Please cite as:
Summers C, Tobin S, Unwin D
Evaluation of the Low Carb Program Digital Intervention for the Self-Management of Type 2 Diabetes and Prediabetes in an NHS England General Practice: Single-Arm Prospective Study
JMIR Diabetes 2021;6(3):e25751
URL: https://diabetes.jmir.org/2021/3/e25751
doi:10.2196/25751
PMID:34499035

Original Paper

Evaluation of Web-Based and In-Person Methods to Recruit Adults With Type 1 Diabetes for a Mobile Exercise Intervention: Prospective Observational Study

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Abstract

Background: Our clinical trial of a mobile exercise intervention for adults 18 to 65 years old with type 1 diabetes (T1D) occurred during COVID-19 social distancing restrictions, prompting us to test web-based recruitment methods previously underexplored for this demographic.

Objective: Our objectives for this study were to (1) evaluate the effectiveness and cost of using social media news feed advertisements, a clinic-based approach method, and web-based snowball sampling to reach inadequately active adults with T1D and (2) compare characteristics of enrollees against normative data.

Methods: Participants were recruited between November 2019 and August 2020. In method #1, Facebook and Instagram news feed advertisements ran for five 1-to-8-day windows targeting adults (18 to 64 years old) in the greater New Haven and Hartford, Connecticut, areas with one or more diabetes-related profile interest. If interested, participants completed a webform so that the research team could contact them for eligibility screening. In method #2, patients 18 to 24 years old with T1D were approached in person at clinical visits in November and December 2019. Those who were interested immediately completed eligibility

screening. Older patients could not be approached due to clinic restrictions. In method #3, snowball sampling was conducted by physically active individuals with T1D contacting their peers on Facebook and via email for 48 days, with details to contact the research staff to express interest and complete eligibility screening. Other methods referred participants to the study similarly to snowball sampling.

Results: In method #1, advertisements were displayed to 11,738 unique viewers and attracted 274 clickers (2.33%); 20 participants from this group (7.3%) volunteered, of whom 8 (40%) were eligible. Costs averaged US $1.20 per click and US $95.88 per eligible volunteer. Men had lower click rates than women (1.71% vs 3.17%; *P*<.001), but their responsiveness and eligibility rates did not differ. In method #2, we approached 40 patients; 32 of these patients (80%) inquired about the study, of whom 20 (63%) volunteered, and 2 of these volunteers (10%) were eligible. Costs including personnel for in-person approaches averaged US $21.01 per inquirer and US $479.79 per eligible volunteer. In method #3, snowball sampling generated 13 inquirers; 12 of these inquirers (92%) volunteered, of whom 8 (67%) were eligible. Incremental costs to attract inquirers were negligible, and total costs averaged US $20.59 per eligible volunteer. Other methods yielded 7 inquirers; 5 of these inquirers (71%) volunteered, of whom 2 (40%) were eligible. Incremental costs to attract inquirers were negligible, and total costs averaged US $34.94 per eligible volunteer. Demographic overrepresentations emerged in the overall cohort (ie, optimal glycemic control, obesity, and low exercise), among those recruited by news feed advertisements (ie, obesity and older age), and among those recruited by snowball sampling (ie, optimal glycemic control and low exercise).

Conclusions: Web-based advertising and recruitment strategies are a promising means to attract adults with T1D to clinical trials and exercise interventions, with costs comparing favorably to prior trials despite targeting an uncommon condition (ie, T1D) and commitment to an intervention. These strategies should be tailored in future studies to increase access to higher-risk participants.

Trial Registration: ClinicalTrials.gov NCT04204733; https://clinicaltrials.gov/ct2/show/NCT04204733

(JMIR Diabetes 2021;6(3):e28309) doi:10.2196/28309

KEYWORDS

type 1 diabetes mellitus; exercise; behavior and behavior mechanisms; mobile phone

Introduction

Background

Type 1 diabetes (T1D) is characterized by beta cell destruction and absolute deficiency, and it increases the risk of cardiovascular disease among the 1.6 million Americans living with it [1]. There is extensive evidence to endorse exercise as therapy to reduce this risk [2]. Yet, data on optimal strategies to promote exercise safely and successfully among those with T1D who are inadequately active are lacking.

Online programs have potential for improving the scalability, reach, and cost-effectiveness of exercise interventions [3]. Effective behavioral interventions to promote lifestyle change typically involve a skills component, self-monitoring, personalized feedback, and/or an electronic tool and resource to facilitate behavior change [4,5]. While in-person exercise interventions are efficacious for health goals, such as weight loss for people with obesity and no other chronic conditions [6], individuals with T1D must spend several hours per day managing their disease [7], so extra time commitments, such as traveling to exercise, must be minimized.

Quality clinical trials are needed to address the diabetes care needs of adults across the lifespan (18 to 65 years). To have generalizable results, clinical trials must enroll participant samples that represent the target population in terms of sociodemographic and clinical characteristics. Recruiting racially, ethnically, and socioeconomically diverse adults using traditional recruitment strategies is challenging [8]. Another challenge is to recruit a nationally representative sample reflective of adults with T1D to capture those who do not meet glycemic control targets or with other comorbidities and other cardiovascular risk factors such as hypertension. Recruiting through social media has great potential to reach populations who would otherwise not participate in research. Social media is an effective strategy for recruiting young adults—98% use the internet and 88% use social media—and the internet is particularly effective for recruiting young adults aged 18 to 34 years with T1D [9,10]. However, less is known about the effectiveness of social media for recruiting middle-aged to older adults aged 35 to 65 years with T1D.

Social media platforms host numerous T1D support groups that facilitate peer and role model support [11,12], and advertisements through two of these groups—College Diabetes Network and Beyond Type 1—successfully recruited young adults with T1D to a self-management education intervention [9]. However, these authors acknowledged that this approach introduces bias, since not all people with T1D choose to engage with these groups. Many analyses have concluded that digital recruitment introduces bias because internet browsing behavior correlates with demographics [13-15]. Therefore, any social media approach is inherently biased, but one potential strategy to diversify viewership is varying the way advertisements are delivered within the social media platform [10,13]. For example, advertisements can be placed within the home page news feed so they are viewed immediately or with unfocused scrolling, rather than having to intentionally visit a specific group page. Another strategy is *snowball sampling*, where initial respondents spread word to peers through social media and other web-based methods such as email [16]. Accordingly, evaluation of a multifaceted web-based recruitment campaign is important to

determine the effectiveness of this approach for the T1D population.

Objectives

Our overall objective was to describe recruitment engagement occurring within various web-based and in-person spaces to investigate the potential for selection bias and threats to external validity when recruiting adults with T1D. We addressed this objective via a substudy analyzing recruitment strategies for a parent study that was focused on a 10-week mobile exercise intervention for inadequately active adults with T1D. The intervention in the parent study used a customized mobile digital app—GlucoseZone (Fitscript LLC)—to provide on-demand instructional exercise videos, access to a text-based exercise coach with expertise in T1D, daily electronic self-monitoring diaries, and monthly data reports from a continuous glucose monitor (CGM) and an exercise smartwatch (Apple Watch 3) that were discussed with their coach in a motivational enhancement therapy session. The feasibility, acceptability, and efficacy of the intervention will be published in forthcoming manuscripts. The specific aims of this substudy were to (1) evaluate the effectiveness and cost of using news feed advertisements, snowball sampling, and an in-person approach at clinical visits to reach inadequately active adults with T1D for a mobile lifestyle intervention and (2) compare sociodemographic and clinical characteristics among responders against normative data.

Methods

Overview

The methods described below are based on our previous investigations of web-based advertising for different populations (ie, heavy-drinking smokers and heavy-drinking young adults with sleep concerns) [17,18]. Our previous studies and this study share the primary objective of evaluating the effectiveness and cost of using web-based advertising to recruit from the population of interest. This study compared social media news feed advertising, in-person approach at clinic visits, web-based snowball sampling, referral from prior studies, and ClinicalTrials.gov postings.

Screening Process Overview

The recruitment campaign targeted individuals who met eligibility criteria for the parent intervention study: 18 to 65 years of age, have T1D or other absolute insulin deficiency diabetes, report inadequate exercise patterns (<3 days per week) [2], interest in participating in a mobile exercise intervention (ClinicalTrials.gov Identifier: NCT04204733), own a smartphone, own and are adherent to a CGM (consistently capture ≥70% of possible readings) [2], and read and speak English. The intervention also required an Apple Watch 3, which was provided to each participant by the research team for the duration of the study. Volunteers with a chronic disease or injury requiring exercise adjustments outside the scope of the mobile intervention were not eligible to participate. Each advertising strategy presented a brief description of the study with an invitation to inquire for more details. Those inquiring were provided a more detailed overview of study requirements and confidentiality policies. Those responsive to this more-detailed overview completed eligibility screening, and those eligible were invited to complete an intake visit at the closest of our two research sites—New Haven or Trumbull, Connecticut (n=9)—or by televideo, which was mandated for participants enrolled after the start of the COVID-19 pandemic (n=11). All participants completed an informed consent process before their intake. For televideo intakes, consenting was done on a separate televideo call the prior week so that intake supplies (blood pressure monitor, scale, etc) could be mailed. The study, screening, and consent process were approved by the Yale University Institutional Review Board.

Advertising Strategies

Participants were recruited for the parent study over a 9-month period between November 12, 2019, and August 9, 2020, with a target enrollment of 20 participants.

Method #1: Social Media News Feed Advertisements

We ran an advertisement (Figure 1) through the paid news feed advertising platform of Facebook, which also includes Instagram, for 20 days total over five windows that were set according to times for which we had the capacity to enroll new volunteers (December 6-14, 2019; May 27-30, 2020; July 19-27, 2020; August 2 and 3, 2020; and August 9, 2020), until our target number of volunteers (N=20) had been enrolled. The advertisement appeared on the landing page of the desktop and mobile versions of Facebook and Instagram of individuals in the target age group (18 to 64 years) who listed at least one interest related to diabetes from a list we constructed by searching Facebook: Cure Type 1 Diabetes, Certified Diabetes Educator, American Diabetes Association, International Diabetes Federation, World Diabetes Day, Joslin Diabetes Center, Cure Diabetes, or Medtronic Diabetes. We specified a spending limit of US $25 per day.

Figure 1. News feed advertisement to reach inadequately active adults with type 1 diabetes.

We restricted the geographic target to a range that made travel to our research offices feasible without compromising the daily number of times the advertisement was displayed (ie, impressions). This area was a 25-mile radius of our city (New Haven, Connecticut) or the adjacent one (Hartford, Connecticut). Although we pilot-tested advertisements in other states when the mandated transition from in-person to televideo methods occurred, they yielded no volunteers (Multimedia Appendix 1), so this analysis is restricted to advertising days in Connecticut.

Wording style was taken from our previous successful social media campaigns [17,18]. Facebook and Instagram run on a shared platform. The platform allocates advertising space using an *auction* process based on the spending *bid* of the advertiser, relevance to the user (ie, web analytic estimated rate of the user acting upon the advertisement), and advertisement quality (ie, past user experience survey results) [19]. We used the platform's bid-optimizing algorithms targeting the lowest cost per click. The platform's auctioning and bid optimization include the

Instagram space. The platform monitored the number of impressions, total reach (ie, number of people seeing the advertisements), advertisement clicks, and total cost for all advertisements. These data allowed us to evaluate efficacy and cost-effectiveness.

By clicking the advertisement, inquirers were directed to a Health Insurance Portability and Accountability Act–compliant webpage (Qualtrics) that displayed an overview of the study: (1) a mobile app for people with T1D to manage exercise, which includes a free 3-month subscription to the mobile app, text-based coaching, a daily mobile diary, and feedback from automated devices (ie, Apple Watch, CGM, and insulin device); (2) 1-hour health assessments and surveys to be completed at the beginning and end of the 3 months; and (3) compensation for participation (US $100), research team contact details, and our confidentiality policy. Inquirers were informed that they could telephone the research team to obtain more information and complete eligibility screening to enroll, or leave their contact details and preferred times to be contacted in a secure webform on the website so that the research team could contact them. Those completing the webform received an email from the research team 1 business day later that confirmed receipt of their inquiry, were provided with a copy of the study overview from the website so that they could review it further as desired, and were notified that they would be telephoned 2 business days later so that they could ask questions about the study and complete eligibility screening. Those who answered or returned this telephone call were considered to be responsive volunteers.

Method #2: In-Person Approach at Clinical Visits

The Yale clinic serving adult patients with T1D did not permit in-person recruitment by researchers, and remote recruitment methods through clinic channels (ie, MyChart) were shut down at the time of our recruitment. Therefore, clinic recruitment was restricted to young adults attending the Yale Children's Diabetes Clinic (ie, those 18 to 24 years old). The principal investigator (PI) (author GIA) successfully recruited a cohort of volunteers from this clinic for a prior study [20] and followed the same protocols for this study. Using medical record review, the PI identified candidates who met the age and T1D diagnosis criteria with appointments between November 12 and December 20, 2019 (ie, 27 days of clinic operation). The initial in-clinic approach occurred in the exam rooms over a 10-minute window before or between interactions with the diabetes provider, which were coordinated with the provider in advance, and utilized the following procedures. The PI knocked on the door. Once receiving the candidate's permission to enter, the PI said, "Hello! I'm a researcher from Yale. We are doing a study on exercise for type 1 diabetes. It provides a free subscription to a mobile application for improving understanding on how exercise affects your health and blood sugar control. Would you like to have more information?" Candidates answering affirmatively were considered to be *inquirers*, analogous to clickers in method #1. The PI verbally reviewed a handout that mirrored method #1 regarding visuals (ie, Figure 1) and content (ie, the study overview webpage) and invited them to ask further questions and complete eligibility screening if they wanted to participate. Those electing to complete screening were considered to be responsive volunteers. Screening was completed immediately in person at the clinic setting. Clinic recruitment was discontinued after December 2019 due to its relative inefficiency (as described in the Results section) and COVID-19 pandemic restrictions.

Method #3: Web-Based Snowball Sampling

Two physically active individuals with T1D—both white non-Hispanic women in the 35-to-65-year age cohort—approached us volunteering to spread information about the study by word-of-mouth from April 9 through May 27, 2020, after learning about it through ClinicalTrials.gov or by word-of-mouth from members of our department. They targeted peer audiences, including a nationwide email list of personal friends with T1D, T1D support groups on Facebook (eg, Phoenix Valley T1D and Honest Exchange), and friends viewing their Facebook profile wall. They reported that they initially posted a link to the ClinicalTrials.gov page couched in a description that they personalized according to the venue (eg, a posting on a support group may have referenced a discussion at that group's last meeting about the importance of exercise), which they followed up with personal exchanges with venue members as needed. These posts and exchanges occurred within private Facebook and email groups and were not monitored by the research team. Interested volunteers could inquire about the study by phone or email through study team contact details available through the role models or the ClinicalTrials.gov page. These *inquirers*, analogous to clickers in method #1, received the same series of responses from the research team as the webform completers: a study overview email 1 business day later and a telephone call 2 business days later, and those answering or returning this telephone call were considered to be responsive volunteers.

Other Methods

Over the course of the 9-month recruitment window, 3 participants in a prior Yale study for T1D [21] expressed interest in volunteering for further studies, and 4 viewers of the study on ClinicalTrials.gov emailed us requesting more information. These 7 people were considered to be *inquirers*, analogous to clickers in method #1. They received the same series of communications from the research team as the webform completers: a study overview email and a telephone call 2 business days later, and those answering or returning this telephone call were considered to be responsive volunteers.

Eligibility Screening

Volunteers completed the eligibility interview with the PI (GIA, an exercise physiologist) by telephone or in person in the clinic setting depending on the mode of recruitment. The interview began with one question from the Paffenbarger Physical Activity Questionnaire that queries weekly frequency of regular activity sufficient to work up sweat, heart thumping, or out of breath [22]. Those responding 3 or more times per week were not eligible to participate.

The second part of the interview included a medical history based on the Physical Activity Readiness Questionnaire [23]. It captured all the volunteers' chronic medical conditions, mobility limitations, medications, and other possible contraindications to exercise within the offerings of the mobile

app (eg, chest pain and dizziness). All positive responses were reviewed by the study physician (author SAW) to rule out exclusion criteria.

Cost-Effectiveness

Costs associated with each method are detailed in Table 1.

Table 1. Costs associated with each recruitment method used in the study.

Recruitment stage	Recruitment method tasks and their costs (US $)			
	News feed	Clinic	Snowball sampling	Other methods
Start-up	• 2 hours ($64.76[a]) to select image, slogan, and Facebook campaign settings • $125.00 to have HIPAA[b]-compliant webform[c]	• 1 hour ($32.38) to design flyer	30 minutes ($16.19) to explain study to each of two snowball sample leaders ($32.38 total)	30 minutes ($16.19) to discuss referral system with principal investigator of previous study
Display advertisement	• $0.012 per viewer for Facebook impression	• 1.14 minutes ($0.62) to screen chart[d] • 30 minutes ($16.19) per viewer to wait in clinic and find opportunity to approach participant	$0.00 (done by snowball sample leaders)	$0.00 (combined into below email that arranged screening)
Provide more information to inquirers[e]	• $0.00 for initial clickers (directed automatically to webform page) • 5 minutes ($2.70) per webform completer to send email template and follow up by phone[e]	• 1 color flyer ($0.20) per inquirer • 5 minutes ($2.70) per inquirer to verbally explain study and answer questions	5 minutes ($2.70) per inquirer to send email template and follow up by phone[e]	5 minutes ($2.70) per inquirer to send email template and follow up by phone[e]
Screening session with responsive volunteers	• 15 minutes ($8.10) per volunteer to answer further questions about study and ask screening questions	• 15 minutes ($8.10) per volunteer to answer further questions about study and ask screening questions	15 minutes ($8.10) per volunteer to answer further questions about study and ask screening questions	15 minutes ($8.10) per volunteer to answer further questions about study and ask screening questions

[a]Personnel rate of $32.38/hour based on principal investigator's salary + fringe.

[b]HIPAA: Health Insurance Portability and Accountability Act.

[c]Reflects 1 month of institutional subscription to Qualtrics (simulates larger trial where 20 days of advertising would occur in a single month).

[d]Calculated as 1 minute per chart / (88% of charts meeting age and type 1 diabetes diagnosis criteria) = 1.14 minutes per qualifying chart.

[e]Individuals not responding to first phone call were considered unresponsive.

Participant Characteristics

The assessments below were taken from the intake visit and used for comparisons to normative data.

Baseline Exercise Levels

The physical activity question in the eligibility screening was followed at the intake appointment by the more granular timeline follow-back for exercise, in which volunteers were asked to recall exercise (ie, type, duration, and Borg Rating of Perceived Exertion scale [24]) for each calendar day going back 60 days using calendar prompts and memory aids (eg, holidays). This assessment has test-retest reliability (r=0.79-0.97) and convergent validity with weekly exercise logs (r=0.65-0.80) [25]. It was chosen since the parent study is a longitudinal design, thus benefitting from weekly repeated measures as opposed to other physical activity questionnaires that offer snapshots.

Demographics

Participants completed a REDCap (Research Electronic Data Capture) form (Vanderbilt University) at the intake appointment. It included age, gender, income, years of education, race, ethnicity, type and duration of diabetes, and mode of therapy (ie, continuous subcutaneous insulin infusion pump or multiple daily injections).

Glycemic Control

Hemoglobin A1c (HbA_{1c}) was assessed by finger prick using the AccuBase A1c Home Test Kit (DTI Laboratories), a US Food and Drug Administration–approved method in which the user captures blood at home via capillary tube, injects the blood into EDTA preservative, and mails it to a central laboratory for analysis by high-performance liquid chromatography.

To save supply costs, participants who completed intake at a facility with a point-of-care HbA_{1c} machine available—DCA Vantage Analyzer (Bayer)—used it instead of the more expensive home test method. These 4 participants were 0.5 to

1.6 percentage points away from the classification cutoff used for analysis (7.0%), so differences between HbA_{1c} methods (typically ≤0.2 percentage points) did not impact results. Moreover, only 2 of these 4 participants ended up involved in the comparison between methods, and these participants were 0.9 to 1.6 percentage points away from the classification cutoff.

Resting Blood Pressure

Resting blood pressure was taken by averaging two brachial artery measurements from the seated position after at least 5 minutes of quiet rest using the Omron BP760N (Omron Healthcare), which includes a rigid cuff that minimizes fitting errors [26]. If the measurements differed by >5 mm Hg, then a third was taken and the closest two were averaged. On the day of the test, participants were asked to avoid confounders of blood pressure, including caffeine, exercise, alcohol, and tobacco, which was verbally confirmed before the test was taken. In accord with registry practices, we defined elevated blood pressure as ≥140/90 mm Hg regardless of medication treatment, since medication treatment can be a poor indicator of hypertension status in this population [27].

The PI manually applied the blood pressure cuff and supervised measurements at the in-person intakes (n=9), and instructed participants to assess themselves by live televideo for the remote intakes (n=11) [26]. All 4 participants with elevated blood pressure were among the latter group, meaning the results were not impacted by "white coat" hypertension (ie, elevation of blood pressure unique to the medical office setting). The less common "masked" hypertension phenomenon (ie, elevation of blood pressure unique to the nonoffice setting) could not be ruled out as a confounder.

Body Mass Index

Weight was taken in kilograms by the Body weight scale (Withings) in light clothing without shoes. Height was self-reported in feet and inches during phone screening and converted to meters. Body mass index was calculated, and values ≥30.0 kg/m^2 were considered obese. Values within 3.0 kg/m^2 of the obesity cutoff were confirmed at the intake visit using a seca 213 portable stadiometer.

Normative Data

We obtained normative data to compare with our participants from the most recent (2016-2018) T1D Exchange Registry reports, a network of 70 US-based endocrinology practices that have enrolled 26,000 patients with T1D to complete a comprehensive questionnaire and grant access to their medical records [27-29].

Statistical Analysis

Analyses were conducted using a significance level of $\alpha<.05$. Data were tabulated in SPSS, version 26 (IBM Corp), and analyzed by the R software environment (The R Foundation).

Evaluation of Recruitment Effectiveness and Cost

For each recruitment method, we calculated the success proportion and cost at each conversion stage of recruitment: (1) viewers to inquirers (clickers of a news feed advertisement or people who contacted the research team in response to another form of advertisement), (2) inquirers to responsive volunteers (those who volunteer to participate after reviewing more information), and (3) responsive volunteers to eligible volunteers (those who pass screening) [13]. Proportions were compared between methods using chi-square tests (Fisher-Freeman-Halton if any cells <5), followed by post hoc pairwise comparisons using chi-square tests (Barnard test if any cells <5) with Benjamini and Hochberg false discovery rate–adjusted P values. We chose these tests over more conservative alternatives (ie, Fisher exact and Bonferroni-adjusted *P* values), since the small cell sizes presented a risk of type II error. *Other* methods were grouped for reporting and were not compared. Costs differed by magnitudes between methods—and some were nil—so were compared qualitatively [30]. Within each method, we compared demographic groups (ie, age and gender), since the study sought to increase age scope from previous reports to include adults 35 to 65 years old. Among the age brackets offered by Facebook analytics, *18 to 24 years* had just 5 clickers (0 enrollees) so was grouped with *25 to 34 years*. Pandemic status (ie, prepandemic vs midpandemic) was similarly tested as a possible confounder.

Comparison of Participant Characteristics to Normative Data

Demographic and clinical characteristics were compared using socially and clinically meaningful binary categories by testing whether the normative data proportion fell within the 95% CI of the proportion of our total sample and each recruitment method, excluding methods with ≤2 enrollees. Note that all of these enrolled cohorts were compared to the normative data but not each other.

Results

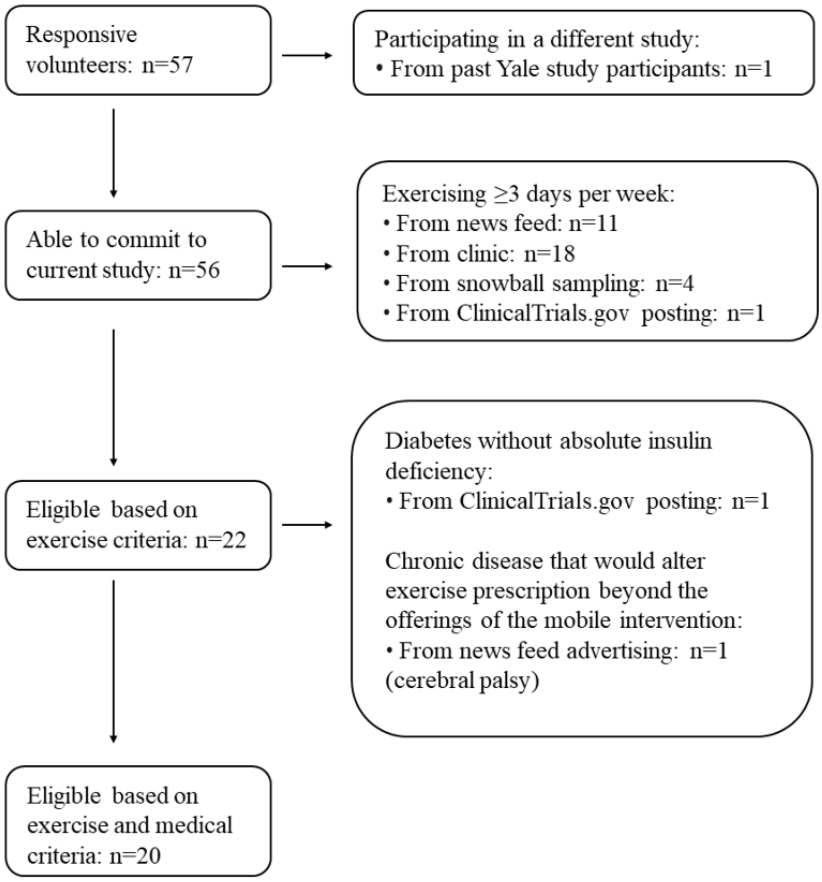
Evaluation of Recruitment Effectiveness and Cost

Method #1: Social Media News Feed Advertisements

The news feed advertisement was displayed 28,274 times (ie, impressions) for a total Facebook charge of US $328.85. Most of these impressions occurred on mobile devices (27,614/28,274, 97.67% vs 659/28,274, 2.33% on desktops). The advertisement was more successful on Facebook than on Instagram (US $1.19 vs US $1.46 per unique click), such that the bid-optimizing algorithm targeted most impressions (24,590/28,274, 86.97%) to the former. The number of unique viewers (n=11,738) was just 0.49% of the Facebook and Instagram users 18 to 64 years old in our geographic area (n=2,240,000), but 65.58% of those with at least one diabetes-related interest (n=17,900).

Among the 11,738 viewers, 274 (2.33%) clicked the advertisement. Among them, 32 (11.7%) expressed some further interest by completing the webform (n=31 after removing 4 blanks or duplicates) or calling research staff (n=1). When research staff contacted these 32 people to provide more information, 11 (34%) did not return the contact and 1 (3%) stated that he could not make the time commitment to the study. The remaining 20 out of the 274 who clicked (7.3%) volunteered to participate, and 8 out of the 20 who volunteered (40%) were eligible (Figure 2).

Figure 2. Participant screening flowchart.



Click rate was approximately 2× higher among women than men (Table 2). To ensure that this difference did not lead to unbalanced enrollment, we set male gender as an additional targeting filter on 4 out of 20 days, resulting in more impressions among men than women and, thus, a similar number of inquirers (ie, clickers) between the genders. Rates of volunteering and eligibility were not different by gender, so the final cohort of eligible volunteers was gender-balanced.

Age did not impact engagement success at any stage of the recruitment process, but the number of impressions (ie, the *overall denominator*) was approximately 7× higher among middle-aged than younger adults, as was the final number who were eligible. Facebook estimates that middle-aged adults outnumber younger adults within the subset of their users we targeted (ie, 13,700 vs 4400), and it is also possible they spend more time on the site. Among participants who clicked the advertisement, younger ones tended to complete the webform more often, but this tendency neither reached significance nor reflected any tendency to actually volunteer more often.

The pandemic period featured less expensive impressions (ie, fewer or less relevant competing advertisements) but also lower click rates, so the cost of enrolling a participant approximately doubled from the prepandemic period. The change in cost during the pandemic was similar for both genders (data not shown), and age could not be compared across time, since there was just 1 enrollee in the 18-to-34-year age category.

People clicking the advertisement on weekends tended to volunteer for the study approximately 2× more often than those who clicked during the week, but this difference neither reached significance nor impacted the final cost of enrolling a participant (US $95.88 on weekdays vs US $93.91 on weekends).

Table 2. News feed advertising details and costs by subgroups.

Recruitment metric	Gender[a]		Age (years)		Time relative to the pandemic		Day of the week	
	Men	Women	18-34	35-64	Before	During	Weekday	Weekend
Facebook costs								
Estimated target audience, n	6300	11,700	4400	13,700	17,900	17,900	17,900	17,900
Money spent, US $	192.22	134.95	28.60	306.84	131.34	197.51	191.43	143.36
Impressions, n	18,655	9521	3264	23,872	8313	19,961	17,086	11,730
Cost per impression, US $	0.010	0.014	0.009	0.013	0.016	0.010	0.011	0.012
Unique viewers, n	6765	4924	1331	9652	3165	8573	N/A[b]	N/A
Cost per unique viewer attracted, US $	0.028	0.027	0.021	0.032	0.041	0.023	N/A	N/A
Clickers, n (% of unique viewers)	116 (1.7)	156 (3.2)[c]	32 (2.4)	242 (2.5)	116 (3.7)[c]	158 (1.8)	165[d]	113[d]
Cost per click attracted, US $	1.66	0.97	0.89	1.34	1.13	1.25	1.16	1.27
Completers of webform, n (% of clickers)[e]	14 (12.1)	18 (11.5)	7 (21.9)	25 (10.3)	11 (9.5)	21 (13.3)	15 (9.1)	17 (15.0)
Responsive volunteers, n (% of clickers)[f]	9 (7.8)	11 (7.1)	3 (9.4)	17 (7.0)	10 (8.6)	10 (6.3)	7 (4.2)	11 (9.7)
Cost per responsive volunteer attracted, US $	21.36	12.27	9.53	18.05	13.13	19.75	31.08	15.88
Eligible volunteers, n (% of responsive volunteers)[g]	4 (44.4)	4 (36.4)	1 (33.3)	7 (41.2)	5 (50.0)	3 (30.0)	4 (57.1)	4 (36.4)
Cost per eligible volunteer attracted, US $	48.06	33.74	28.60	43.83	26.27	65.84	47.86	35.84
Other costs, US $								
Start-up[h]	94.88	94.88	94.88	94.88	94.88	94.88	94.88	94.88
Contacting webform completers	37.80	48.60	18.90	67.50	29.70	56.70	40.50	45.90
Screening responsive volunteers for eligibility	72.90	89.10	24.30	137.70	81.00	81.00	56.70	89.10
Total costs: cost per eligible volunteer enrolled, US $	99.45	91.88	166.68	86.70	67.38	143.36	95.88	93.31

[a]Excludes viewers with uncategorized gender (43/11,738, 0.4%); 2 out of these 43 viewers (4.7%) clicked the advertisement and 0 volunteered for the study.

[b]N/A: not applicable; this value was not traceable.

[c]Higher for women vs men (χ^2_1=25.9, *P*<.001) and before vs during pandemic (χ^2_1=32.9, *P*<.001), but not different by age (χ^2_1=0.02, *P*=.89).

[d]The percentage cannot be calculated because the number of unique viewers (ie, the denominator) was not traceable.

[e]Not different by any of the categories (gender: χ^2_1<0.001, *P*>.99; age: χ^2_1=2.6, *P*=.11; time: χ^2_1=0.6, *P*=.44; weekday vs weekend: χ^2_1=1.8, *P*=.18).

[f]Proportion of clickers volunteering (called *conversion* in the literature). It was not different by any of the categories (gender: χ^2_1<0.001, *P*>.99; age: Barnard test *P*=.89; time: Barnard test *P*=.60; weekday vs weekend: χ^2_1=2.5, *P*=.11).

[g]Not different by any of the categories (gender: Barnard test *P*=.79; age: Barnard test *P*=.91; time: Barnard test *P*=.43; weekday vs weekend: Barnard test *P*=.53).

[h]Start-up costs (Table 1) covered all participants, so were divided evenly between the two categories of each comparison.

Method #2: In-Person Approach at Clinic Visits

Among the 40 candidates who were approached, 32 (80%) were interested to hear about the study. After hearing the study overview, 12 of them declined to participate (4 due to the time commitment, 5 due to the CGM requirement, 1 due to the requirement to complete daily mobile diaries, and 2 provided no reason); the remaining 20 out of 32 inquirers (63%) volunteered to participate. Among them, 18 were excluded because they were already regularly exercising (Figure 2). The remaining 2 participants out of 20 volunteers (10%) were eligible and enrolled. Stratifying the results by gender revealed no differences in uptake at any stage (Table S1 in Multimedia Appendix 2), the age was uniformly 18 to 24 years old as stated in the Methods, and the time period for this strategy was exclusively prepandemic.

Method #3: Web-Based Snowball Sampling

Snowball sampling generated 13 volunteer inquiries by email, among whom 12 (92%) responded when the PI followed up by telephone. Among these, 4 were excluded because they were already regularly exercising. The remaining 8 out of 12

volunteers (67%) were eligible and enrolled. Stratifying the results by gender or age revealed no differences in uptake at any stage (Table S2 in Multimedia Appendix 2), and the only time this strategy was employed was midpandemic. These participants resided in seven different states, unlike the other recruitment methods, which restricted targeting to Connecticut.

Other Methods: Referral From Prior Study and ClinicalTrials.gov Posting

These methods yielded 7 inquiries, among whom 5 volunteered to participate (71%). Among them, 3 were disqualified (Figure 2). The other 2 out of 5 volunteers (40%) were eligible and enrolled.

Comparison Between Methods

As expected, the cost of a unique viewer was lower when approached by news feed advertisement versus in clinic (US $0.028 vs US $16.81) (Table 3). On the other hand, news feed advertisements were less likely than in-person clinic approaches to yield inquiries about the study (274/11,738, 2.33% vs 32/40, 80%; $P<.001$) or responsive volunteers from those inquiries (20/274, 7.3% vs 20/32, 63%; $P<.001$). However, responsive volunteers from news feed advertisements were more likely than those from in-person clinic approaches to be eligible for the study (8/20, 40% vs 2/20, 10%; $P=.03$). Thus, the overall cost of 1 eligible volunteer was approximately 5× lower when approached by news feed versus in clinic (US $95.88 vs US $479.79).

Snowball sampling was more likely than news feed and clinic methods to convert inquirers to responsive volunteers and responsive volunteers to eligible volunteers. Although the latter comparison was only significant against the clinic recruitment (8/12, 67% vs 2/20, 10%; $P<.001$), overall, these differences combined with its low start-up and personnel costs meant snowball sampling was 4× to 23× less expensive than news feed and clinic methods.

Table 3. Comparison of recruitment methods.

Recruitment metric	Recruitment method			
	News feed	Clinic	Snowball sampling	Other methods
Days of action, n	20	27	48	271
Direct incremental marketing costs				
Money spent, US $	328.85	672.40	0.00	0.00
Impressions, n	28,274	40	N/A[a]	N/A
Cost per impression, US $	0.012	16.81	0.00	0.00
Unique viewers, n	11,738	40	N/A	N/A
Cost per unique viewer attracted, US $	0.028	16.81	0.00	0.00
Inquirers[b], n (% of unique viewers)	274 (2.3)	32 (80.0)[c]	13[d]	7[d]
Cost per inquirer attracted, US $	1.20	21.01	0.00	0.00
Completers of webform, n (% of inquirers)	32 (11.7)	N/A	N/A	N/A
Responsive volunteers[e], n (% of inquirers)	20 (7.3)	20 (62.5)[c]	12 (92.3)[f,g]	5 (71.4)
Cost per responsive volunteer attracted, US $	16.44	33.62	0.00	0.00
Eligible volunteers[h], n (% of responsive volunteers)	8 (40.0)	2 (10.0)[i]	8 (66.7)[g]	2 (40.0)
Cost per eligible volunteer attracted, US $	41.11	336.20	0.00	0.00
Other costs, US $				
Start-up	189.76	32.38	32.38	16.19
Contacting and explaining study to inquirers	86.40	92.80	35.10	18.90
Screening responsive volunteers for eligibility	162.00	162.00	97.20	40.50
Total costs: cost per eligible volunteer enrolled, US $	95.88	479.79	20.59	34.92

[a]N/A: not applicable; this value was not traceable.

[b]Defined as person who clicks (news feed advertisement) or requests more information from the research team (other recruitment methods).

[c]Greater than news feed by chi-square (inquirers: χ^2_1=919.8, *P*<.001; responsive volunteers: χ^2_1=72.1, *P*<.001).

[d]The percentage cannot be calculated because the number of unique viewers (ie, the denominator) was not traceable.

[e]Refers to proportion of clickers volunteering (called *conversion* in the literature) (3-way *P*<.001).

[f]Greater than news feed by Barnard test (*P*<.001).

[g]Greater than clinic by Barnard test (response rate: *P*=.048; eligibility: *P*<.001).

[h]3-way *P*=.003. Not significant for news feed versus snowball sampling (Barnard test *P*=.23).

[i]Less than news feed by Barnard test (*P*=.03).

Comparison of Participant Characteristics to Normative Data

The sample characteristics are given in Table 4. Most enrolled participants (18/20, 90%) had T1D, and the rest (2/20, 10%) had latent autoimmune diabetes of adulthood. The sample was gender-balanced with an average age of 42.3 (SD 15.0) years. Most participants were Caucasian (19/20, 95%), had completed a 4-year college degree (14/20, 70%), and had a household income greater than US $50,000 per year (17/20, 85%). The majority of participants (17/20, 85%) managed their diabetes with a continuous subcutaneous insulin infusion pump, with 3/20 (15%) using multiple daily injections. All used a CGM in accordance with inclusion criteria. Over half of the participants (12/20, 60%) had HbA_{1c} above target (ie, HbA_{1c} ≥7.0%). Half (10/20) were exercising an average of less than 0.5 days per week, and half (10/20) had obesity. A smaller fraction had uncontrolled blood pressure (20%). In comparison to the T1D Exchange Registry, the sample overrepresented low exercise, HbA_{1c} meeting target, and obesity. Division by recruitment methods revealed that news feed advertising overrepresented obesity and older age, whereas snowball sampling overrepresented HbA_{1c} meeting target and low exercise.

Table 4. Sample characteristics of the full enrolled cohort and subsets for each method, each compared against normative data from the T1D Exchange Registry.[a]

Characteristic	Full enrolled cohort (N=20)		Subset enrolled from news feed (n=8)		Subset enrolled from snowball sampling (n=8)		Normative data from T1D Exchange Registry, n (%)
	n (%)	95% CI of %	n (%)	95% CI of %	n (%)	95% CI of %	
Age (≥50 years)	9 (45)	23-68	6 (75)	35-97[b]	3 (38)	9-76	3445/11,919 (29)
Sex (female)	11 (55)	32-77	5 (63)	24-91	4 (50)	16-84	6188/11,919 (52)
Race or ethnicity (Caucasian)	19 (95)	75-100	8 (100)	63-100	8 (100)	63-100	10,134/11,841 (86)
Education (bachelor's degree or higher)	14 (70)	46-88	6 (75)	35-97	6 (75)	35-97	5669/11,054 (51)
Advantaged income (≥US $50,000)	17 (85)	62-97	6 (75)	35-97	8 (100)	63-100	6112/8575 (71)
Pump therapy	17 (85)	62-97	7 (88)	47-100	7 (88)	47-100	7371/11,785 (63)
Continuous glucose monitor use	20 (100)	83-100[b]	8 (100)	63-100[b]	8 (100)	63-100[b]	1685/6564 (26)
Duration of diabetes (<10 years)	7 (35)	15-59	2 (25)	3-65	3 (38)	9-76	2436/11,901 (20)
Hemoglobin A_{1c} (≥7.0%)	12 (60)	36-81[b]	7 (88)	47-100	2 (25)	3-65[b]	4851/6181 (78)
Low exercise (<0.5 days/week)	10 (50)	27-73[b]	3 (38)	9-76	5 (63)	24-91[b]	848/7153 (12)[c]
Obesity (BMI ≥30.0 kg/m^2)	10 (50)	27-73[b]	7 (88)	47-100[b]	2 (25)	3-65	2571/10,204 (25)
Uncontrolled blood pressure	4 (20)	6-44	1 (13)	0-53	3 (38)	9-76	1648/11,697 (14)

[a]The enrolled cohort and each subset were compared against normative data but not each other.

[b]The 95% CI of the study cohort or subset does not include normative value, indicating bias.

[c]Taken from 2010-2012 iteration of the T1D Exchange Registry, since not yet published for 2016-2018 iteration.

Discussion

Principal Findings

This substudy evaluated the effectiveness, cost, and demographic representation achieved by web-based and in-person recruitment strategies for enrolling inadequately active adults aged 18 to 65 years with T1D into a mobile exercise intervention. The strategies collectively achieved cost-effective recruitment of adults that met our inclusion criteria of CGM users with inadequate baseline exercise patterns. Snowball sampling was the most cost-effective method and reached participants with exceptionally low exercise levels, but it overrepresented individuals with optimal glycemic control. We also tested other methods, including social media news feed advertising and in-person clinic recruitment. Among these methods, news feed advertising was more cost-effective than clinic recruitment, with a yield rate that would be satisfactory for a large clinical trial (1 participant per 2 to 3 days of advertising). Its initial engagement of men was more challenging than of women, but this was easily addressed by directing more impressions to men, since their responsiveness and eligibility were equal to women once they clicked the advertisement. Although prior literature found that social media is less effective for recruiting middle-aged and older adults compared to young adults [13], we observed that it was easier to target the middle-aged and older population because a greater number of them had diabetes-related profile interests. These results justify the previously highlighted need to diversify recruitment strategies [13-15] by including online methods and a variety of advertisement delivery modes within those methods.

The underrepresentation of elevated average blood glucose (ie, above-target HbA_{1c}) by snowball sampling led to a similar bias in the final cohort, which is problematic since such individuals have increased risk of mortality due to cardiovascular disease, and exercise can make blood glucose go too high [2] without proper guidance by an exercise intervention such as ours. Another contributor to this bias may have been the inclusion criteria of owning a CGM, which is associated with better glycemic control [2]. The final cohort also overrepresented low exercise levels and obesity, but these differences are inherent to the research question, since inadequate exercise was an inclusion criterion and leads to risk of obesity in the T1D population [29,31].

Comparison With Previous Work

Online forums have many uses in the T1D community, including emotional support [11], promotion of events, circulation of educational resources [32], and interactive technical support from peers and mentors with diabetes technology [11]. Snowball sampling or direct messages on media produced by these forums were, therefore, low cost and high return, although they were demographically biased recruitment strategies in our study (ie, overrepresenting optimal glycemic control and possibly other factors beyond our statistical power) and in previous work (ie,

overrepresenting women and college education) [9,11,33,34]. Others have used news feed advertising for young adults [10], a strategy we successfully extended to middle-aged and older adults but failed to reproduce among the younger adults.

Young adulthood (ie, 18 to 34 years old) is a time of critical health and psychosocial concerns in T1D (eg, pregnancy, transition from pediatric to adult care, and parental to personal health insurance), but consensus statements recognize that this age group is understudied in clinical trials [2]. Successful strategies for reaching this group include targeting by the age listed on social media profile [10] or medical record [10,21], or online support groups specific to young adults [9]. We, unfortunately, did not design our web-based methods to achieve such targeting; our news feed advertisements were targeted based on diabetes-related profile interests, which were uncommon among young adults, and the individuals who volunteered to start our snowball sampling happened to be middle-aged rather than young adults. Nonetheless, the limited number of young adults who were reached by our advertisements—32 clicked on news feed advertisements and 3 inquired from snowball sampling—were equally, if not more, likely than their older counterparts to be responsive and eligible. Taken together with the relative inefficiency of recruiting young adults through our clinic, these data indicate that web-based recruitment is an important strategy for reaching young adults with T1D but requires careful targeting to ensure they are reached.

Compared with this limited literature on web-based recruitment for T1D interventions, clinic-based recruitment strategies are more common [10,35,36] and some have found that they are more effective than web-based recruitment [10]. We, however, found the opposite. Some contributing factors may not be generalizable to all other studies. First, we had remote data collection, whereas studies holding intervention sessions or laboratory tests at clinics may benefit from recruiting in the same clinic to target individuals accustomed to visiting it [10,35,36]. Second, our major exclusion criterion (ie, regular exercise at baseline) could not be screened on medical records, leading to high ineligibility rates. Third, we had restrictions on approaching candidates over 25 years old through clinic channels. Fourth, our clinic did not allow mailing lists, which had higher eligibility and cost-effectiveness than in-person clinic recruitment in previous studies of T1D and type 2 diabetes [10,37]. Even those authors, however, noted that the reach of a clinic-based mailing list is limited [10] compared to the large pool that social media can access quickly (eg, 11,738 viewers over 20 days in our study). Overall, our findings highlight that web-based recruitment for T1D warrants more exploration relative to the clinic-based channels, especially when clinic visits are not required for data collection.

News feed advertising on Facebook has demonstrated cost-effectiveness in previous research. In a systematic review of 35 studies that assessed cost, the median cost of enrolling an eligible candidate was US $14.41 [13], which is substantially less expensive than our result (US $95.88). There are several factors that likely contributed to this cost discrepancy, but the most substantial is likely that only 10 studies in the systematic review were clinical trials. In a review restricted to clinical trials, 6 out of 16 (38%) of the reported studies yielded a result more expensive than ours [38]. It is also noteworthy that we included costs outside of direct Facebook charges (eg, personnel time), which most studies reviewed did not [38].

The first review [13] also assessed other factors that can elevate costs: engagement (ie, clicks per impression), conversion (ie, responsive volunteers per click), and eligibility (ie, volunteers eligible per volunteers responsive). Our rates of engagement and eligibility were lower than those of prior studies, but our rate of conversion outscored most of the studies reviewed. In summary, the driver of our cost was the low rate of initial engagement (ie, click rate) and the low proportion of responsive volunteers who met the eligibility criteria. The low click rates may reflect the low proportion of the population affected by T1D (0.5%) [1]. We targeted broader diabetes-related interests, but it is likely many of the individuals did not have diabetes despite their interest, or had the more common type 2 diabetes. They would not have found the intervention study appealing. We also note that click rates became lower during the COVID-19 pandemic, which coincided with the onset of warmer weather. Therefore, our intervention may have been more appealing during colder weather and/or times when volunteers were following a more typical daily schedule without quarantine modifications. Unfortunately, we could not survey nonclickers for factors influencing their decision not to click. One speculative explanation is that warmer weather and school quarantines prompted adults to initiate outdoor activities with young relatives, thus, not needing a mobile intervention to guide their exercise.

The low eligibility, meanwhile, was caused by the exclusion criteria of exercising 3 or more days per week. This challenge is not surprising, since 33% of adults with T1D report exercising 5 or more days per week, and another 55% report exercising 1 to 4 days per week [29]. Other important factors may have accounted for the cost-effectiveness of the results. For instance, our study required participants to have a CGM and to participate in a 10-week intervention with a mobile phone. In comparison, only 26% of adults, nationally, currently use a CGM [28], and most previous studies required less volunteer commitment; most studies involved brief web-based assessments or interventions [13]. These factors could have attenuated engagement, conversion, and enrollment of our recruitment process and could have driven up costs.

A prior study [10] faced similar challenges of engaging adult viewers in an advertisement calling for those with diabetes—predominantly T1D, as they were young adults—and then screening for those who met additional criteria, in their case, suboptimal glycemic control (HbA_{1c} ≥8.0%) and low socioeconomic status. They achieved higher engagement than our study (ie, cost per click was US $0.45), but their conversion rate was lower (59/7031, 0.84%) and their eligibility rate was similar (27/59, 46%), such that the cost of enrolling one participant was three times higher (US $334). The engagement difference may be attributable to two differences in the targeting strategies. First, our study targeted advertisements to diabetes based on profile interests, whereas the prior study used *likes* of diabetes-related posts. Further study is required regarding the

differing implications of these two virtual behavior characteristics; we can speculate that individuals *liking* posts are more inclined to actively engage with content (eg, by clicking) rather than passively viewing. Second, our study's advertising theme was "understanding how exercise affects blood sugar control," whereas the prior study's themes were diabetes-related imagery, compensation, urgency and time running out, altruism, the study team's empathy, call to action, and difficult aspects of managing diabetes. The eligibility rate similarity was expected, since this study and the previous study had criteria that applied to a minority of the T1D population: inadequate exercise [29] and low socioeconomic status [28], respectively. The conversion rate difference is more difficult to interpret, since the prior study did not report the contents of the landing page reached from clicking. However, the landing page is likely to include a description of the required assessments, compensation, and intervention offerings. Study requirements (ie, two visits with clinical and psychosocial assessments) and compensation (US $100 vs US $75) were similar, and all of our participants stated that compensation did not influence their desire to participate. Intervention offerings included a customized mobile digital app offering exercise coaching, biosensor feedback, and daily diary self-monitoring in this study versus occupational therapy for diabetes management in the prior study. In summary, although it was relatively challenging for us to initially attract clickers, the conversion to responsive volunteers of 7.3% was high compared to other studies of people with and without T1D, implying that mobile exercise support is appealing to people with T1D, and efforts to scale up its dissemination are warranted.

Limitations

Limitations of this study should also be noted. First, we did not perform the complex social network mining required to trace the snowball sampling as carefully as we traced the news feed advertisements and clinic recruitment. Doing so might have lent insights into better targeting the snowball sampling, but would likely be resource intensive compared to the user-friendly tracking tools of the Facebook advertising dashboard. Second, the sample was too underpowered to address the representativeness of the enrolled cohorts. The data suggest that snowball sampling should be used cautiously because of the possibility to overrepresent optimal HbA_{1c}, but there may be other differences between methods that were undetectable due to limited sample size, number of assessments, and stages of the recruitment process where they were taken. Third, the small sample left insufficient room to rotate strategies, such as the gender and activities of advertisement models and snowball sample leaders. In particular, we only featured women, whereas previous reports suggest that men are more effective at recruiting both genders [36]; also, weekend advertisement clicks tended to convert to responsive volunteers more frequently than weekday clicks, but this trend did not reach statistical significance as it might have with a larger sample. Fourth, the design was observational so cannot infer direction of associations. Fifth, a CGM was required for participation and we were only able to recruit those with a current CGM. Although CGM use increased in this population, nationally, from 7% in 2010-2012 to 26% in 2016-2018 [28], and is being urgently recommended by the standard of care [2], CGMs are still not used by the majority. The study also tended to overrepresent those using insulin pumps as opposed to multiple daily injections, which was perhaps related to the CGM requirement biasing toward people with greater technology uptake.

Conclusions

Despite these limitations, this study demonstrated that web-based recruiting strategies targeting physically inactive adults with T1D are cost-effective and efficient compared to traditional methods, as well as similar strategies in other populations [38]. Adults with T1D are a hard-to-reach group and face several barriers (eg, fear of hypoglycemia, actual hypoglycemia, neuropathy, and social stigma) to achieving the target exercise recommendations of exercising at least every other day [2,39,40]. Thus, having another avenue for recruitment and anonymity (ie, the comfort of one's own home) to participate in physical activity is essential. Data from this study lend insight into the scalability of this approach by demonstrating that web-based recruitment strategies are viable and steady channels for recruitment of individuals with T1D and other risk factors. Future studies should attempt tailoring of these methods to better reach vulnerable subgroups among people with T1D, including young adults, those with suboptimal glycemic control, and racial and economic minorities. Possible tailoring strategies could include snowball sampling starting with purposefully recruited individuals from these subgroups or news feed advertising through social media platforms besides Facebook (eg, Reddit and YouTube).

Acknowledgments

The authors thank Madilyn Augustine, Jenna Burton, Irene Chernova, Anthony Cifre, Jack LaVigne, Allison McNeilly, Natalia Roberts, David Robledo, Marisa Rodgers, Chanelle Simmons, Kathleen Tackos, and Asiya Way for their contributions to the implementation of the study.

The clinical trial including recruitment was funded by a Robert E Leet and Clara Guthrie Patterson Trust Mentored Research Award, Bank of America, NA, Trustee, and the Michael and Rosemary Ryan Pediatric Diabetes Research Fund. GIA was supported by a fellowship from the Office of Academic Affiliations at the United States Veterans Health Administration. EKS was partially supported by the VA (Veterans Affairs) Merit Award (No. 1I01CX001825) from the US Department of Veterans Affairs Clinical Sciences Research and Development Service. SG was supported by mentored research scientist awards from the National Institutes of Health (K99NR018886) and the American Academy of Sleep Medicine (220-BS-19). The contents do not represent the views of the US Department of Veterans Affairs or the United States Government.

Authors' Contributions

GIA, LMN, MSK, CB, BIG, EKS, JSB, RW, SAW, and LMF contributed to the study concept and design. GIA, LMN, MSK, SAW, and LMF contributed to the advertisement and survey design. GIA collected and organized the data. GIA, SG, SJ, and LMF formulated the analytic plan for this substudy. GIA conducted the statistical analyses. GIA and SG drafted the manuscript, and all authors provided input and approved the final manuscript.

Conflicts of Interest

EKS has received unrestricted research support from Dexcom (to the Baltimore VA Medical Center and to the University of Maryland) for the conduction of clinical trials; Dexcom did not support this work monetarily or in-kind. SAW serves as a speaker for Medtronic and as a consultant for Zealand Pharmaceuticals; neither of these entities supported the above study.

Multimedia Appendix 1
Results of advertisements outside Connecticut.
[XLS File (Microsoft Excel File), 36 KB - diabetes_v6i3e28309_app1.xls]

Multimedia Appendix 2
Stratification of clinic and snowball sampling results by demographics.
[DOCX File , 18 KB - diabetes_v6i3e28309_app2.docx]

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Abbreviations

CGM: continuous glucose monitor
HbA_{1c}: hemoglobin A_{1c}
PI: principal investigator
REDCap: Research Electronic Data Capture
T1D: type 1 diabetes
VA: Veterans Affairs

Edited by G Eysenbach; submitted 01.03.21; peer-reviewed by AS Brazeau, L Wisk; comments to author 18.03.21; revised version received 12.04.21; accepted 08.05.21; published 08.07.21.

Please cite as:
Ash GI, Griggs S, Nally LM, Stults-Kolehmainen M, Jeon S, Brandt C, Gulanski BI, Spanakis EK, Baker JS, Whittemore R, Weinzimer SA, Fucito LM
Evaluation of Web-Based and In-Person Methods to Recruit Adults With Type 1 Diabetes for a Mobile Exercise Intervention: Prospective Observational Study
JMIR Diabetes 2021;6(3):e28309
URL: https://diabetes.jmir.org/2021/3/e28309
doi:10.2196/28309
PMID:34047700

Original Paper

Comparison of Communication Channels for Large-Scale Type 2 Diabetes Risk Screening and Intervention Recruitment: Empirical Study

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Abstract

Background: Clinical trials have shown that type 2 diabetes (T2D) is preventable through lifestyle interventions targeting high-risk people. Nevertheless, large-scale implementation of risk identification followed by preventive interventions has proven to be challenging. Specifically, recruitment of participants into preventive interventions is an important but often overlooked part of the intervention.

Objective: This study aims to compare the reach and yield of different communication channels to engage people at increased risk of T2D to fill in a digital screening questionnaire, with emphasis on reaching those at most risk. The participants expressing their willingness to participate is the final step in the risk screening test, and we aim to determine which channels had the most participants reach this step.

Methods: We established a stepwise web-based T2D risk screening tool with automated feedback according to the T2D risk level and, for those who were eligible, an invitation to participate in the StopDia prevention intervention study conducted in a primary health care setting. The risk estimate was based on the Finnish Diabetes Risk Score; history of repeatedly measured high blood glucose concentration; or, among women, previous gestational diabetes. We used several channels to invite people to the StopDia web-based screening tool, and respondents were classified into 11 categories based on the channel through which they reported having learned about StopDia. The demographics of respondents reached via different communication channels were compared using variance analysis. Logistic regression was used to study the respondents' likelihood of progressing through risk screening steps.

Results: A total of 33,399 persons started filling the StopDia screening tool. Of these, 86.13% (28,768/33,399) completed the test and named at least one communication channel as the source of information about StopDia. Altogether, 26,167 persons filled in sufficient information to obtain risk estimates. Of them, 53.22% (13,925/26,167) were at increased risk, 30.06% (7866/26,167)

were men, and 39.77% (10,136/25,485) had low or middle education levels. Most frequently mentioned channels were workplace (n=6817), social media or the internet (n=6712), and newspapers (n=4784). The proportion of individuals at increased risk was highest among those reached via community pharmacies (415/608, 68.3%) and health care (1631/2535, 64.33%). The communication channel reaching the largest percentage of interested and eligible men (1353/3979, 34%) was relatives or friends. Health care (578/1069, 54.07%) and radio or television (225/487, 46.2%) accounted for the largest proportion of people with lower education.

Conclusions: Communication channels reaching a large number of people, such as social media and newspapers, were the most effective channels for identifying at-risk people. Personalized approaches increased the engagement of men and less-educated people. Community pharmacies and health care services reached people with a particularly high T2D risk. Thus, communication and recruitment channels should be selected and modified based on the intended target group.

International Registered Report Identifier (IRRID): RR2-10.1186/s12889-019-6574-y

(JMIR Diabetes 2021;6(3):e21356) doi:10.2196/21356

KEYWORDS

communication; digital tool; prevention; public health campaign; risk identification; screening; social media; study recruitment; type 2 diabetes; mobile phone

Introduction

Background

Diabetes is one of the most common noncommunicable diseases and affects 10%-15% of adult populations in different countries, and most patients have type 2 diabetes (T2D) [1]. Furthermore, T2D can remain undiagnosed for several years, and a considerable proportion of people with T2D are not aware of their disease [2,3]. Poorly controlled or untreated T2D can lead to serious micro- and macrovascular complications [4,5], and the treatment of these comorbidities accounts for most of the costs related to T2D [6].

Evidence from studies conducted among different populations has shown that T2D is preventable by providing lifestyle interventions to people at increased risk [7-10]. To identify people who are at risk and would thus benefit from lifestyle interventions, several risk scores have been developed [11]. One of the most widely used tools is the Finnish Diabetes Risk Score (FINDRISC) [10]. It includes 8 questions, 4 of which deal with modifiable risk factors (BMI; waist circumference; consumption of vegetables, fruits, and berries; and physical activity). Thus, in addition to being a risk screening tool, the FINDRISC can also be considered as a brief intervention to increase awareness of T2D prevention possibilities [12].

Despite the research evidence of the efficacy of lifestyle interventions, large-scale implementation of risk identification followed by preventive interventions has proven to be challenging. A common shortcoming is that participant enrollment is often seen as a preliminary phase that precedes the actual intervention. In reality, successful recruitment may determine the outcome and effectiveness of the entire intervention. In interventions including screening and participant recruitment, the PIPE (Penetration, Implementation, Participation, and Effectiveness) framework for designing and evaluating health promotion programs provides steps that can be identified [13]. First, as many people as possible need to be made aware of and interested in taking up the screening (reach). Second, the respondents who are at risk need to be motivated to participate in the intervention (yield). Furthermore, preventive interventions do not always reach the right target group. For example, men and people with lower socioeconomic status are known to be more susceptible to diabetes, yet they tend to be less represented in prevention programs [14-17]. Nevertheless, there is evidence to suggest that people with lower socioeconomic status can benefit equally from lifestyle interventions, if only they can be reached and enrolled to participate [17,18].

Few studies have been published that compared different communication strategies to identify individuals at increased risk for T2D [19-21]. New methods such as mobile technology and social media are currently complementing traditional methods in the recruitment of study participants to intervention studies [22-26]. The COVID-19 pandemic has created an unprecedented need for web-based solutions, including the recruitment of research participants [27,28]. Previous studies have, to a large extent, analyzed traditional recruitment methods or few web-based solutions.

Stop Diabetes (StopDia) was a large-scale, multidisciplinary study on the prevention of T2D [29] conducted during 2016-2019 in Finland. One of the main aims of StopDia was to increase the coverage of screening and recruitment of people at increased risk for T2D. Using a web-based screening and recruitment tool allowed us to analyze the differences in the effects of communication channels in a substantially larger participant pool than in previous studies.

Objectives

In this study, we aim to compare the reach and yield of different communication channels in engaging people to fill in a digital screening questionnaire and to express their interest in taking part in the StopDia randomized controlled trial (RCT). Furthermore, we explore the potential of different channels to reach the underrepresented population groups and demographic groups that previous research has indicated as being at the highest risk of T2D, such as men [4] and people with lower education [30].

Methods

Context

This study is a part of the StopDia RCT (*NCT03156478*) to investigate T2D prevention with lifestyle counseling delivered via a mobile app alone or in combination with a group setting [29]. The study is based on anonymized data collected during the study participant recruitment phase of the RCT from users of the StopDia web-based risk screening tool.

The methodology of the project as a whole and regarding the development of the recruitment strategy was based on the Self-Determination Theory (SDT) [31]. The SDT comprises a continuum from external factors of motivation to internal factors, such as enjoyment, personal values, perception of autonomy and self-efficacy, and relatedness.

The recruitment campaign brand and tone of voice was aimed at creating positive, relatable feelings, particularly for our target audience. Evidence-based tactics such as using an informal tone of voice, avoiding medical and moralizing terminology, including visual content, and creating an easy-to-use design at the screening tool were used [32,33].

The key messages on the recruitment campaign were tailored and targeted for the primary audience, known to be at elevated risk, and also hard to reach to health interventions: men with middle or lower levels of education. We tested the contents in social media and optimized the contents and communication channels accordingly.

The interactive and stepwise web-based risk screening tool was available in Finnish on the StopDia website [34]. The risk screening tool could be filled in by anyone entering the site, and the tool provided the users with automated feedback on their risk level. The participants for the StopDia RCT were recruited from the provinces of North Savo, South Karelia, and Päijät-Häme in Finland during the 12-month period from March 1, 2017, to February 28, 2018. Thus, only persons who entered a postal code matching the study region were eligible and included in this study.

Respondents' answers to the questions of the web-based risk screening tool, as well as the date and time of screening completion, were saved to a database. We were not able to collect respondents' contact or identification information at this stage because of the obligatory face-to-face informed consent to participate and agreement to data collection in the clinical trial. Several responses from the same IP address were allowed, acknowledging the fact that the same device could be used by several people, for example, in public service facilities. The IP addresses were saved to a database but were not used in the study. The site visitors were informed that filling in the risk screening questionnaire on the website was considered as consent to use the anonymized data in the research. The Research Ethics Committee of the North Savo Hospital District has processed the ethical application and granted a permit (467/2019) to perform the study.

StopDia Digital Screening Tool

The web-based risk screening tool was available on the website [34] and could be accessed by a web browser on a desktop computer or a mobile device. The tool contained the FINDRISC T2D risk questionnaire and some additional questions (Figure 1). The FINDRISC is a validated, self-administered questionnaire used to calculate a score that gives an estimate of the respondents' 10-year risk of developing T2D [10]. It is composed of questions on age (in years); BMI (calculated by dividing weight [kg] with height [m] squared); waist circumference (cm); the intake of fruits, berries, and vegetables (daily or not daily); physical activity (at least 30 minutes per day or less than 30 minutes per day); blood pressure medication (yes or no); history of high blood glucose concentration (yes or no); and family history of diabetes (no family history; grandparent, aunt, uncle or first cousin, but no own parent, brother, sister or child; or parent, brother, sister or own child). A total FINDRISC score of at least 12 of the maximum 26 was defined to indicate an increased risk of T2D. The additional questions were about sex (male or female), previous gestational diabetes in women (yes or no), high blood glucose (fasting glucose concentration of 6.1-6.9 mmol/L or 2-hour glucose concentration of 7.8-11.0 mmol/L in the oral glucose tolerance test) measured repeatedly in the past (yes or no), educational level (university, college, vocational school, high school, or elementary school), and respondents' own perception of their risk of T2D (very low, low, average, high, or very high). In the analysis, universities and colleges were classified as providing high education.

Figure 1. The StopDia web-based type 2 diabetes risk screening tool, starting with questions on sex, postal code, and age.

The StopDia RCT inclusion criteria, in addition to living in the study area and having an increased risk for T2D, were age (eligible if 18-70 years); the possibility of using computers, smartphones, or tablets with internet connection (yes or no); and having own email address (yes or no). Exclusion criteria were prevalent diabetes (no, type 1 diabetes, T2D, or diabetes of unknown type), pregnancy (yes or no), and cancer treatment within the past 6 months (yes or no). These criteria defined the respondents' progress through the steps of the risk screening tool. Respondents who were excluded but were at increased T2D risk based on their answers received a web-based information brochure and instructions to contact their health care services for guidance. The respondents did not receive financial or other compensation to fill in the form.

Furthermore, the communication channel through which respondents had learned about StopDia was enquired ("Where did you learn about StopDia?"). The respondents could state their communication channel by selecting one or many of the 11 predetermined categories or they could provide a free-text answer. The participants were also asked, "Did someone specifically ask you to fill in the StopDia digital screening tool?" with predefined options (health care professional, pharmacist, relative, colleague or boss, or nobody). A free-text answer was also an option for this question.

Finally, participants who were deemed eligible to participate were asked whether they would *be interested* in participating in the StopDia study. Those who replied "yes" were shown the StopDia three-page study information letter and consent forms, after which they were asked whether they *were willing* to participate in StopDia. As it became apparent early during the recruitment, one-third of respondents left the site at this point; to increase engagement, we decided to change the final step slightly by replacing the question "Are you willing to participate in StopDia lifestyle intervention study?" with a less decisive question, "Would you like to get the instructions to make an appointment with the StopDia study nurse?" As stated earlier, we were not able to collect information on who actually booked an appointment with the study nurse.

Strategies to Reach Possible Participants

We collaborated with local public organizations to disseminate information about the StopDia study and to enhance risk identification at nurse and physician appointments, dental care, maternity services, occupational health care, and social services. Collaboration was established with pharmacies in the study areas, and 31 pharmacies arranged T2D screening days. Other collaborators included patient associations, nongovernmental organizations (NGOs), and employers. The study group regularly posted content on social media (Facebook, YouTube, Twitter, and Instagram) and paid for social media visibility (both promoted posts and advertisements). A summary of the campaign statistics is provided in Multimedia Appendix 1.

We sent several press releases and collaborated with local media. Up to 500 lay articles were published about the study in local and national media. To target men, we organized and participated in many local events (ice hockey games, camping, and hunting fairs). We also collaborated with local food banks to get in contact with hard-to-reach population groups with economic difficulties.

The main recruitment campaign message, "Take control of your risk – One-third of Finns are at risk of diabetes, are you?" was distributed via different communication channels. The slogan

was followed by a brief explanation of the study and the screening tool web address. The aim was to use a message that emphasized self-efficacy in risk reduction. The same message along with instructions on how to participate in the study was used in print materials (a total of more than 150,000 posters, leaflets, printed FINDRISC questionnaires, and StopDia measuring tapes for measuring waist circumference with the FINDRISC questionnaire printed on it; Figure 2), advertisements on local buses (Figure 3), and in digital materials (video advertisements on collaborators' information screens and intranet, content on social media [Facebook, Twitter, and YouTube], and targeted emails for the workforce at the partnering organizations).

Figure 2. StopDia printed campaign materials: poster, flyer, measuring tape with the type 2 diabetes screening questionnaire. More than 150,000 pieces of print materials were delivered to health care and other public services, nongovernmental organizations, pharmacies, local workplaces, and shops.

Figure 3. StopDia advertisement on local buses with a short version of the campaign slogan: "Take control of your risk – take the test."

The printed campaign materials were delivered to local establishments (eg, health care and other public services, NGOs, pharmacies, workplaces, and shops) and could be ordered on the StopDia website.

One of the key marketing materials we produced was a short video (Figure 4), in which a well-known Finnish comedian filled in the web-based risk screening tool.

Figure 4. Screen capture of a StopDia marketing video with a Finnish comedian, published and promoted on YouTube, Facebook, Instagram, and Twitter. In the video, the comedian is filling in the web-based risk screening tool.

An example of our social media campaigns is a Facebook advertisement, “Have you seen this man?” (Figure 5), aiming to reach men at T2D risk. The advertisement was promoted as a paid advertisement on Facebook and Instagram and shared by local Facebook groups. In addition, the advertisement was distributed via the StopDia stakeholder newsletter.

Figure 5. A Facebook advertisement published on local Facebook groups with the text: “Have you seen this man.” The caption of the picture says: “Lost: 3000 men. Identifying characteristics: Man. Last seen in: South Karelia, North Savo, or Päijät-Häme.” The advertisement was accompanied with the text: “If seen, please ask him to fill in the StopDia web-based risk screening tool.”.

Classification of Different Communication Channels

The communication channels were categorized primarily according to the respondents' answers to the question, "Where did you learn about StopDia?" (Table 1).

Furthermore, based on the answer to the question, "Did someone specifically ask you to fill in the StopDia risk screening tool?" we categorized the recruitment process as either "active" (if the respondent mentioned someone) or "passive" (if the answer was "nobody"). These terms were adopted from previous research [35] and modified to fit this study. Specifically, we made the distinction that persons not directly associated with the research staff such as physicians, pharmacists, and relatives were considered to be active recruiters if they directly had recommended someone to participate.

Table 1. Categorization of communication channels based on the self-reported source of information.

Communication channel category	Predetermined answer options included in the channel category	Free-text mentions included in the channel category
Newspaper	• Newspaper or magazine (web-based or print)[a]	Press and web-based newspapers
Radio or television	• Radio or television[a]	Radio or television; specific television program
Workplace	• My workplace[a] • Manager or colleague[b]	Workplaces, manager, coworker, work emails, schools, and universities
Pharmacy	• Pharmacy[a] • Pharmacist[b]	Community pharmacy, the pharmacist
Health care	• Health care professional at an appointment[a] • Health care service desk or other service desk[a] • Health care worker[b]	Physician, dentist, nurse, dietician, optician, school health care, health care center, maternity clinic, and other municipal service desks
Event	• Sports event, fair, or other public event[a]	Seminar, exhibition, public event, training session, sports event, and presentation
NGO[c]	• Patient organization or other organization (such as Diabetes Association or Heart Association)[a]	Patient organization, the Rotaries, labor union, and other NGOs
StopDia	• StopDia study website[a]	The StopDia project itself, its webpage, and personnel, persons doing face-to-face recruitment
Social media and internet	• Facebook or Twitter[a]	Twitter, Facebook, WhatsApp, YouTube, Snapchat, Tumblr, Reddit, Instagram, blogs or search engines, and named media persons
Relative or friend	• Relative, friend or acquaintancea,[b]	Friend, wife, husband, daughter, son, and other family members
Other	• Somewhere else, where?[a,b] • Free-text answer	Fitness advisors, swimming halls, libraries, marketplaces, buses, personal email, SMS text message, Donald Duck, and other real and imaginary characters

[a]Answer options to the question: "Where did you learn about the StopDia study (you may select multiple options)?"

[b]Answer options to the question: "Did someone specifically ask you to fill in the StopDia digital screening tool?"

[c]NGO: nongovernmental organization.

Statistical Analyses

Answers from the respondents were checked and implausible values for body weight (<30 kg or >200 kg; n=100), waist (<59 cm or >151 cm; n=381), and height (<139 cm or >202 cm; n=81) were coded as missing values, but the other answers of these respondents were left intact and used to calculate their FINDRISC scores. These limits were chosen based on the lowest and highest measured values in a random population-based survey in Finland [36].

The demographic characteristics of the respondents who were reached via different communication channels were compared using a variance analysis. Logistic regression analysis was used to study the respondents' likelihood of progressing through the risk screening steps (Figure 1), with "workplaces" as the reference channel, using the general linear function in RStudio with the binomial family.

Data were analyzed using SPSS Statistics version 25 (IBM Corp) and RStudio version 3.3.4 [37].

Results

Respondents' Progress Through the Risk Screening Tool

The flow chart of the stepwise recruitment is presented in Figure 6.

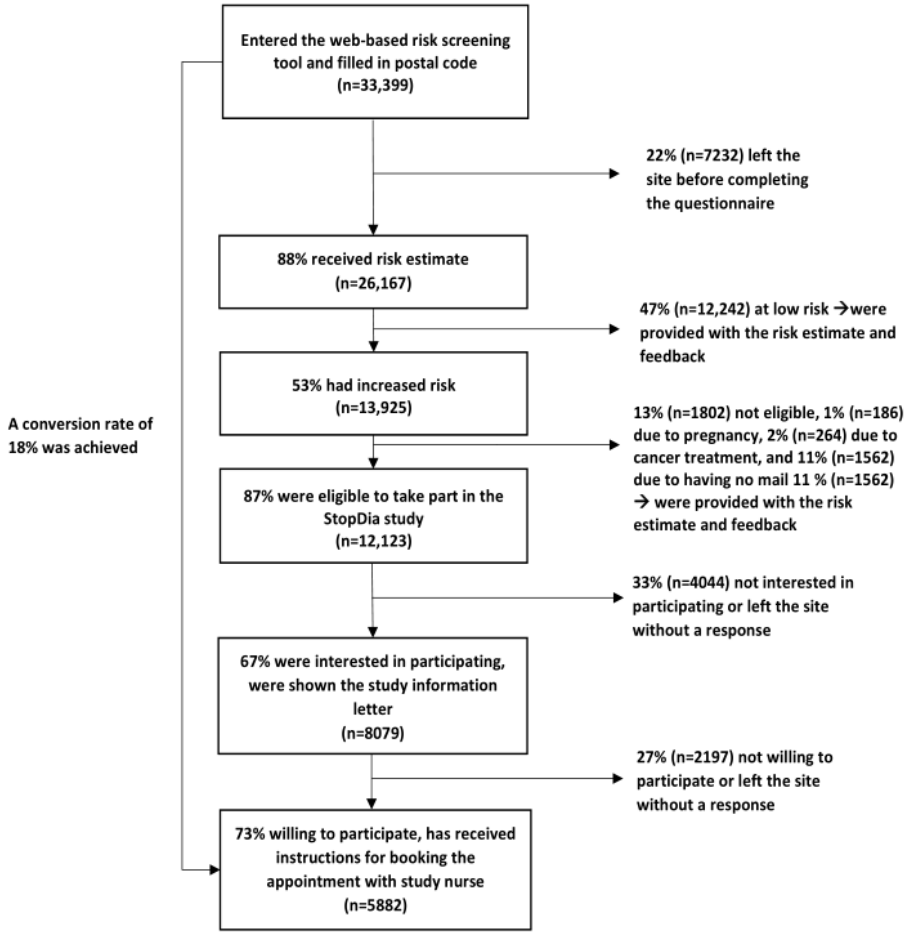
In total, 33,399 persons with a postal code matching the study area started filling in the web-based risk screening tool.

Of these, 23.45% (7832/33,399) left the site without entering enough information to obtain a T2D risk estimate. The most frequently omitted question was waist circumference (n=3932).

Of the respondents who completed the questionnaire, 53.22% (13,925/26,167) had an increased T2D risk. On the basis of the eligibility criteria of the StopDia RCT, 12.94% (1802/13,925) respondents with increased risk were excluded, and the most common reason for exclusion was not having an email address (1562/13,925, 11.21%). Of these excluded respondents without email, 37.26% (582/1562) were men and 52.37% (818/1562) had low education, and their mean FINDRISC score was 15.3 (SD 3.2).

Altogether, 12,123 respondents were deemed eligible to participate and were asked whether they would *be interested* in taking part in the StopDia study. A total of 66.64% (8079/12,123) of the eligible, responded as being interested, and of them 72.8% (5882/8079) expressed their willingness and asked for instructions to participate in StopDia. The conversion rate of our recruitment process from reach to willingness to participate was 17.61% (5882/33,399).

Figure 6. Flow diagram depicting the respondents' progression through the stepwise StopDia web-based risk screening tool. Conversion rate is the proportion of persons who were willing to participate (n=5882) of those who entered the web-based risk screening tool (n=33,399).

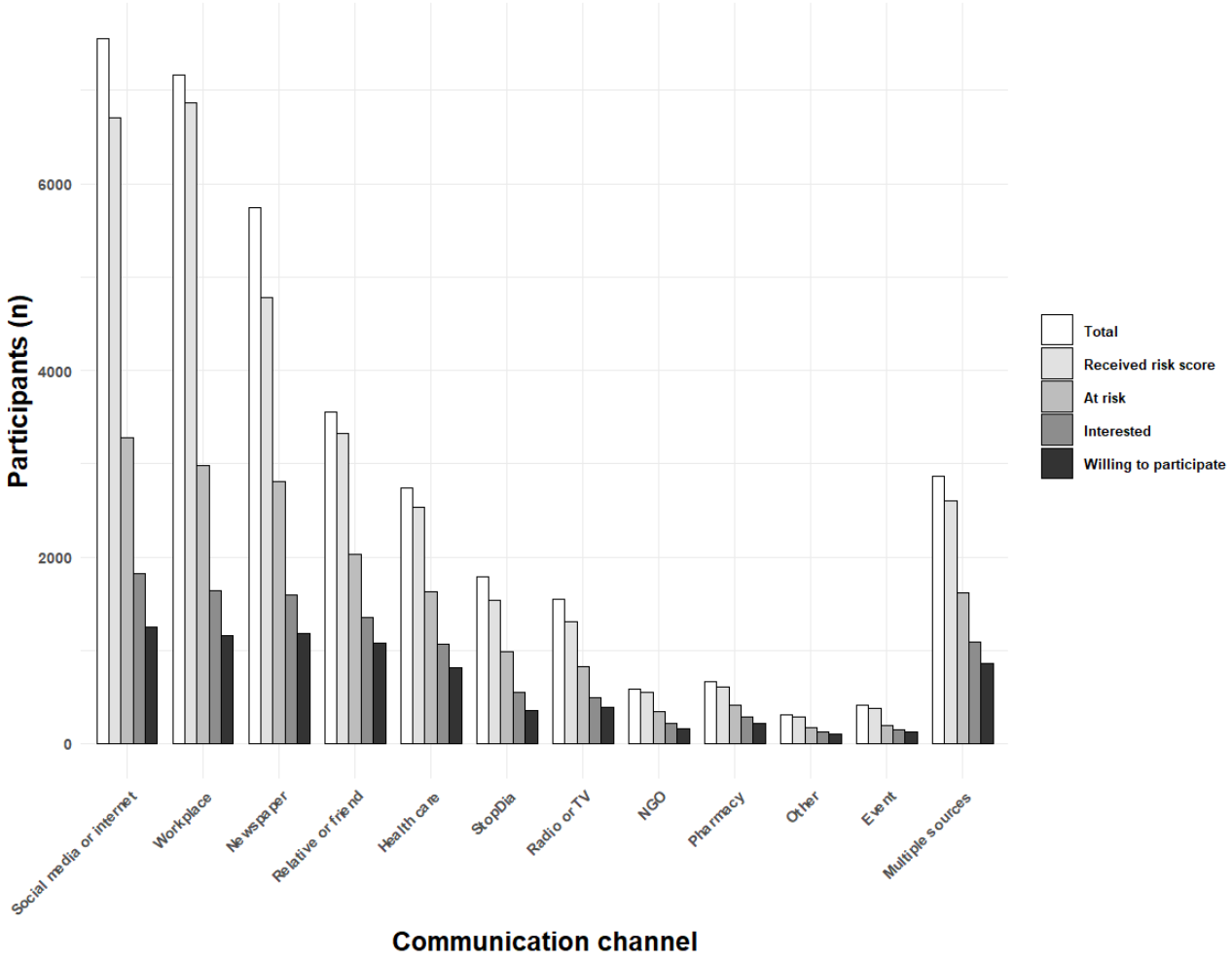


Comparison of the Reach and Yield of Different Communication Channels

A total of 28,756 respondents named at least one communication channel through which they had learned about StopDia. Of these, 8.86% (2546/28,756) named two communication channels and 1.12% (323/28,756) named three or more communication channels.

The largest number of respondents were engaged via social media, workplaces, and newspapers (Figure 7), and the least frequently mentioned channels were events, NGOs, and pharmacies. Consequently, the highest absolute number of people at risk and interested in participating in the StopDia study were reached via social media, workplaces, and newspapers. Many individuals at increased risk were also reached through relatives and friends and via multiple communication channels.

Figure 7. The number of participants progressing through the different steps of the risk screening tool. NGO: nongovernmental organization; TV: television.



The effectiveness of different communication channels to get people to progress through the StopDia web-based risk screening tool, receive a risk estimate, and eventually become interested in participating is presented as odds ratios (ORs), with workplace as the reference channel, as shown in Table 2. People who reached through workplaces were most likely to complete the risk screening and get an estimate of their risk, followed by NGOs and a relative or a friend. The least effective channels in this regard were newspapers and radio or television (TV). Multiple communication channels as well as health care services and pharmacies were less effective in prompting the respondents to fill in enough information to receive the risk estimate compared with the reference channel.

Table 2. Communication channel and likelihood (odds ratio) of progressing through the StopDia risk screening tool.

Communication channel	Filled in the questionnaire and received risk estimate, OR[a] (95% CI)	At risk, OR (95% CI)	Eligible (if at risk), OR (95% CI)	Interested to participate (if eligible), OR (95% CI)	Agreed to participate (if interested), OR (95% CI)
Workplace	Reference	Reference	Reference	Reference	Reference
Event	0.44 (0.28-0.72)	1.31 (1.00-1.72)	1.18 (0.90-1.53)	12.04 (4.49-49.2)	1.14 (0.72-1.78)
Social media and internet	0.34 (0.29-0.39)	1.28 (1.19-1.38)	1.05 (0.97-1.13)	1.68 (1.45-1.96)	1.34 (1.15-1.56)
Newspaper	0.21 (0.18-0.24)	1.83 (1.69-1.98)	1.21 (1.12-1.31)	2.06 (1.74-2.43)	0.67 (0.57-0.80)
Pharmacy	0.50 (0.35-0.73)	2.86 (2.31-3.53)	2.11 (1.74-2.56)	3.67 (2.43-5.81)	1.74 (1.29-2.35)
Radio or television	0.22 (0.18-0.27)	2.30 (2.00-2.64)	1.42 (1.25-1.61)	2.13 (1.63-2.82)	2.25 (1.78-2.84)
Relative or friend	0.73 (0.59-0.91)	2.08 (1.89-2.30)	1.84 (1.67-2.03)	2.98 (2.43-3.68)	1.92 (1.62-2.29)
Health care	0.54 (0.43-0.67)	2.41 (2.15-2.70)	1.81 (1.62-2.01)	3.00 (2.38-3.79)	1.84 (1.52-2.22)
StopDia	0.25 (0.20-0.30)	2.32 (2.04-2.65)	1.38 (1.22-1.56)	1.29 (1.02-1.62)	1.56 (1.23-1.97)
NGO[b]	0.88 (0.52-1.64)	2.59 (2.00-3.36)	2.28 (1.79-2.91)	2.94 (1.82-5.03)	1.44 (0.99-2.10)
Other	0.50 (0.39-0.65)	1.32 (1.16-1.51)	1.17 (1.03-1.33)	1.60 (1.24-2.09)	2.24 (1.74-2.89)
Multiple channels[c]	0.39 (0.33-0.47)	2.31 (2.09-2.54)	1.80 (1.64-1.97)	3.00 (2.46-3.67)	1.74 (1.47-2.06)

[a]OR: odds ratio.

[b]NGO: nongovernmental organization.

[c]Respondents could select or mention multiple communication channels.

Of the respondents who were provided with a risk estimate, the highest likelihood of being at increased risk was among those who were reached via pharmacies, NGOs, and health care (Table 2). Respondents who mentioned the StopDia website or personnel as communication channels were also more likely to be at increased risk. The lowest likelihood of being at an increased risk was among the respondents who were reached via workplaces. The lowest likelihood of being eligible among respondents at increased risk was among those who were reached via workplaces, events, or social media.

Eligible persons whose communication channel was the workplace were least likely to express interest in participating in the StopDia study. The most efficient communication channels in this step were events, pharmacies, health care services, a relative or friend, NGOs, and multiple communication channels. Finally, of the eligible and interested, those who mentioned radio or TV as their communication channel were most likely to and those who mentioned newspapers were least likely to be willing to participate in StopDia when offered the possibility to make an appointment with the study nurse.

Characteristics of the Respondents Reached Via Different Communication Channels

Among the 26,167 respondents who received their risk estimates, 13,925 (53.21%) were at increased risk (Table 3). The highest proportion of people at an increased risk was among those who were reached via pharmacies (415/608, 68.3%), health care (1631/2535, 64.34%), and a relative or friend (836/1306, 64.01%). Overall, 23.58% (7877/33,399) of those who received their risk estimate and 22.47% (1815/8076) of those who were interested in participating in the StopDia study were men. The proportion of men was highest among those who were reached through a relative or friend. The workplace was the least effective channel for reaching men.

Table 3. Characteristics of the respondents who received an estimate on their risk, by communication channel (n=26,167).

Communication channel	Total (n=26,167), n (%)	Men, n (%; 95% CI[a])	Age (years), mean (SD)	Low or middle education, n (%; 95% CI[a])	At risk, n (%; 95% CI[a])
Workplace	6871 (26.25)	1136 (16.53; 15.67-17.43)	47 (11)	1776 (25.83; 24.81-26.88)	2983 (43.41; 42.25-44.59)
Social media and internet	6712 (25.65)	2269 (33.81; 32.68-34.95)	45 (14)	2896 (44.59; 43.38-45.80)	3439 (48.76; 47.57-49.96)
Newspaper	4784 (18.28)	1616 (33.78; 32.45-35.13)	51 (13)	1931 (41.46; 40.00-42.89)	2808 (58.7; 57.29-60.08)
Relative or friend	3327 (12.71)	1428 (42.92; 41.25-44.61)	50 (14)	1504 (46.12; 44.42-47.84)	2026 (60.9; 59.23-62.54)
Health care	2535 (9.68)	2535 (28.88; 27.14-30.67)	50 (15)	1213 (48.70; 46.74-50.66)	1631 (64.34; 62.45-66.18)
StopDia	1537 (5.87)	516 (33.57; 31.25-35.97)	54 (13)	647 (44.04; 41.52-46.59)	986 (64.15; 61.72-66.51)
Radio or television	1306 (4.99)	427 (32.7; 30.21-35.29)	55 (13)	600 (46.66; 43.94-49.39)	830 (63.55; 60.91-66.12)
Pharmacy	608 (2.32)	154 (25.3; 22.0-28.9)	51 (14)	236 (39.3; 35.4-43.2)	415 (68.3; 64.5-71.8)
NGO[b]	547 (2.09)	179 (31.1; 27.5-35.1)	51 (16)	200 (36.9; 32.9-41.0)	338 (61.79; 57.65-65.77)
Event	375 (1.43)	128 (34.1; 29.5-39.1)	50 (15)	136 (36.9; 32.1-41.9)	199 (53.1; 48.0-58.1)
Other	283 (1.08)	65 (23; 18.5-28.2)	51 (13)	78 (30; 24.8-35.8)	167 (59; 53-65)
Multiple channels[c]	2602 (9.94)	789 (30.32; 28.59-32.12)	50 (13)	1045 (40.87; 38.98-42.79)	1620 (62.26; 60.38-64.10)
All	26,167 (100.00)	7866 (30; 29.51-30.62)	49 (14)	10,136 (39.77; 39.17-40.37)	13,925 (53.22; 52.61-53.82)

[a]Binomial variable CIs were calculated using the Wilson method.

[b]NGO: nongovernmental organization.

[c]Respondents could select multiple communication channels and were included in all the mentioned categories.

The mean age of all respondents and of those who were interested in participating was 49 (SD 14) years and 53 (SD 11) years, respectively (Table 4). The respondents who were reached via radio or TV were the oldest and those who were reached via social media were the youngest. The overall proportion of respondents with low or middle education was 40.8% (11,275/27,632), and among those who were interested in participating in StopDia, the proportion was 37.17% (3003/8079). The largest proportion of people with low or middle education was reached through health care and a relative or friend, and the lowest proportion, through workplaces.

Table 4. Characteristics of the respondents who were eligible and interested to participate in StopDia, by communication channel (n=8079).

Communication channel	Total (n=8079), n (%)	Men, n (%; 95% CI[a])	Age (years), mean (SD)	Low or middle education, n (%; 95% CI[a])
Workplace	1641 (20.31)	163 (9.93; 8.58-11.48)	51 (9)	384 (23.82; 21.81-25.96)
Social media and internet	1819 (22.51)	399 (22; 20.09-23.89)	50 (11)	704 (39.55; 37.30-41.84)
Newspaper	1595 (19.74)	363 (22.76; 20.77-24.88)	55 (11)	578 (36.84; 34.49-39.25)
Relative or friend	1353 (16.74)	465 (34.37; 31.88-36.94)	55 (11)	602 (44.89; 42.25-47.56)
Health care	1069 (13.23)	260 (24.32; 21.84-26.98)	54 (11)	485 (45.84; 42.86-48.85)
StopDia	544 (6.73)	147 (27; 23.5-31.0)	56 (10)	205 (38.7; 34.6-42.9)
Radio or television	487 (6.03)	128 (26.3; 22.6-30.4)	58 (9)	221 (45.8; 41.4-50.2)
Pharmacy	287 (3.55)	61 (21.7; 17.3-26.9)	54 (11)	105 (36.7; 31.3-42.4)
NGO[b]	222 (2.74)	56 (25.2; 20.0-31.3)	53 (13)	89 (40.3; 34.0-46.9)
Event	149 (1.84)	27 (18.1; 12.8-25.1)	58 (10)	49 (33.3; 26.2-41.3)
Other	121 (1.49)	23 (19; 13.0-26.9)	53 (8)	29 (27.6; 20.0-36.9)
Multiple channels[c]	1084 (13.41)	248 (22.89; 20.51-25.50)	53 (11)	400 (37.31; 34.47-40.25)
All	8079 (100.00)	1815 (22.47; 21.58-23.40)	53 (11)	3003 (37.85; 36.79-38.92)

[a]Binomial variable CIs were calculated using the Wilson method.

[b]NGO: nongovernmental organization.

[c]Respondents could select multiple communication channels and were included in all mentioned categories.

Effect of Active Versus Passive Recruitment

Of all respondents, 15.07% (5035/33,399) replied that they had been actively asked or recommended by somebody to determine their T2D risk. Active recruitment increased the likelihood of eligible respondents expressing interest in participating in StopDia, compared with passive recruitment (1808/4431, 40.8% vs 6268/19,814, 31.63%; *P*<.001). Active recruitment increased the likelihood among men (539/1638, 32.91% vs 1276/5609, 22.75%; *P*<.001) and among women (1269/2972, 45.45% vs 4992/14,204, 35.15%; *P*<.001) and across educational levels (low: 164/1788, 9.17% vs 536/6143, 8.72%; *P*=.01; middle: 608/1788, 34% vs 1695/6143, 27.59%; *P*<.001; high: 3912/6143, 63.68% vs 1016/1788, 56.82%; *P*<.001). Sex or educational level did not modify the differences between active and passive recruitment.

Discussion

Principal Findings

This study compared different communication channels with regard to their ability to reach people who are at risk of developing T2D and to engage them to take part in a T2D prevention study. A wide spectrum of channels was used, and some of them applied modern approaches, such as social media. The conversion rate (proportion of those who were eligible and willing to participate from the total number reached) of our recruitment (5882/33,399, 17.61%) was close to the rate achieved via recruitment through workplaces and media in previous eHealth studies [38].

Of those individuals who completed the web-based screening tool, 53.21% (13,925/26,167) were at risk, 30.01% (7877/26,167) were men, and 39.77% (10,136/25,485) had low or middle education. The largest absolute number of persons reached altogether and at risk was through social media and the internet, workplace, and newspapers. The proportion of at-risk people was the highest among those reached via community pharmacies (415/608, 68.3%) and health care (1631/2535, 64.33%).

A relative or friend was the communication channel that reached the largest percentage of men who were interested in participating in StopDia (1353/3979, 34%). Health care (578/1069, 54.07%) and radio or TV (225/487, 46.2%) reached the largest proportion of interested persons with lower education.

The PIPE framework provides steps that should be considered when designing and evaluating disease prevention programs [13]. Important indicators are *penetration* (the proportion of target group reached) and *participation* (the proportion of invited people who participated in the intervention). Of the residents aged 18-70 years in the study areas of North Savo (population 165,325), South Karelia (population 86,541) and Päijät-Häme (population 133,575) [39], a total of 33,399 people used our StopDia digital screening tool during the study period. This accounted for 8.67% (33,399/385,411) of the target population in these areas. On the basis of findings from a population-based survey [40], we can estimate that 1 in 4 adults (approximately 96,360) in these areas are at an increased risk of T2D. Consequently, we can calculate that our screening strategy managed to reach up to 14.44% (13,925/96,360) of the population at risk in the study areas within one year. Furthermore, of those who completed the screening, 53.21% (13,925/26,167) were at increased risk, which is twice as many as estimated in the general population. This suggests that our targeted communication strategy was able to reach the population segment at risk.

On the basis of our results, the selection of the most appropriate communication channels clearly depends on the primary goal of the outreach strategy. If the aim is to increase awareness among the general population, channels that reach the largest number of people should be used. If the aim is to find people at risk and engage them in preventive interventions, more personalized approaches may be useful. The largest number of respondents was obtained via social media, workplaces, and newspapers. These channels were thus effective in increasing population knowledge on the ongoing StopDia lifestyle intervention RCT and T2D risk factors in general. However, the proportion of people at risk among those reached via these channels was much smaller than that reached through pharmacies and health care. Workplace campaigns conducted via email can be especially effective in engaging people to test their risk, but they are not likely to reach those most at risk, thus decreasing health disparities [14].

In the planning phase, we assumed that health care providers and pharmacies would be the most important recruitment channels by incorporating opportunistic screening into their everyday activities. Therefore, we established an active network with local health care operators, produced and printed many materials, and organized training sessions for service providers and information days in pharmacies. This phase of organizational engagement is considered a pivotal part of this process [38,41]. However, it proved to be a challenge to integrate screening activities into the everyday work of health care professionals, and thus, the total number of respondents reached via these channels was low. On the other hand, among the people who were reached via health care and pharmacies, the proportion of individuals who had an increased risk for T2D and who were more likely to be interested in participating was the highest. Therefore, health care and pharmacy services could be important collaborators in targeted screening, but they cannot replace other channels that can reach other important population groups, such as people who use health care services infrequently. Thus, our findings suggest that risk screening should be a joint effort between different sectors of society, and it cannot be covered by the health care sector only. In addition, increasing public awareness and risk screening should be included in the health care sector as a defined function, as it proved to be a challenge to implement it as part of the existing services. It is important to consider that it also requires new skills from health care professionals, such as communication and marketing.

Interestingly, relatives and friends proved to be an important communication channel, especially for men, although the primary channel where the relatives themselves had received information about the StopDia project was not known. For example, our social media campaign “Have you seen this man?” aiming to reach men at T2D risk, produced a temporal peak in our screening tool visits, with most of the respondents being

men. The valuable role of relatives and friends should be acknowledged while choosing channels and formulating recruitment messages in future campaigns.

Another a priori assumption was that personal prompting from somebody, such as a relative or a health care professional, would increase the likelihood of being interested in participating, as reported in a previous study [42]. This assumption was also true in our study. However, activities that required the study personnel to be present, such as community events and fairs, had very low overall reach and yield.

Our results also suggest that being exposed to the recruitment message via several communication channels increases interest in participation, compared with, for example, single media. Similar results have been observed in other large-scale lifestyle intervention recruitment studies [43]. Amplifying the reach of the message using multiple opportunistic approaches, such as recruitment through social media and journalistic media coverage, has been reported to be promising in the existing literature [44]. In general, formulating inclusive recruitment messages is crucial, especially in reaching the hard-to-reach populations [45]. Using an informal, warm tone of voice and relatable characters in promotional videos could have contributed to the success of the digital marketing efforts of our study.

Digital communications via social media may offer new ways to reach people who are often underrepresented in health interventions, such as the less-educated population groups and men [42,46]. Diabetes prevention research conducted in Australia, on the other hand, reported meager success in social media marketing [43]. Our results suggest that low threshold information delivered via digital channels is an efficient way to engage people with lower socioeconomic status. Lack of email address (or unwillingness to reveal it) may still be an important barrier for participation in interventions, including a digital component, especially among non–office-going men. Up to 12.94% (1802/13,925) of respondents at risk were deemed ineligible to participate in the StopDia study, and of them, 3 out of 4 were deemed ineligible because of a lack of email address. Among them, 37.01% (667/1802) of men and 47% (847/1802) of people with lower education were overrepresented, and their mean FINDRISC score was higher than that of all respondents (15.3 vs 12.0). This is an important finding, as men and less-educated people are in danger of being sidetracked in the future when new digital tools replace the traditional screening and intervention models. Thus, people from low socioeconomic groups might need financial aid to participate in prevention activities.

It must also be taken into account that part of the population faces difficulties with digital services and the most vulnerable people can lack internet access altogether; for example, 19% of Finnish persons with only a basic level of education have never used the internet [47]. In member states of the European Union, 43% of the population is reported to have less than basic digital skills [48].

Health policies and interventions can have greater efficacy among those with higher education than those with lower education [14,49]. There is also accumulating evidence that so-called high-agency population interventions based on traditional media campaigns and leaflets are likely to reinforce socioeconomic inequalities in health [50]. On the other hand, there seems to be no difference in the effectiveness of prevention interventions between educational groups, as long as they are reached and are participating in the programs [18,51]. On the basis of the results of our recruitment strategy, we now have useful information on ways to reach these underserved population groups.

The FINDRISC questionnaire was originally developed for use by both health care personnel and by people themselves, as a quick and simple tool to assess one's risk of developing T2D within 10 years of age. Our study showed that the FINDRISC questionnaire can be used as a web-based tool to screen and recruit participants in a T2D prevention study. Not surprisingly, the FINDRISC question that was most often omitted was waist circumference, probably because people tend not to own a measuring tape. We were anticipating this and tried to overcome the problem by printing and distributing copious measuring tapes with FINDRISC printed on the reverse side, for example, in local pharmacies and exercise facilities. In the future, the necessity of waist circumference measurement in a web-based screening tool should be weighed against its effect on the test completion rate.

The most important caveat in our recruitment strategy was that we were not able to contact the respondents but had to rely on them being proactive in making the appointment with the study nurse, either over the phone or using a web-based system, depending on the area. As StopDia was a clinical trial, we could not collect any contact information from the respondents before they had signed an informed consent face-to-face with the study nurse. Of the eligible respondents, 48.52% (5882/12,123) were willing to participate in the StopDia study; however, only 3271 people attended the RCT baseline visit, of whom 11.07% (362/3271) were found to have previously undiagnosed T2D and were thus excluded from the StopDia RCT [52]. The number of randomized participants in the StopDia RCT was 2909, which is less than half of the number eligible and willing based on the screening site data. Even though the proportion is in line with findings from other studies [53,54], in future programs, special attention should be given to making the path from risk identification to intervention recruitment as smooth and effortless as possible, to improve the uptake of interventions at this important *window of opportunity* [55].

The strengths and limitations of our study must be addressed. Our study complements the scarce knowledge on the effectiveness of traditional marketing and digital campaigns to recruit participants representing different population groups in a T2D prevention study. We were able to reach a large proportion of the target population, and the ample data on real-life screening processes provide a rich source of research. The findings from the stepwise screening process are readily usable in prevention implementation programs.

As we were using a web-based screening tool with self-reported data, we saw a relatively large number of entries that were not completed, 21.66% (7232/33,399) of all respondents or where the entered data were not plausible. In addition, multiple

responses from the same IP address were allowed, as the same device might be used by several people, for example, members of the same family or users of public service desks. It is thus likely that we may have had multiple answers from the same respondents included in the data. These limitations need to be considered when interpreting the results.

Importantly, we had no objective data on the communication channel and had to rely on respondents' answers. The free-text answers to the communication channel question were not always clear, and the categorization into one of our selected categories was sometimes arbitrary. However, free-text answers were provided by only 4.84% (1616/33,399) of all persons who named a communication channel.

Conclusions

We investigated the effectiveness of a large-scale traditional and digital marketing campaign to recruit participants in a T2D prevention study. With a comprehensive communication strategy that used several recruitment channels, we were able to reach a significant proportion of people with increased T2D risk in the study areas. Channels, such as social media and newspapers, that reach many people proved to be the most effective in risk identification. On the other hand, more personalized approaches increased the engagement of usually underrepresented groups, such as men and less-educated people. Health care services and pharmacies have reached people with a particularly high T2D risk. To increase recruitment and study enrollment, the screening path should be as smooth and effortless as possible for the user, avoiding transition points that will lead to the loss of eligible participants. To ensure the large-scale implementation of risk identification followed by preventive interventions, it is important to apply multiple different tactics to reach the target population as part of the existing service system.

Acknowledgments

The authors acknowledge all the people, including health and social care workers and pharmacists in the three StopDia counties, who participated in the recruitment, as well as stakeholders who supported the activities (cities of Kuopio, Varkaus, and Siilinjärvi; Ylä-Savon SOTE; Finnish Heart Association; Finnish Diabetes Association; and Association of Finnish Pharmacies). The authors also thank Kennet Harald for his help in performing statistical analyses and acknowledge Juha Kekäläinen and Juho Viitasalo for their work in the development of the StopDia digital tools and Terhi Seppälä, Marko Uutela, Tiina Laatikainen, Markku Peltonen, Saara Vanhatalo (née Pentikäinen), and Johanna Leväsluoto for participating in the design of the communication strategy. The authors are also grateful to the representatives of the target group for their valuable contributions to the study.

STOP DIABETES—from knowledge to solutions, this project is funded by the Strategic Research Council at the Academy of Finland [56] in 2016-2019 (grant 303537). The Academy of Finland also partly funded the project T2D-DATA (grant 322466) that supported the publication of this paper. The Academy of Finland had no role in designing the study; collecting, managing, or analyzing the data; interpreting the results; writing the manuscript; or deciding to submit the manuscript for publication. This study was partially funded by the Association of Finnish Pharmacies. The funding body had no role in designing the study, data collection, analysis, interpretation of the data, or writing of the manuscript.

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Conflicts of Interest

JM is a founding partner of ESiOR Oy and a board member of Siltana Oy. EA has received a consulting fee from Merck & Co. These companies were not involved in conducting this study.

Multimedia Appendix 1
StopDia recruitment campaign communications outputs and reach.
[PDF File (Adobe PDF File), 71 KB - diabetes_v6i3e21356_app1.pdf]

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Abbreviations

FINDRISC: Finnish Diabetes Risk Score
NGO: nongovernmental organization
PIPE: Penetration, Implementation, Participation, and Effectiveness
RCT: randomized controlled trial
T2D: type 2 diabetes
TV: television

Edited by R Kukafka, C Richardson; submitted 19.06.20; peer-reviewed by K Reuter, C Ledford; comments to author 01.10.20; revised version received 26.11.20; accepted 13.07.21; published 09.09.21.

Please cite as:
Jalkanen K, Järvenpää R, Tilles-Tirkkonen T, Martikainen J, Aarnio E, Männikkö R, Rantala E, Karhunen L, Kolehmainen M, Harjumaa M, Poutanen K, Ermes M, Absetz P, Schwab U, Lakka T, Pihlajamäki J, Lindström J, The StopDia Study Group
Comparison of Communication Channels for Large-Scale Type 2 Diabetes Risk Screening and Intervention Recruitment: Empirical Study
JMIR Diabetes 2021;6(3):e21356
URL: https://diabetes.jmir.org/2021/3/e21356
doi:10.2196/21356
PMID:34499036

Publisher:
JMIR Publications
130 Queens Quay East.
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