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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 A₁c (HbA₁c) 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; HbA₁c 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 HbA₁c decreased from 7.6% to 7.0% (P=.004). There were no severe hypoglycemia events.
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

Conclusions: The personalized mHealth program was feasible, acceptable, and produced significant reductions in HbA1c (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.

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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

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(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/m² to 26.7 kg/m² (P<.001).

Conclusions: The personalized mHealth program was feasible, acceptable, and produced significant reductions in HbA1c (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.

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Introduction

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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].

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Methods

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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 (HbA1c) ≥ 6.5% in the past 1 year or if they were on medication for type 2 diabetes, or (2) prediabetes, if they had an HbA1c 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 (HbA1c) 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 HbA1c, 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 HbA1c 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 HbA1c 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 the 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 HbA1c, weight, and BMI, the patients were further split for subgroup analyses: (1) by baseline HbA1c ≤7% or >7%, and (2) by baseline BMI<27.5 kg/m² (normal and overweight) or ≥27.5 kg/m² (obese). The HbA1c cut-off was selected based on the HbA1c 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=0.05. 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=0.05. 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=0.23; gender: P=0.21; ethnicity: P>0.99; diabetes status category: P=0.52, medication adjustment category: P=0.65; HbA1c category: P=0.69; BMI: P>0.99) 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\textsubscript{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.

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

\textsuperscript{a}HbA\textsubscript{1c}: glycated hemoglobin.  
\textsuperscript{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\textsubscript{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\textsuperscript{2} to 26.7 kg/m\textsuperscript{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.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Visit 1, mean (SD)</th>
<th>Visit 2, mean (SD)</th>
<th>(P) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA(_1c) (%)</td>
<td>7.6 (1.1)</td>
<td>7.0 (0.8)</td>
<td>.004</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>76.8 (15.6)</td>
<td>73.9 (13.8)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>BMI (kg/m(^2))</td>
<td>27.8 (5.4)</td>
<td>26.7 (4.8)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

\(^a\)HbA\(_1c\): glycated hemoglobin.
\(^b\)BMI: body mass index.

Subgroup Analyses by Baseline HbA\(_1c\) Category

For patients who had baseline HbA\(_1c\) \(\leq 7\%\), 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\(_1c\) \(\leq 7\%\) or >7\%.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Baseline HbA(_1c) (\leq 7%) (n=7)</th>
<th>Baseline HbA(_1c) &gt;7% (n=14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA(_1c) (%)</td>
<td>6.7 (0.3)</td>
<td>8.1 (1.0)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>75.0 (13.5)</td>
<td>73.0 (12.2)</td>
</tr>
<tr>
<td>BMI (kg/m(^2))</td>
<td>26.8 (5.1)</td>
<td>28.3 (5.7)</td>
</tr>
</tbody>
</table>

\(^a\)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 \(\geq 27.5\) kg/m\(^2\) (obese).

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Normal and overweight (n=11)</th>
<th>Obese (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA(_1c) (%)</td>
<td>7.7 (1.3)</td>
<td>7.6 (0.9)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>65.5 (8.7)</td>
<td>64.6 (8.1)</td>
</tr>
<tr>
<td>BMI (kg/m(^2))</td>
<td>23.5 (2.1)</td>
<td>32.5 (3.6)</td>
</tr>
</tbody>
</table>

\(^a\)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 HbA₁c in 3 months, ending the program with an average HbA₁c of 7%. Reduction of HbA₁c 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 HbA₁c 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 HbA₁c or higher BMI would yield greater improvements in both HbA₁c 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 HbA₁c 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 HbA₁c 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**

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**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.

References


Abbreviations

BMI: body mass index
CGM: continuous glucose monitoring
HbA1c: glycated hemoglobin A1c
mHealth: mobile health

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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 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

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**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.
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
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.

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.

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.

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.
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>
<thead>
<tr>
<th>Table 1. Costs associated with each recruitment method used in the study.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruitment stage</td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td>Start-up</td>
</tr>
<tr>
<td>Display advertisement</td>
</tr>
<tr>
<td>Provide more information to inquirers</td>
</tr>
<tr>
<td>Screening session with responsive volunteers</td>
</tr>
</tbody>
</table>

---

**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 (HbA1c) 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 HbA1c 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 HbA1c 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/m² were considered obese. Values within 3.0 kg/m² 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 α<.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).
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.

<table>
<thead>
<tr>
<th>Recruitment metric</th>
<th>Gender</th>
<th>Age (years)</th>
<th>Time relative to the pandemic</th>
<th>Day of the week</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Men</td>
<td>Women</td>
<td>18-34</td>
<td>35-64</td>
</tr>
<tr>
<td>Facebook costs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated target audience, n</td>
<td>6300</td>
<td>11,700</td>
<td>4400</td>
<td>13,700</td>
</tr>
<tr>
<td>Money spent, US $</td>
<td>192.22</td>
<td>134.95</td>
<td>28.60</td>
<td>306.84</td>
</tr>
<tr>
<td>Impressions, n</td>
<td>18,655</td>
<td>9521</td>
<td>3264</td>
<td>23,872</td>
</tr>
<tr>
<td>Cost per impression, US $</td>
<td>0.010</td>
<td>0.014</td>
<td>0.009</td>
<td>0.013</td>
</tr>
<tr>
<td>Unique viewers, n</td>
<td>6765</td>
<td>4924</td>
<td>1331</td>
<td>9652</td>
</tr>
<tr>
<td>Cost per unique viewer attracted, US $</td>
<td>0.028</td>
<td>0.027</td>
<td>0.021</td>
<td>0.032</td>
</tr>
<tr>
<td>Clickers, n (% of unique viewers)</td>
<td>116 (1.7)</td>
<td>156 (3.2)^c</td>
<td>32 (2.4)</td>
<td>242 (2.5)</td>
</tr>
<tr>
<td>Cost per click attracted, US $</td>
<td>1.66</td>
<td>0.97</td>
<td>0.89</td>
<td>1.34</td>
</tr>
<tr>
<td>Completers of webform, n (% of clickers)^f</td>
<td>14 (12.1)</td>
<td>18 (11.5)</td>
<td>7 (21.9)</td>
<td>25 (10.3)</td>
</tr>
<tr>
<td>Responsive volunteers, n (% of clickers)^f</td>
<td>9 (7.8)</td>
<td>11 (7.1)</td>
<td>3 (9.4)</td>
<td>17 (7.0)</td>
</tr>
<tr>
<td>Cost per responsive volunteer attracted, US $</td>
<td>21.36</td>
<td>12.27</td>
<td>9.53</td>
<td>18.05</td>
</tr>
<tr>
<td>Eligible volunteers, n (% of responsive volunteers)^g</td>
<td>4 (44.4)</td>
<td>4 (36.4)</td>
<td>1 (33.3)</td>
<td>7 (41.2)</td>
</tr>
<tr>
<td>Cost per eligible volunteer attracted, US $</td>
<td>48.06</td>
<td>33.74</td>
<td>28.60</td>
<td>43.83</td>
</tr>
<tr>
<td>Other costs, US $</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Start-up^b</td>
<td>94.88</td>
<td>94.88</td>
<td>94.88</td>
<td>94.88</td>
</tr>
<tr>
<td>Contacting webform completers</td>
<td>37.80</td>
<td>48.60</td>
<td>18.90</td>
<td>67.50</td>
</tr>
<tr>
<td>Screening responsive volunteers for eligibility</td>
<td>72.90</td>
<td>89.10</td>
<td>24.30</td>
<td>137.70</td>
</tr>
<tr>
<td>Total costs: cost per eligible volunteer enrolled, US $</td>
<td>99.45</td>
<td>91.88</td>
<td>166.68</td>
<td>86.70</td>
</tr>
</tbody>
</table>

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 =25.9, P<.001) and before vs during pandemic (χ^2 =32.9, P<.001), but not different by age (χ^2 =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: Barnard test P=.99; age: Barnard test P=.11; time: Barnard test P=.44; weekday vs weekend: Barnard test P=.18).

f Proportion of clickers volunteering (called conversion in the literature). It was not different by any of the categories (gender: Barnard test P=.99; age: Barnard test P=.89; time: Barnard test P=.43; weekday vs weekend: Barnard test P=.53).

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.

<table>
<thead>
<tr>
<th>Recruitment metric</th>
<th>Recruitment method</th>
<th>Snowball sampling</th>
<th>Other methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days of action, n</td>
<td>News feed</td>
<td>20</td>
<td>271</td>
</tr>
<tr>
<td></td>
<td>Clinic</td>
<td>27</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Snowball sampling</td>
<td>48</td>
<td></td>
</tr>
</tbody>
</table>

**Direct incremental marketing costs**

- **Money spent, US $**
  - News feed: 328.85
  - Clinic: 672.40
  - Snowball sampling: 0.00
  - Other methods: 0.00

- **Impressions, n**
  - News feed: 28,274
  - Clinic: 40
  - Snowball sampling: N/A
  - Other methods: N/A

- **Cost per impression, US $**
  - News feed: 0.012
  - Clinic: 16.81
  - Snowball sampling: 0.00
  - Other methods: 0.00

- **Unique viewers, n**
  - News feed: 11,738
  - Clinic: 40
  - Snowball sampling: N/A
  - Other methods: N/A

- **Cost per unique viewer attracted, US $**
  - News feed: 0.028
  - Clinic: 16.81
  - Snowball sampling: 0.00
  - Other methods: 0.00

- **Inquirers**, n (% of unique viewers)
  - News feed: 274 (2.3)
  - Clinic: 32 (80.0)
  - Snowball sampling: 13 (2.3)
  - Other methods: 4 (0.0)

- **Cost per inquirer attracted, US $**
  - News feed: 1.20
  - Clinic: 21.01
  - Snowball sampling: 0.00
  - Other methods: 0.00

- **Completers of webform, n (% of inquirers)**
  - News feed: 32 (11.7)
  - Clinic: N/A
  - Snowball sampling: N/A
  - Other methods: N/A

- **Responsive volunteers**, n (% of inquirers)
  - News feed: 20 (7.3)
  - Clinic: 20 (62.5)
  - Snowball sampling: 12 (92.3)
  - Other methods: 5 (71.4)

- **Cost per responsive volunteer attracted, US $**
  - News feed: 16.44
  - Clinic: 33.62
  - Snowball sampling: 0.00
  - Other methods: 0.00

- **Eligible volunteers**, n (% of responsive volunteers)
  - News feed: 8 (40.0)
  - Clinic: 2 (10.0)
  - Snowball sampling: 8 (66.7)
  - Other methods: 2 (40.0)

- **Cost per eligible volunteer attracted, US $**
  - News feed: 41.11
  - Clinic: 336.20
  - Snowball sampling: 0.00
  - Other methods: 0.00

**Other costs, US $**

- **Start-up**
  - News feed: 189.76
  - Clinic: 32.38
  - Snowball sampling: 32.38
  - Other methods: 16.19

- **Contacting and explaining study to inquirers**
  - News feed: 86.40
  - Clinic: 92.80
  - Snowball sampling: 35.10
  - Other methods: 18.90

- **Screening responsive volunteers for eligibility**
  - News feed: 162.00
  - Clinic: 162.00
  - Snowball sampling: 97.20
  - Other methods: 40.50

**Total costs: cost per eligible volunteer enrolled, US $**

- News feed: 95.88
- Clinic: 479.79
- Snowball sampling: 20.59
- Other methods: 34.92

---

- **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: χ²₁=919.8, P<.001; responsive volunteers: χ²₁=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**: 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 HbA₁c above target (ie, HbA₁c ≥ 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, HbA₁c meeting target, and obesity. Division by recruitment methods revealed that news feed advertising overrepresented obesity and older age, whereas snowball sampling overrepresented HbA₁c 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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Full enrolled cohort (N=20)</th>
<th>Subset enrolled from news feed (n=8)</th>
<th>Subset enrolled from snow-ball sampling (n=8)</th>
<th>Normative data from T1D Exchange Registry, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>95% CI of %</td>
<td>n (%)</td>
<td>95% CI of %</td>
</tr>
<tr>
<td>Age (≥50 years)</td>
<td>9 (45)</td>
<td>23-68</td>
<td>6 (75)</td>
<td>35.97b</td>
</tr>
<tr>
<td>Sex (female)</td>
<td>11 (55)</td>
<td>32-77</td>
<td>5 (63)</td>
<td>24-91</td>
</tr>
<tr>
<td>Race or ethnicity (Caucasian)</td>
<td>19 (95)</td>
<td>75-100</td>
<td>8 (100)</td>
<td>63-100</td>
</tr>
<tr>
<td>Education (bachelor’s degree or higher)</td>
<td>14 (70)</td>
<td>46-88</td>
<td>6 (75)</td>
<td>35-97</td>
</tr>
<tr>
<td>Advantaged income (≥US $50,000)</td>
<td>17 (85)</td>
<td>62-97</td>
<td>6 (75)</td>
<td>35-97</td>
</tr>
<tr>
<td>Pump therapy</td>
<td>17 (85)</td>
<td>62-97</td>
<td>7 (88)</td>
<td>47-100</td>
</tr>
<tr>
<td>Continuous glucose monitor use</td>
<td>20 (100)</td>
<td>83-100b</td>
<td>8 (100)</td>
<td>63-100b</td>
</tr>
<tr>
<td>Duration of diabetes (&lt;10 years)</td>
<td>7 (35)</td>
<td>15-59</td>
<td>2 (25)</td>
<td>3-65</td>
</tr>
<tr>
<td>Hemoglobin A1c (≥7.0%)</td>
<td>12 (60)</td>
<td>36-81b</td>
<td>7 (88)</td>
<td>47-100</td>
</tr>
<tr>
<td>Low exercise (&lt;0.5 days/week)</td>
<td>10 (50)</td>
<td>27-73b</td>
<td>3 (38)</td>
<td>9-76</td>
</tr>
<tr>
<td>Obesity (BMI ≥30.0 kg/m²)</td>
<td>10 (50)</td>
<td>27-73b</td>
<td>7 (88)</td>
<td>47-100b</td>
</tr>
<tr>
<td>Uncontrolled blood pressure</td>
<td>4 (20)</td>
<td>6-44</td>
<td>1 (13)</td>
<td>0-53</td>
</tr>
</tbody>
</table>

aThe enrolled cohort and each subset were compared against normative data but not each other.

bThe 95% CI of the study cohort or subset does not include normative value, indicating bias.

cTaken 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 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 HbA1c) 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 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 volunteered 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 (HbA1c ≥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 HbA1c, 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).

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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 ]

References


9. 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.


Abbreviations

- **CGM**: continuous glucose monitor
- **HbA1c**: hemoglobin A1c
- **PI**: principal investigator
- **REDCap**: Research Electronic Data Capture
- **T1D**: type 1 diabetes
- **VA**: Veterans Affairs

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