A Mobile Phone-based Program to Promote Healthy Behaviors among Adults with Prediabetes who Declined Participation in Free Diabetes Prevention Programs: A Pilot Randomized Controlled Trial

Dina H. Griauzde MD, MS¹,²,³; Jeffrey T. Kullgren MD, MS, MPH¹,²,³; Brad Liestenfeltz BSN, RN⁴; Tahoora Ansari MPH⁵; Emily H. Johnson BS²; Allison Fedewa MS⁶; Laura R. Saslow PhD⁴; Caroline Richardson MD²,³; Michele Heisler MD, MPA¹,²,³,⁵

¹ VA Center for Clinical Management Research, VA Ann Arbor Healthcare System, Ann Arbor, Michigan
² University of Michigan Medical School, Ann Arbor, Michigan
³ University of Michigan Institute for Healthcare Policy and Innovation, Ann Arbor, Michigan
⁴ University of Michigan School of Nursing, Ann Arbor, Michigan
⁵ University of Michigan School of Public Health, Ann Arbor, Michigan
⁶ University of Michigan School of Dentistry, Ann Arbor, Michigan

Corresponding Author: Dina Griauzde MD, MSc

2800 Plymouth Road, Building 14, Room G100-36, Ann Arbor, MI 48109-2800
Phone: 734-647-4844; Fax: 734-647-3301; Email: dhafez@med.umich.edu

Co-author e-mail addresses:
Jeffrey Kullgren: jkullgre@med.umich.edu
Brad Liestenfelz: bliesten@umich.edu
Tahoora Ansari: tbansari@umich.edu
Emily Johnson: ehjohnso@med.umich.edu
Allison Fedewa: fedewaa@umich.edu
Caroline Richardson: caroli@med.umich.edu
Michele Heisler: mheisler@med.umich.edu

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**Background:** Despite evidence that Diabetes Prevention Programs (DPPs) can delay or prevent progression to type 2 diabetes mellitus (T2DM), few individuals with prediabetes enroll in offered programs. This may be in part because many individuals with prediabetes have low levels of autonomous motivation (i.e. motivation that arises from internal sources) to prevent T2DM.

**Objectives:** To examine: 1) whether adults with prediabetes who had previously declined participation in local and online DPPs that were offered at no out-of-pocket cost would agree to participate in and engage with a mobile health (mHealth) intervention designed to increase autonomous motivation for healthy behaviors; 2) to examine changes in autonomous motivation among adults offered two versions of the mHealth program compared to usual care; and 3) to assess satisfaction with and recommended changes to the program.

**Methods:** This was a 12-week, parallel, 3-arm pilot randomized controlled trial. Participants were randomized to (1) a group who received information about prediabetes and strategies to prevent T2DM (control); (2) a group who received an mHealth smartphone application that aims to increase autonomous motivation among users (app-only); or (3) a group who received the application plus a physical activity tracker and wireless-enabled digital scale for self-monitoring (app-plus). We evaluated rates of intervention uptake (number of individuals enrolled / number of individuals assessed for eligibility), retention (number of 12-week survey completers / number of participants), and adherence (number of device-usage days). Using difference-in-difference analysis, we examined change in autonomous motivation (measured using the Treatment Self-Regulation Questionnaire). We conducted post-intervention qualitative interviews with participants.

**Results:** Sixty-nine of 244 (28%) of eligible individuals were randomized. Fifty-five individuals (80%) completed the 12-week survey. Retention rates were significantly greater among app-plus participants than participants in the other two study arms combined (p=0.004, $\chi^2$). There were no significant differences in adherence rates between app-only and app-plus participants (43 days vs. 37 days; p=0.34).
Among all participants, mean autonomous motivation measures were relatively high at baseline (6.0 of 7.0 scale), and there were no statistically significant within-group or between-group differences in follow-up scores. In qualitative interviews (n=15), participants identified reasons that they enjoyed using the app (e.g. encouraged self-reflection), reasons that they did not enjoy using the app (e.g., did not consider personal circumstances), and strategies to improve the intervention (e.g., increased interpersonal contact).

**Conclusions:** Among individuals with prediabetes who did not engage in free DPP programs, this mHealth intervention was feasible and acceptable. These findings underscore the importance of developing and testing novel strategies of varying intensities and delivery modalities to meet the diverse needs and preferences of the many individuals with prediabetes who do not participate in offered formal programs. Future work should (1) examine the effectiveness of a refined intervention on clinically-relevant outcomes (e.g. weight loss) among a larger population of DPP non-enrollees with low baseline autonomous motivation and (2) identify other factors associated with DPP non-enrollment, which may serve as additional potential targets for interventions.

**Trial Registration:** NCT03025607. Registered February 2017.

**KEYWORDS:** prediabetes, type 2 diabetes mellitus, prevention, autonomous motivation, behavior change
**BACKGROUND:**

Type 2 diabetes mellitus (T2DM) is a key driver of death, disability, and healthcare spending in the United States (U.S.).\(^1,^2\) In 2015, more than 30 million U.S. adults had T2DM, while 84 million more were estimated to have prediabetes, a condition associated with an increased risk of developing T2DM.\(^1\) Diabetes Prevention Programs (DPPs) can help individuals with prediabetes to achieve modest weight loss through diet and physical activity changes that reduce the 3-year risk of developing T2DM by over 50%.\(^3,^4\) Accordingly, DPPs are now offered throughout the U.S., and a growing number of health plans,\(^5\) including Medicare,\(^6\) offer DPPs to eligible plan members at no out-of-pocket cost.

Despite widespread availability of DPPs and public health efforts that aim to increase DPP engagement, rates of program uptake remain extremely low.\(^7,^8\) To date, strategies to increase DPP uptake have targeted extrinsic barriers to participation (e.g. lack of time and cost) through provision of web-based DPPs\(^9\) and insurance coverage with limited success.\(^5,^6\) In contrast, to our knowledge, no current strategies address intrinsic barriers to participation, such as low levels of motivation to prevent T2DM, yet prior literature suggests lack of motivation may be a key barrier to DPP engagement.\(^10\) Accordingly, it is necessary to develop and test scalable approaches to help increase the motivation of the millions of Americans who have prediabetes but are not yet taking actions to reduce their risk of progression to T2DM. Such strategies may be most effective if they draw on principles from Self-Determination Theory to increase autonomous motivation (i.e. motivation that arises from internal sources and aligns with personal interests and values).\(^11,^12\) Greater levels of autonomous motivation correlate positively with dietary adherence,\(^13\) weight loss,\(^14,^15\) physical activity,\(^16,^17\) DPP participation,\(^10\) and maintenance of healthy behaviors over time.\(^18,^19\)

Mobile smartphone-based health applications (mHealth) that are easy to use and do not require a significant time commitment may be effective and highly scalable approaches to increase autonomous motivation to prevent T2DM among those with prediabetes.\(^20,^21\) One mHealth application under development, for example, promotes personal wellbeing by helping users to (1) identify their core values
(e.g. to be a good parent); (2) reflect on their adherence to these values; and (3) develop the energy and willpower to live in accordance with their core values by improving key health behaviors (e.g. sleep, physical activity, and diet). The mHealth application integrates user-entered health information with contextual data (e.g., local weather, day of the week) and then delivers brief tailored messages and health tips to help individuals gain awareness of and control over the factors in real-time that influence their ability to engage in self-care behaviors. In this way, the app helps users connect their daily habits and routines with personal interests and values, thereby strengthening autonomous motivation to engage in healthy behaviors. Yet, it is not known whether adults who have already declined participation in offered DPP programs are willing to participate in and then engage in offered mHealth programs.

Accordingly, in this 3-arm, pilot randomized controlled trial, we tested the feasibility of recruiting DPP non-enrollees into an mHealth intervention and the acceptability of the m-Health program – used alone and also in conjunction with Fitbit devices (e.g. activity tracker and wireless internet-enabled scale) to encourage self-monitoring – among individuals with prediabetes who had declined participation in online or face-to-face DPPs offered at no-out-of-pocket expense by their health plans. Because we hypothesized that autonomous motivation would be a key proximal mediator of behavior changes among those who did engage with the intervention, we also estimated the change in study participants’ autonomous motivation during the 12-week intervention period. Because Fitbit devices can also enhance motivation and self-efficacy through Self-Determination Theory principles and self-monitoring techniques, we further hypothesized that autonomous motivation to prevent T2DM would increase to a greater degree among individuals who used the application in conjunction with Fitbit devices compared to individuals who used the application alone or who were assigned to the control arm.

Methods

Design
We conducted a 12-week, parallel, 3-arm pilot randomized controlled trial between May 2017 and February 2018. Sixty-nine participants were randomized to 1 of 3 arms (Figure 1): (1) a group who received information about prediabetes and evidence-based ways to decrease progression to T2DM as well as a list of resources for mHealth tools for monitoring diet, physical activity, and weight (control group); (2) a group who received the same information as the control group and the mobile smartphone application (app-only); and (3) a group who received the same information as the control group as well as the mobile smartphone application and Fitbit devices (e.g. activity tracker and wireless internet-enabled scale) whose results were automatically synced with the mobile application and informed the application’s tailored messaging (app-plus). The protocol was approved by the University of Michigan Institutional Review Board (HUM00111389).

**Figure 1. Study flow diagram**
Setting and Participants

The intervention was delivered remotely. Inclusion criteria were: (1) non-enrollment in a DPP at least 6-months after invitation from one’s health plan to participate at no out-of-pocket cost (i.e. DPP non-enrollee); (2) prediabetes based on American Diabetes Association criteria of a hemoglobin A1c (HbA1c) level between 5.7% and 6.4%; (3) access to a personal smartphone; and (4) access to home wireless internet. We excluded women who were pregnant or intended to become pregnant during the intervention period.

We had a unique opportunity to recruit locally, as our institution’s self-funded health insurers recently began to offer face-to-face and online DPP options to health plan members (i.e. employees,
retirees, and students of the University of Michigan or their dependents) with prediabetes at no out-of-pocket cost, yet only six percent of program invitees enrolled in a DPP within the first six months (September 2015 – February 2016) of the program (unpublished communication). For this pilot study, the University’s health plans provided the study team with a random 18.5 percent sample (727/3926) of DPP non-enrollees. Additionally, we posted study recruitment information on the University’s health research website to allow interested and potentially eligible individuals to contact our team directly.24 We attempted to contact all individuals by telephone to invite them to participate in this study. Three attempts were made to contact each individual; a voicemail with the study team’s contact information was left after the second attempt. Individuals interested in study participation were screened by telephone to ensure they met study eligibility criteria, and an informed consent was obtained electronically using the RedCap survey platform.25

**Allocation**

Individuals who met study inclusion criteria, provided written informed consent, and completed a baseline questionnaire were assigned to the three study groups using 1:1:1 central computerized randomization. The allocation sequence was generated using Stata 14. A web-based tool, the University of Michigan computerized randomization system (TATUM - Treatment Assignment Tool-UM), was used to allow for blinded treatment allocation. We used stratified randomization with variable block lengths to ensure a balance of age and gender between groups. Due to the nature of the intervention, it was not possible to blind the participants. Those performing the analyses, however, were blinded to treatment assignment arms.

**Intervention**

All participants received the Center for Disease Control and Prevention’s 2-page educational handout on prediabetes and evidence-based strategies to prevent progression to T2DM as well as a list of free mHealth resources for monitoring weight and physical activity. App-only and app-plus participants
also received emailed instructions for setting up the application. App-plus participants received their Fitbit devices and set-up instructions via postal mail. A study team member was available by telephone and e-mail to answer study-related questions and to troubleshoot technical issues; there was no other planned contact between participants and study team members during the study period.

App-only and app-plus participants were asked to use the smartphone application daily to chart the following health-related habits and behaviors: (1) Sleep; (2) Presence; (3) Activity; (4) Creativity; and (5) Eating (S.P.A.C.E.). In addition to charting S.P.A.C.E. on a daily basis, users were asked to reflect on and chart their alignment with personal core values (i.e. life purpose). These charted data then informed tailored messages and health tips as well as predictions of an individual’s energy and willpower for the coming day. These predictions are intended to help individuals gain awareness of and control over the factors that influence their health behaviors. App-plus participants were also asked to use the Fitbit scale and activity tracker daily to self-monitor weight and physical activity, respectively. These devices interfaced with the application platform such that the Fitbit data informed delivered tailored messages and health tips.

Within the application, users were asked if they wished to receive a daily reminder to chart their day. Users who desired a daily reminder received a push notification at a self-selected time, which reminded them to chart their day. Users who did not desire a daily reminder received no other reminders to use the study-specific device(s).

**Quantitative Measures**

**Feasibility and Acceptability**

We evaluated the intervention’s feasibility (recruitment and retention rates) and acceptability (adherence, and qualitative experience). Program feasibility was determined by calculating the intervention uptake rate, defined as the number of participants recruited to the intervention divided by the
total number of potentially eligible participants. We also calculated the rate of intervention uptake among only those whom we reached by telephone.

To determine the study retention rate, we calculated the rate of completion of the 12-week survey among all individuals enrolled in the study.

Among app-only and app-plus participants, we measured adherence to the application, defined as the number of days that users entered data into the application during the 12-week intervention period. Among app-plus participants, we measured participant adherence to the Fitbit activity tracker and scale, defined as the number of total days that each of these devices were used during the intervention period.

**Online surveys**

Prior to randomization, individuals who consented to study participation were asked to complete an online survey via RedCap, a secure web application. This first survey was used to collect demographic and socioeconomic information including age, gender, race, ethnicity, education, and household income. We used the 7-item, validated Treatment Self-Regulation Questionnaire (TSRQ) to measure autonomous motivation to prevent T2DM. Following the 12-week intervention period, participants were emailed a link to a second survey. This survey asked participants to complete the same validated instrument that was collected at baseline. Participants were provided with a $10 gift card following completion of each survey (i.e. baseline and 12-weeks).

**Semi-structured telephone interviews**

Following the 12-week intervention period, we invited all individuals in the app-only and app-plus groups to participate in a semi-structured telephone interview. During the interviews, we explored participants’ experiences with the application and Fitbit devices, if applicable. Participants also discussed health behavior changes that occurred as a result of program participation and suggested potential
strategies to strengthen and refine the intervention. Interview participants received a $20 gift card as compensation for their time.

Sample size

Based on prior studies of autonomous motivation among University of Michigan employees,\textsuperscript{10} we anticipated that the baseline level of autonomous motivation to prevent T2DM among those who declined DPP participation after invitation by their health plan to be 5.7 (measured on a 1 to 7 scale with 1 being the lowest and 7 being the highest). During the 12-week intervention period, we anticipated that autonomous motivation would increase by 0.6 points in the app-only arm and by 0.8 points in the app-plus arm. Assuming a standard deviation of 1.0 for change in autonomous motivation in both arms, we required 29 participants in each arm to provide 80\% power to detect these changes in autonomous motivation in the intervention arms compared to the control arm. Prior research demonstrates that a 0.5-point increase in autonomous motivation is associated with significantly greater weight loss and increased physical activity compared to individuals who did not achieve this increase in autonomous motivation.\textsuperscript{18} To account for the possibility that some participants may be lost to follow-up during our 12-week intervention, we conservatively inflated our sample size by 20\% to enroll 35 participants in each arm.

Due to administrative changes within the health plan and competing research interests within our institution, the plan provided us with a limited list (18.5\% sample) of individuals who were potentially eligible for our study. As such, we were unable to meet our recruitment target. Using our realized sample size (n=69), we conducted a post-hoc power analysis, which showed that we had 80\% power to detect a mean difference of 0.38 or more in the intervention arms compared to the control arm.

Statistical Analysis

Quantitative Data Analysis
We used logistic regression to compare differences in rates of engagement between the two intervention arms. We used linear regression to compare differences in adherence (i.e. app-usage days) between the intervention arms. We compared changes in autonomous motivation among app-only and app-plus participants vs. control participants using a difference-in-differences analytic approach. For continuous outcome measures, we modeled the effect using linear regression, and for dichotomous outcomes we modeled the effect using logistic regression. The difference-in-difference is the interaction term between a categorical variable indicating the study group (i.e. control vs. app-only vs. app-plus) and a categorical variable indicating the data collection time point (i.e. baseline vs. 12-week follow-up). The difference-in-differences design accounts for the possibility that temporal trends unrelated to the intervention may have influenced the study outcome. All analyses were conducted using Stata 14 (StataCorp LP, College Station, TX).

Qualitative Data Analysis

Semi-structured interviews were recorded, transcribed verbatim, and imported into a qualitative analysis software, Dedoose (SocioCultural Research Consultants, Los Angeles, CA). Two investigators independently read and coded transcribed interviews. Interviews were then coded jointly using consensus conferences and analyzed using directed content analysis.20

Consistent with a mixed-methods sequential explanatory design,31 we integrated the quantitative and qualitative findings in the final stage of data analysis, which enabled us to interpret our quantitative data in the context of qualitative participant experiences.

Results

Sample

Demographic and socioeconomic characteristics were assessed at baseline (Table 1). Most of the participants were female (64%), white (65%), and educated, with 91% attaining education beyond high
school. The mean age was 51.7 years (11.2). At baseline, mean autonomous motivation score was 6.0 (SD 1.0) among control group participants, 5.8 (SD 1.0) among app-only participants, and 6.0 (SD 1.0) among app-plus participants.

Table 1. Baseline characteristics of study participants.

<table>
<thead>
<tr>
<th>Characteristics (N(%)or mean (SD))</th>
<th>Control (N=23)</th>
<th>App-only (N=24)</th>
<th>App-plus (N=22)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographics</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Mean age</td>
<td>51.3 (11.0)</td>
<td>52.1 (12.0)</td>
<td>51.6 (11.1)</td>
</tr>
<tr>
<td>Female</td>
<td>15 (65.2)</td>
<td>15 (62.5)</td>
<td>14 (63.6)</td>
</tr>
<tr>
<td>Body mass index in kg/m²²</td>
<td>33.0 (10.4)</td>
<td>30.7 (9.3)</td>
<td>33.4 (7.8)</td>
</tr>
<tr>
<td>Minority race¹</td>
<td>6 (28.6)</td>
<td>11 (45.8)</td>
<td>7 (31.8)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High school graduate</td>
<td>3 (13.0)</td>
<td>1 (4.2)</td>
<td>1 (4.6)</td>
</tr>
<tr>
<td>More than high school</td>
<td>20 (87.0)</td>
<td>22 (91.7)</td>
<td>21 (95.5)</td>
</tr>
<tr>
<td>Household income</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than $50,000</td>
<td>7 (31.8)</td>
<td>6 (27.3)</td>
<td>6 (28.6)</td>
</tr>
<tr>
<td>$50,000-$100,000</td>
<td>8 (36.4)</td>
<td>12 (54.6)</td>
<td>6 (28.6)</td>
</tr>
<tr>
<td>More than $100,000</td>
<td>7 (31.8)</td>
<td>4 (18.2)</td>
<td>9 (42.9)</td>
</tr>
<tr>
<td><strong>Autonomous motivation to prevent T2DM²</strong></td>
<td>6.01 (1.0)</td>
<td>5.80 (1.0)</td>
<td>5.96 (1.0)</td>
</tr>
</tbody>
</table>

¹Defined as any race other than White.
²Measured on a scale of 1-7 using the Treatment Self-Regulation Questionnaire (TSRQ). Higher scores indicate greater levels.

Quantitative Analyses

Recruitment

Figure 1 shows the flow of participants through the study. Contact information for a total of 740 individuals identified as potentially eligible for study participation was provided to us by their health plan, and 37 individuals identified as potentially eligible by self-report via a health research portal. We were unable to reach the majority of potentially eligible individuals (527/777, 68%). Among the 253 individuals whom we assessed for eligibility, 244 were eligible to participate, and 69 (28%) of these eligible individuals consented to study participation and were randomized to 1 of 3 study arms.
Retention

Among those randomized (n=69), 55 (80%) completed the 12-week survey. Rates of survey completion varied across study arms. Among participants in control, app-only, and app-plus groups, completion rates were 16 of 23 (70%), 17 of 24 (71%), and 22 of 22 (100%) respectively. Retention differed significantly between app-plus participants and participants in the other two study arms combined (p=0.004, \( \chi^2 \)).

Adherence

During the 12-week intervention period, app-only participants used the app for a mean of 43 days (SD 26.6) while app-plus participants used the app for a mean of 37 days (SD 26.2); p-value (0.34).

Among app-plus participants (n=22), 16 (73%) used the Fitbit activity tracker for a mean of 32 days (SD 12.0), and 13 (59%) used the Fitbit scale for a mean of 15.9 days (SD 15.4). Of note, three app-only participants paired their personal Fitbits with the app, although they were not instructed to do so as part of the study; these individuals used the Fitbit for a mean of 21 days (SD 8).

Exploratory quantitative outcomes

Table 2 shows the changes in autonomous motivation across study groups. There were no statistically significant within-group or between-group differences in self-reported autonomous motivation.

<table>
<thead>
<tr>
<th>Table 2. Difference-in-difference analysis for autonomous motivation scores at 12-weeks as compared to baseline.(^1)</th>
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<tbody>
<tr>
<td><strong>Baseline mean (SE)</strong></td>
</tr>
<tr>
<td>-------------------------</td>
</tr>
<tr>
<td><strong>Autonomous motivation score(^2)</strong></td>
</tr>
<tr>
<td>Control (n=16)</td>
</tr>
<tr>
<td>App-only (n=17)</td>
</tr>
<tr>
<td>App-plus (n=22)</td>
</tr>
</tbody>
</table>

\(^1\)All values in this table are predicted from the model.
Participant experiences with the intervention

Among the 24 app-only participants invited to participate in an interview, 5 individuals (20%) agreed to take part. Among the 22 app-plus participants invited to participate in an interview, 10 individuals (45%) agreed to take part. During these interviews, key themes emerged regarding participants’ perceptions of the application, capturing those aspects of the application that they liked or disliked (Table 3).

Table 3. Participant perceptions of m-Health application and representative quotes

<table>
<thead>
<tr>
<th>Participant perceptions</th>
<th>Representative Quotes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Encouraged self-reflection</td>
<td>“I liked the idea of being encouraged to think about purposes and how that played out in your daily life…I normally charted the day at bedtime…and it was useful to reflect back on the day and think about that to some extent.” (App-plus)</td>
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<tr>
<td></td>
<td>It makes me decompress from my day and just think, &quot;How could I have made my day better? What did I do? What didn't I do?” (App-plus)</td>
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<tr>
<td>Supported healthy behaviors</td>
<td>“I was more conscious of what I ate. I started…drinking more water, less caffeinated beverages, less carbonated beverages…I wasn't as tired. I set a goal where I was going to bed by a certain time.” (App-only)</td>
</tr>
<tr>
<td></td>
<td>“When I go see my doctor, it's kind of like, ‘...you need to exercise more...you need to change your diet.’ But the nice thing about [the app] was [it] broke it down into these things that you could learn about that allowed you to have a better understanding [of] your health condition…and also how you can sort of prevent certain health risks from happening.” (App-only)</td>
</tr>
</tbody>
</table>
|                              | “There [were] a lot of questions about how I feel today…it just seemed to be a...
Among the 13 interviewees who identified components of the application that they enjoyed, the majority (n=8) appreciated the application’s support for self-reflection. For example, one app-only participant commented, “I liked how you had to rank how [you were] feeling [each day]...I thought [that was] an interesting way just to take a step back, just sort of a self-assessment.” Others (n=5) noted that the application supported adherence to healthy behaviors over time through daily charting of health habits (e.g. diet, physical activity, and sleep), light-touch health tips, and educational videos. As noted by one app-only participant, “[the application] was a good reminder...to help push [me] to keep moving...doing more and more.”

Among the 11 participants who identified components of the application that they did not enjoy, almost half (n=5) commented that daily use of the application felt burdensome as a result of minimal day-to-day variation in individual health behaviors, redundancy of educational content, and perceived arbitrariness of future predictions. One app-plus participant commented that he was initially motivated to chart daily, but “after a while...I lost interest in trying to understand what it was doing for me other than just keeping track and telling me that tomorrow it’s supposed to rain. You might have a bad day.” Four
individuals voiced frustration with certain health tips delivered by the application, as these failed to recognize personal or environmental circumstances that transiently influenced one’s health habits, energy or willpower. For example, a app-plus participant noted, “One time I was on vacation, and I have to work really hard to get the vacation. And I had a drink every single day, not a lot, just maybe one, and there was a thing that came up about sleeping and limiting your alcohol intake, and I'm going, ‘Oh, for God's sakes. I shouldn't even put any of that down.’”

Among app-plus interviewees, all (n=10) used the Fitbit activity tracker, and most (n=6) noted that it facilitated engagement in routine physical activity. For example, one participant said, “I live about two miles away from our office. I ended up much more in the mode of, ‘I’m gonna walk if it's all possible.’” Several participants specifically appreciated the activity tracker’s concrete step count goal, and one noted that “looking at [activity] from a more lucid mathematical standpoint was very helpful. It made me more active without having to engage in an abrupt behavior or thought change.”

Among app-plus interviewees, eight used the scale and appreciated the ease with which the data synced with the Fitbit application. One participant commented, “I thought it was wonderful...[you just] step on this little device and magically it goes into your statistics, and I get a running account of if my weight's going up or down or whatever.” Similarly, another noted, “I just step on the scale and it's recorded in the Fitbit app, and that was handy 'cause it keeps a record.”

Thirteen interview participants identified specific health behavior changes that resulted from participation in this intervention. These included increased physical activity (n=9), improved dietary habits (n=8), increased awareness of other factors that influence health and wellbeing such as social connectedness and adequate sleep (n=6).

Thirteen interview participants suggested strategies to enhance the intervention. Five participants recommended adding some level of “human contact” to better support behavioral change. An app-plus participant commented, “I would have enjoyed talking with an actual person...to get more advice.” Three
participants thought that more concrete goal-setting could better help participants achieve health goals. For example, an app-plus participant noted “[the app] didn't seem to offer…concrete things to do. It just sort of asking me to reflect on how I did in sort of pretty unstructured ways. [I wanted to] be able to set concrete things to do…Instead of just asking me how active I was, ask if I [met my goal of] walking at least four miles a day…” and another suggested the addition of concrete nutritional advice so that participants may know “what not to eat, what to eat, and what are the nutritional values of different things, and how you can manage your day based on your work schedule, when you should be eating, what you should be eating, how much you should be eating and you could still feel hungry.”

Discussion

To our knowledge, this is the first study to test an intervention to support healthy behaviors among individuals with prediabetes who had recently declined participation in online or face-to-face DPPs offered at no cost. Our findings demonstrate that it is indeed feasible to recruit DPP non-enrollees to an mHealth intervention. Nearly one-third of eligible individuals enrolled in this intervention despite previously declining to participate in free online and group-based DPPs offered by our University’s self-funded insurers. Further, the application – used alone and also in conjunction with Fitbit devices – was acceptable among intervention group participants, as indicated by high levels of adherence and positive qualitative experiences. Retention differed significantly between app-plus participants and participants in the other two study arms, suggesting that the Fitbit devices enhanced the intervention’s acceptability and perceived value to participants.

We examined the intervention’s preliminary efficacy on autonomous motivation to prevent T2DM, which we hypothesized to be a key proximal mediator of behavior change. Our analyses did not demonstrate statistically significant differences in levels of autonomous motivation between intervention arms. It is plausible that we were unable to discern changes in autonomous motivation due to higher-than-predicted baseline levels of autonomous motivation and resultant ceiling effect of the TSRQ. While
high baseline levels of autonomous motivation may have occurred by random chance, it is also possible that these high levels identify a non-random subset of DPP non-enrollees who are motivated to prevent T2DM, yet face other barriers to DPP enrollment (e.g. lack of time). Given the importance of autonomous motivation for initiating and sustaining healthy behaviors, it is critically important to characterize autonomous motivation levels among the broader population of DPP non-enrollees and conduct a larger scale effectiveness trial to examine changes in autonomous motivation specifically among individuals with lower baseline levels. Another possibility is that 12 weeks was too short a time period to observe significant improvements in autonomous motivation; prior studies have examined changes over longer time periods. In addition, future research should explore factors other than low levels of autonomous motivation that may deter DPP uptake to inform additional targeted interventions to specifically address these barriers.

Mobile smartphone applications and other mHealth technologies are increasingly used as tools to promote lifestyle change,\textsuperscript{32} and technology-assisted translations of the DPP have been used to improve program reach.\textsuperscript{33} While such programs may be cost-effective and convenient, their effectiveness is variable, and little is known about the populations most likely to engage in or benefit from mHealth programs.\textsuperscript{33,34} Without such knowledge, these programs cannot be specifically tailored or disseminated to those most likely to benefit from them. In contrast, we recruited individuals who declined participation in free DPPs and demonstrated that they were willing to engage in a mHealth program. Our findings expand the growing body of mHealth literature and may inform future efforts to personalize diabetes prevention initiatives. For example, those with prediabetes who do not engage in DPPs may be offered a low-intensity mHealth alternative through which they can improve health behaviors to decrease progression to diabetes. By developing and testing diverse approaches with differing intensities and modalities to prevent T2DM, we can create a robust menu of lifestyle change options that meet individuals’ needs, preferences, and goals.

Limitations
First, we aimed to enroll 35 individuals to each study arm, but we were unable to meet this recruitment target due to administrative changes within the health plan and competing research interests within our institution. Thus, we had limited power to detect changes in autonomous motivation. Second, our results may not be generalizable to other populations; we recruited individuals from a single regional health plan and baseline autonomous motivation scores were higher than expected among our study participants. Future work could aim to engage a broader cohort of DPP non-participants with lower levels of baseline autonomous motivation as well as to be sufficiently powered to examine changes in objective health behaviors and outcomes (e.g., weight). Behavior changes leading to improved health outcomes may be mediated by other factors than autonomous motivation. Finally, due to the small sample size, all results of this pilot study should be interpreted with caution.

Conclusions

National initiatives\textsuperscript{35,36} and policies\textsuperscript{37} promote DPPs as the dominant diabetes prevention strategy, yet the ability of DPPs to improve population health is compromised by low program uptake. Alternative strategies are urgently needed to help the large majority of individuals with prediabetes prevent T2DM and T2DM-related complications. Our findings underscore the promise of low-intensity mHealth programs to promote healthy behaviors among individuals with prediabetes who do not desire participation in formal DPPs. This intervention may be refined by incorporating participant-identified preferences for increased interpersonal contact and concrete goal setting. In future work, we plan to test the refined intervention in a larger-scale effectiveness trial to evaluate changes in autonomous motivation, as well as in other potential mediators, DPP participation, physical activity, and clinical measures of changes in weight and HbA1c.

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Conflicts of Interest

Dr. Griauzde, Brad Liestenfeltz, Tahoora Ansari, Emily Johnson, Allison Fedewa, Dr. Richardson, and Dr. Heisler declare that they have no conflicts of interest. Dr. Kullgren has received consulting fees from SeeChange Health and HealthMine, and a speaking honorarium from AbilTo, Inc.

References


Abbreviations

DPP, Diabetes Prevention Program; mHealth, mobile health; T2DM, Type 2 Diabetes Mellitus; SDT, Self-Determination Theory; hemoglobin A1c, HbA1c; Treatment Self-Regulation Questionnaire, TSRQ