Promoting Problem-Solving Among Low-Income Adults with Type 2 Diabetes: A Cluster-Randomized Trial of Mobile Diabetes Detective

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Abstract

Background: Problem-solving skills are essential to the successful management of type 2 diabetes but challenging to develop for low-resource medically underserved individuals. mHealth interventions have shown positive impact on diabetes management but few focus specifically on problem-solving.

Objective: To evaluate the efficacy of an mHealth intervention, Mobile Diabetes Detective (MoDD), for facilitating problem-solving and self-care among underserved adults with type 2 diabetes.

Methods: This cluster-randomized non-blinded clinical trial included 219 participants with type 2 diabetes (HbA1c > 7.5%) from 8 Federally Qualified Health Centers that serve low-resource communities. The intervention arm (n=111) used MoDD for 4 weeks and up to 1 year. The control arm (n=108) received standard diabetes education and usual care. The primary hypotheses were improvement in HbA1c, diabetes problem-solving abilities, and diabetes self-care behaviors from baseline to 4 weeks, 3 months, and 12 months. Secondary hypotheses were improvement in diabetes self-efficacy and diabetes distress. Data were analyzed for both within group change and between group differences at each study milestone.

Results: Participants (n=219) were predominantly female (67%), ethnically and racially diverse (51% Hispanic, 42% African American), with mean glycated hemoglobin HbA1c=9.9% at baseline. There was no change in HbA1c at 4 weeks in either arm; both arms reduced HbA1c from baseline to 3 months (intervention: -0.58% (p=0.005); control: -1.03% (p<0.001)); only the intervention arm reduced HbA1c from baseline to 12 months (intervention: -0.45% (p=0.01); control: -0.37% (p=0.047). There was no improvement in diabetes problem-solving, and mixed results in diabetes self-care behaviors. Both arms improved diabetes self-efficacy at 3 and 12 months; the intervention arm reported increase in diabetes distress at 3 and 12 months. The only difference in outcomes between study arms was in following a diabetes-specific diet at 12 months with the control arm reporting higher adherence (intervention: 4.48, control: 5.17, p=0.004).

Conclusions: All participants improved blood glucose management at 3 months but only the intervention arm sustained improvement over time; there was no change in diabetes problem solving abilities. These findings suggest potential benefits of using mHealth interventions for underserved individuals with type 2 diabetes and the need for further research on improving problem-solving with mHealth. Clinical Trial: NCT02021591

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Conclusions. All participants improved blood glucose management at 3 months but only the intervention arm sustained improvement over time; there was no change in diabetes problem solving abilities. These findings suggest potential benefits of using mHealth interventions for underserved individuals with type 2 diabetes and the need for further research on improving problem-solving with mHealth.

Trial Registration: NCT02021591

Keywords: mHealth, intervention, self-management, problem solving, clinical trial

1. INTRODUCTION

Well-developed problem-solving is essential to the successful management of type 2 diabetes (1–3), results in better diabetes self-care (4–7), and leads to improvements in clinical outcomes (8–10). Problem-solving is defined as the process of translating techniques for self-care into self-management behaviors, and an ability to implement effective solutions to overcoming personal, environmental, social, and knowledge-based barriers to self-management (9). Problem-solving is central to many self-management and behavior change programs (11–14). The Association of Diabetes Care & Education Specialists (ADCES) includes problem-solving as a critical self-care behavior (15).

However, developing problem-solving skills presents a considerable challenge (16). Interventions for promoting problem-solving often rely on healthcare professionals who deliver problem-solving education and training in individual or group settings (9,10, 17–23). While these interventions have proven benefits, they are often inaccessible to individuals who reside in medically underserved, low resource communities with limited access to diabetes self-management education (24) (24). With over 97% of Americans owning a cell phone (25), and cell phone ownership rates even higher worldwide and among members of ethnic and racial minorities (26), mHealth and text-messaging interventions can reach broader, more diverse populations (27–29). Past research has established the efficacy of mHealth interventions for diabetes self-management (30,31) with smaller effect sizes for minority populations (32). However, while mHealth interventions often incorporate support for healthy eating, monitoring blood glucose, and being physically active, they lag far behind in supporting problem-solving (33). Thus far, only a few research programs investigated fully-automated interventions for facilitating problem-solving (22,23) and none focused on mobile technologies.

In this research, we developed and evaluated an mHealth intervention, Mobile Diabetes Detective (MoDD), for facilitating problem-solving and self-care behaviors to improve HbA1c (34). MoDD is theoretically grounded in problem-solving frameworks (6) and was developed using user-centered design approach (35). We tested MoDD in a cluster-randomized non-blinded clinical trial with medically underserved individuals with type 2 diabetes. The primary hypotheses were improvement in HbA1c, diabetes problem-

solving abilities, and diabetes self-care behaviors from baseline to 4 weeks, 3 months, and 12 months. Secondary hypotheses were improvement in diabetes self-efficacy and diabetes distress.

2. METHODS

2.1. Settings and Sample

Eight Federally Qualified Health Centers (FQHCs) in the New York Metropolitan area that are members of Clinical Directors Network (CDN), a primary care practice-based research network (PBRN), were recruited to participate in this study. All FQHCs provided care to patients from low-resource communities with a high proportion of patients either insured by Medicaid or uninsured. The population served by each FQHC reflected the characteristics of its community in terms of race, ethnicity, and preferred language. FQHCs varied in the type of diabetes education provided and in availability of an endocrinologist on-site. To reduce the potential impact of differing clinical practices on the study outcomes, the inclusion criteria for FQHCs were: (a) operational for ≥ 2 years; (b) provide primary care to ≥ 5,000 adult patients per year; (c) have an established diabetes self-management education and support program (DSMES); (d) have ≥ 2 staff members who provide diabetes education on site; and (e) previous participation in at least one Bureau of Primary Health Care (BPHC)–sponsored Health Disparities Collaborative (HDC) project (36).

The participants met the following eligibility criteria: (a) age 18-65 years; (b) a diagnosis of type 2 diabetes with HbA1c ≥ 7.5%; (c) a patient of the health center for at least 6 months; (d) participated in at least one diabetes education session (group or individual) at the study site in the last 6 months; (e) proficient in either English or Spanish; (f) owns a basic or more advanced cell phone. The exclusion criteria were: (a) pregnancy; (b) presence of serious illness (e.g., cancer diagnosis with active treatment); (c) presence of cognitive impairment; and (d) plans for leaving the FQHC in the next 12 months. Further details on participants and recruitment are available elsewhere (37).

The study was approved by the Institutional Review Boards (IRBs) of Columbia University Medical Center, Clinical Directors Network (CDN), and NYU School of Medicine, and registered on Clinicaltrials.gov (Protocol ID: NCT02021591); all participants provided written informed consent either in Spanish or English prior to participation.

2.2. Study design and procedures

The study was conducted between 2012 and 2018. To prevent cross-contamination between patients within the same center, the study used a cluster-randomized non-blinded clinical trial design with participating FQHCs randomized to either the intervention arm (n=4) or control arm (n=4). Due to different approaches to the delivery of DSMES within different FQHCs, the sites were stratified as: 1) DSMES delivered via group classes, certified diabetes educators (CDEs) on site; 2) DSMES delivered in personal consultations, no CDEs on site. The FQHCs were randomized into intervention and control arms within their stratum. Patients recruited from intervention arm sites received the MoDD application immediately after baseline assessment and intervention training. At the end of the study period (1 year) and completion of the final follow-up assessments, patients recruited from control arm sites received access to the MoDD application and instructions for using it.

The study protocol included 4 study visits: (T1) Consent/Baseline visit; (T2) 4 weeks, the end of the main intervention period; (T3) 3 months; and (T4) 12 months. Immediately following the T1 visit, participants in the intervention arm received an additional training visit (T1.1) during which study staff trained them on the use of MoDD. During the T1 visit, participants in both arms were provided with a voucher to purchase test strips for their blood glucose (BG) meters (two strips per day for the 4 weeks of the main intervention period) and $10 in cash to offset costs for using text messaging and data during the study. All participants received a diabetes education brochure developed by the NYC Department of Health and Mental Health Hygiene. Further details on the sessions are available elsewhere (37).

Research staff instructed participants in the intervention arm to use MoDD independently either via its text messaging or web app features for a minimum of 4 weeks and up to the final follow-up visit (12 months); no BG strips or incentives were provided after the initial 4 weeks. To ensure all participants had access to MoDD web app, we equipped the FQHCs with dedicated laptops; participants in both arms could use these laptops and receive additional training. Notably, with the exception of the training visit, all other study procedures (compensation for study visits, blood glucose monitoring test strips, data plans, access to computers on sites, etc.) were the same across study arms. Further details on the trial design are available on

clinicaltrials.gov (NCT02021591). There were no changes to the study protocol or trial outcomes after trial commencement.

2.3. Randomization and Blinding

Randomization of FQHCs into study arms was done using random number sequence generated by the statistician. The statistician was blinded to the identity of the sites using numbers assigned to FQHCs during randomization. Because randomization was at the FQHC level, blinding beyond randomization was not possible. To minimize selection bias, all eligible participants from each FQHC were recruited until target sample size was achieved.

2.4. Intervention

MoDD is a fully-automated mHealth intervention designed for independent use by individuals with type 2 diabetes. Individuals use MoDD's web app or text messaging to record their daily BG readings captured with conventional BG meters. MoDD's web app displays these readings as patterns organized within categories (waking, before and after each meal, and at bedtime) and highlights patterns with consistent deviations from ranges recommended by healthcare providers (between 70 and 130 for fasting BG, and between 70 and 180 for after-meal BG, see Figure 1).

MoDD then asks individuals to follow the steps of the problem-solving framework (34): **1) *select a glycemic control pattern*** they wish to improve (for example, "High blood glucose after breakfast"); **2) *identify a potential behavioral trigger*** – a behavior that may be contributing to the selected pattern (for example "I rarely include protein in my breakfast"); individuals review triggers available in MoDD knowledge base (35) and select a trigger they perceive as consistent with their behaviors; and **3) *set an action-oriented goal*** by choosing a healthier alternative from a list of offered trigger-appropriate choices (for example, "Include a tablespoon of peanut butter or a boiled egg with breakfast"). MoDD monitors for changes in BG levels within the selected pattern (e.g., changes in blood glucose after breakfast over time) and provides individuals with ***tailored feedback via text messages*** about their progress towards achievement of target BG ranges (see Figure 1).

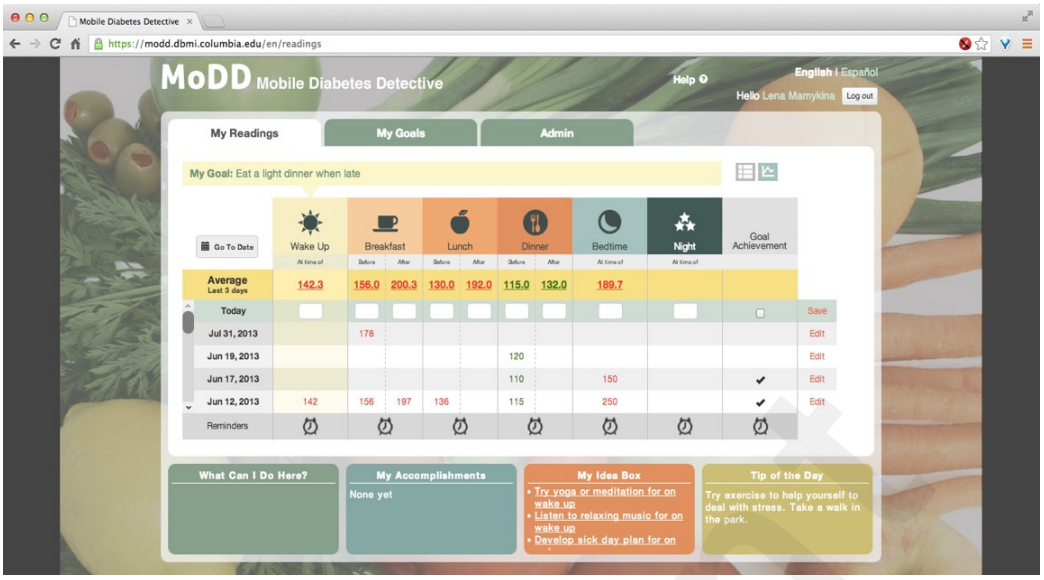

Figure 1: MoDD screenshot.

MoDD was developed using an iterative user-centered design process with individuals with type 2 diabetes recruited from FQHCs not participating in the trial. MoDD utilizes an extensive knowledge base designed and validated with practicing diabetes educators and individuals with type 2 diabetes (35). The knowledge base includes an extensive list of behavioral triggers and action-oriented goals, each accompanied by a short *educational segment* explaining why certain behaviors may lead to changes in BG levels; these segments are tailored to participants' levels of health literacy assessed during MoDD registration (T1.1). Furthermore, it includes *motivational messages* tailored to participants' levels of readiness to change dietary behaviors and physical activity behaviors (38), also assessed during MoDD registration. Further details on MoDD design are described elsewhere (39). No changes were made to MoDD during the trial.

2.5. Primary and Secondary Outcomes

The primary outcomes were HbA1c extracted from participants' electronic medical records (EMR), individuals' problem-solving abilities (Diabetes Problem-Solving Inventory, DPSI (34)), and diabetes self-care behaviors (Summary of Diabetes Self-Care Activities Questionnaire, SDSCA (40)). DPSI was delivered by study personnel who received at least 10 hours of training and 5 synchronization sessions to ensure consistency. Secondary outcomes included diabetes self-efficacy (Diabetes Self-Efficacy, DSES (41)) and diabetes distress (Problem Areas in Diabetes, PAID (42)).

We hypothesized that exposure to MoDD would result in the following:

H1. (Primary) Improvement in individuals' HbA1c, problem-solving abilities (DPSI), and self-care behaviors (SDSCA) from baseline to 4 weeks, 3 months, and 12 months.

H2. (Secondary) Improvement in individuals' self-efficacy (DSES), and in diabetes distress (PAID) from baseline to 4 weeks, 3 months, and 12 months.

2.6. Power analysis

We were guided by published studies in establishing anticipated effect sizes. With a power of 90% and an alpha level of 0.05 (two-tailed), and an intra-cluster correlation coefficient (ICC) of 0.02, we estimated the number of participants needed within each FQHC to be 18 with the total sample size of 144 participants needed to achieve sufficient power. We anticipated a loss of 10% of the sample at 3 months and 12 months, and inflated the number of participants with the recruitment target of 200 participants.

2.7. Statistical Analyses

The primary hypotheses in this study focused on improvement in primary outcomes (HbA1c, problem-solving, and diabetes self-care behaviors) from baseline to 4 weeks, 3 months, and 12 months. We used an individual growth model, a special case of linear mixed models, to estimate HbA1c scores at baseline, 4 weeks, 3 months, and 12 months and compared these estimates between different milestones within each study arm, and between the intervention and the control arms. The model included a site-specific random intercept to allow different baseline scores for different participating sites and for repeated measures data. The dependent variables were HbA1c, problem-solving (DPSI) and diabetes self-care behaviors (SDSCA). The independent variables were study arm (intervention versus control arm), time period (baseline, 4 weeks, 3 months, and 12 months). We used the interaction term between study arms and time period for the comparison between the two study arms. Similar models were used for each secondary outcome (diabetes distress [PAID], diabetes self-efficacy [DSES]). We used critical values of p=0.0167 (=0.05/3, Bonferroni correction) to adjust for multiple comparisons (n=3: baseline to 4 weeks, 3 months, and 12 months).

A similar linear mixed model was used to examine the association between MoDD usage and change in outcome (HbA1c) for the intervention arm. Usage was measured by the number of MoDD logins and total BG readings entered into MoDD. Because both of these variables were skewed, we used log-transformations for these variables.

3. RESULTS

3.1. Participants and Sites

Given the cluster-randomized design of this trial, we report on recruitment and retention at both the cluster- and participant-levels (Figure 2). Ten (10) FQHCs were assessed for eligibility and eight (8) were recruited to participate in the trial (2 sites declined to participate). These 8 sites were randomized to the intervention arm (n=4, median number of participants per site=31; range: 30-34) and control arm (n=4, median number of participants=30.5; range: 30-31). No sites were lost to follow-up.

Potential participants were identified through referral by FQHC providers, direct mailings, posted fliers, and by study staff approaching adults with a type 2 diabetes diagnosis in the waiting area. A total of 542 adult patients were identified as potentially eligible and approached for recruitment. Of these, 150 (28%) did not meet eligibility criteria (most common reason: lack of diabetes diagnosis), 139 (26%) declined participation, and 253 consented to participate in the study. Five individuals were deemed not eligible after additional chart review and excluded from the study; 248 were randomized into the two study conditions according to their corresponding FQHC: 126 to the intervention arm (MoDD); 122 to the control arm (usual care). Of the 248 patients randomized, 219 (88%) completed a baseline assessment and received the allocated intervention (111 in the intervention arm; 108 in the control arm).

Survey-based outcome measures were collected during study visits. For these outcomes, the following participants did not complete the scheduled milestones: for baseline: 31 participants (28%) in the intervention arm, 21 participants (19%) in the control arm; for the 3-month follow-up: 23 (21%) in the intervention arm, and 19 (18%) in the control arm; for the 12-month follow-up: 24 (22%) in the intervention arm, and 13 (12%) in the control arm.

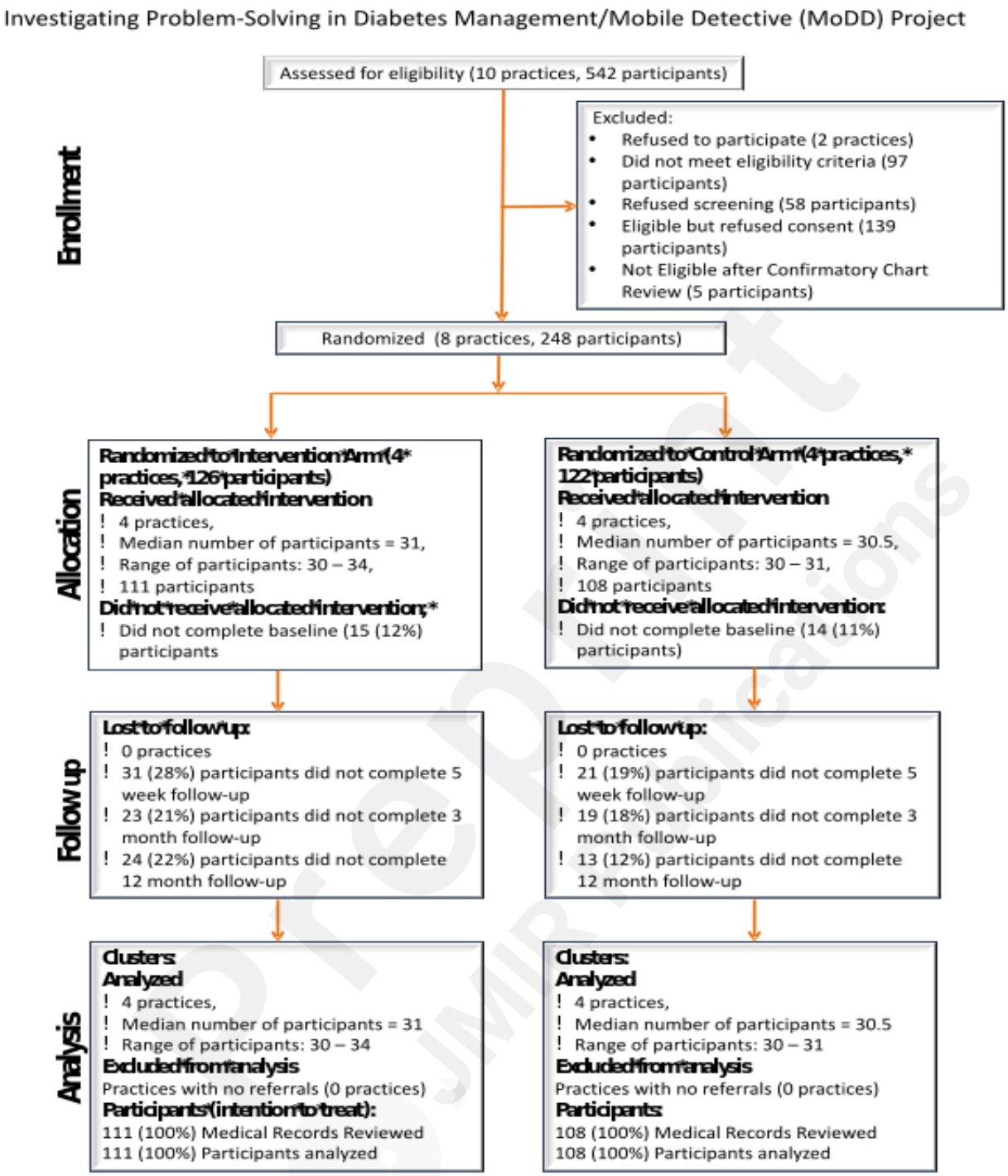

Figure 2: MoDD trial CONSORT diagram

HbA1c measured as part of usual care was extracted from the participants' EMR; as a result, HbA1c were unavailable for participants who missed their regularly scheduled visits with providers. HbA1c were not available the following participants; *for baseline*: 17 (15%) in the intervention arm and 19 (18%) in the

control arm; *for 4-week follow-up*: 62 (56%) in the intervention arm and 72 (68%) in the control arm; *for 3-month follow-up*: 73 (66%) in the intervention arm and 52 (49%) in the control arm; *for 12-month follow-up*: 30 (27%) in the intervention arm, and 32 (30%) in the control arm.

3.2. Baseline characteristics and comparison

Of 248 adults enrolled in the study, 219 were included in the final intention-to-treat analysis (111 intervention arm, 108 control arm). The sample was predominantly female (67%) with a mean age of 51.7 years (ranging from 23 to 66). The majority of participants were Hispanic (51%) or African American (42%) with 45% born in the United States. More than two thirds of the participants (63%) had not finished high school, over half (68%) was unemployed at the time of the study, and over a half (52%) reported annual income of less than $10,000. The majority (89%) received health insurance through either Medicare or Medicaid or were uninsured. On average, the participants had poor glycemic control (mean HbA1c=9.89% (85 mmol/mol, 95% CI: 9.62% - 10.16%). A preliminary report on the baseline characteristics is available elsewhere (37). Table 1 here reflects the final sample after completion of the final analysis.

	Total (219)	Intervention (111)	Control (108)
Age	52 (23-66)	51 (23 - 66)	52 (25 - 65)
Gender (female)	147 (67%)	78 (70%)	69 (64%)
Race/ethnicity			
African American	92 (42%)	52 (47%)	40 (37%)
Hispanic	112 (51%)	53 (48%)	59 (55%)
Non-Hispanic white	9 (4%)	4 (4%)	5 (5%)
Asian, mixed, or other	116 (53%)	55 (50%)	61 (56%)
Born in the United States	98 (45%)	61 (55%)	37 (34%)
Primary language			
English	115 (53%)	63 (57%)	52 (48%)
Spanish	54 (25%)	28 (25%)	26 (24%)
Bilingual	40 (18%)	18 (16%)	22 (20%)
Educational attainment			
None - grade 11	139 (63%)	65 (59%)	74 (69%)
High school or more	78 (36%)	46 (41%)	32 (30%)
Employed	92 (42%)	56 (50%)	36 (33%)
Medicare/Medicaid/Uninsured	188 (86%)	91 (82%)	97 (90%)
Annual income >%10,000	113 (52%)	67 (60%)	46 (43%)
Married	99 (45%)	45 (40%)	54 (50%)

Depressive symptoms (PHQ-2)	47 (21%)	32 (28%)	15 (14%)

Table 1: Demographic characteristics of the sample

3.3. Characterizing usage

On average, participants in the intervention arm logged in 29 times (range from 0 to 759), recorded 246 BG readings using text messaging or MoDD web interface (range from 0 to 3949), and set 4 goal while in the study (range from 0 to 29); these numbers varied greatly across participants (see Figure 2 in supplementary materials).

3.4. Outcomes

There were no harms or adverse events reported during the study.

3.4.1. Descriptive statistics per cluster

The breakdown of outcomes by FQHC cluster is available in supplementary materials (Table 1 and Figure 3). Overall, there was high variability in both direction and magnitude of change between different clusters. This was particularly the case for FQHCs in the intervention arm; whereas FQHCs in the control arm showed a relatively consistent trend in the change of HbA1c over time, two of the FQHCs in the intervention arm did not show any change in HbA1c.

3.4.2. Primary Outcomes

The breakdown of all primary and secondary outcomes is available in Table 2.

Analysis of ***within group improvement in outcomes between study milestones*** for the intervention and control arms showed the following:

For HbA1c, there was no change at 4 weeks in either arm; both arms reduced HbA1c from baseline to 3 months (intervention: -0.58% ($p=0.005$); control: -1.03% ($p<0.001$)); only the intervention arm reduced HbA1c from baseline to 12 months (intervention: -0.45% ($p=0.01$); control: -0.37% ($p=0.047$, not significant after adjusting for multiple comparisons).

For problem-solving abilities (DPSI), there was no change in either arm at any follow-up timepoint.

For diabetes self-care activities (SDSCA), the results were mixed for different sub-scales. For general diet, both arms improved at 4 weeks and 3 months but only the intervention arm improved from baseline to 12 months. For *specific diet*, the control arm improved for all three milestones; the intervention arm only improved at 3 months. For *exercise*, the intervention arm improved at 4 weeks and 12 months, and control arm improved at 3 months. For *frequency of blood glucose testing*, only the intervention arm showed improvement at 4 weeks and 3 months. For *diabetes foot care*, the intervention arm showed improvement at 3 months, and both arms showed improvement at 12 months.

Analysis of ***between group difference in primary outcomes*** showed no statistically significant differences between arms for HbA1c and DPSI (Table 1 in Supplementary Materials). There was a statistically significant difference for SDSCA Diet Specific at 12 months (intervention: mean=4.48 (4.14; 4.81); control: mean=5.17 (4.84; 5.49), p=0.004) with control arm showing better diet management than the intervention arm (see Table 1 in Supplementary Materials).

3.4.3. Secondary Outcomes

Analysis of change in secondary outcomes showed improvement in problem areas in diabetes (PAID) for intervention arm at 3 months and 12 months. For diabetes self-efficacy (DSES), the control arm improved at 4 weeks, and both arms improved at 3 months and 12 months.

There were no significant differences between groups for either secondary outcome and either follow-up.

	Intervention		Control	
	Mean (CT)/Mean change (CI)	p-value	Mean (CT)/Mean change (CI)	p-value
Primary Outcomes				
HbA1c (%)				
Baseline (BL)	9.81 (9.42; 10.2)		9.95 (9.55; 10.34)	
HbA1c change: BL to 4w	-0.53 (-1.; 0.)	0.17	-0.44 (-1.; 0.)	0.2
HbA1c change: BL to 3m	-0.58 (-1.08; -0.08)	**0.005***	-1.03 (-1.52; -0.55)	**<0.0001***
HbA1c change: BL to 12m	-0.45 (-0.86; -0.04)	**0.01***	-0.37 (-0.81; -0.08)	0.047
DPSI				

Baseline (BL)	3.89 (3.56; 4.2)		3.84 (3.52; 4.16)	
DPSI change: BL to 4w	0.02 (-0.1; 0.1)	0.7	0.06 (-0.0; 0.)	0.32
DPSI change: BL to 3m	- 0.03 (-0.18; 0.12)	0.6	0.13 (-0.02; 0.26)	0.04
DPSI change: BL to 12m	0.01 (-0.12; 0.16)	0.81	- 0.09 (-0.22; 0.04)	0.1
SDSCA				
SDSCA General Diet (GD)				
Baseline (BL)	4.09 (3.62; 4.56)		4.41 (3.94; 4.89)	
SDSCA/GD change: BL to 4w	0.8 (0.28; 1.31)	**0.0002***	0.88 (0.37; 1.39)	**<0.0001***
SDSCA/GD change: BL to 3m	0.77 (0.27; 1.27)	**0.0002***	0.74 (0.24; 1.24)	**0.0004***
SDSCA/GD change: BL to 12m	0.83 (0.33; 1.33)	**<0.0001***	0.43 (-0.06; 0.92)	0.04
SDSCA Specific Diet (SD)				
Baseline (BL)	4.39 (4.09; 4.69)		3.97 (3.67; 4.27)	
SDSCA/SD change: BL to 4w	0.46 (-0.02; 0.94)	0.02	0.94 (0.48; 1.4)	**<0.0001***
SDSCA/SD change: BL to 3m	0.45 (0.00; 0.91)	0.02	0.7 (0.25; 1.16)	**0.0003***
SDSCA/SD change: BL to 12m	0.1 (-0.38; 0.55)	0.64	1.2 (0.75; 1.65)	**<0.0001***
SDSCA Exercise (E)				
Baseline (BL)	3.17 (2.6; 3.74)		3.14 (2.57; 3.71)	
SDSCA/E change: BL to 4w	0.92 (0.37; 1.47)	**<0.0001***	0.34 (-0.2; 0.88)	0.13
SDSCA/E change: BL to 3m	0.48 (-0.04; 1.02)	0.03	0.69 (0.17; 1.21)	**0.002***
SDSCA/E change: BL to 12m	0.55 (0.01; 1.07)	**0.01***	0.46 (-0.05; 0.98)	0.03
SDSCA Blood Glucose Tracking (BG)				
Baseline (BL)	3.88 (3.33; 4.43)		4.43 (3.88; 4.98)	
SDSCA/BG change: BL to 4w	1.17 (0.55; 1.8)	**<0.0001***	0.37 (-0.25; 0.99)	0.15
SDSCA/BG change: BL to 3m	0.89 (0.28; 1.5)	**0.0006***	0.45 (-0.16; 1.06)	0.08
SDSCA/BG change: BL to 12m	0.52 (-0.1; 1.13)	0.04	- 0.21 (-0.81; 0.39)	0.4
SDSCA Foot Care (FC)				
Baseline (BL)	5.01 (4.39; 5.63)		5.28 (4.65; 5.9)	
SDSCA/FC change: BL to 4w	0.63 (-0.02; 1.28)	0.02	0.14 (-0.49; 0.66)	0.77
SDSCA/FC change: BL to 3m	0.78 (0.16; 1.41)	**0.003***	0.2 (-0.43; 0.82)	0.45
SDSCA/FC change: BL to 12m	1.23 (0.62; 1.88)	**<0.0001***	0.81 (0.2; 1.42)	**0.002***
Secondary Outcomes				
PAID				
Baseline (BL)	40.52 (35.28; 45.77)		34.1 (28.78; 39.43)	
PAID change: BL to 4w	4.85 (-0.19; 9.89)	0.02	4.6 (-0.3; 9.49)	0.02
PAID change: BL to 3m	5.82 (0.95; 10.7)	**0.004***	6.13 (1.27; 10.97)	0.03
PAID change: BL to 12m	9.59 (4.71; 14.48)	**<0.001***	4.33 (-0.4; 9.05)	0.03
DSE				
Baseline (BL)	6.95 (6.63; 7.27)		7.11 (6.78; 7.43)	
DSES change: BL to 4w	0.36 (-0.02; 0.75)	0.02	0.47 (0.09; 0.85)	**0.003***
DSES change: BL to 3m	0.59 (0.21; 0.96)	**0.0002***	0.72 (0.35; 1.1)	**<0.0001***
DSES change: BL to 12m	0.45 (0.08; 0.83)	**0.004***	0.7 (0.33; 1.07)	**<0.0001***

Table 2: Change in outcomes across study milestone for each of the arms (positive value indicates increase, (*) indicates statistical significance after adjusting for multiple comparisons (critical values of p=0.0167).

Dosage effect analysis

Overall, there was no association between MoDD usage and HbA1c within the intervention arm. The level of engagement was not associated with the change in HbA1c from baseline to 12m (p=0.26 for logins, and p=0.7 for BG readings).

4. DISCUSSION

This study examined the impact of an mHealth intervention for facilitating problem-solving on diabetes self-management among ethnically diverse low-resource communities.

For all primary outcomes, the study showed no difference between study arms at any of the milestones; however, there was a difference in the way HbA1c changed between different milestones within each of the two arms. Participants in the intervention arm achieved a statistically significant improvement in HbA1c from baseline to 3-month follow-up, which remained statistically significant at 12 months. This improvement is consistent with previous reports of computer-based interventions in diabetes self-management (43),(28) and interventions for problem-solving (44). While the effect size of this improvement was relatively modest (-0.45%), it is larger than the pooled decrease in HbA1c reported in the recent meta-analysis of HIT interventions for medically underserved communities (28). Participants in the control arm achieved comparable improvement at 3 months; however, it was not sustained at the 12 month follow-up. This short-term improvement in HbA1c is somewhat unexpected and could be due to the Hawthorne effect (45), regression to the mean, and the impact of usual care. However, this decrease in HbA1c for the control arm was not sustained at 12 months highlighting the benefit of the intervention for achieving sustained positive change. The high compliance rate with the 12-month follow-up for both arms adds further strength to this result.

There was no change in problem-solving abilities in either study arm. However, it is possible that the measure of problem-solving abilities in this study, DPSI, with its focus on individuals' ability to overcome specific barriers to self-management, was less sensitive to changes in individuals' way of reasoning and problem-solving around high blood glucose levels, which was the focus of the MoDD intervention. This suggests the need for new instruments to measure different aspects of diabetes problem-solving.

For diabetes self-care behaviors, study results were mixed. The consistent increase in the frequency of BG monitoring is not surprising, given that MoDD both encouraged and supported BG tracking. However, the higher frequency of BG measurements was not sustained at 12 months, highlighting barriers to continued BG checking for individuals with type 2 diabetes, including its high cost and potential inconvenience and discomfort. The rest of self-care activities improved inconsistently across study arms and milestones, highlighting challenges in both achieving sustained behavior change and reliably measuring this change with self-reports. Technologies for self-monitoring of meals, physical activity, and adherence to medication can help to more objectively assess changes in these behaviors; however, there are barriers to adoption of these technologies among medically underserved communities that also experience low technological health literacy (46).

Participants in both arms reported moderate to high diabetes distress (PAID) at baseline. Furthermore, participants in the intervention arm, who scored above the clinically established threshold for high diabetes distress (above 40, (47)) and also scored high on depression, reported increase in diabetes distress for each of the study milestones, as compared to no such increase in the control arm. This finding, while concerning, is not surprising, and may be attributed to the increased awareness of high blood glucose levels among participants in the intervention arm who reported higher frequency of BG monitoring (48). Previous research highlighted the need to address diabetes distress with new interventions (48) and this study further reiterates this need.

This study highlighted both the potential of innovative mHealth interventions that target medically underserved communities, and barriers to adopting such interventions and participating in research studies for members of these communities. Close to a quarter of participants deemed eligible refused to participate in the study, which reflects historically complex relationships between these communities and health care (49) as well as competing priorities. Furthermore, many participants of this study lacked basic technology literacy and needed additional technology training (37). While these trends continue to exist, previous research also highlighted the possibility of reducing health disparities with technological interventions (50). For example, widely adopted, inexpensive and scalable technologies, like text messaging, can lower the barrier to engagement with health interventions for diverse communities and have been shown efficacious in past

research (51). Furthermore, deeper engagement with community organizations may help to build trust with local communities and serve as a source of peer educators which might enable more active participation of their members (52).

The main strength of the study is its focus on an mHealth intervention and on economically disadvantaged minority communities. As these communities experience greater prevalence of diabetes and limited access to diabetes care and education, mHealth interventions, if efficacious, have a great potential to ease diabetes burden and improve individuals' health. Cluster randomization and consistency among study arms at baseline contribute to strong internal validity of this trial.

However, there are limitations. First, a relatively high refusal rate may have led to selection bias. Second, reliance on model estimates for the 3 and 12-month HbA1c outcomes to account for missing and misaligned data points may have introduced bias. To account for this, we used linear mixed models, which have particular strengths in providing unbiased estimates for missing values. Finally, behavioral measures used in the study relied on self-assessments by participants and may have been subject to bias, particularly when delivered via an interview with research coordinators.

In summary, this study showed that use of a mHealth intervention for problem-solving in diabetes self-management led to a short-term (3 months) decrease in HbA1c for both study arms, and sustained (12 months) improvement in HbA1c for the intervention arm, with no difference in HbA1c between study arms for any of the milestones. This outcome suggests the feasibility of automated technological interventions that provide guidance and assistance for engaging in diabetes problem-solving and self-management. Given the continuing increase in prevalence of type 2 diabetes, mHealth solutions that supplement the care provided by medical personnel have the potential to engage broader populations of individuals with diabetes.

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7. AUTHORS' RELATIONSHIPS AND ACTIVITIES

The authors have no relevant relationships and activities to disclose.

8. CONTRIBUTION STATEMENTS

All authors participated in planning the trial, interpreting the results, and editing the manuscript. LM wrote the first draft. HJ performed statistical analysis.

The first author serves as the guarantor and takes full responsibility for the work as a whole, including the study design, access to data, and the decision to submit and publish the manuscript.

The authors have no relevant conflicts of interests.

9. DATA AVAILABILITY

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

10. Abbreviations

BG: Blood Glucose

CDE: Certified Diabetes Educator

DPSI: Diabetes Problem-Solving Inventory

DSES: Diabetes Self-Efficacy Scale

EMR: Electronic Medical Record

FQHC: Federally Qualified Health Center

HbA1c: Glycated Hemoglobin

MoDD: Mobile Diabetes Detective

PAID: Problem Areas in Diabetes

SDSCA: The Summary of Diabetes Self-Care Activities

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Supplementary Files

Multimedia Appendixes

Supplementary appendixes.
URL: http://asset.jmir.pub/assets/75bfaca6478feae43449f2401b63203a.docx

CONSORT (or other) checklists

MoDD CONSORT Checklist.
URL: http://asset.jmir.pub/assets/051adfe09b13a44f60bd407897030c1a.pdf