Effects of a Tailored Text Messaging Intervention Among Diverse Adults With Type 2 Diabetes: Evidence From the 15-Month REACH Randomized Controlled Trial

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OBJECTIVE

Text messaging interventions have high potential for scalability and for reductions in health disparities. However, more rigorous, long-term trials are needed. We examined the long-term efficacy and mechanisms of a tailored text messaging intervention.

RESEARCH DESIGN AND METHODS

Adults with type 2 diabetes participated in a parallel-groups, 15-month randomized controlled trial and were assigned to receive Rapid Education/Encouragement and Communications for Health (REACH) for 12 months or control. REACH included interactive texts and tailored texts addressing medication adherence and non-tailored texts supporting other self-care behaviors. Outcomes included hemoglobin A_{1c} (HbA_{1c}), diabetes medication adherence, self-care, and self-efficacy.

RESULTS

Participants ($N = 506$) were approximately half racial/ethnic minorities, and half were underinsured, had annual household incomes <$35,000, and had a high school education or less; 11% were homeless. Average baseline HbA_{1c} was 8.6% ± 1.8%; 70.0 ± 19.7 mmol/mol) with $n = 219$ having HbA_{1c} ≥8.5% (69 mmol/mol). Half were prescribed insulin. Retention was over 90%. Median response rate to interactive texts was 91% (interquartile range 75%, 97%). The treatment effect on HbA_{1c} at 6 months (−0.31%; 95% CI −0.61%, −0.02%) was greater among those with baseline HbA_{1c} ≥8.5% (−0.74%; 95% CI −1.26%, −0.23%), and there was no evidence of effect modification by race/ethnicity or socioeconomic disadvantage. REACH improved medication adherence and diet through 12 months and self-efficacy through 6 months. Treatment effects were not significant for any outcome at 15 months. REACH reduced barriers to adherence, but barrier reduction did not mediate outcome improvements.

CONCLUSIONS

REACH engaged at-risk patients in diabetes self-management and improved short-term HbA_{1c}. More than texts alone may be needed to sustain the effects.

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Medication nonadherence is a leading challenge for the U.S. healthcare system, with associated avoidable costs reaching $300 billion annually (1). Among adults with type 2 diabetes, medication adherence is necessary to achieve adequate glycemic control and avoid complications, yet two-thirds of patients are not meeting adherence targets (2). Patients experience myriad barriers to adherence, including interference with daily activities, fear of side effects, and skepticism around medication benefits (3). Racial/ethnic minorities and persons with low socioeconomic status experience more barriers, leading to lower rates of adherence (4), and worse glycemic control and general health relative to their counterparts (4,5). For these reasons, medication adherence has been the target of many recently developed mobile health (mHealth) interventions (6).

Although these interventions have had promising effects, many risk not benefiting all patients due to technology-related access and cost issues (7). Text messages are already used by patients at risk for poor adherence. Text content can address adherence barriers, and texts can directly support adherence by helping patients self-cue adherence behavior (8). Text messaging is the most common cell phone activity across the 96% of U.S. adults owning cell phones (9,10), is not Internet-dependent, and requires little technological expertise. Moreover, engagement with automated text messages tends to be higher than with other forms of mHealth (8).

Evidence that text messaging interventions can improve diabetes medication adherence in the short term (i.e., for 3–6 months) is accumulating (11), but long-term trials are needed, particularly among patients at high risk for nonadherence (12,13). Few diabetes text messaging interventions have been studied in underserved or minority groups (11), limiting our understanding of how this type of intervention affects those who could benefit most (14). Exploring intervention effects in at-risk subgroups can help to ensure that technology-delivered interventions would not widen disparities if scaled.

Furthermore, we know very little about the mechanisms by which text messaging interventions improve adherence. Most studies report overall effects, without examining what content or functionality contributed to effects. Theories of health behavior specify how certain factors (e.g., beliefs, attitudes, behaviors) impact outcomes. mHealth interventions can deliver content addressing these factors, providing opportunities to understand if changes in these factors drive effects (15). Mediation analysis based on theory provides key guidance on how or why interventions may have been effective and next steps to enhance and sustain effects.

The current study addresses these gaps by evaluating a tailored, theory-based text messaging intervention, called Rapid Education/Encouragement and Communications for Health (REACH) (16,17), in a diverse sample of adults with diabetes for 15 months with a 12-month intervention period and a postintervention follow-up 3 months later to assess the sustained effects. Our trial had goals of enrolling at least 50% of participants who were racial/ethnic minorities and at least 50% with low socioeconomic status to examine subgroup effects. In addition, we sought to understand mechanisms of the intervention effects. Specifically, we evaluated if intervention content reduced targeted theory-based barriers to adherence and if those reductions mediated improvements in adherence or glycemic control. Further, feedback from intervention participants helped illustrate which intervention elements participants perceived as most useful.

RESEARCH DESIGN AND METHODS

This was a three-arm randomized controlled trial (RCT) evaluating two mobile phone–delivered interventions (REACH and Family-Focused Add-on for Motivating Self-Care [FAMS]) on diabetes outcomes (17). FAMS was delivered with REACH, adding components for the first 6 months to include monthly phone coaching to set diabetes self-care goals and improve family/friend involvement in self-care and the option to invite an adult friend/family member to receive text messages about self-care goals (18). Details on both interventions, the RCT protocol, and FAMS effects have been published (16–19). Herein, we present a priori analyses examining the effects of receiving REACH on hemoglobin A_{1c} (HbA_{1c}), medication adherence, and other diabetes self-care behaviors. Procedures were approved by the Vanderbilt University institutional review board. This study is registered with ClinicalTrials.gov (NCT02409329).

Study Participants

Between May 2016 and December 2017, we recruited adult patients from 13 community health center locations and three Vanderbilt primary care locations who were diagnosed with type 2 diabetes and prescribed a daily diabetes medication. Partnering clinics shared lists of potentially eligible patients to whom we mailed letters before calling to describe the study and assess their interest and eligibility. Study staff also recruited from clinic/community events and in clinic waiting rooms. We were able to contact 61% of our potential pool of 3,426 patients (2,091/3,426) (Fig. 1). Exclusion criteria included non-English speaking, not having a cell phone with text messaging capability, having auditory limitations or unable to orally communicate, failing a cognitive screener, unable to text after demonstration by a research assistant (RA), and most recent HbA_{1c} $<$6.8% (51 mmol/mol).

Study Design and Procedure

Enrollment included completing consent, a survey, and an HbA_{1c} test. RAs entered participant data into Research Electronic Data Capture (REDCap) (20). After enrollment, our team's statistician used R software (v.3.5.1) to randomize participants (details in Supplementary Material) using optimal multivariate matching to ensure a covariate balance across study conditions (21). Participants were randomized to control or intervention arms; then those randomized to intervention were matched and randomized to REACH only or REACH with FAMS for a 2:1:1 design. This design optimized our ability to assess effects of receiving any REACH relative to control while also supporting an exploration of the effects of REACH with FAMS. After randomization, RAs called participants to explain their assigned condition; participants who did not complete this call within 3 weeks were administratively withdrawn (17). MEMOTEXT (Bethesda, MD), a digital health platform, used relevant participant information transferred from REDCap via an application programming interface to tailor, schedule, and send text messages (16). Survey and HbA_{1c} test procedures were

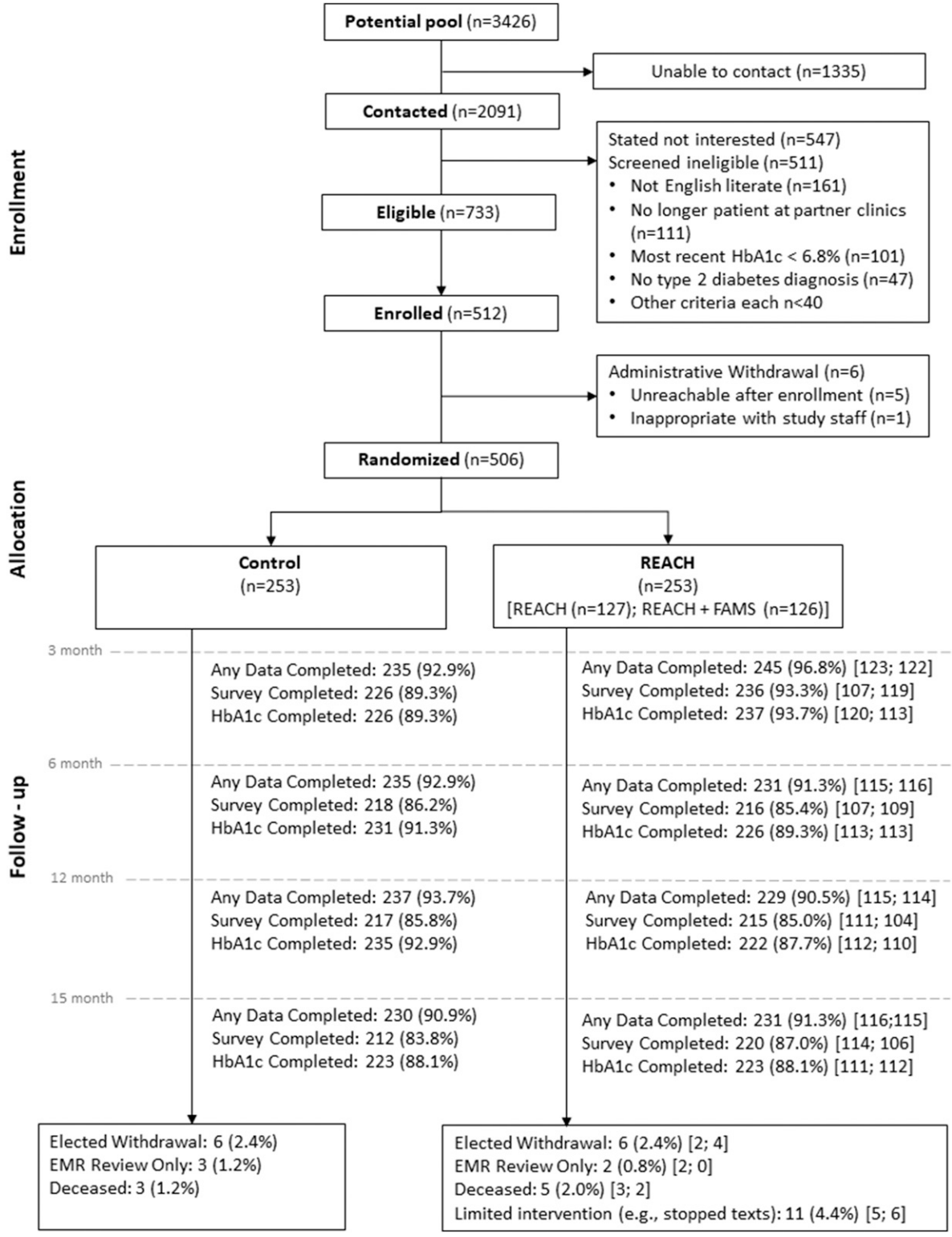

Figure 1—CONSORT flow diagram.

repeated at 3, 6, 12, and 15 months after baseline. Participants were compensated up to $210 for completing all study measures. We did not compensate participants for responding to texts nor provide cell phones or data plans. All study participants received access to a helpline to ask questions about the study and their diabetes medications, text messages advising how to access study HbA_{1c} results, and quarterly newsletters with information on living with diabetes. To encourage retention, we also sent birthday cards and provided study-branded magnets, water bottles, and t-shirts at follow-up assessments. The last follow-up assessment was completed April 2019.

We used strategic purposeful sampling to invite a subset of intervention participants to complete an interview after their RCT participation. Interviews assessed what aspects of REACH participants found most helpful to inform which intervention elements contributed to intervention effects (17). Sampling sought balance on age, sex, race, education, income, clinic site, and owning a basic versus a smart phone. Interviews were conducted in person or by phone and took ~20 min to complete. All interviews were audio recorded and transcribed. Compensation for the interview was $40.

Intervention

All participants assigned to REACH received three types of automated text messages: self-care promotion one-way texts, interactive texts that asked about medication adherence, and adherence feedback texts that provided weekly feedback and encouragement based on responses to the interactive texts. Self-care promotion texts either addressed a nonmedication self-care behavior (i.e., diet, exercise, self-monitoring of blood glucose) or were tailored to address participants' self-identified barriers to medication adherence and their prescribed diabetes medications. When participants completed assessments at 3 and 6 months, text content was updated to reflect their most recent barriers and prescribed medications. For the first 6 months, self-care promotion and interactive texts were sent daily. Half of the participants assigned to receive REACH also received FAMS for the first 6 months. After 6 months, all intervention participants continued to receive REACH with the option to receive fewer texts for the remaining 6 months of the intervention (the low-dose option). If a participant chose the low-dose option, they received three or four self-care promotion one-way messages each week and one weekly interactive message until the intervention period ended; otherwise, both types of texts continued daily.

Measures

Participants reported clinical and sociodemographic characteristics, including measures of subjective healthy literacy (22) and numeracy (23).

Outcomes. Our primary outcome was HbA_{1c}, collected by venipuncture or point-of-care by the patients' clinic or using an HbA_{1c} kit provided and analyzed by CoreMedica Laboratories (Lee's Summit, MO). The kits have been validated against venipuncture and are preferred by patients (24). We used kits to enhance retention and ensure unbiased results by obtaining HbA_{1c} results from participants who did not go to their clinic frequently. Our secondary outcome was medication adherence, assessed with both the Adherence to Refills and Medications Scale for Diabetes (ARMS-D) (25) and the Summary of Diabetes Self-Care Activities medications subscale (SDSCA-MS) (26). We also assessed tertiary outcomes including physical activity (International Physical Activity Questionnaire, short form [IPAQ-SF]) (27), dietary behavior (Personal Diabetes Questionnaire [PDQ] subscale assessing use of dietary information for decision making) (28), and diabetes self-efficacy (Perceived Diabetes Self-Management Scale, four-item version [PDSMS-4]) (29). Self-report measures' psychometric properties are detailed in Supplementary Table 1.

Theory-Based Barriers to Adherence. In our formative work for the trial, we developed an assessment based on the Information-Motivation-Behavioral skills (IMB) model of diabetes medication adherence (30) to identify each user's barriers to adherence and validated it as predictive of adherence behavior (31). We used this measure to assess each participant's barriers to adherence during the intervention period. This measure produced a score for 36 barriers (31 for those not prescribed insulin) on a scale from 1 (never) to 10 (a lot). We identified each participant's four highest-scored barriers, selecting randomly among tied barriers, and summed these four barrier scores to generate a barrier sum score with a possible range from 4 to 40. For participants assigned to intervention, text message content addressed each of the participant's four highest-scored barriers with tailoring updated at 3 and 6 months.

Response Rate. We calculated the participants' response rate to interactive text messages by dividing each participant's number of responses (any response) by the total number of interactive texts sent to that participant.

Analyses

All analyses were performed using R v.3.5.1. The study was designed to enroll $N = 500$ to have power to detect a 0.5% reduction in HbA_{1c} (17). We employed multiple imputation with chained equations to address missing data ($m = 1{,}000$ imputed data sets) and included all randomized participants in analyses. Statistical significance was determined at the $\alpha = 0.05$ level. All analyses compared those receiving the REACH intervention (i.e., REACH or REACH with FAMS) to control except for a subgroup analysis estimating effects of also receiving FAMS.

Outcomes. We used generalized estimating equations (GEE) with a working-exchangeable correlation structure and identity link (32), adjusting for baseline and allowing a time-treatment interaction. For our HbA_{1c} model, we allowed for a three-way interaction between time, treatment group, and baseline HbA_{1c} because there was descriptive evidence that participants with higher baseline values experienced larger intervention effects than those with lower baseline values. For each outcome, we performed an omnibus test of the treatment effect using a robust variance-covariance based Wald statistic. We used ordinary least squares linear regression with Huber-White heteroscedasticity-consistent SEs (33) to obtain point estimates and 95% CIs for the intervention effect on each outcome at each time point.

Subgroup Analyses. The Supplementary Material details subgroup analyses and results. We explored effect modification on HbA_{1c} by participant characteristics, including minority race/ethnicity and whether the participant had at least one marker of socioeconomic disadvantage (to include household income $<$$25,000, homeless, uninsured, years of education completed $<$12 years), and intervention characteristics, such as receiving REACH only versus REACH with FAMS and choosing the low-dose option after 6 months.

Theory-Based Barriers to Adherence. We used ordinary least squares regression to determine the treatment effect on the four highest-scored barriers, which were unique for each participant and targeted by one-way text messages for REACH participants. We calculated a barrier sum score for each participant's highest-scored barriers at baseline and monitored changes in those barriers over the first 6 months of the intervention

period. At baseline, participants assigned to REACH had higher barrier sum scores on average compared with the control group. Therefore, we developed a logistic propensity score model to generate weighted data for analyses correcting for this initial imbalance (detailed in Supplementary Material). Resulting weighted data showed a balance across conditions on the initial barrier sum scores and were used to examine changes in the barrier sum scores between the treatment groups. We then performed mediation analyses to evaluate if REACH's effects on medication adherence and HbA_{1c} were mediated by the barrier sum score (34). For all analyses involving the barrier sum scores, we used the nonparametric bootstrap estimator in conjunction with imputation to form SEs to account for estimation of the propensity score.

Participant Feedback. To help inform which intervention content contributed to the effects, we examined participants' interview feedback regarding what aspects of REACH were perceived as most helpful. We conducted a thematic analysis with NVivo version 11 to identify, organize, and interpret themes in interview transcripts. We constructed a codebook based on coders' preliminary read of the transcripts and then applied the codebook to a subset of the transcripts to clarify definitions and resolve discrepancies. Next, all transcripts were coded independently, with one-third being coded by both reviewers to evaluate interrater reliability ($\kappa = 0.89$). We described themes occurring among at least one-third ($n \geq 15$) of interviewed participants.

RESULTS

Participant Characteristics

Of patients we contacted for recruitment, 26% (547/2,091) stated they were not interested, and 24% (511/2,091) were ineligible after screening (Fig. 1). Of those screened as eligible, 70% (512/733) enrolled, and $N = 506$ were randomized. Approximately half were female, racial/ethnic minority, underinsured, reported annual incomes <$35,000, and had ≤12 years of education; over 11% were homeless (Table 1). About half were prescribed insulin, and average HbA_{1c} was 8.6% (70 mmol/mol). Matched randomization led to strong balance across conditions at baseline, with all P values >0.05 and all standardized mean differences <0.20 (Table 1) except for the barrier sum score (standardized difference 0.21; $P < 0.05$), which we weighted prior to analysis. Measure completion rate was ≥90% at each of the follow-up assessments and did not differ across conditions (Fig. 1). The barriers to medication adherence most commonly included in participants' top four barriers were the same across the intervention and control groups (Supplementary Table 2). Intervention participants responded to a mean of 81% (median 91%; interquartile range 75%, 97%) of the interactive text messages over the 12-month intervention; 56% of participants chose the low-dose option.

Outcomes

Regardless of statistical significance of specific point estimates, treatment effects for all prespecified outcomes demonstrated growing effects from baseline through 6 months, which subsequently reduced at later follow-up times (Figs. 2 and 3). Figure 2 depicts the estimated overall average treatment effect and illustrates predicted mean HbA_{1c} values for different baseline HbA_{1c} values. Although the omnibus test did not achieve statistical significance ($P = 0.26$), significant treatment effects were found at 3 months (−0.26%; 95% CI −0.48%, −0.05%; $P = 0.018$) and 6 months (−0.31%; 95% CI −0.61%, −0.02%; $P = 0.039$). Estimated treatment effects were not significant at 12 and 15 months. Estimates from the full GEE model are shown in Supplementary Table 3. In response to evidence of larger treatment effects among participants with baseline HbA_{1c} ≥8.5% (69 mmol/mol), we replicated the GEE model restricted to those participants ($n = 219$). For this subset, there was a significant omnibus test ($P = 0.036$) (Supplementary Table 4), with treatment effects at 3 months (−0.44%; 95% CI −0.84%, −0.03%; $P = 0.034$) and 6 months (−0.74%; 95% CI −1.26%, −0.23%; $P = 0.005$), but there was no evidence of a 12-month effect (−0.21%; 95% CI −0.78%, 0.36%; $P = 0.475$).

Figure 3 presents the treatment effect estimates for secondary and tertiary outcome measures at each time point. REACH improved diabetes self-efficacy through 6 months, and medication adherence and dietary behavior though 12 months. However, we did not find evidence of sustained 15-month effects for any behavior. There was an overall treatment effect on medication adherence (SDSCA-MS omnibus $P = 0.003$), dietary behavior (omnibus $P = 0.003$), and self-efficacy (omnibus $P = 0.006$) but not on physical activity ($P = 0.465$). Improvements in medication adherence as assessed by the ARMS-D (not in the figure) were not significant per the omnibus test ($P = 0.434$), although the pattern was consistent with the SDSCA-MS (ARMS-D 6-month effect 0.54; $P = 0.055$).

Subgroup Analyses

We found no evidence of subgroup differences in HbA_{1c} based on participant or intervention characteristics (see Supplementary Material).

Theory-Based Barriers to Adherence

There was a treatment effect on barrier sum scores at 3 months (−1.98; 95% CI −3.56, −0.39), although the 6-month effect was nonsignificant (−1.27; 95% CI −3.05, 0.50). There was not sufficient evidence to suggest an indirect effect (i.e., an effect via 3-month barrier sum score) on the 6-month REACH effect for medication adherence (SDSCA-MS indirect effect 0.066; bootstrapped 95% CI −0.046, 0.178) or HbA_{1c} (indirect effect 0.022; bootstrapped 95% CI −0.271, 0.315).

Participant Feedback

Of the 46 participants invited to complete a follow-up interview, 36 (78%) did so. Interviewed participants' characteristics were similar to those of the larger sample: 56% were female; 67% were non-White (53% Black); 44% had ≤12 years of education; and 67% had annual household incomes <$35,000. We identified the following commonly mentioned themes regarding REACH's helpfulness: *1*) medication reminders and feedback ($n = 25$), *2*) accountability ($n = 19$), *3*) encouragement ($n = 17$), and *4*) information ($n = 17$).

The most common themes of medication reminders and feedback and accountability reflected the two-way adherence text messages and associated feedback messages.

> *One of the worst times I had was in the evenings, remembering to take my medicines. . . the text would help me remember to take my medicine [and] helped me get on a regular schedule. (Hispanic, White, Male, 44 years old)*

Table 1—Patient characteristics at baseline ($N = 506$)

Characteristic	REACH ($n = 253$)	Control ($n = 253$)	Standardized difference
Age, years	55.8 ± 9.8	56.1 ± 9.4	0.036
Sex, male	114 (45.1)	118 (46.6)	0.032
Race/ethnicity[a]			
Non-Hispanic White	121 (48.0)	121 (48.2)	0.004
Non-Hispanic Black	99 (39.3)	99 (39.4)	0.000
Non-Hispanic other race(s)	16 (6.3)	16 (6.4)	0.000
Hispanic	16 (6.3)	15 (6.0)	0.016
Socioeconomic status			
Education, years[b]	14.0 ± 3.0	14.1 ± 3.3	0.009
Annual household income[c]			
<$10,000	39 (16.9)	53 (22.8)	0.148
$10,000–$34,999	96 (41.6)	93 (39.9)	0.033
$35,000–$54,999	32 (13.8)	36 (15.4)	0.045
≥$55,000	64 (27.7)	51 (21.9)	0.134
Health insurance[d]			
Uninsured	51 (15.6)	66 (26.2)	0.137
Public only	61 (24.4)	65 (25.8)	0.036
Private	138 (55.2)	121 (48.0)	0.134
Homeless[e]	32 (12.7)	26 (10.4)	0.072
Diabetes duration, years	10.8 ± 7.5	11.3 ± 8.4	0.059
Brief Health Literacy Scale	13.0 ± 2.6	13.2 ± 2.4	0.076
Subjective Numeracy Scale	4.4 ± 1.3	4.4 ± 1.3	0.009
Medication regimen			
Oral medications only	128 (50.6)	132 (52.2)	0.032
Oral medications and insulin	84 (33.2)	79 (31.2)	0.042
Insulin only	41 (16.2)	42 (16.6)	0.011
Clinic site, CHC	107 (42.3)	109 (43.1)	0.016
Diabetes self-efficacy (PDSMS-4)	13.9 ± 3.5	13.9 ± 3.7	0.002
Physical activity (IPAQ-SF)	2,204.8 ± 2,711.1	2,354.6 ± 2,863.2	0.054
Dietary behavior (PDQ)	3.0 ± 1.6	3.0 ± 1.7	0.002
Medication adherence			
ARMS-D	39.8 ± 3.8	40.2 ± 3.4	0.117
SDSCA medications subscale	6.3 ± 1.2	6.4 ± 1.2	0.075
IMB barrier sum score	18.4 ± 11.7	15.9 ± 12.0	0.212
HbA_{1c}, % (mmol/mol)	8.6 ± 1.8 (70.0 ± 19.7)	8.5 ± 1.8 (69.0 ± 19.7)	0.049

Data are mean ± SD or *n* (%). Standardized difference was calculated using Cohen *d*. CHC, Community Health Center. [a]Three participants did not report race/ethnicity. [b]Eight participants did not report years of education. [c]42 participants did not report income. [d]Four participants did not know their insurance status. [e]Seven participants did not report information on housing; homeless is as defined by U.S. Department of Health and Human Services, Section 330(h)(5)(A) and Health Resources and Services Administration, Bureau of Primary Health Care, Program Assistance Letter 99–12, Health Care for the Homeless Principles of Practice.

> *[The texts] made me want to be accountable for something that I know I needed to do, as far as my health goes. It made me proud to know that I could do it. Where I could respond with, "Yes, I took my medicine every day. I didn't skip [any]"... And then, when I didn't feel fine, I could say, "I didn't take the medicine this day" and I felt like I was getting encouragement. (Non-Hispanic, Black, Female, 37 years old)*

Encouragement and information provided by the one-way texts, which included messages designed to address each participants' unique barriers to medication adherence, were infrequently mentioned. When participants did mention one-way messages, they most frequently commented on the helpfulness of information on meal planning and healthy eating.

> *I never changed [my] diet. I never went in a store and actually looked like, "This got 80 carbs, this got 80 sugars. I'm not going to get it." I actually will look at it [now]...because I know the REACH program told me watch the labels. (Non-Hispanic, Black, Female, 26 years old)*

> *Maybe 1 day you don't really think about it, but then the next day, you get some message and it makes you say...today, I think I'll fix some fresh vegetables or steam some vegetables or something like that. (Non-Hispanic, Black, Female, 59 years old)*

CONCLUSIONS

An individually tailored, theory-based text messaging intervention improved HbA_{1c} and diabetes self-efficacy at 6 months and medication adherence and dietary behavior at 6 and 12 months in a diverse sample of adults with type 2 diabetes. As might be anticipated, participants with the highest baseline HbA_{1c} had the largest treatment effect at 6 months. This finding is consistent with another recent study of a diabetes application (35), suggesting mHealth interventions may be most useful for patients with elevated glycemia. Although we did not find sustained effects at 15 months, our 6- and 12-month effects are encouraging given the diversity in our sample

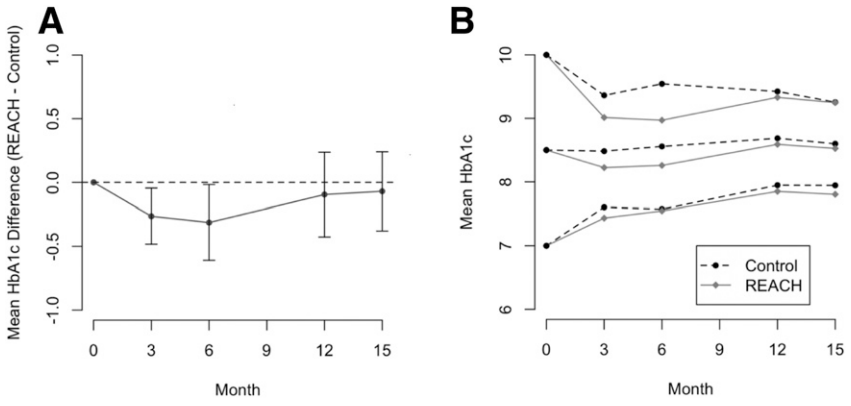

Figure 2—REACH treatment effects on HbA_{1c} over 15 months. *A*: Estimated overall effect of REACH on mean HbA_{1c} (adjusted for baseline) at each time point, with 95% CIs. *B*: Stratified estimation of REACH effect on mean HbA_{1c} based on the full GEE model with interactions; depicted are the estimated effects at each time point for subgroups of individuals with baseline HbA_{1c} of 7.0% (53 mmol/mol), 8.5% (69 mmol/mol), and 10.0% (86 mmol/mol).

and inclusion of traditionally underrepresented groups. We also examined a priori moderators of intervention effects on HbA_{1c} and found no effect modification by participants' race/ethnicity or socioeconomic disadvantage, nor by receipt of additional intervention components (i.e., phone coaching and the option to invite a support person to receive texts) or opting for fewer texts after the first 6 months.

Because one-way text messages included content addressing adherence barriers per the IMB model of diabetes medication adherence, we assessed the effects of this content on barriers to adherence across conditions and examined if reductions in barriers drove (mediated) improvements in medication adherence or HbA_{1c}. Although there was evidence of a treatment effect on barriers from baseline to 3 months, there was no evidence of subsequent barrier reductions nor sufficient evidence to conclude that improvements in barrier scores mediated these 6-month treatment effects. Barrier reductions were short-term, whereas improvements in adherence and high response rates to the interactive texts assessing adherence were both maintained for 12 months. In interview feedback, participants emphasized the interactive texts asking about adherence when describing REACH's helpfulness. Thus, adherence improvements occasioned by REACH are likely primarily attributable to these interactive texts rather than the one-way content targeting users' personal adherence barriers. On the other hand, dietary behaviors were only addressed with one-way texts, and the treatment effect on dietary adherence was also significant at 6 and 12 months. Participant feedback indicates the texts pertaining to diet were the most helpful one-way texts. To date, few mHealth interventions incorporate theories of health behavior (36). As this field continues to grow, more studies are needed that use theory to target their content and empirically test what components drive outcomes.

Similar interventions have demonstrated improvements on HbA_{1c} at 6 months (37,38), but persistence of those effects has largely been unexplored (11) prior to this study. We are aware of only one study testing an intervention similar to REACH beyond 12 months. Dobson et al. (39) reported sustained improvements in HbA_{1c} 15 months after their intervention ended. However, their results should be interpreted with caution because half of the intervention participants elected to stop the program early, and follow-up data were affected by large and differential loss to follow-up. In contrast, our retention and response rate remained high, which is a major strength of our study. REACH's effects on all outcomes showed a similar pattern: effects up to 6 months or 12 months which diminished after the intervention. The relapse in HbA_{1c} predated relapse in self-reported behaviors. In a meta-analysis of RCTs evaluating applications for diabetes, studies with shorter intervention durations ($\leq$6 months) had larger HbA_{1c} reductions than those with longer durations ($>$6 months), indicating that mHealth effects may attenuate over time (40).

Our conclusion from our findings in the context of the extant literature is that text messaging is an ideal mechanism for engaging adults at-risk for poor outcomes in diabetes self-management, but additional components may be needed over time to sustain effects. REACH helped patients remember their medications and reduced initial adherence barriers, but some barriers may be difficult to address with text content alone. Addition of tailored components such as counseling with a clinical pharmacist, diabetes self-management education, or health coaching may be needed to address some barriers (e.g., beliefs and behavioral skills deficits) to maintain behavioral improvements. Integration of REACH with clinical care may also sustain treatment effects on HbA_{1c}. Patients' adherence data collected via the text messages and/or persistent barriers to adherence could inform medication regimen changes to sustain adherence and enhance impact on HbA_{1c}. An important next step is to meaningfully integrate mHealth interventions that improve self-care into clinical care to determine if effects can be enhanced and sustained.

Limitations include our use of self-report measures for behavioral outcomes, which have low participant burden but are subject to recall and social desirability bias. However, consistency in the pattern of results across the objective measure of HbA_{1c} and the self-reported behaviors lends credibility to the self-report findings. Physical activity is a complicated behavior to assess and intervention effects on physical activity were difficult to detect due to very large SEs. Our findings may not generalize to other regions or to other patient populations. However, oversampling racial/ethnic minorities and patients with lower socioeconomic status enhances generalizability to adults with diabetes at higher risk for poor outcomes. Pragmatic elements of our trial (e.g., few exclusion criteria, recruiting from community clinics, and not paying for/providing phones or plans) enhance the real-world applicability of our findings.

Tailored, automated, interactive text messages can engage diverse adults with

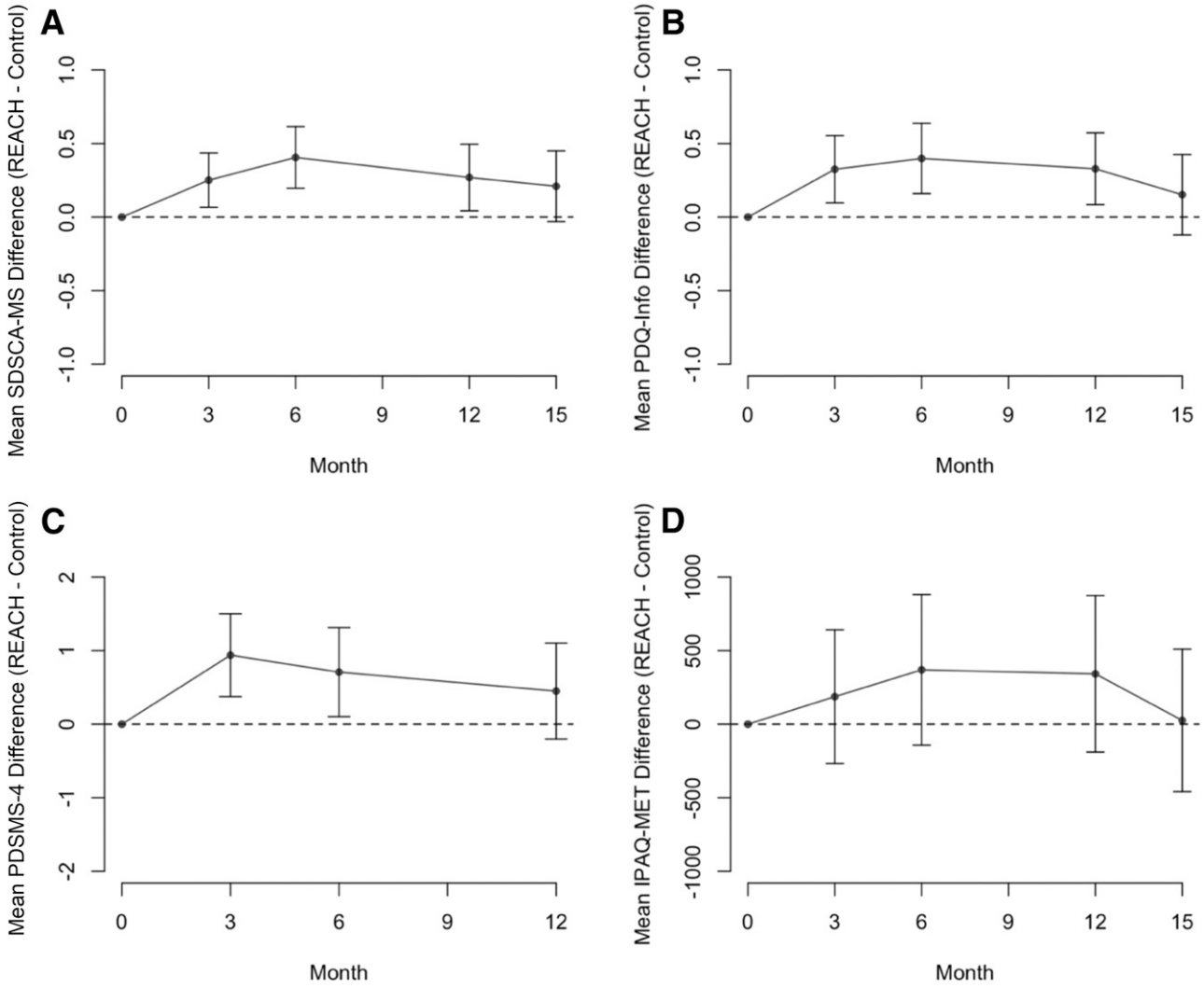

Figure 3—REACH effects on self-care behaviors over 15 months. Estimated effect of REACH on mean secondary/tertiary outcomes (adjusted for baseline) at each time point, with 95% CIs. *A*: Medication adherence as assessed by the SDSCA-MS. *B*: Dietary behavior as assessed by the PDQ subscale Use of Dietary Information for Decision Making. *C*: Self-efficacy as assessed by the PDSMS-4. *D*: Physical activity as assessed by the IPAQ-SF.

type 2 diabetes in medication adherence and dietary behavior and can substantively improve glycemic control among patients with elevated glycemia in the short-term. To sustain effects, it may be necessary for robust text messaging interventions like REACH to be meaningfully integrated into clinical care or with other effective interventions.

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