

# Trial to Examine Text Message–Based mHealth in Emergency Department Patients With Diabetes (TEXT-MED): A Randomized Controlled Trial

Sanjay Arora, MD; Anne L. Peters, MD; Elizabeth Burner, MD, MPH; Chun Nok Lam, MPH; Michael Menchine, MD, MPH

**Study objective:** Increasingly, low-income inner-city patients with diabetes utilize emergency departments (EDs) for acute and chronic care. We seek to determine whether a scalable, low-cost, unidirectional, text message–based mobile health intervention (TEXT-MED) improves clinical outcomes, increases healthy behaviors, and decreases ED utilization in a safety net population.

**Methods:** We conducted an randomized controlled trial of 128 adult patients with poorly controlled diabetes (glycosylated hemoglobin [Hb A<sub>1c</sub>] level  $\geq 8\%$ ) in an urban, public ED. The TEXT-MED group received 2 daily text messages for 6 months in English or Spanish. The primary outcome was change in Hb A<sub>1c</sub> level. Secondary outcomes included changes in medication adherence, self-efficacy, performance of self-care tasks, quality of life, diabetes-specific knowledge, ED utilization, and patient satisfaction.

**Results:** Hb A<sub>1c</sub> level decreased by 1.05% in the TEXT-MED group compared with 0.60% in the controls ( $\Delta 0.45$ ; 95% confidence interval [CI]  $-0.27$  to  $1.17$ ) at 6 months. Secondary outcomes favored the TEXT-MED group, with the most sizable change observed in self-reported medication adherence (as measured by the Morisky Medication Adherence Scale, an 8-point validated scale with higher scores representing better adherence), which improved from 4.5 to 5.4 in the TEXT-MED group compared with a net decrease of  $-0.1$  in the controls ( $\Delta 1.1$  [95% CI  $0.1$  to  $2.1$ ]). Effects were larger among Spanish speakers for both medication adherence ( $1.1$  versus  $-0.3$ ;  $\Delta 1.4$ ; 95% CI  $0.2$  to  $2.7$ ) and Hb A<sub>1c</sub> ( $-1.2\%$  versus  $-0.4\%$ ) in the TEXT-MED group. The proportion of patients who used emergency services trended lower in the TEXT-MED group (35.9% versus 51.6%;  $\Delta 15.7\%$ ; 95% CI  $9.4\%$  to  $22\%$ ). Overall, 93.6% of respondents enjoyed TEXT-MED and 100% would recommend it to family/friends.

**Conclusion:** The TEXT-MED program did not result in a statistically significant improvement in Hb A<sub>1c</sub>. However, trends toward improvement in the primary outcome of Hb A<sub>1c</sub> and other secondary outcomes, including quality of life, were observed, the most pronounced being improved medication adherence. TEXT-MED also decreased ED utilization. These findings were magnified in the Spanish-speaking subgroup. Technologies such as TEXT-MED represent highly scalable, low-cost, and widely accessible solutions for safety-net ED populations. [Ann Emerg Med. 2013;■:1-10.]

Please see page XX for the Editor's Capsule Summary of this article.

0196-0644/\$-see front matter

Copyright © 2013 by the American College of Emergency Physicians.

<http://dx.doi.org/10.1016/j.annemergmed.2013.10.012>

## INTRODUCTION

### Background

Diabetes is a mounting public health epidemic affecting 25 million (just over 1 in 10) adults in the United States.<sup>1,2</sup> Low-income, underserved, inner-city, and minority groups who receive care in safety-net systems are disproportionately affected.<sup>3-5</sup> This is particularly evident in Latinos, who are twice as likely as non-Latino whites to develop diabetes and are 50% more likely to die from the condition.<sup>1,6,7</sup> Healthy eating, regular exercise, and medication adherence can improve glycemic control and health outcomes in patients with diabetes.<sup>8-11</sup> Traditionally, diabetes teaching and support occurs in an outpatient setting; however, patients in public safety-net systems face severe structural (eg, appointment availability) and personal (eg, time,

finances, health behaviors) barriers to establishing regular outpatient care. Increasingly, these patients are utilizing emergency departments (EDs) for both acute and chronic diabetes management.<sup>12-14</sup> Innovative approaches are needed to reach, engage, and activate at-risk populations to bridge the gap between urgent visits to the ED and follow-up care. Automated mobile health (mHealth) programs offer pragmatic, cost-effective, highly engaging, and scalable solutions that can affect population health by initiating a transition between acute ED encounters and long-term diabetes management.

mHealth is broadly defined as the use of mobile telephones as a vehicle to provide public health or medical interventions. Early reports of mHealth solutions for diabetes care are generally positive.<sup>5,15-20</sup> However, most existing programs are complex,

**Editor's Capsule Summary***What is already known on this topic*

Mobile health interventions hold the promise of improving health outcomes with low-cost disease management interventions.

*What question this study addressed*

This randomized trial of 128 low-income type 2 diabetic patients examined whether unidirectional daily text messaging of generic care reminders improved glucose profile and other measures of self-care.

*What this study adds to our knowledge*

The intervention produced only modest improvement in diabetes metrics but was viewed favorably by participants and offers some evidence that this limited type of mobile health intervention is feasible.

*How this is relevant to clinical practice*

If more rigorous studies of similar interventions are replicated, larger-scale and more comprehensive implementation of mobile technology–assisted disease management will be warranted.

requiring bidirectional remote monitoring of blood glucose levels and more expensive Smartphones to access advanced mobile telephone features (eg, applications [“apps”]/mobile Web). Such technologic complexity drives higher total costs and decreases adoption. National estimates show that more than 80% of inner-city and Latino patients have and use text message–capable telephones, but comparatively few have Smartphones.<sup>21</sup> Consequently, most existing mHealth solutions may be inaccessible for low-income patients and the health systems that serve them.

**Importance**

Text messages can be accessed on almost any mobile telephone to support an understandable, engaging, and low-cost self-management dialogue. Further, text-based interventions can provide the frequency of interaction and personal touch required to effect meaningful change in diabetes self-management behaviors. A recent investigation of a unidirectional (broadcast) text message–based intervention for low-resource ED patients with poorly controlled diabetes produced promising results.<sup>22</sup> After a 3-week pilot study, subjects reported improvements in healthy behaviors, diabetes self-efficacy (the belief that one is able to care for oneself), and medication adherence, along with high program satisfaction. In accordance with these encouraging results, a 6-month text message program was developed in

Spanish and English called TExT-MED (Trial to Examine Text Message Based mHealth in ED Patients With Diabetes), with the goal of improving glycemic control, promoting self-care behaviors, and augmenting self-efficacy.

**Goals of This Investigation**

The aim of the present study was to evaluate a broadly scalable mHealth intervention (health-related daily text messages for 180 days) for resource-poor ED patients with diabetes. Special emphasis was given to Spanish-speaking patients because they are a highly vulnerable and understudied population.

**MATERIALS AND METHODS****Study Design**

This was an open-label RCT of the TExT-MED intervention compared with a control group receiving usual care. Clinical follow-up was determined by treating physicians, and no additional clinical appointments were made as part of the study protocol for patients in either group. In addition to usual care, subjects randomized to TExT-MED received daily text messages delivered to their mobile telephone in English or Spanish, according to patient preference. Text messages were delivered by a third-party message delivery service (Rip Road LLC, New York, NY). Patients in the treatment group were able to opt out of the program at any time by texting “stop” in English or “para” in Spanish in response to any message.

At enrollment, subject characteristics were collected, including but not limited to sex, age, income, and education. The primary outcome of interest was the change in Hb A<sub>1C</sub> at 6 months between groups. Secondary outcomes, including changes in medication adherence, self-efficacy, performance of self-care tasks, quality of life, and diabetes-specific knowledge, were collected at enrollment and at 6-month follow-up. Health care use was evaluated during the study period for both groups. Program satisfaction was assessed at the 6-month follow-up visit for those patients in the intervention group. All subjects, regardless of treatment allocation, received modest compensation (\$175 during 6 months) for time and travel costs associated with study follow-up visits. Subjects randomized to the TExT-MED intervention were upgraded to an unlimited messaging plan if they were not already part of one. This occurred for 3 subjects, and they were given \$20 per month to upgrade their plans.

**Setting and Selection of Participants**

This study was conducted in the ED at Los Angeles County Hospital of the University of Southern California, the largest safety-net hospital of the public care system in Los Angeles County, serving more than 170,000 resource-poor patients annually. Patients are overwhelmingly low income and frequently from ethnic minority groups (70% Latino, 14% black), and they usually lack insurance.

Inclusion criteria were that participants speak and read English or Spanish, use text messages on their mobile telephones,

have type 2 diabetes, and have Hb A<sub>1C</sub> level greater than or equal to 8%. We elected to include only subjects with Hb A<sub>1C</sub> level greater than or equal to 8% (measured by the research assistant with the Afinion AS-100 point-of-care meter; Axis-Shield PoC AS, Oslo, Norway) in the RCT because they have the greatest potential to demonstrate a treatment effect. Exclusion criteria were overt psychosis/critically ill/altered mental status, inability to provide written informed consent, and pregnancy. Institutional review board approval was obtained and the trial was registered at [ClinicalTrials.gov](http://ClinicalTrials.gov) (identifier NCT01403831) before study initiation.

### Interventions

The Los Angeles County Hospital of the University of Southern California ED uses the Wellsoft Emergency Department Information System (version 11; Wellsoft, Somerset, NJ) for patient tracking. The system was modified to “flag” patients who were aged 18 years or older and with diabetes, allowing research assistants to identify and approach a consecutive sample of potentially eligible patients during daytime hours between August 2011 and November 2011. All patients flagged by the Wellsoft system regardless of socioeconomic status, cell telephone ownership, living situation, language, and comorbid conditions were approached for potential enrollment. After informed consent, subjects were assigned to a treatment group by computer-generated random assignment, using a permuted block randomization scheme of variable block length to ensure that approximately equal numbers of subjects were assigned to each group at any point during the enrollment process.

TEXT-MED is a unidirectional text-message intervention developed to enhance patient motivation, self-efficacy, and ability to perform diabetes self-care behaviors while providing text message “triggers” to engage in self-care activities and medication adherence. In the TEXT-MED system, patients received 2 messages (9 AM and 5 PM) delivered to their mobile telephones daily for 6 months. All messages were in text-compatible 160-character phrases. Specific content for each message was developed through an iterative process combining (1) currently available materials from the National Diabetes Education Program (public domain, bilingual, nonbranded, written at a fifth-grade reading level, and available in both English and Spanish); (2) multidisciplinary expert opinion from an endocrinologist, a qualitative researcher, and a certified diabetes educator; (3) knowledge gaps and areas of specific interest identified in previous work with the target population (eg, hypoglycemia symptoms, healthy food choices)<sup>4</sup>; and (4) previous mHealth experience gained through pilot work at Los Angeles County Hospital of the University of Southern California (eg, optimizing message frequency, complying with mobile carrier requirements). The TEXT-MED curriculum contains messages in the following 4 categories:

- Educational/motivational (1 per day). These messages were based on National Diabetes Education Program content areas: Blood Glucose Control, Blood Pressure, Cholesterol,

Controlling Diabetes, Foot Care, Healthy Eating, Heart Disease, Physical Activity, Recipes, and Social Support. Sample educational/motivational text-messages included “Having diabetes can lead to a heart attack or stroke—but it doesn’t have to,” “Controlling your blood glucose, blood pressure, and cholesterol—can mean a longer and healthier life,” and “Eat more fruits, vegetables, beans, and whole grains and less salt and fat.”

- Medication reminders (3 per week). Medication reminder messages provided a trigger to increase adherence with prescribed medications. A sample reminder message is “Medication reminder! Don’t leave home without your medications.”
- Healthy living challenges (2 per week). These messages offered patients a concrete, attainable goal for the day. The challenges were based on healthy living principles championed by the American Diabetes Association and the National Diabetes Education Program. Sample challenge messages included “Challenge! Don’t drink any soda or juice today. Only drink water or milk” and “Challenge! Look at food labels and find a snack that has less than 100 calories.”
- Trivia (2 per week). These messages were derived from National Diabetes Education Program materials and designed to educate and engage patients and were presented in question form. The answer to the question was sent out 1 hour after the initial trivia message was received. Sample trivia text is “Trivia: Eating too much sugar and other sweet foods is a cause of diabetes. A. True; B. False.”

### Outcomes Measures

All outcomes were assessed at a nonclinical appointment with a study research assistant. The primary outcome of interest, Hb A<sub>1C</sub>, was measured with the Afinion AS-100 (Axis-Shield PoC AS) Food and Drug Administration–approved capillary point-of-care meter, which reports National Glycohemoglobin Standardization Program–aligned values. Medication adherence was estimated with the Morisky Medication Adherence Scale–8, which is a validated self-report of medication-receiving behavior.<sup>23</sup> Self-efficacy, the belief that one can complete tasks and reach goals, was measured with the Diabetes Empowerment Scale Short Form, a validated tool allowing an overall assessment of diabetes-related psychosocial self-efficacy.<sup>24</sup> Performance of self-care tasks was measured with the Summary of Diabetes Self Care Activities Scale, a 25-item self-report measure assessing diet, exercise, medication taking, foot care, and smoking.<sup>25,26</sup> Patients’ quality of life was measured with the Problem Areas in Diabetes Scale, a validated, 20-item measure of diabetes-related emotional distress.<sup>27,28</sup> Diabetes-specific knowledge was evaluated with the Michigan Diabetes Knowledge Test, consisting of 23 general diabetes knowledge questions.<sup>29</sup> ED utilization was calculated by examining the visit log during the intervention period for each patient in the Los Angeles County electronic health record. Participant satisfaction was assessed in the intervention group only with a locally developed mHealth satisfaction survey, which has been used in pilot mHealth work.<sup>22</sup> This survey contains

Likert-type questions assessing various aspects of the program, including perceived efficacy, opinions on types and frequency of text messages, appropriateness of level of text message content, and willingness to continue with or recommend the program to family or friends.

### Primary Data Analysis

In accordance with previous work at Los Angeles County Hospital of the University of Southern California showing a mean Hb A<sub>1C</sub> level of 9.9%, with SD of 1.69 in subjects similar to the study target group, a sample size of 90 patients (45 per group) provides 80% power to detect a treatment effect of 1% absolute decrease in Hb A<sub>1C</sub> across treatment groups (with 2-tailed  $\alpha=.05$ ). We elected to augment the sample size to account for up to an anticipated 30% rate of loss to follow-up, enrolling 128 total subjects (64 per group).

Descriptive statistics were generated for all variables and each was graphically analyzed. The analysis followed intent-to-treat principles. Mann-Whitney *U* test was used to assess the primary outcome of Hb A<sub>1C</sub> across treatment groups at 6 months.  $P<.05$  was considered statistically significant. Secondary outcomes, including changes in medication adherence, self-efficacy, diabetes knowledge, quality of life, and self-care activities, were assessed with a similar framework. The significance of secondary outcomes was assessed with Student's *t* test. Satisfaction with the TExT-MED intervention was assessed through descriptive analyses. The proportion of patients in the treatment group who opted out was obtained from the text message delivery provider. Finally, the outcomes for the subgroup of patients who received the messages in Spanish were analyzed separately with the above methods.

Loss to follow-up and missing data were substantial concerns for this trial. We planned to account for this with sample size inflation and a data imputation strategy in the primary analysis. Because both control and the TExT-MED groups demonstrated marked improvement in the primary outcome, carrying the last value forward would likely underestimate treatment effects. A simple mean substitution would reduce the natural variance expected to be observed in the sample and bias away from the null. To perform an analysis based on intent-to-treat principles in which all patients have outcome assessments, we imputed missing data. For the imputation, we calculated slopes for both the control and treatment groups and did not introduce randomness. We elected to apply the control group slope to impute missing data for both groups because this is a more conservative approach and minimizes the chance of a type 1 error.

## RESULTS

Of 416 patients with diabetes, 153 met all eligibility requirements. Reasons for exclusion are detailed in the Figure. Of eligible patients, the majority (84%) agreed to participate and 128 were randomized. At 6 months, 92 patients completed their exit interviews (47 intervention, 45 control). Baseline

characteristics of the total sample and each group are provided in Table 1. Graphs detailing individual and group level data are shown in Appendix E1 (available at [www.annemergmed.com](http://www.annemergmed.com)).

### Main Results

The primary outcome of median Hb A<sub>1C</sub> decreased by 1.05% in the TExT-MED group compared with 0.60% in the control group ( $\Delta$  0.45; 95% CI  $-0.27$  to  $1.17$ ). Similar trends toward greater improvement in the treatment group were observed in all secondary outcomes. The most sizable change was in medication adherence, which improved from 4.5 to 5.4 in the TExT-MED group compared with a net decrease of  $-0.1$  in the controls ( $\Delta$  1.1; 95% CI  $0.1$  to  $2.1$ ). The proportion of patients who used emergency services during the 6-month follow-up period trended lower in the TExT-MED group compared with usual care (35.9% versus 51.6%). However, the proportion who used primary care was similar between groups (56.3% versus 53.1%) (Table 2). Sensitivity analyses conducted with a per-protocol method and imputation by mean substitution did not substantially alter the main findings. Subjects rated satisfaction with the TExT-MED program very highly. The majority of patients believed the program was a good way to learn about diabetes (25.5% strongly agree, 68.1% agree), enjoyed the program (40.4% strongly agree, 53.2% agree), and understood all of the messages (53.2% strongly agree, 36.2% agree). One hundred percent of respondents would recommend TExT-MED to a family member or friend with diabetes (Table 3). No patients opted out of the program.

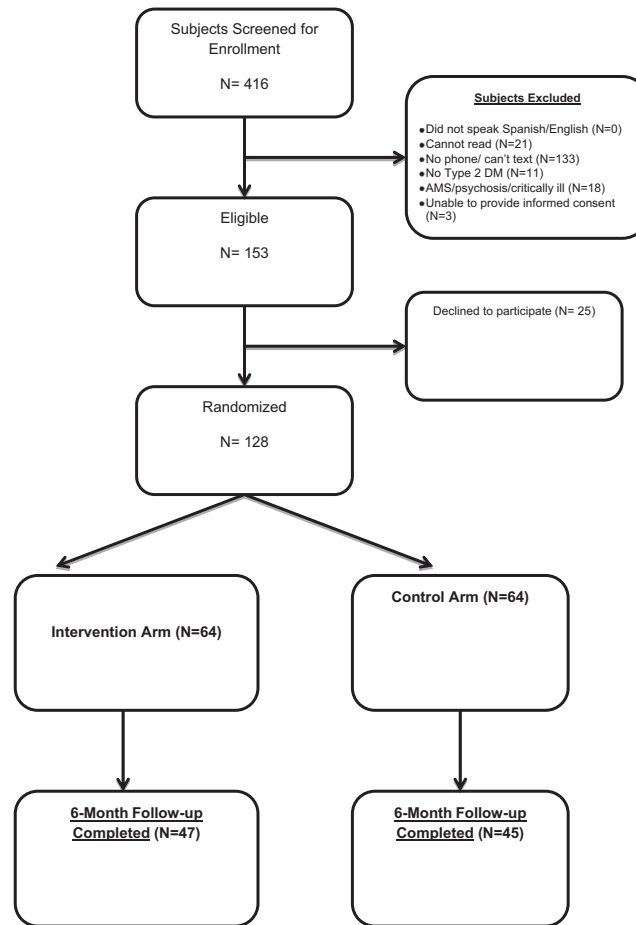
When the data were analyzed among Spanish speakers ( $n=92$ ), the effect of TExT-MED was larger for both medication adherence (1.1 versus  $-0.3$ ;  $\Delta$  1.4; 95% CI  $0.2$  to  $2.7$ ) and Hb A<sub>1C</sub> ( $-1.2\%$  versus  $-0.4\%$ ) in the TExT-MED group. Additionally, trends toward greater improvement in other secondary outcomes were more pronounced (Table 2).

### LIMITATIONS

Limitations to our study include that patients were recruited from a single safety-net ED, thereby limiting the generalizability of the findings. However, the findings of this study are similar to those seen in the Mobile Diabetes Intervention Study and other mHealth interventions for diabetes that were conducted in more diverse settings, suggesting a consistent effect. Also, medication adherence was measured by self-report, introducing potential recall bias. But we have no reason to believe this bias would be different across the treatment groups, and the Morisky Medication Adherence Scale is a validated and widely used tool for measuring this metric.

Subject satisfaction with the program was high, but this may represent social desirability bias wherein subjects reply favorably because they think the investigator wants them to. Although we cannot assess this directly, the fact that no patient opted out of the intervention during the trial adds confidence to our satisfaction results.

Another limitation of this investigation is that we did not examine which messages or message types were most effective but instead report on the overall program. Future evaluations should



**Figure.** Patient flow. *DM*, Diabetes mellitus; *AMS*, Altered mental status.

focus on which components of the program are most engaging and effective. ED utilization was measured by examining the Los Angeles County electronic medical record, which could underrepresent subjects' total number of ED visits. Again, we have no reason to believe these missed visits would differ across treatment groups.

The randomization process resulted in a lower proportion of Spanish speakers in the intervention group. Because Spanish speakers showed greater improvement, this imbalance may have biased our results toward the null.

Finally, 28% of enrolled subjects were lost to follow-up. However, we accounted for this in the design, statistical power was maintained, it did not differ across treatment groups, and therefore our estimates of the treatment effects are likely unbiased.

## DISCUSSION

In this trial of resource-poor English and Spanish speakers in a safety net ED, the TExT-MED program did not result in a statistically significant improvement in Hb A<sub>1C</sub> level. However, trends toward improvement in the primary outcome of Hb A<sub>1C</sub> and other secondary outcomes were observed, with the most

pronounced being improved medication adherence. Increased medication adherence makes TExT-MED a noteworthy success because efficacious pharmacotherapy can delay disease progression and mitigate diabetes complications.<sup>30-33</sup> Among Spanish speakers, the TExT-MED intervention appeared to produce a more pronounced improvement in glycemic control compared with that of controls. TExT-MED users were extremely satisfied with the program and remarkably eager to recommend the program to family members or friends.

Historically, patients in safety-net hospitals or public health systems have been difficult to reach, engage, and retain.<sup>34-36</sup> They experience long delays between provider visits, experience fragmented care, and often have language or cultural discordance with their providers. Innovative strategies using case management, community health workers, and health system navigators have been developed to address these failures and the health outcome disparities they produce. Though often successful, these strategies are cost and labor intensive, making them generally difficult to implement and maintain.<sup>37-40</sup> Unlike these other interventions, mHealth solutions such as TExT-MED (unidirectional, broadcast text messages) require minimal capital/personnel investment, making them particularly attractive to underresourced systems. Moreover, because this mHealth

**Table 1.** Characteristics of the study sample.\*

Characteristics	Baseline, Total		Intervention		Control	
	(n=128)		(n=64)		(n=64)	
Age, mean (SD) y	50.7	(10.2)	50.5	(10.3)	51.0	(10.2)
Number of children	2.8	(2.1)	2.8	(2.2)	2.9	(2.1)
<b>Sex</b>						
Male	46	(36)	26	(40)	20	(31)
Female	82	(64)	38	(60)	44	(69)
<b>Race/ethnicity</b>						
Hispanic/Latino	112	(87)	55	(86)	57	(89)
Black	11	(9)	6	(9)	5	(8)
White	3	(2)	2	(3)	1	(2)
Asian/Pacific Islander	2	(2)	1	(2)	1	(1)
<b>Language</b>						
English	36	(28)	24	(37)	12	(19)
Spanish	92	(72)	40	(63)	52	(81)
<b>Blood pressure, mm Hg</b>						
Systolic (mean, SD)	136.6	23.3	136.0	25.5	137.1	21.1
Diastolic (mean, SD)	74.4	14.6	74.2	16.1	74.7	13.1
Height, in. (mean, SD)	64.4	3.3	64.7	3.5	64.2	3.2
Weight, lb (mean, SD)	186.8	49.4	191.3	57.0	182.4	40.3
Years with diabetes (mean, SD)	10.5	8.6	10.9	10.4	10.1	6.5
Hb A <sub>1c</sub> (mean, SD)	10.1	1.7	10.2	1.7	10.0	1.7
Has regular medical provider	74	(58)	35	(55)	39	(61)
<b>Medical history</b>						
High blood pressure	83	(65)	38	(59)	45	(70)
High cholesterol	67	(52)	35	(55)	32	(50)
Heart disease	19	(15)	11	(17)	8	(13)
Kidney disease	16	(13)	7	(11)	9	(14)
History of stroke	9	(7)	5	(8)	4	(6)
HIV/AIDS	0		0		0	
Arthritis	43	(34)	25	(39)	18	(28)
Depression	48	(38)	19	(30)	29	(45)
Smoke	19	(15)	12	(19)	7	(11)
<b>Alcohol</b>						
Daily	2	(2)	1	(2)	1	(2)
Once a week	6	(5)	3	(5)	3	(5)
Once a month	11	(9)	6	(9)	5	(8)
Rarely	25	(19)	14	(23)	11	(17)
Never	84	(65)	40	(63)	44	(6)
Receiving diabetes medications	102	(80)	47	(73)	55	(86)

\*Data are presented as No. (%) unless otherwise indicated.

solution leverages readily available and familiar technology for patients and does not require the use of more costly Smartphones, it can rapidly be brought to a population scale.

The TExT-MED study contributes to the increasing body of literature suggesting that mHealth is a feasible adjunct tool for chronic disease.<sup>5</sup> Quinn et al<sup>15</sup> reported results of the Mobile Diabetes Intervention Study, in which subjects randomized to a combination of a bidirectional mHealth intervention coupled with enhanced clinical care had significant improvements in glycemic control compared with controls. Subjects in the Mobile Diabetes Intervention Study who received the mHealth intervention in isolation showed a trend toward improved glycemic control that did not reach statistical significance. Kollman et al<sup>18</sup> reported on an mHealth intervention requiring patients to send daily blood glucose values by text messages to a central monitoring center. Here again, the authors report a

nonsignificant improvement in glycemic control. This solution requires very active patient participation, bidirectional communication, and clinician oversight. In an RCT by Kim<sup>17</sup> of 60 patients with type 2 diabetes, patients in the intervention group sent daily blood glucose values to a Web server and, in accordance with these data, received individualized management strategies by text messages. Although effective in decreasing Hb A<sub>1c</sub> level by 1.15% at 12 weeks, this system is also bidirectional, involves using the Internet, and requires ongoing physician involvement. The generalizability of previous successful mHealth diabetes solutions is limited because they involved inputs from the patients, a practitioner to monitor and provide real-time instructions, or private clinical settings with established patients. The TExT-MED program does not require any of these components. Further, TExT-MED was developed with a focus on behavior change, rather than strict glycemic control.

**Table 2.** Main study findings.

Scales (Mean, SD)	All Patients (n=128)						Spanish Speaking (n=92)					
	Intervention (n=64)		Control (n=64)		$\Delta$ ( $\Delta I$ - $\Delta C$ ), 95% CI	P Value	Intervention (n=40)		Control (n=52)		$\Delta$ ( $\Delta I$ - $\Delta C$ ), 95% CI	P Value
	Baseline	$\Delta 6$ Months	Baseline	$\Delta 6$ Months			Baseline	$\Delta 6$ Months	Baseline	$\Delta 6$ Months		
<b>Hb A<sub>1c</sub> (median)</b>	10.10	-1.05	9.85	-0.60	-0.45	0.230 <sup>†</sup>	10.10	-1.2	9.85	-0.4	-0.80	0.025 <sup>†</sup>
Range	8.0 to 14.0	-5.9 to 2.8	8.0 to 15.1	-6.8 to 2.1			8.0 to 14.0	-5.9 to 2.8	8.0 to 15.1	-6.8 to 2.1		
IQR	8.4 to 11.55	-1.9 to 0.10	8.65 to 11.0	-2.05 to 0.18			8.40 to 11.80	-2.3 to 0.5	8.50 to 11.10	-1.6 to 0.2		
<b>Morisky Medication Adherence Scale (n=102)*</b>		(n=47)		(n=55)								
Mean	4.5	0.9	5.2	-0.1	1.1 (0.1 to 2.1)		5.0	1.1	5.4	-0.3	1.4 (0.2 to 2.7)	
SD	2.4	2.5	2.0	2.5			2.4	2.7	2.0	2.6		
<b>Diabetes Empowerment Scale Short Form (Empowerment Scale)</b>												
Mean	3.6	0.4	3.6	0.3	0.1 (-0.2 to 0.4)		3.5	0.5	3.5	0.3	0.2 (-0.2 to 0.6)	
SD	0.9	0.8	0.8	0.9			0.9	0.9	0.8	0.9		
<b>PAID</b>												
Mean	45.4	-20.5	47.4	-13.8	-6.7 (-14 to 0.7)		42.4	-22.4	47.5	-14.2	-8.2 (-16.7 to 0.2)	
SD	23.6	24.1	24.6	17.5			21.7	23.7	25.37	17.2		
<b>Michigan Diabetes Knowledge Test (items 1-14)</b>												
Mean	7.3	0.5	6.5	1.2	-0.7 (-1.5 to 0.1)		7.0	0.5	6.3	1.3	-0.8 (-1.8 to 0.2)	
SD	2.3	2.3	2.4	2.3			2.2	2.4	2.4	2.4		
<b>SDSCA: general diet</b>												
Mean	3.1	1.6	3.0	1.5	0.1 (-0.7 to 0.8)		3.1	1.6	3.2	1.4	0.2 (-0.8 to 1.2)	
SD	2.4	2.2	2.2	2.3			2.5	2.4	2.2	2.3		
<b>SDSCA: specific diet</b>												
Mean	4.0	0.8	4.2	0.3	0.5 (-0.1 to 1.1)		4.3	0.8	4.3	0.3	0.5 (-1.7 to 1.1)	
SD	1.6	1.9	1.5	1.2			1.5	1.8	1.6	1.3		
<b>SDSCA: exercise</b>												
Mean	2.4	1.1	2.9	0.5	0.6 (-0.3 to 1.5)		2.7	0.9	2.7	0.8	0.1 (-1.1 to 1.1)	
SD	2.4	2.4	2.6	2.7			2.4	2.6	2.7	2.7		
<b>SDSCA: blood glucose test</b>												
Mean	2.7	1.4	3.2	0.8	0.6 (-0.4 to 1.5)		2.5	1.6	3.3	0.7	0.9 (-0.2 to 1.9)	
SD	2.8	2.7	2.9	2.7			2.7	2.2	2.9	2.7		
<b>SDSCA: foot care</b>												
Mean	3.9	1.5	4.1	1.4	0.1 (-0.8 to 1.0)		4.7	1.1	4.4	1.1	0.0 (-1.1 to 1.0)	
SD	2.6	2.7	2.5	2.5			2.5	2.6	2.5	2.5		

PAID, Problem areas in diabetes; SDSCA, Summary of Diabetes Self Care Activities Scale.

\*Morisky Medication Adherence Scale at baseline had only n=102 because patients reporting no regular medications did not fill out the scale.

<sup>†</sup>P value comparing change from baseline to 6 months between the 2 groups performed by t test (expected Hb A<sub>1c</sub> level performed by Mann-Whitney U test).

**Table 3.** Evaluation of TExT-MED intervention group at 6 months (N=47; 28 Spanish, 19 English).\*

Satisfaction Assessment Question	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Using text messages is a good way to teach me about diabetes	12 (25.5)	32 (68.1)	2 (4.3)	1 (2.1)	0
I have enjoyed the TExT-MED program	19 (40.4)	25 (53.2)	3 (6.4)	0	0
I was able to understand all the text messages	25 (53.2)	17 (36.2)	5 (10.6)	0	0
I liked getting text messages every day (Monday through Friday)	15 (31.9)	23 (48.9)	9 (19.1)	0	0
I liked getting text messages on the weekends (Saturday and Sunday)	17 (36.2)	20 (42.6)	10 (21.3)	0	0
The text messages every day came at times that were good for me	19 (40.4)	27 (57.4)	5 (10.6)	2 (4.3)	0
I was motivated by the healthy living challenges	12 (25.5)	28 (59.6)	5 (10.6)	8 (17)	0
I liked the trivia questions	8 (17.0)	31 (66.0)	8 (17.0)	0	0
The medication reminders helped me remember to take my medications	17 (36.2)	25 (53.2)	5 (10.6)	0	0
	<b>Too basic/easy</b>		<b>About right</b>		<b>Too hard/complicated</b>
The information in the text message	1 (2.1)		37 (78.7)		9 (19.1)
	<b>Too few</b>		<b>About right</b>		<b>Too many</b>
The number of text messages each day	2 (4.3)		40 (85.1)		5 (10.6)
The number of medication reminders each week	6 (12.8)		36 (76.6)		5 (10.6)
	<b>Less</b>		<b>Stay the same</b>		<b>More</b>
If the program were to continue, I would like the number of daily text messages to be	1 (2.7)		28 (75.7)		8 (21.6)
			<b>Yes</b>		<b>No</b>
I would like to continue receiving text messages about diabetes			37 (78.7)		10 (21.3)
I would recommend this program to a friend or someone in my family			47 (100)		0

\*Data are presented as No. (%) unless otherwise indicated.

Riley et al<sup>41</sup> recently conducted a review of mHealth interventions through the lens of a behavioral theorist and observed that only 1 of the interventions aimed at disease management specified a theoretical framework (Social Cognitive Theory) and none of the medication adherence evaluations used behavioral theory to guide message development. These authors concluded that a “theory-driven iterative model of mobile intervention development holds promise for improving not only our mobile health behavior interventions but also our theoretical and empirical understanding of health behavior change.” We respond to this gap in the literature by developing TExT-MED largely within the framework of the Health Belief Model of health behavior,<sup>42</sup> which has been applied and validated in many diseases and health behaviors, particularly in diabetes and lifestyle change.<sup>43</sup> The model uses concepts of patients’ perceptions of disease, in combination with their individual modifying factors and the cues to action they receive, to generate a likelihood of undertaking a health behavior. Interventions using the Health Belief Model emphasize education to change patient perceptions in favor of the desired health behavior and use cues to spur the wanted action.

Spanish-speaking patients merit special consideration when public health interventions focused on diabetes are considered. Spanish speakers are the fastest-growing segment of the population, have a higher prevalence of diabetes, are more likely to have poor glycemic control and peripheral neuropathy, and are less likely to have a regular source of health care or insurance.<sup>1,3-5,7</sup> Further, in a recent analysis of

the Diabetes Study of Northern California trial, Spanish speakers who were language discordant with their primary care physician had substantially poorer glycemic control than those who were language concordant.<sup>44</sup> Also, automated telephone calls have been effective at encouraging engagement and reducing Hb A<sub>1C</sub> among Spanish speakers with diabetes even when this intervention was not successful among English speakers.<sup>45</sup> The fact that TExT-MED provides language and culturally concordant messaging may explain why there were more pronounced reductions in Hb A<sub>1C</sub> in the TExT-MED group compared with controls in the subgroup of Spanish speakers.

In conclusion, although TExT-MED did not result in a statistically significant difference in the primary outcome of Hb A<sub>1C</sub>, trends toward improvement were observed in the primary outcome and all secondary outcomes, including self-efficacy and reduced ED utilization. The most pronounced effect was observed in improved medication adherence. Differences in all outcomes were larger in the Spanish-speaking subgroup. The TExT-MED findings should be validated in larger trials but add to the increasing body of literature supporting mHealth as an innovative public health solution for safety-net EDs that is effective, highly scalable, low cost, and widely accessible.

*The authors acknowledge the cohort members who participated so willingly in the study and Randali deSantos, BS, for assistance with data collection.*



Supervising editor: David L. Schriger, MD, MPH

Author affiliations: From the Keck School of Medicine, Department of Emergency Medicine (Arora, Burner, Lam, Menchine) and the Department of Medicine (Peters), University of Southern California, Los Angeles, CA.

Author contributions: SA had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. SA, ALP, and MM were responsible for study concept and design. EB and CNL were responsible for acquisition of data. SA, EB, CNL, and MM were responsible for analysis and interpretation of data. SA, ALP, EB, and MM were responsible for drafting the article. SA, CNL, and MM were responsible for statistical analysis and critical revision of the article for important intellectual content. SA and MM were responsible for study supervision and obtaining funding. SA takes responsibility for the paper as a whole.

Funding and support: By *Annals* policy, all authors are required to disclose any and all commercial, financial, and other relationships in any way related to the subject of this article as per ICMJE conflict of interest guidelines (see [www.icmje.org](http://www.icmje.org)). The intellectual property rights to the TEXT-MED program have been purchased from the University of Southern California by Agile Health, LLC. After study completion and data analysis, Drs. Arora and Menchine were hired by Agile Health, LLC to serve as consultants on the development of future text-based mobile health products. No other authors reported disclosures. The McKesson Foundation and Agile Health LLC had no role in the design and conduct of the study; the collection, management, analysis, and interpretation of the data; or the preparation, review, or approval of the article. This study was supported by a “mobilizing for health” grant from the McKesson Foundation (Drs. Arora and Menchine).

Publication dates: Received for publication July 16, 2013. Revisions received September 3, 2013, and October 7, 2013. Accepted for publication October 10, 2013.

Presented at the Society for Academic Emergency Medicine national meeting, May 2013, Atlanta, GA.

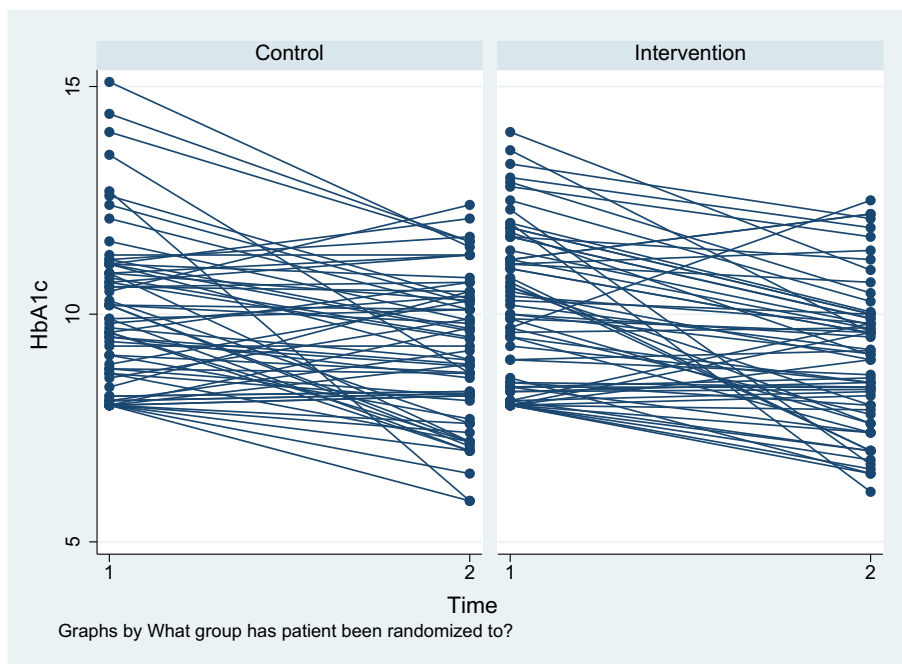
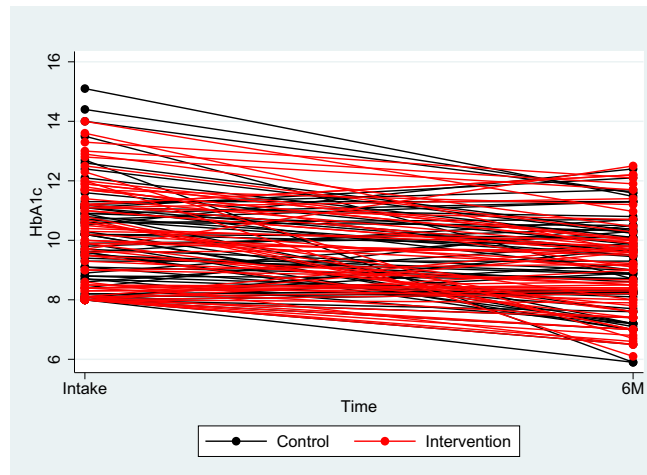
Address for correspondence: Sanjay Arora, MD, E-mail [sanjay.arora@usc.edu](mailto:sanjay.arora@usc.edu).

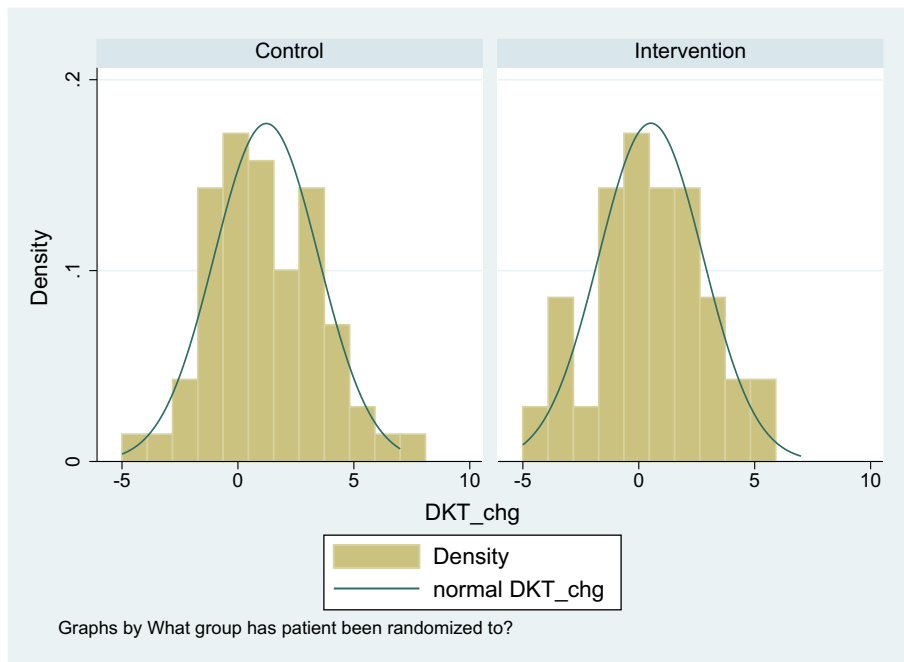
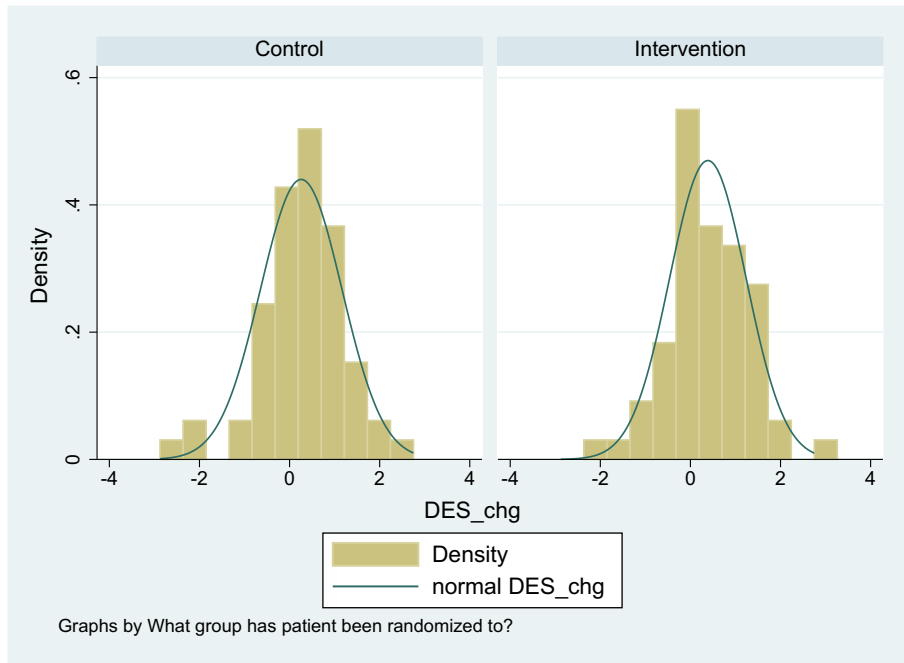
## REFERENCES

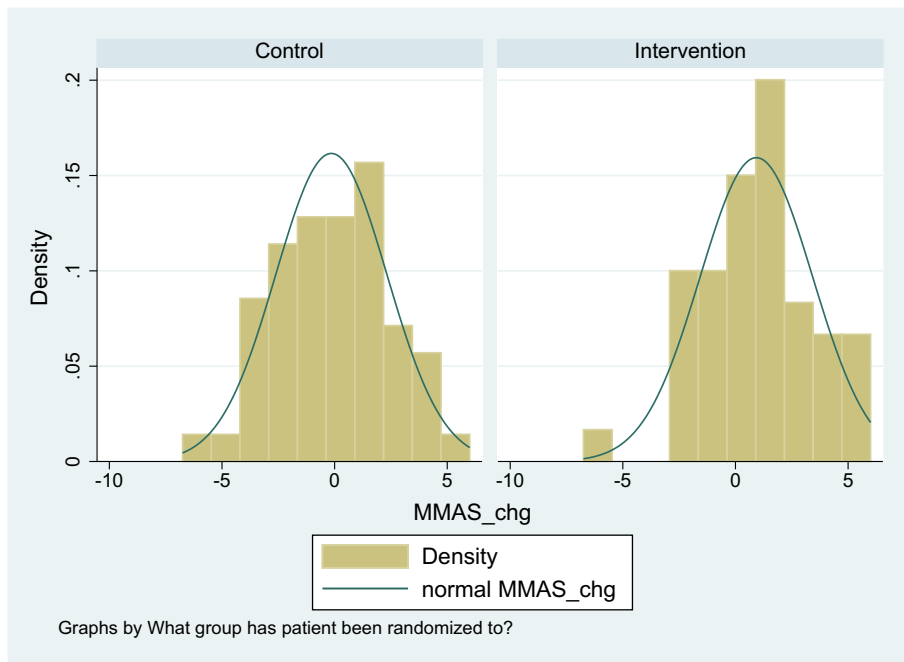
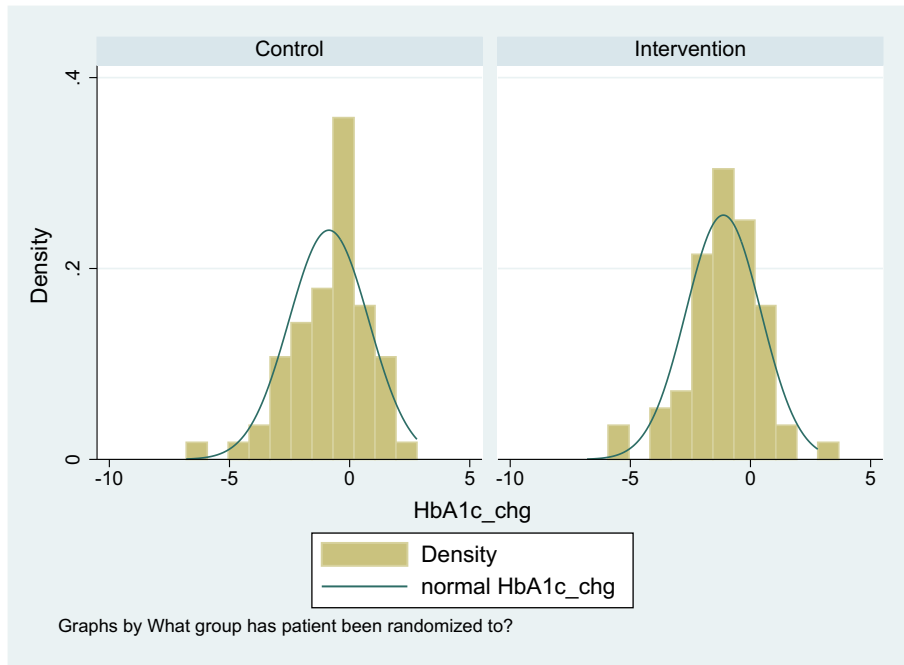
- Centers for Disease Control and Prevention. National diabetes fact sheet. Published January 26, 2011. Available at: [http://www.cdc.gov/diabetes/pubs/pdf/ndfs\\_2011.pdf](http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf). Accessed August 15, 2011.
- American Diabetes Association. Economic costs of diabetes in the US in 2012. *Diabetes Care*. 2013;36:1033-1046.
- Menchine MD, Vishwanath A, Arora S. Prevalence, health and demographics of emergency department patients with diabetes. *West J Emerg Med*. 2010;11:419-422.
- Arora S, Marzec K, Gates C, et al. Diabetes knowledge in predominantly Latino patients and family caregivers in an urban emergency department. *Ethnicity Disease*. 2011;21:1-6.
- de Jongh T, Gurol-Urganci I, Vodopivec-Jamsek V, et al. Mobile phone messaging for facilitating self-management of long-term illnesses. *Cochrane Database Syst Rev*. 2012(12):CD007459.
- Centers for Disease Control and Prevention. Deaths: final data for 2005. *Natl Vital Stat Rep*. 2008;56:1-120.
- Harris MI, Eastman RC, Cowie CC, et al. Racial and ethnic differences in glycemic control of adults with type 2 diabetes. *Diabetes Care*. 1999;22:403-408.
- Castaneda C, Layne JE, Munoz-Orians L, et al. A randomized controlled trial of resistance exercise training to improve glycemic control in older adults with type 2 diabetes. *Diabetes Care*. 2002;25:2335-2341.
- Hu FB, van Dam RM, Liu S. Diet and risk of type II diabetes: the role of types of fat and carbohydrate. *Diabetologia*. 2001;44:805-817.
- American Diabetes Association: Position Statement. Implications of the UKPDS. *Diabetes Care*. 2002;25(suppl 1):s28-s32.
- Coates VE, Boore JR. Knowledge and diabetes self-management. *Patient Educ Couns*. 1996;29:99-108.
- Dagogo-Jack S, Funnell MM, Davidson J. Barriers to achieving optimal glycemic control in a multi-ethnic society: a US focus. *Curr Diabetes Rev*. 2006;2:285-293.
- Goepp JG, Chin NP, Massad J, et al. Pediatric emergency department outreach: solving medical problems or revealing community solutions? *J Health Care Poor Underserved*. 2004;15:522-529.
- Menchine MD, Arora S, Camargo CA, et al. Prevalence of undiagnosed and suboptimally controlled diabetes by point-of-care HbA1C in unselected emergency department patients. *Acad Emerg Med*. 2011;18:326-329.
- Quinn CC, Shardell MD, Terrin ML, et al. Cluster-randomized trial of a mobile phone personalized behavioral intervention for blood glucose control. *Diabetes Care*. 2011;34:1934-1942.
- Franklin VL, Waller A, Pagliari C, et al. A randomized controlled trial of Sweet Talk, a text-messaging system to support young people with diabetes. *Diabet Med*. 2006;23:1332-1338.
- Kim HS. A randomized controlled trial of a nurse short-message service by cellular phone for people with diabetes. *Int J Nurs Stud*. 2007;44:687-692.
- Kollmann A, Riedl M, Kastner P, et al. Feasibility of a mobile phone-based data service for functional insulin treatment of type 1 diabetes mellitus patients. *J Med Internet Res*. 2007;9:e36.
- Faridi Z, Liberti L, Shuval K, et al. Evaluating the impact of mobile telephone technology on type 2 diabetic patients' self-management: the NICHE pilot study. *J Eval Clin Pract*. 2008;14:465-469.
- Bell AM, Fonda SJ, Walker MS, et al. Mobile phone-based video messages for diabetes self-care support. *J Diabetes Sci Technol*. 2012;6:310-319.
- Livingston G. Latinos and digital technology. PEW Internet & American Life Project February 9, 2011. Available at: <http://pewhispanic.org/files/report/134.pdf>. Accessed March 10, 2013.
- Arora S, Peters AL, Agy C, et al. A mobile health intervention for inner city patients with poorly controlled diabetes: proof-of-concept of the TEXT-MED program. *Diabetes Technol Ther*. 2012;14:492-496.
- Morisky DE, Ang A, Krousel-Wood M, et al. Predictive validity of a medication adherence measure in an outpatient setting. *J Clin Hypertens (Greenwich)*. 2008;10:348-354.
- Anderson RM, Fitzgerald JT, Gruppen LD, et al. The Diabetes Empowerment Scale-Short Form (DES-SF). *Diabetes Care*. 2003;26:1641-1642.
- Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. *Diabetes Care*. 2000;23:943-950.
- Vincent D, McEwen MM, Pasvogel A. The validity and reliability of a Spanish version of the Summary of Diabetes Self-Care Activities Questionnaire. *Nurs Res*. 2008;57:101-106.
- Welch G, Weinger K, Anderson B, et al. Responsiveness of the Problem Areas in Diabetes (PAID) questionnaire. *Diabet Med*. 2003;20:69-72.
- Welch GW, Jacobson AM, Polonsky WH. The Problem Areas in Diabetes scale. An evaluation of its clinical utility. *Diabetes Care*. 1997;20:760-766.
- Fitzgerald JT, Funnell MM, Hess GE, et al. The reliability and validity of a brief diabetes knowledge test. *Diabetes Care*. 1998;21:706-710.

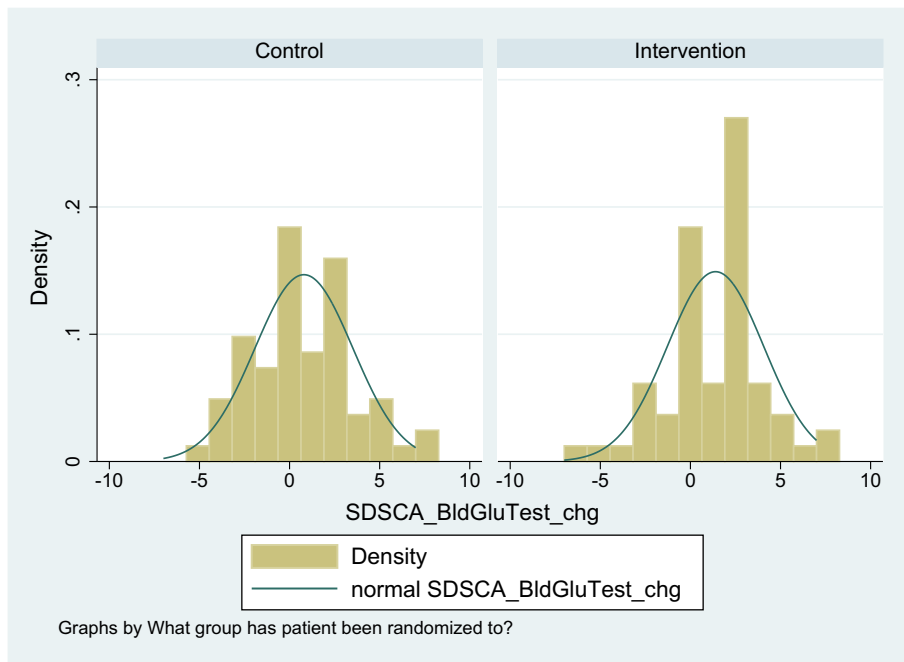
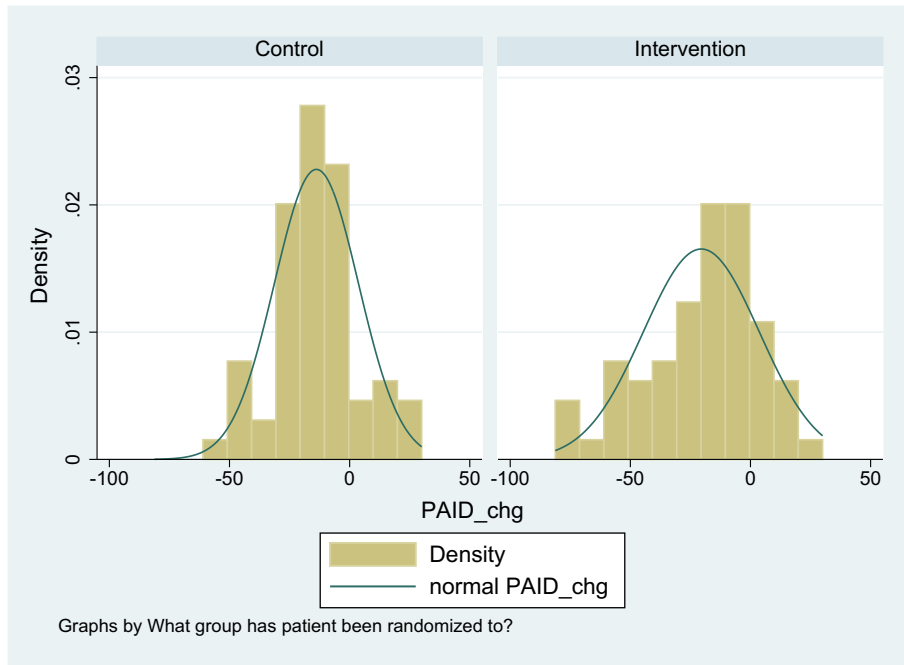
30. Ho PM, Rumsfeld JS, Masoudi FA, et al. Effect of medication nonadherence on hospitalization and mortality among patients with diabetes mellitus. *Arch Intern Med*. 2006;166:1836-1841.
31. UK Prospective Diabetes Study Group. UKPDS 28: a randomized trial of efficacy of early addition of metformin in sulfonylurea-treated type 2 diabetes. *Diabetes Care*. 1998;21:87-92.
32. Cramer JA, Benedict A, Muszbek N, et al. The significance of compliance and persistence in the treatment of diabetes, hypertension and dyslipidaemia: a review. *Int J Clin Pract*. 2008;62:76-87.
33. Cramer JA. A systematic review of adherence with medications for diabetes. *Diabetes Care*. 2004;27:1218-1224.
34. Osborn CY, Cavanaugh K, Wallston KA, et al. Health literacy explains racial disparities in diabetes medication adherence. *J Health Commun*. 2011;16(suppl 3):268-278.
35. Zeber JE, Miller AL, Copeland LA, et al. Medication adherence, ethnicity, and the influence of multiple psychosocial and financial barriers. *Admin Policy Ment Health*. 2011;38:86-95.
36. Cooper LA, Roter DL, Bone LR, et al. A randomized controlled trial of interventions to enhance patient-physician partnership, patient adherence and high blood pressure control among ethnic minorities and poor persons: study protocol NCT00123045. *Implement Sci*. 2009;4:7.
37. Comellas M, Walker EA, Movsas S, et al. Training community health promoters to implement diabetes self-management support programs for urban minority adults. *Diabetes Educ*. 2010;36:141-151.
38. Sixta CS, Ostwald S. Strategies for implementing a promotores-led diabetes self-management program into a clinic structure. *Diabetes Educ*. 2008;34:285-298.
39. Deakin T, McShane CE, Cade JE, et al. Group based training for self-management strategies in people with type 2 diabetes mellitus. *Cochrane Database Syst Rev*. 2005(2):CD003417.
40. Jandorf L, Stossel LM, Cooperman JL, et al. Cost analysis of a patient navigation system to increase screening colonoscopy adherence among urban minorities. *Cancer*. 2013;119:612-620.
41. Riley WT, Rivera DE, Atienza AA, et al. Health behavior models in the age of mobile interventions: are our theories up to the task? *Transl Behav Med*. 2011;1:53-71.
42. Janz NK, Becker MH. The Health Belief Model: a decade later. *Health Educ Q*. 1984;11:1-47.
43. Polly RK. Diabetes health beliefs, self-care behaviors, and glycemic control among older adults with non-insulin-dependent diabetes mellitus. *Diabetes Educ*. 1992;18:321-327.
44. Fernandez A, Schillinger D, Warton EM, et al. Language barriers, physician-patient language concordance, and glycemic control among insured Latinos with diabetes: the Diabetes Study of Northern California (DISTANCE). *J Gen Intern Med*. 2011;26:170-176.
45. Piette JD, Weinberger M, McPhee SJ, et al. Do automated calls with nurse follow-up improve self-care and glycemic control among vulnerable patients with diabetes? *Am J Med*. 2000;108:20-27.

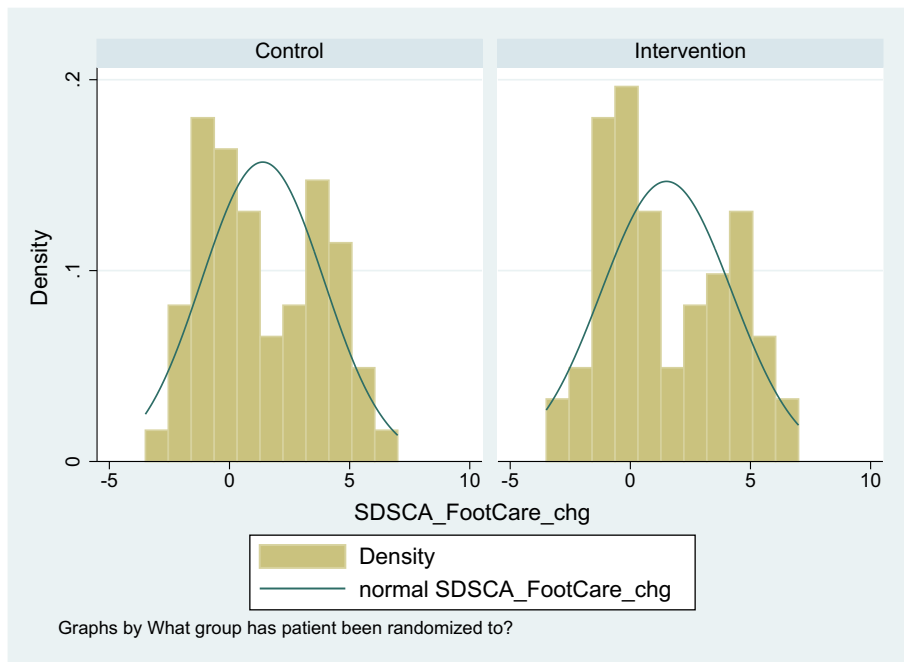
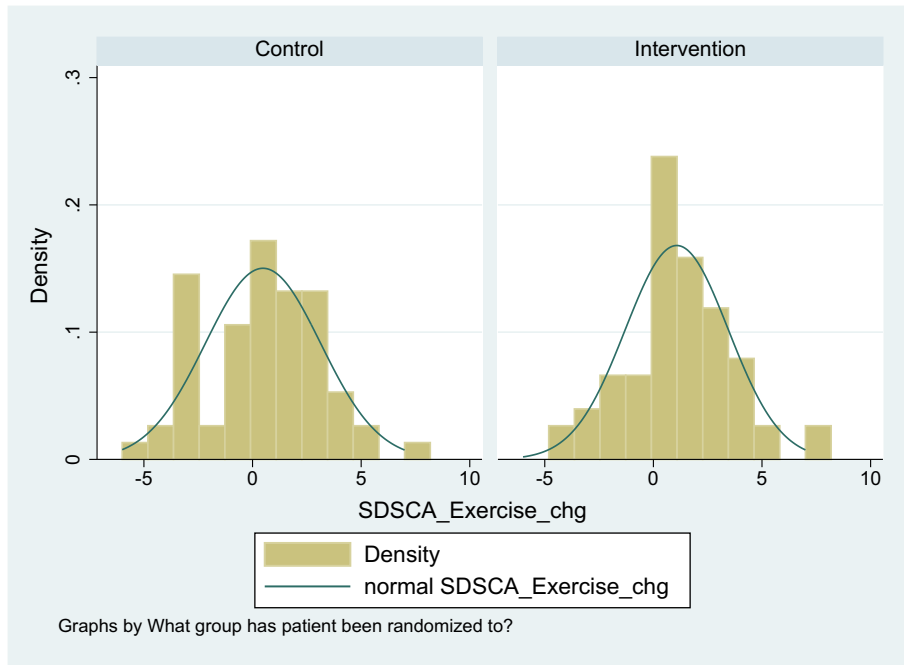
**APPENDIX E1. SUPPLEMENTAL GRAPHS OF INDIVIDUAL AND GROUP LEVEL DATA.**

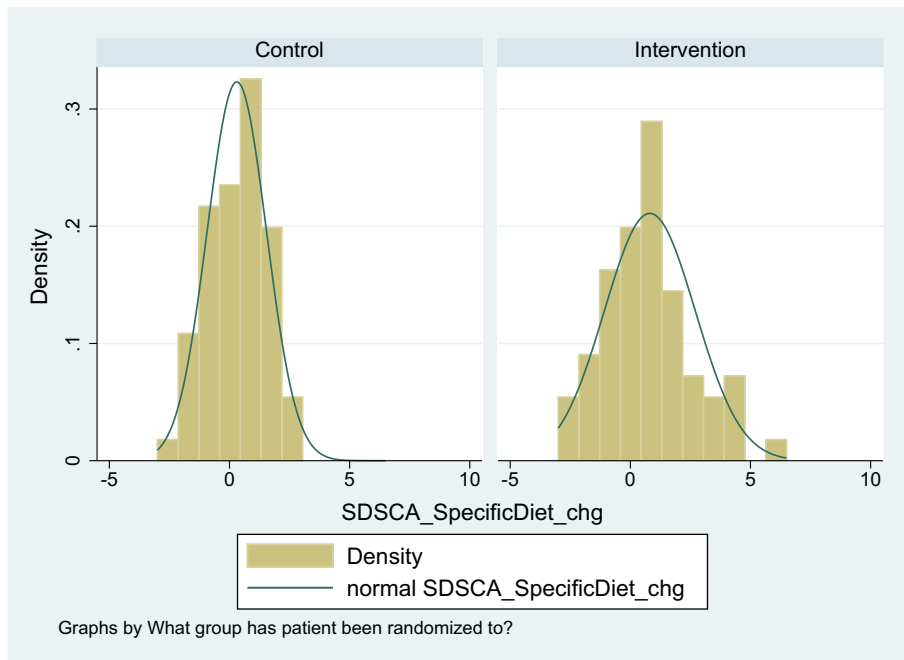
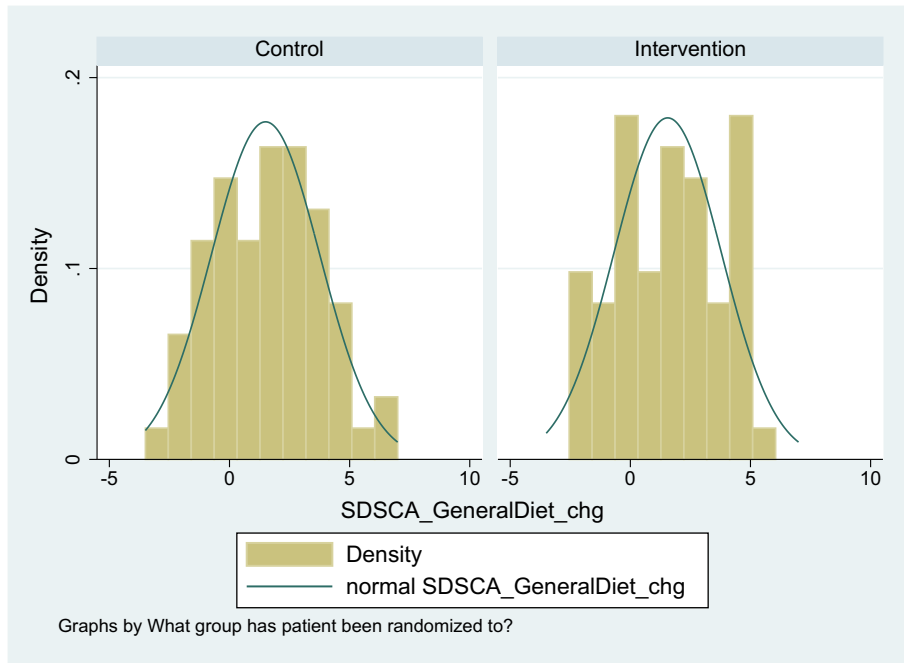














**Editor's Capsule Summary** *What question this study addressed:*

This randomized trial of 128 low-income type 2 diabetic patients examined whether unidirectional daily text messaging of generic care reminders improved glucose profile and other measures of self-care. *What this study adds to our knowledge:* The intervention produced only modest improvement in diabetes metrics but was viewed favorably by participants and offers some evidence that this limited type of mobile health intervention is feasible.