Dulce Digital: An mHealth SMS-Based Intervention Improves Glycemic Control in Hispanics With Type 2 Diabetes

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EMERGING TECHNOLOGIES AND THERAPEUTICS

OBJECTIVE

Type 2 diabetes is growing in epidemic proportions and disproportionately affects lower-income, diverse communities. Text messaging may provide one of the most rapid methods to overcome the "digital divide" to improve care.

RESEARCH DESIGN AND METHODS

A randomized, nonblinded, parallel-groups clinical trial design allocated *N* = 126 low-income, Hispanic participants with poorly controlled type 2 diabetes to receive the Dulce Digital intervention or usual care (UC). Dulce Digital participants received up to three motivational, educational, and/or call-to-action text messages per day over 6 months. The primary outcome was HbA_{1c}; lipids, blood pressure, and BMI were secondary outcomes. Satisfaction and acceptability were evaluated via focus groups and self-report survey items.

RESULTS

The majority of patients were middle-aged (mean age 48.43 years, SD 9.80), female (75%), born in Mexico (91%), and uninsured (75%) and reported less than a ninth-grade education level (73%) and mean baseline HbA_{1c} 9.5% (80 mmol/mol), SD 1.3, and fasting plasma glucose 187.17 mg/dL, SD 64.75. A statistically significant time-by-group interaction effect indicated that the Dulce Digital group achieved a significantly greater reduction in HbA_{1c} over time compared with UC (P = 0.03). No statistically significant effects were observed for secondary clinical indicators. The number of blood glucose values texted in by participants was a statistically significant predictor of month 6 HbA_{1c} ($P < 0.05$). Satisfaction and acceptability ratings for the Dulce Digital intervention were high.

CONCLUSIONS

Use of a simple, low-cost text messaging program was found to be highly acceptable in this sample of high-risk, Hispanic individuals with type 2 diabetes and resulted in greater improvement in glycemic control compared with UC.

Type 2 diabetes is growing in epidemic proportions in the U.S. and worldwide. The International Diabetes Federation estimates that by 2040 there will be 642 million people living with diabetes worldwide, an increase of >50% compared with the present day (1). The U.S. has the highest prevalence of diabetes among developed nations (i.e., 11% of the population between 20 and 79 years of age) (1), and individuals of ethnic/minority and low socioeconomic status are disproportionately affected (2,3). A

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recent study (4) in the 26 states and District of Columbia that expanded Medicaid under the Affordable Care Act found that diabetes diagnoses increased by 23% in 2014 compared with the previous year. Hispanic individuals in the U.S. experience higher rates of type 2 diabetes and, once diagnosed, exhibit poorer glycemic control than non-Hispanic white individuals (3,5).

Diabetes self-management education (DSME) and support is an effective method to improve clinical and cost outcomes (6,7) and can be successfully tailored for ethnically diverse populations (e.g., Philis-Tsimikas et al. [8]). However, many at-risk individuals are unable to access DSME and support because of practical (e.g., work, transportation, caregiving) and health care access barriers (9–12). In fact, in 2012 only 4.7% of the 21 million people with diagnosed diabetes accessed any accredited DSME program (9). To improve patient and practice performance outcomes, alternative methods must efficiently and effectively extend the reach of the care team to those in need of additional support to reach clinical targets. The widespread adoption of mobile phone technologies, including among low-income and older adults (13), highlights the potential for mobile health (mHealth) technology to circumvent the practical barriers inherent to traditional (e.g., face-to-face) visits.

Short messaging service (SMS), or text messaging, is among the most frequently used mobile communication methods and has been adopted by an estimated three-quarters of mobile users worldwide (14). Text messaging is simple to implement and may provide one of the most rapid methods to overcome the recently implicated limitation of the "digital divide" (15) to improve care. In the U.S., texting among adults in 2011 was higher among Hispanics (83%) and African Americans (76%) than among non-Hispanic whites (70%) (16). Ninety-nine percent of received text messages are opened, and 90% are read within 3 min of receipt (17). Thus, text messaging represents an opportunity to provide frequent, daily, low-cost, and interactive communication that could prove beneficial for population-level diabetes interventions.

Recent research syntheses have shown that mHealth interventions improve adherence and clinical control in patients with type 2 diabetes (18–20). However, most studies were small and nonrandomized and resulted in limited clinical improvements (20–23). Further, few studies have examined the implications of integrating these mHealth technologies into care or the feasibility and acceptability of such approaches in underserved populations (19,24). The current study addresses these gaps by investigating the glycemic benefit and acceptability of a culturally tailored, SMS-based DSME and support intervention (Dulce Digital) among underserved Hispanics with poor control in federally qualified health centers in Southern California.

RESEARCH DESIGN AND METHODS

Study Sample and Setting

Between October 2012 and February 2014, 126 individuals consented and enrolled into the Dulce Digital study (Fig. 1). The sample included Spanish-speaking and English-speaking Hispanic men and women, 18–75 years of age, who were uninsured or underinsured (Medicaid) and had type 2 diabetes and poor glycemic control (as indicated by an HbA_{1c} level of $\geq$7.5% [58 mmol/mol]). Individuals with plans to move outside the region and those with a severe physical or mental condition that would interfere with participation were excluded. Participants were recruited from clinic sites within Neighborhood Healthcare, a network of federally qualified health centers in San Diego and Riverside counties that serves predominantly low-income

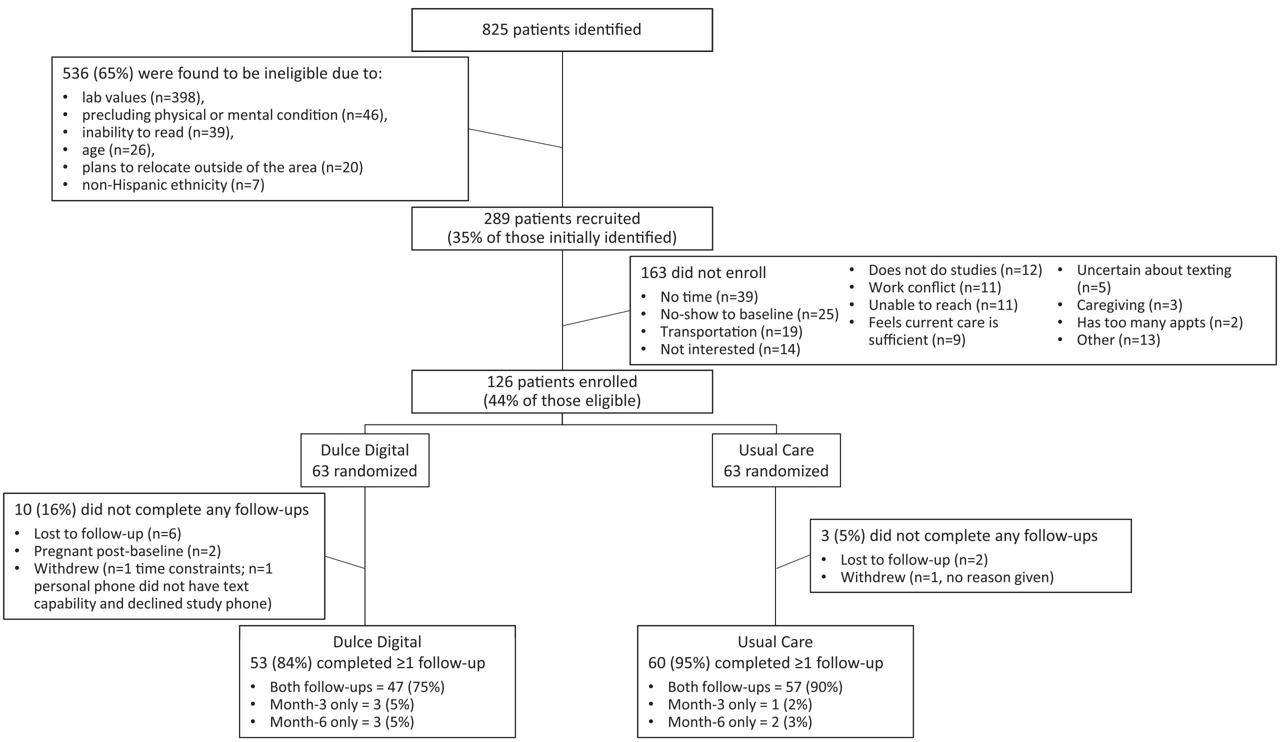

Figure 1—CONSORT flow diagram. appts, appointments.

individuals of an ethnic/racial minority. All procedures were approved by the Scripps Health Institutional Review Board.

Study Design and Intervention

The intervention was tested using a parallel-groups, nonblinded, randomized design. Blocked random assignment with equal allocation was used to assign participants to Dulce Digital or usual care (UC), using a randomly generated numbers sequence. Participants were informed of group assignment after the baseline assessment.

At the baseline visit, all participants viewed a 15-min diabetes educational video developed by Scripps. All participants received a blood glucose meter (OneTouch Verio Meter; LifeScan, Inc., Milpitas, CA), testing strips, and instructions on use. A physical assessment with fasting venous blood draw and study questionnaires were completed at baseline, month 3, and month 6. Assessments were performed by trained, bilingual research assistants at clinic sites in English and Spanish. Participants received an incentive at each assessment and continued to receive UC at the clinic for the study duration. UC services available to all patients included visits with a primary care physician, certified diabetes educator, and group DSME, although the use of the services was dependent on physician and patient initiative.

After randomization, participants assigned to Dulce Digital (n = 63) were provided with instructions on how to receive and send text messages. Participants who did not have a cell phone with texting capability were provided one (Kajeet, Inc., McLean, VA) (n = 22) at no cost for the duration of the study. Participants using their own phones had the costs of the additional texts covered by the study ($12/month). Content for the text messages was primarily derived from our culturally appropriate DSME curriculum (Project Dulce), which has been shown to improve clinical, behavioral, and cost outcomes in this population and others (8,25,26). In addition to the core educational messages derived from Project Dulce (e.g., "Use small plates! Portions will look larger and you may feel more satisfied after eating."), the Dulce Digital intervention provided ongoing support via motivational messages (e.g., "It takes a team! Get the support you need—family, friends and support groups can help you to succeed."), medication reminders (e.g., "Tick, tock. Take your medication at the same time every day!"), and blood glucose monitoring prompts (e.g., "Time to check your blood sugar. Please text back your results."). All content was converted into 119 brief, ≤160 character, text message–friendly format and sent out via a contracted patient health management technology platform (Rip Road LLC, New York, NY). Two to three messages a day were sent at study start, with frequency tapering over 6 months. Message timing was standardized across all participants and correlated with traditional meal or testing times. Blood glucose–monitoring prompts encouraged participants to text message in their next observed value; one value ≥250 or ≤70 mg/dL or three values between 181 and 250 mg/dL prompted a bilingual study coordinator to call the participant to assess possible reasons for hyperglycemia/hypoglycemia and to encourage as-needed follow-up with providers. The study coordinator also contacted the participant if there was no blood glucose value sent in for 1 week. Medical management was not provided by the coordinator.

Demographic and Outcome Measures

Participants self-reported sociodemographic characteristics. Information regarding prescribed medications was extracted from electronic health records. HbA_{1c} and lipids (total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides) were conducted by the laboratories of Quest Diagnostics (West Hills, CA), which adhere to guidelines set forth by the College of American Pathologists. Systolic and diastolic blood pressure were measured with a standardized protocol according to guidelines using a standard digital sphygmomanometer (HEM-907XL; Omron). Body weight and height were measured using a traditional balance scale and stadiometer to the nearest 0.1 lb and 0.2 inch, respectively. Finally, Dulce Digital participants (only) completed self-report items at the month 6 assessment visit to evaluate intervention feasibility and acceptability. To obtain further detail regarding participants' perceptions of Dulce Digital, two 90-min focus groups were conducted with a randomly selected 20% of intervention group participants.

Statistical Analysis

Data analysis was performed using IBM SPSS Statistics for Windows, version 23.0 (IBM Corporation, Armonk, NY) and Hierarchical Linear and Nonlinear Modeling software (HLM7; Scientific Software International, Lincolnwood, IL) by A.L.F. Descriptive statistics were obtained, and distributions were examined for normality. The triglyceride variable was significantly skewed as was the natural log transformed to normalize the distribution; however, because no appreciable differences between analyses using transformed versus untransformed variables were observed, results are presented for untransformed data only.

Mixed models were used to examine whether the two groups evidenced differential rates of change over time for HbA_{1c} and secondary outcomes (i.e., time-by-group interactions). To evaluate a possible dosage effect on the primary outcome in Dulce Digital, the number of text messages and the number and duration of study coordinator phone calls were examined as predictors of month 6 HbA_{1c} level while controlling for baseline HbA_{1c} level. All analyses controlled for age and sex.

RESULTS

Participant Characteristics

The majority of patients were middle-aged, female, born in Mexico, and uninsured and reported less than a ninth-grade education (Table 1). At baseline, the overall sample (N = 126) exhibited poor glycemic control (mean HbA_{1c} 9.5% [80 mmol/mol], SD 1.3; fasting plasma glucose 187.17 mg/dL, SD 64.75); mean lipid values were close to target, and blood pressure averages were in the normal range. No between-group differences were observed in clinical outcomes at baseline (P values >0.10).

Thirteen (10.3%) participants were lost to follow-up (Fig. 1). At baseline, these participants reported higher annual incomes (P = 0.002) and were less likely to own a cell phone (P = 0.04) than those who completed at least one follow-up assessment; no other statistically significant differences were observed (P values >0.05).

Clinical Control Outcomes

Using an intent-to-treat approach, all N = 126 participants were included in multilevel modeling analyses examining differences in the rates of change over time between the groups. Group means for all indicators at baseline, month 3, and month 6 are shown in Table 2. A statistically significant time-by-group interaction

Table 1—Baseline characteristics for the Dulce Digital and UC groups

	Dulce Digital (*n* = 63)	UC (*n* = 63)
Age, years, mean (SD)	47.8 (9.0)	49.1 (10.6)
Sex		
Female	46 (73)	48 (76)
Male	17 (27)	15 (24)
Country of origin		
Mexico	59 (93)	55.0 (89)
U.S.	2 (3)	4.0 (6)
Other	2 (3)	3.0 (5)
Preferred Language		
Spanish	59 (94)	57 (91)
English	4 (6)	6 (9)
Education§		
Less than ninth-grade education	46 (76)	44 (70)
Ninth-grade education or higher	17 (24)	19 (30)
Insurance coverage§		
Insured	15 (24)	16 (25)
Uninsured	48 (76)	47 (75)
Household monthly income§		
<$1,000/month	18 (29)	23 (37)
$1,000 to $1,999/month	35 (55)	33 (52)
≥$2,000/month	10 (16)	7 (11)
Marital status§		
Married or living with partner	45 (72)	44 (69.8)
Unmarried	18 (28)	19 (30.2)
Cell phone use		
Own cell phone	54 (86)	51 (81)
Use text messaging	39 (72)	44 (86)
Age of diabetes diagnosis, mean (SD)	38.6 (9.2)	40.7 (10.5)
Prescribed medications		
Oral medication*	46 (73)	40 (64)
Insulin*	2 (3)	5 (8)
Combination therapy (oral plus insulin)	15 (24)	14 (22)

Data are reported as *n* (%), unless otherwise noted. Data are based on all individuals who completed a baseline assessment (*N* = 126). *Indicates a statistically significant difference between groups ($P < 0.05$). §Education, income, insurance, and marital status categories were collapsed for ease of presentation.

effect was observed for the primary outcome, HbA_{1c} ($P = 0.03$), indicating that Dulce Digital exhibited greater improvement in glycemic control across time compared with UC (Fig. 2*A*). The Dulce Digital group exhibited a significantly lower mean HbA_{1c} level compared with UC at both month 3 (8.5 ± 1.2% [69.0 ± 13.1 mmol/mol] vs. 9.3 ± 1.9% [78.0 ± 20.8 mmol/mol], $P = 0.03$) and month 6 (8.5 ± 1.2% [69.0 ± 13.1 mmol/mol] vs. 9.4 ± 2.0% [78.0 ± 20.8 mmol/mol], $P = 0.03$), after controlling for baseline HbA_{1c}. No significant time-by-group interaction effects were observed for any other clinical indicators. Because of significant group differences in the number of individuals prescribed oral ($P = 0.03$) and injectable ($P = 0.02$) antihyperglycemic agents at baseline (Table 1), these variables were examined as covariates in HbA_{1c} analyses. Neither medication status at baseline nor changes in medications over the 6-month period altered the results. Further, the proportion of individuals who received medication changes during the study did not differ significantly between Dulce Digital (*n* = 37; 51%) and UC (*n* = 32; 59%; $P = 0.38$).

Dosage-Effect Analyses

Participants in the Dulce Digital intervention received an average of 354.17 text messages (SD 44.94); variation is attributable to a small number of participants (*n* = 6) who chose to discontinue receiving texts prior to the end of the study and to receiving additional texts during the 1-month window for completing the final study visit. Participants texted back 3–352 blood glucose values (mean 57.77 blood glucose values, SD 60.01). The number of blood glucose values texted in by participants predicted month 6 HbA_{1c} ($P = 0.03$); with each additional blood glucose value sent in, an additional 0.006 decrease in HbA_{1c} level was observed at month 6 (Fig. 2*B*). The number of text messages sent out to participants was not a significant predictor of month 6 HbA_{1c} levels ($P = 0.28$). Nineteen of 63 (30%) participants in the Dulce Digital intervention received phone calls from the study coordinator in response to out-of-range blood glucose values. For these *n* = 19 participants, the number of coordinator phone contacts ranged from 3 to 13 calls/participant (mean 7.63 calls, SD 2.81); the modal call duration was 5 min. Neither the number nor the total duration of coordinator phone calls per participant predicted month 6 HbA_{1c} levels (*P* values >0.05).

Feasibility and Acceptability

In response to the subset of self-report items administered in the Dulce Digital group (only) at month 6, the vast majority of participants indicated that the text messages helped them to manage their diabetes "a lot" (96%), that they would continue receiving Dulce Digital text messages if given the choice (96%), and that they would recommend Dulce Digital to a friend or family member with diabetes (97%). Consistent with these findings, focus group participants (*n* = 12) indicated high acceptability; common themes that emerged indicated that text messages were sufficient in frequency and easy to understand. However, individuals who were provided with a separate study phone reported that it was inconvenient to carry two phones.

CONCLUSIONS

To our knowledge, this is the first randomized controlled trial using a text message–based DSME and support intervention to demonstrate significantly greater improvements in glycemic control compared with UC in a high-risk, underserved, Hispanic population. These findings suggest that, if implemented on a wider scale, simple, low-cost, text message–based mHealth approaches such as Dulce Digital have the potential to achieve a significant public health benefit in diabetes, a chronic health condition that is rapidly increasing in the Hispanic and other underserved populations.

In this study, all patients had an initial HbA_{1c} level ≥7.5%, with the majority (61.9%) exhibiting an HbA_{1c} level ≥9%,

Table 2—Clinical outcome means for the Dulce Digital and UC groups

	Baseline		Month 3		Month 6	
Clinical indicator	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)
HbA_{1c}*						
%						
Dulce Digital	63	9.5 (1.2)	50	8.5 (1.2)	50	8.5 (1.2)
UC	63	9.6 (1.4)	57	9.3 (1.9)	59	9.4 (2.0)
mmol/mol						
Dulce Digital	63	80 (13.1)	50	69 (13.1)	50	69 (13.1)
UC	63	81 (15.3)	57	78 (20.8)	59	78 (20.8)
Fasting blood glucose (mg/dL)						
Dulce Digital	63	184.0 (63.2)	50	164.6 (46.4)	50	161.3 (49.7)
UC	63	190.3 (66.7)	57	186.5 (66.8)	59	186.5 (68.5)
Total cholesterol (mg/dL)						
Dulce Digital	63	178.9 (38.1)	50	170.3 (32.4)	50	175.2 (33.1)
UC	63	193.7 (48.2)	57	193.7 (44.0)	59	192.6 (39.6)
HDL (mg/dL)						
Dulce Digital	63	44.5 (11.5)	50	42.9 (12.1)	50	42.3 (10.5)
UC	63	48.0 (14.6)	57	48.3 (13.0)	59	46.4 (10.7)
LDL (mg/dL)						
Dulce Digital	61	96.7 (32.8)	48	91.2 (28.0)	48	95.9 (29.8)
UC	58	108.1 (32.2)	53	106.2 (28.4)	54	107.5 (33.8)
Triglycerides (mg/dL)						
Dulce Digital	63	186.3 (104.3)	50	192.3 (139.7)	50	185.4 (95.9)
UC	63	197.5 (144.9)	57	207.9 (172.3)	59	204.6 (129.6)
SBP (mmHg)						
Dulce Digital	58	122.8 (15.9)	46	120.6 (14.3)	45	122.4 (17.2)
UC	63	124.7 (21.9)	52	123.1 (17.9)	53	120.5 (17.6)
DBP (mmHg)						
Dulce Digital	58	75.1 (9.6)	46	72.9 (8.5)	45	73.7 (11.1)
UC	63	74.7 (10.8)	52	72.7 (9.1)	53	72.3 (10.4)
BMI (kg/m^2)						
Dulce Digital	63	31.5 (6.0)	49	31.7 (5.2)	50	31.9 (5.4)
UC	63	32.2 (6.6)	57	32.0 (6.1)	58	32.1 (6.6)
Weight (lb)						
Dulce Digital	63	173.1 (34.6)	49	176.2 (33.0)	50	174.1 (27.8)
UC	63	176.4 (41.6)	57	174.2 (39.7)	58	175.2 (41.6)

All analyses controlled for age and sex; however, unadjusted means are reported. DBP, diastolic blood pressure; SBP, systolic blood pressure. *Indicates a statistically significant time-by-group interaction effect ($P < 0.05$).

thus placing them at high risk for diabetes complications. The Dulce Digital group mean did not reach the optimal level of <7.0–7.5%. However, during the 6-month intervention, 68% of Dulce Digital participants achieved reductions in HbA_{1c} levels, with individual decreases ranging from −0.1% to −4.6%. Overall, Dulce Digital achieved a mean 1% reduction in HbA_{1c}, which exceeds the average effect size reported in reviews of other mHealth approaches (pooled $HbA_{1c}\Delta$ = −0.5%) (18–20) and the average HbA_{1c} reduction reported in a recent synthesis of 118 traditional DSME trials (average $HbA_{1c}\Delta$ = 0.74%) (27). Baseline HbA_{1c} levels in the reviewed studies ranged from near normal (6.5%) to extremely elevated (9.8%), which is similar to the results of our study. In one review from Greenwood et al. (28), it was noted, unsurprisingly, that when study participants' mean baseline HbA_{1c} level was at or close to goal, a small intervention effect was seen. The relationship of the baseline HbA_{1c} level to the intervention effect demonstrates the importance of choosing the optimal population for interventions. With the current broad use of diabetes registries and the ease of identifying higher-risk individuals using population health management methods, it may be worthwhile to focus initial efforts of technology interventions in our higher-risk patients. An HbA_{1c} reduction of the magnitude found in the current study should not be underestimated and should be considered not only statistically significant but also clinically relevant; it rivals the effects of some glucose-lowering medications (29–31) and has been associated with decreased risk for retinopathy, nephropathy, and neuropathy (32–34).

Notably, the number of blood glucose values texted in by participants predicted month 6 HbA_{1c} values. Individuals who sent in more blood glucose values may have been more actively engaged with the intervention (and were thus reading more of the DSME messages) and/or more active participants in their health. Nonetheless, additional research is needed to reach conclusions about the mechanism underlying this relationship. Results did not indicate a significant "dosage" effect between text message frequency and HbA_{1c} level. However, further research is warranted to determine the "optimal" frequency of texts, acknowledging that optimization will likely need to be individualized according to each patient's unique needs and preferences. Similarly, the number of phone contacts with the study coordinator (in response to blood glucose values) did not predict month 6 HbA_{1c} levels. This finding is not surprising given the brief, safety-focused nature of these calls; the coordinator did not provide health coaching or in-depth clinical guidance but rather assessed for emergent safety risks and recommended physician follow-up as appropriate.

No statistically significant intervention effects were observed for secondary clinical indicators. However, this may be due to the fact that, on average, blood pressure and lipids were close to target levels at baseline, leaving little room for improvement. Further, the Dulce Digital content was not designed to address lipid or blood pressure control.

The current results should be interpreted in the context of several limitations. First, although attrition was comparable to that observed in prior studies (35), attrition was higher in the intervention group relative to the UC group. Thus, it is possible that participants who remained in the study were more engaged. A worst-case scenario sensitivity analysis is presented in Supplement A. Second, it is unknown how much of the intervention content was received (i.e., read or comprehended) by participants. Nonetheless, the number of blood glucose values texted in may be construed as an indirect indicator of intervention engagement. Third, 44% of potentially eligible individuals were enrolled, with the

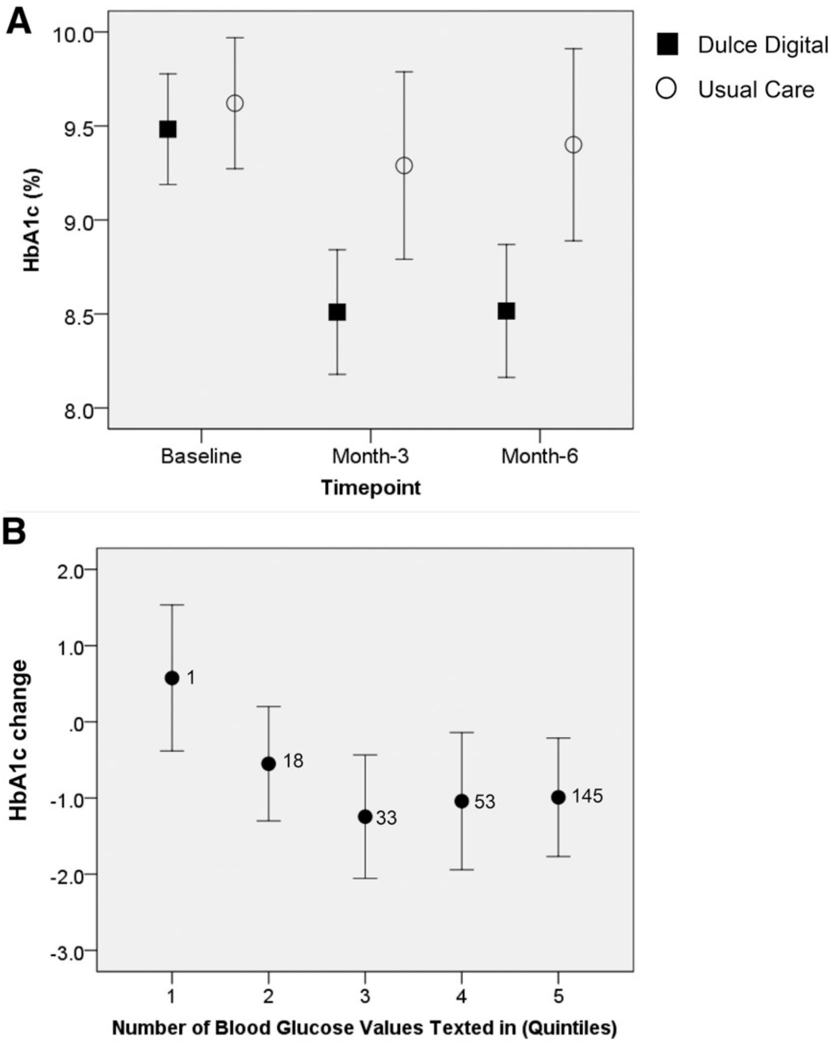

Figure 2—*A*: HbA_{1c} means and 95% CIs for the Dulce Digital and UC groups at baseline, month 3, and month 6. *B*: Association between the number of blood glucose values texted in by participants with a change in HbA_{1c} level from baseline to month 6 in the Dulce Digital group. Values adjacent to error bars represent the mean number of texts for each quintile. Note: The texting variable was analyzed as a continuous variable but was binned into quintiles for graphical presentation. Although HbA_{1c} change is represented on the *y*-axis for ease of interpretation, the month 6 HbA_{1c} level was used as the outcome variable (with control for baseline HbA_{1c} level) in regression analyses. Because of the curvilinear appearance of this relationship, the texting predictor was also examined using a quadratic term; however, the quadratic variable was not statistically significant.

majority reporting practical barriers that are commonly experienced in underserved populations (e.g., no transportation, work conflict, caregiving responsibilities, other time conflict). Thus, it is expected that by introducing the Dulce Digital program as part of routine clinic care, program reach could be expanded to individuals who could not attend additional (research-required) visits. Finally, this trial was not designed to examine cost-effectiveness. However, with respect to sustainability and scalability of an intervention such as Dulce Digital compared with other low-resource settings, the promise of text message–based programs is great. There is no additional cost for the technical infrastructure whether it is delivered to 400 or 4,000 individuals. The cost to the patient/user is only related to the text messages, and for Dulce Digital (in particular) a smartphone is not required. In other research, a significant population-level cost savings was attributed to a text-messaging program designed to facilitate diabetes care coordination in a predominantly African American population (22). This study included a care management component facilitated by nurses or medical assistants.

Dulce Digital offers a potential solution to the burgeoning primary care demand-capacity imbalance to better address the complex needs of the growing number of individuals with type 2 diabetes. Text-messaging approaches are attractive as a chronic disease public health intervention for a number of reasons, including their frequent use, enormous reach, low cost, and relative simplicity. Mobile phone and texting use is high among Hispanics (16), a group that experiences disparate diabetes prevalence and outcomes. Moreover, the present investigation indicated that the Dulce Digital approach was highly acceptable in this population. This model is flexible, lending itself to adaptation for other chronic conditions (e.g., arthritis, chronic pain) and for delivery by other personnel to address the health needs of underserved populations across the nation. Future investigations should examine the sustainability of the improvements in glycemic control beyond 6 months; expanding intervention content to target additional populations at risk for diabetes and other cardiometabolic indicators that are central to diabetes control (e.g., blood pressure, lipids); and individualizing text message content and delivery timing and frequency to each patient's unique needs and progress.

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A.P.-T. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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