Text Message Support for Weight Loss in Patients With Prediabetes: A Randomized Clinical Trial

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OBJECTIVE

Although the benefits of in-person Diabetes Prevention Program (DPP) classes for diabetes prevention have been demonstrated in trials, effectiveness in clinical practice is limited by low participation rates. This study explores whether text message support enhances weight loss in patients offered DPP classes.

RESEARCH DESIGN AND METHODS

English- and Spanish-speaking patients with prediabetes (*n* = 163) were randomized to the control group, which only received an invitation to DPP classes as defined by the Centers for Disease Control and Prevention, or to the text message–augmented intervention group, which also received text messages adapted from the DPP curriculum for 12 months.

RESULTS

Mean weight decreased 0.6 pounds (95% CI −2.7 to 1.6) in the control group and 2.6 pounds (95% CI −5.5 to 0.2) in the intervention group (*P* value 0.05). Three percent weight loss was achieved by 21.5% of participants in the control group (95% CI 12.5–30.6), compared with 38.5% in the intervention group (95% CI 27.7–49.3) (absolute difference 17.0%; *P* value 0.02). Mean glycated hemoglobin (HbA_{1c}) increased by 0.19% or 2.1 mmol/mol (95% CI −0.1 to 0.5%) and decreased by 0.09% or 1.0 mmol/mol (95% CI −0.2 to 0.0%) in the control group and intervention participants, respectively (absolute difference 0.28%; *P* value 0.07). Stratification by language demonstrated a significant treatment effect in Spanish speakers but not in English speakers.

CONCLUSIONS

Text message support can lead to clinically significant weight loss in patients with prediabetes. Further study assessing effect by primary language and in an operational setting is warranted.

Approximately one-third of Americans have prediabetes, defined by a blood glucose level above the upper limit of normal but below the threshold for the diagnosis of diabetes. Patients with prediabetes are at elevated risk of developing type 2 diabetes, heart attack, and stroke (1), with low-income and Latino patients representing a disproportionate share of those who progress to diabetes (2,3). Moderate weight loss is effective in preventing progression from prediabetes to overt diabetes, with benefits that persist long-term even with partial weight regain (4–6). Intensive behavioral interventions are effective for diabetes prevention (5,7), with a 16% reduction in risk for every kilogram (2.2 pounds) of weight loss (8).

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However, uptake of these interventions may be low, particularly for patients of low socioeconomic status (9); only 6% of patients eligible for Diabetes Prevention Program (DPP) classes participate at our safety net institution. Furthermore, lifestyle interventions are resource intensive and often challenging for safety-net providers to administer (10). Novel strategies that address cost and accessibility are needed to promote behavioral modification and weight loss, especially among patients of low socioeconomic status. We hypothesized that text message support would lead to greater weight loss in participants with prediabetes than an invitation to DPP classes alone.

RESEARCH DESIGN AND METHODS

Overall Study Design

This randomized, comparative effectiveness trial was conducted from April 2014 to April 2015 at Sam Sandos Westside Family Health Center (Westside), a federally qualified health center that is part of the Denver Health integrated health care system. The protocol was approved by the Colorado Multiple Institutional Review Board. All participants provided written informed consent.

Participants

Eligible patients were aged 18 or older without diabetes, with glycated hemoglobin (HbA_{1c}) from 5.7 through 6.4% and BMI between 25 and 50 kg/m^2, who confirmed having access to a mobile phone with text message capability. Patients with comorbid illness with life expectancy $<$12 months (e.g., terminal cancer or Child-Pugh class C hepatic cirrhosis), patients with diabetes based on an ICD-9 code in the previous 3 years, institutionalized individuals or individuals not planning to stay in the area at least 6 months, and those who did not speak English or Spanish were excluded.

Recruitment and Randomization

In March 2014, eligible patients were recruited to attend one of several enrollment sessions where the study was described, and, if interested, they signed a written consent. Using a clock-generated seed through SAS Enterprise Guide Software version 9.1 (Cary, NC), consented participants (n = 163) were randomized by the Denver Health Center for Health Services Research team to the text message–augmented intervention (n = 82) or to the control group (n = 81).

Intervention

Text message content was developed beginning August 2013 using the National DPP curriculum content and refined with input from Westside clinic patients with prediabetes during six focus groups (three in English and three in Spanish) held in early 2014. In the focus groups, participants were asked questions about their use of text messaging as well as specific questions relating to sample messages. Participants expressed a preference for encouraging messages, helped us decide on a schedule of six messages per week, and guided us in creating messages better tailored to the Latino community. Participants were prompted for self-reported weights once weekly. Messages were grouped around a DPP curriculum theme and fell into a number of categories: skill teaching (such as keeping a diary and tracking calories or fat), problem solving (such as for relapses or the holidays), motivation, stress reduction, specific recipes, web links for additional resources, and activity promotion messages. Finalized messages were uploaded into the Patient Relationship Manager (PRM), a software platform created in partnership between Denver Health, EMC Consulting, and Microsoft as previously described (11). PRM allows messages to be sent to selected participants on a predetermined schedule, facilitates screening of incoming participant messages, and provides a platform for documentation of participant interactions.

On 21 April 2014, intervention participants began receiving six messages per week (in English or Spanish) relating to nutrition, physical activity, and motivation, as well as a once-weekly text message asking participants to report their most recent weight. Intervention participants were also eligible for individual motivational interviewing appointments with a health coach, generally by telephone. Control participants did not receive weekly messages or motivational interviewing but, like intervention participants, were eligible for all standard-of-care weight loss resources at Denver Health, including access to DPP classes and individual appointments with a nutritionist or nurse for diet support.

Assessments

Participants attended weigh-in sessions at baseline and 6 and 12 months. Weights were collected on a study-designated scale and blood pressures were collected routinely through primary care visits. Consistent with standard care, participants were invited to have a laboratory HbA_{1c} test performed if it had not been checked in the previous 6 months. In addition, participants completed an end-study survey to assess participation in other weight loss programs.

Outcomes

The primary outcome was change in mean weight. Secondary outcomes were percent of participants with at least 3 and 5% weight loss, change in mean HbA_{1c}, change in mean systolic blood pressure, and operating costs per participant receiving the intervention.

Statistical Analysis

A sample size of 60 participants per group had 89% power to detect a difference in mean weight loss between the two groups of 3.7 pounds, a weight loss consistent with a previously published study of text message support for weight loss (12).

Comparisons between the intervention and control groups and baseline demographics were performed to determine balance between the two groups. Differences between the study groups were identified for protocol language. Further analysis of the primary outcome indicated a significant interaction between study group and protocol language (P = 0.049). Consequently, all outcomes were analyzed for the entire study population and stratified by protocol language. The intervention group was compared with the control group for all primary and secondary outcomes. The primary analysis was intent to treat and excluded five participants who became pregnant during the intervention and one participant diagnosed with diabetes between recruitment and the beginning of the intervention. Baseline weights were carried forward for the participants who either dropped out of the study or had no end-study weight; a secondary per-protocol analysis excluded these participants (Supplementary Fig. 1). Follow-up

systolic blood pressure and HbA_{1c} were not imputed, and missing values were not replaced by baseline values; both were analyzed as missing at random. Follow-up systolic blood pressure was missing for 3.8% of participants, whereas follow-up HbA_{1c} was missing for 24.8% of participants. The Wilcoxon signed rank test was used for continuous outcome measures, and either the χ^2 test of proportions or the Fisher exact test was used for categorical variables. All analyses were conducted using SAS (version 9.3; SAS Institute, Cary, NC).

RESULTS

A Denver Health data warehouse query identified 1,116 eligible patients, and 163 of these patients were randomized, with 157 participants completing the trial (Supplementary Fig. 1). A larger percentage of Spanish-speaking participants were randomized to the intervention group (Table 1); we therefore report results for the entire study population as well as stratified by language.

Outcomes

The weight loss measures observed at 6 months (Supplementary Table 1) were similar to those seen at 12 months, and we summarize here the outcome measures at 12 months. The mean weight decreased 0.6 pounds (95% CI −2.7 to 1.6) in the control group and 2.6 pounds (95% CI −5.5 to 0.2) in the text message group (*P* value 0.05) (Table 2). In the control group, 17 participants (21.5% [95% CI 12.5–30.6]) lost 3% of baseline weight compared with 30 participants in the intervention arm (38.5% [95% CI 27.7–49.3]) (absolute difference 17.0%; *P* value 0.02). There was no significant difference in 5% baseline weight loss (Fig. 1). Mean HbA_{1c} increased by 0.19% or 2.1 mmol/mol (95% CI −0.1 to 0.5%) and decreased by 0.09% or 1.0 mmol/mol (95% CI −0.2 to 0.0%) in the control and intervention participants, respectively (absolute difference 0.28% or 3.1 mmol/mol; *P* value = 0.07) (Table 2). A larger proportion of intervention participants (22%) experienced a decrease in HbA_{1c} greater than the absolute 6% variance of the HbA_{1c} assay than control group participants (7%; *P* value $<$ 0.05) (Fig. 2). There was no statistical difference in obtaining an end-study HbA_{1c} for the control participants (69.6%) compared with the intervention participants (80.8%; *P* value 0.14). Also, there was no significant association of having had an end-study HbA_{1c} and achieving 3% weight loss; 31.5% of participants with an end-study HbA_{1c} achieved that outcome compared with 25.6% of participants who did not present for an end-study HbA_{1c} (*P* value 0.50). Mean systolic blood pressure increased by 6.4 mmHg (95% CI 3.2–9.5) in the control group and 0.35 mmHg (95% CI −2.8 to 3.5) in the intervention group (absolute difference 6.05; *P* value = 0.01) (Table 2).

Spanish speakers in the control group experienced a change of mean weight of −0.5 pounds (95% CI −3.2 to 2.3) vs. –5.1 pounds (95% CI −8.0 to −2.1) in Spanish-speaking participants receiving the text message intervention (absolute difference 4.6 pounds; *P* value $<$ 0.01) (Table 2). Among Spanish speakers, 24 in the intervention arm (47.1% [95% CI 33.4–60.8]) lost 3% of baseline weight, compared with 7 (20.6% [95% CI 7.0–34.2]) in the control group (Fig. 1). There was no significant difference between the two groups in 5% weight loss for Spanish speakers. English speakers in the text message group did not achieve significant change in mean or percent weight loss compared with the control group (Table 2 and Fig. 1).

Table 1—Baseline demographic characteristics, by intent-to-treat population and protocol language

	Intervention	Control	*P* value
All study participants (baseline measure)			
Total participants	78	79	–
Age (years), mean (SD)	47.7 (12.4)	45.2 (10.6)	0.34
Weight (pounds), mean (SD)	194.9 (42.2)	201.6 (39.7)	0.22
Systolic BP (mmHg), mean (SD)	121.8 (14.8)	115.8 (13.3)	0.03
Mean HbA_{1c} (SD)	5.9% (0.3) 41 mmol/mol (3.3)	6.0% (0.3) 42 mmol/mol (3.3)	0.63
Male, *n* (%)	23 (29.5)	15 (19.0)	0.12
Female, *n* (%)	55 (70.5)	64 (81.0)	–
Protocol in English, *n* (%)	27 (34.6)	45 (57.0)	0.01
Protocol in Spanish, *n* (%)	51 (65.4)	34 (43.0)	–
Participants receiving protocol in English (baseline measure)			
Total participants	27	45	–
Age (years), mean (SD)	47.5 (13.6)	47.9 (10.5)	0.91
Weight (pounds), mean (SD)	222.6 (52.3)	212.0 (39.1)	0.60
Systolic BP (mmHg), mean (SD)	127.3 (17.5)	116.9 (13.3)	0.03
Mean HbA_{1c} (SD)	5.8% (0.3) 40 mmol/mol(3.3)	6.0% (0.3) 42 mmol/mol (3.3)	0.19
Male, *n* (%)	10 (37.0)	9 (20.0)	0.11
Female, *n* (%)	17 (63.0)	36 (80.0)	–
Participants receiving protocol in Spanish (baseline measure)			
Total participants	51	34	–
Age (years), mean (SD)	47.9 (11.9)	41.6 (9.9)	0.02
Weight (pounds), mean (SD)	180.2 (26.1)	187.8 (36.8)	0.61
Systolic BP (mmHg), mean (SD)	118.7 (12.3)	114.2 (13.4)	0.13
Mean HbA_{1c}, mean (SD)	6.0% (0.3) 42 mmol/mol (3.3)	5.9% (0.3) 41 mmol/mol (3.3)	0.71
Male, *n* (%)	13 (25.5)	6 (17.6)	0.40
Female, *n* (%)	38 (74.5)	28 (82.4)	–

BP, blood pressure.

Table 2—Mean (95% CI) of 12-month follow-up measures for Intervention and Usual Care, by intent-to-treat population and protocol language

	Intervention	Control	Between-group difference	*P* value
All study participants	*n* = 78	*n* = 79		
Weight (pounds)	192.2 (181.6, 202.8)	201.0 (191.9, 210.2)	−8.8 (−22.7, 5.1)	0.10
Weight change (pounds)	−2.6 (−5.5, 0.2)	−0.56 (−2.7, 1.6)	−2.1 (−5.6, 1.4)	0.05
Systolic BP (mmHg)	122.5 (119.4, 125.7)	122.8 (119.7, 126.0)	−0.31 (−4.8, 4.1)	0.98
Change in systolic BP (mmHg)	0.35 (−2.8, 3.5)	6.4 (3.2, 9.5)	−6.0 (−10.5, −1.5)	0.01
HbA_{1c}	5.8% (5.8, 5.9)	6.1% (5.8, 6.5)	−0.31% (−0.61, −0.01)	0.05
	40 mmol/mol (40, 41)	43 mmol/mol (40, 48)	−3.4 mmol/mol (−7.3, −0.1)	
Change in HbA_{1c} (mg/dL)	−0.09% (−0.2, −0.0)	0.19% (−0.1, 0.5)	−0.29% (−0.58, 0.01)	0.07
	−1.0 mmol/mol (−2.2, 0.0)	2.1 mmol/mol (−1.1, 5.5)	−3.2 mmol/mol (−6.3, 0.1)	
Participants receiving protocol in English	*n* = 27	*n* = 45		
Weight (pounds)	224.5 (200.7, 248.3)	211.4 (199.1, 223.7)	13.1 (−10.7, 36.9)	0.62
Weight change (pounds)	1.9 (−4.0, 7.9)	−0.64 (−3.8, 2.6)	2.6 (−3.5, 8.6)	0.41
Systolic BP (mmHg)	126.3 (120.6, 132.1)	122.7 (118.5, 126.9)	3.6 (−3.3, 10.5)	0.21
Change in systolic BP (mmHg)	−1.9 (−8.7, 5.0)	4.9 (0.5, 9.3)	−6.8 (−14.4, 0.9)	0.06
HbA_{1c}	5.8% (5.7, 5.9)	6.0% (5.8, 6.1)	−0.17% (−0.39, 0.05)	0.25
	40 mmol/mol (39, 41)	42 mmol/mol (40, 43)	1.9 mmol/mol (−4.3, 0.5)	
Change in HbA_{1c} (mg/dL)	−0.03% (−0.2, 0.1)	−0.00% (−0.1, 0.1)	−0.03% (−0.19, 0.14)	>0.99
	0.3 mmol/mol (−2.2, 1.1)	0.00 mmol/mol (−1.1, 1.1)	0.3 mmol/mol (2.1, 1.5)	
Participants receiving protocol in Spanish	*n* = 51	*n* = 34		
Weight (pounds)	175.1 (167.8, 182.4)	187.3 (174.5, 200.1)	−12.2 (−25.7, 1.4)	0.29
Weight change (pounds)	−5.1 (−8.0, −2.1)	−0.46 (−3.2, 2.3)	−4.6 (−8.8, −0.4)	<0.01
Systolic BP (mmHg)	120.5 (116.7, 124.3)	123.0 (117.9, 128.1)	−2.5 (−8.6, 3.7)	0.50
Change in systolic BP (mmHg)	1.6 (−1.8, 5.0)	8.5 (4.0, 13.1)	−7.0 (−12.5, −1.5)	0.02
HbA_{1c} (mg/dL)	5.9% (5.8, 6.0)	6.4% (5.7, 7.0)	−0.50% (−1.00, 0.01)	0.07
	41 mmol/mol (40, 42)	46 mmol/mol (39, 53)	5.5 mmol/mol (−10.9, 0.1)	
Change in HbA_{1c} (mg/dL)	−0.12% (−0.2, 0.0)	0.42% (−0.2, 1.1)	−0.54% (−1.05, −0.03)	0.03
	1.3 mmol/mol (−2.2, 0.0)	4.6 mmol/mol (−2.2, 12.0)	5.9 mmol/mol (−11.5, −0.3)	

BP, blood pressure.

The impact of the intervention on the HbA_{1c} and blood pressure in the Spanish-speaking participants was consistent with that observed across the entire cohort (Table 2 and Fig. 2). No treatment effect on the HbA_{1c} was found for the English-speaking participants; however, mean systolic blood pressure increased by 4.9 mmHg (95% CI 0.5–9.3) for control group English-speaking participants and decreased by 1.9 mmHg (95% CI −8.7 to 5.0) for intervention group English-speaking participants (absolute difference 6.8 mmHg; *P* value 0.06) (Fig. 2 and Table 2).

A sensitivity analysis was performed to evaluate the impact of missing data resulting from the 10 participants who did not present for the 12-month weigh or dropped from the study, as well as 3 participants who underwent gastric bypass surgery during the intervention period. Upon removing these participants from the analysis, the mean weight decreased 1.9 pounds more in the intervention group compared with the control group (*P* value 0.09) with more intervention participants achieving 3% weight loss (absolute difference 17.0%; *P* value 0.03) and a nonsignificant difference in 5% weight loss. The change in mean HbA_{1c} was 0.19% or 2.1 mmol/mol (95% CI −0.1 to 0.5%) for the control group participants and −0.10% or −0.1.1 mmol/mol (95% CI −0.2 to 0.0%) for the intervention participants (absolute difference 0.29% or 3.3 mmol/mol; *P* value = 0.06). The change in mean systolic blood pressure was 6.3 mmHg (95% CI 3.1–9.6) for the control group participants and −0.28 mmHg (95% CI −3.3 to 2.7) for the intervention participants (absolute difference 6.58 mmHg; *P* value 0.004). The impact on HbA_{1c} and systolic blood pressure followed patterns similar to those in the primary analysis (Supplementary Table 2).

Our Denver Health DPP database indicated that 10 intervention participants participated in DPP classes during the intervention compared with 9 control group participants. In an end-of-study survey, 26 control group participants (35.6%) reported participating in "any other weight loss program" vs. 21 intervention participants (29.2%). Six control group participants (8.3%) reported taking a "weight loss pill" and six a "nutritional supplement" (11.1%) vs. zero and six participants (8.2%), respectively, in the intervention group.

Operational costs (Supplementary Table 3) were calculated to determine potential for program sustainability. Total program operational cost was assessed at $22,113.61 over the 1-year intervention period, which equates to a monthly cost of $1,842.80 and an average per message cost of $0.75. Technical costs included vendor phone line charges of $17 per month (total $204) and message handling charges of $0.01 per message (total $293.24). Personnel hours (627.6 h, total cost $21,616.37) included an average 17 h per month of consultation from a supervising physician and 35 h per month of direct participant support from research personnel, including daily review and management of text messages received from participants and conducting

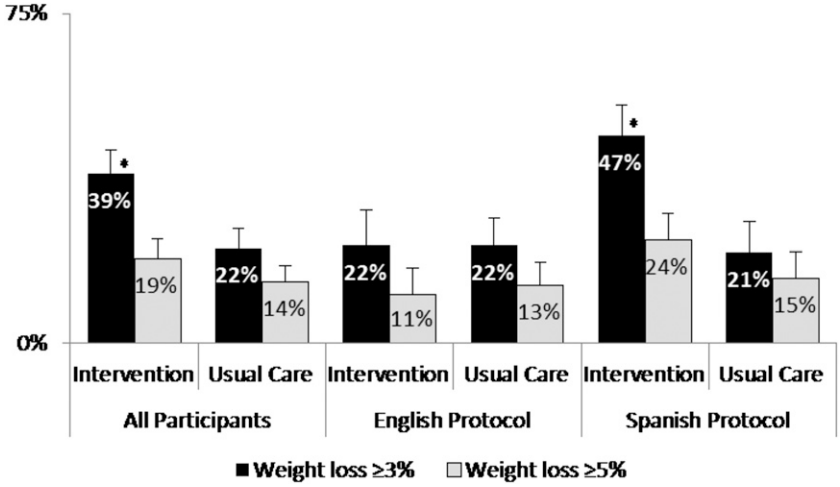

Figure 1—Percent of Intervention and Usual Care achieving 12-month follow-up weight loss goals, by intent-to-treat population and protocol language. *$P < 0.05$, comparison between Intervention and Usual Care groups.

participant outreach via phone call based on identified need. A total of 111 participant support phone calls (mean length 3.56 min; range 1–20 min; mode 1 min) were documented in PRM over the program period. Research-specific activities associated with participant recruitment and with collecting and analyzing data to measure program outcomes were not included in operating cost calculations. Administrative overhead costs associated with information technology infrastructure (e.g., technical support, software licenses, and hardware maintenance) were likewise not included.

CONCLUSIONS

Recipients of text message support achieved 3% weight loss at 12 months more frequently than control group participants, with an associated modest impact on mean HbA_{1c} and systolic blood pressure.

This trial shows promise for a novel modality to help safety net patients with prediabetes lose weight, and it also raises important questions. The study suggests that text message support can lead to greater weight loss in Spanish speakers compared with English speakers. The number needed to treat for 3% weight loss across the entire cohort was six in an intervention with relatively low operating costs, suggesting that text messaging could offer a low-cost, wide-reaching, and effective modality. These findings are important given *1*) the high rates of prediabetes and associated health risks in the U.S. population and *2*) the need for new approaches to weight loss support considering the cost and accessibility barriers associated with our traditional approaches.

There are a number of important questions to consider as we interpret these study results. First, is 3% weight loss clinically relevant? The literature suggests cardiovascular benefits with this degree of weight loss that are consistent with the observed impact on HbA_{1c} and blood pressure and suggests that even modest weight loss can prevent diabetes, as every kilogram lost decreases the risk of diabetes by 16% (8). Also, why do Spanish speakers experience the treatment effect whereas English speakers do not? We are not aware of a description in the literature of a variable impact by language of text messaging support. Preliminary analysis of end-study surveys and focus groups suggests key differences by language in the motivational impact of text messages, as well as divergent strategies of incorporating family and friends into weight loss efforts. In addition, a yet unanswered question is whether the text message support approach can be operationalized outside of a study setting to reach large numbers of patients and remain clinically effective at low cost.

End-of-study surveys were collected to assess self-reported participation in other weight loss programs. This helped identify three participants (two in the control group and one in the intervention group) who underwent gastric

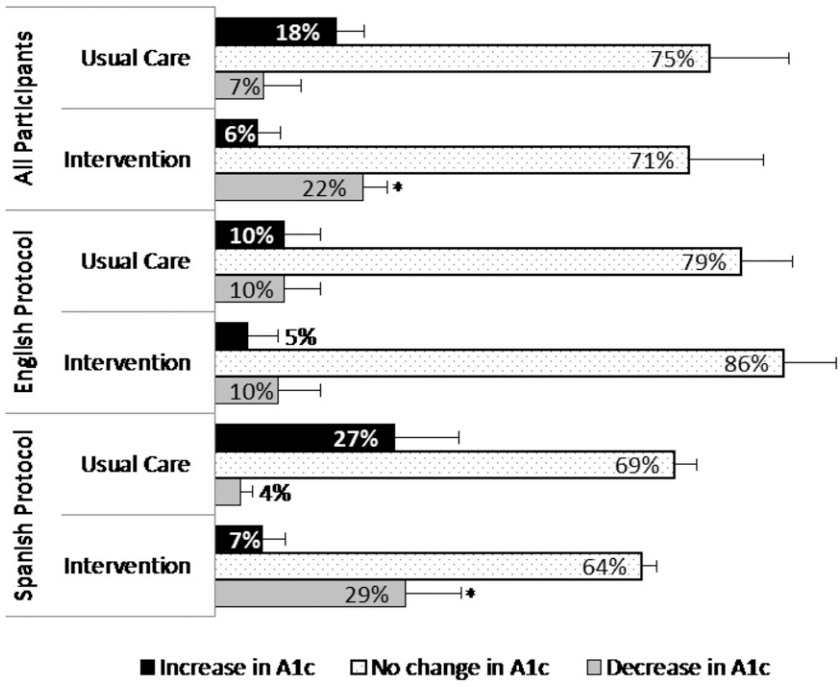

Figure 2—Percent in categories of 12-month follow-up HbA_{1c} measures between Intervention and Control groups, by intent-to-treat population and protocol language. *$P < 0.05$, comparison between Intervention and Usual Care groups. Decrease in HbA_{1c} is ≥6% decrease in HbA_{1c} from baseline; no change is between, but not including, −6 and +6% of baseline HbA_{1c}; increase in HbA_{1c} is ≥6% increase in HbA_{1c} from baseline.

bypass surgery. Our primary analysis included these participants, whereas a sensitivity analysis excluded them without significantly changing the study outcomes. Overall participation in other weight loss programs was high and slightly higher in the control group participants, who also reported a higher use of weight loss medicines and nutritional supplements. This may partially explain the weight loss in the control group participants, as we had anticipated they would stay weight neutral at best. Participation in DPP classes was 12.1% and nearly equal in the two groups, as well as consistent with a Denver Health DPP analysis in which 16% of eligible patients chose to enroll in classes with 51% (n = 517) attending at least one class at any time.

Text messaging offers an opportunity to improve health as advances in technology have made cell phones less expensive and more accessible to the poor. Although in its infancy, text messaging has been used to improve self-management in asthma, hypertension, and diabetes (14–16). In addition to chronic disease management, text message support has been used in the public health arena for smoking cessation programs (17), sex education, STD/HIV prevention (18), and adherence to sunscreen usage (19). Success with regard to weight loss has been shown in a domestic pilot study as well as in several studies in other countries (12,14,19–26). A recent study showed efficacy of text messaging in cardiac risk factor reduction in participants with cardiovascular disease (27). This study adds to the text message literature as it addresses the prediabetes population in a safety net institution, has longer-term follow-up than other published interventions, and uses a randomized, controlled design with an intent-to-treat analysis.

There are a number of important limitations of this study to consider. Although these results are encouraging, they arise from a relatively small study in one safety net health care system. It will be essential to study the impact of this text message approach in a larger population and across diverse health care systems, as well as to analyze the effects when operationalized outside of a study setting. In addition, future studies should explore an assortment of patient-centered virtual DPP modalities (web based, mobile application based, text message based, etc.) that can be tailored to an individual's preferences and needs (type of diet, exercise, etc.). Also, it is possible that a given participant did not receive all of the intended text messages due to a technical issue with our text message platform, the text message gateway vendor, the participant's cell phone service provider, or the recipient's cell phone. The fidelity of text message receipt was limited to self-report through an end-study survey. Only five participants reported not receiving 20 or more text messages throughout the 1-year intervention, which precluded a useful text message dosing analysis, yet confirmed that the majority of participants reported receiving almost all of the messages. Finally, a higher proportion of Spanish speaking participants were randomly assigned to the intervention. Stratification by language allowed us to separate out the effect sizes by language and demonstrate the divergent treatment effect.

Text message support can lead to clinically significant weight loss in patients with prediabetes in a safety net health care system, with the intervention effect observed in Spanish speakers. Further study is needed to explore the generalizability of these findings across diverse safety net health care systems and patient populations.

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