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Effectiveness of an App and Provider Counseling for Obesity Treatment in Primary Care

Gary G. Bennett, PhD[1,2], **Dori Steinberg, PhD, MS, RD**[1], **Sandy Askew, MPH**[1], **Erica Levine, MPH**[1], **Perry Foley, MPH, MSW**[1], **Bryan C. Batch, MD**[3,4], **Laura P. Svetkey, MD, MHS**[4,5], **Hayden B. Bosworth, PhD**[6], **Elaine M. Puleo, PhD**[7], **Ashley Brewer, RD, LDN**[8], **Abigail DeVries, MD**[8], and **Heather Miranda, MHA, RD, LDN**[9]

[1]Duke Global Digital Health Science Center, Duke Global Health Institute, Durham, North Carolina;

[2]Department of Psychology and Neuroscience, Duke University, Durham, North Carolina;

[3]Department of Medicine, Division of Endocrinology, Duke University Medical Center, Durham, North Carolina;

[4]Sarah W. Stedman Nutrition and Metabolism Center, Duke University Medical Center, Durham, North Carolina;

[5]Department of Medicine, Division of Nephrology, Duke University Medical Center, Durham, North Carolina;

[6]Center for Health Services Research in Primary Care, Durham Veterans Affairs Medical Center, Durham, North Carolina;

[7]School of Public Health and Health Sciences, University of Massachusetts, Amherst, Massachusetts;

[8]Piedmont Health, Inc., Carrboro, North Carolina;

[9]Wake County Human Services, Raleigh, North Carolina

Abstract

Introduction: Obesity treatment is less successful for socioeconomically disadvantaged populations, particularly when delivered in primary care. Digital health strategies can extend the reach of clinical obesity treatments to care settings serving patients at highest risk.

Methods: Track was an effectiveness RCT of a 12-month digital weight-loss intervention, embedded within a community health center system. Participants were 351 adult patients (aged 21–65 years) with obesity and hypertension, diabetes, and hyperlipidemia. Patients were randomized to usual care (n = 175) or an intervention (n = 176) comprising app-based self-monitoring of behavior change goals with tailored feedback, a smart scale, dietitian-delivered

Address correspondence to: Gary G. Bennett, PhD, Duke Global Digital Health Science Center, Duke Global Health Institute, 310 Trent Drive, Box 90519, Durham NC 27708. gary.bennett@duke.edu.

SUPPLEMENTAL MATERIAL

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counseling calls, and clinician counseling informed by app-generated recommendations, delivered via electronic health record. The primary outcome was 12-month weight change. Randomization began on June 18, 2013, final assessments were completed on September 10, 2015. Data analysis was conducted in 2016 and 2017. The trial retained 92% of usual care and 96% of intervention participants at 12 months.

Results: The Track intervention produced larger weight losses relative to usual care at 6 months (net effect: −4.4 kg, 95% CI = −5.5, −3.3, $p < 0.001$) and 12 months (net effect: −3.8 kg, 95% CI = −5.0, −2.5, $p < 0.001$). Intervention participants were more likely to lose ≥ 5% of their baseline weight at 6 months (43% vs 6%, $p < 0.001$) and 12 months (40% vs 17%, $p < 0.001$). Intervention participants completing ≥ 80% of expected self-monitoring episodes (−3.5 kg); counseling calls (−3.0 kg); or self-weighing days (−4.4 kg) lost significantly more weight than less engaged intervention participants (all $p < 0.01$).

Conclusions: A digital obesity treatment, integrated with health system resources, can produce clinically meaningful weight-loss outcomes among socioeconomically disadvantaged primary care patients with elevated cardiovascular disease risk.

Trial registration: This study is registered at www.clinicaltrials.gov, NCT01827800.

INTRODUCTION

Obesity and its consequences remain epidemic.[1,2] The condition is recalcitrant to treatment in all groups, but most weight-loss trials report suboptimal outcomes among socioeconomically disadvantaged populations.[3] These treatment outcome disparities extend to the primary care setting. Weight-loss outcomes in primary care−based investigations typically underperform those from efficacy trials, particularly among socioeconomically disadvantaged patients.[4] Primary care is a critical context in which to strengthen obesity treatment outcomes.[5] Clinicians are uniquely positioned to positively influence patient behavior change,[6] yet they deliver weight-loss counseling infrequently, particularly to those patients at highest obesity risk.[7]

Digital health approaches hold promise for extending the reach of highly personalized, low-cost, evidence-based obesity treatments to a range of clinical care settings.[8] Non-commercial digital health apps[9] produce 1-year weight losses of up to 5 kg when they include contact from a human interventionist.[10] However, little is known about the translational potential of these treatments; most trials have been short in duration, conducted outside clinical practice, and tested among highly motivated populations.[11–13]

The present trial compares the effectiveness of usual care to a digital obesity treatment, combined with counseling from primary and ancillary care providers, on 12-month weight change among patients with socioeconomic disadvantages and elevated cardiovascular disease risk.

METHODS

The trial design is presented in greater detail elsewhere.[14] Briefly, this was a two-arm, effectiveness RCT of the 12-month “Track” intervention among patients with obesity and a

diagnosis of hypertension, diabetes, and hyperlipidemia. The primary outcome was 12-month weight change. Secondary outcomes included ≥ 5% weight loss, waist circumference, blood pressure, fasting lipids, glucose, and HbA1c over 12 months. All study activities were approved by the Duke University IRB and the community health system's advisory board; all participants provided written informed consent. Randomization began on June 18, 2013, final assessments were completed on September 10, 2015. Data analysis was conducted in 2016 and 2017.

The trial was conducted in collaboration with Piedmont Health, a private, nonprofit community health system, which operates in a seven-county service area in central North Carolina. Piedmont Health patients are predominantly racial/ethnic minority (70%); impoverished (96% are <200% of the federal poverty level); and either uninsured (45%) or hold public insurance (32% Medicaid/State Children's Health Insurance Program). Registered dietitians are based at each health center. Piedmont Health uses the GE Centricity CPS, version 12, electronic health record (EHR).

Study Sample

The trial was designed to target patients with both obesity and elevated cardiovascular disease risk, those who are commonly encountered in real-world primary care settings and for whom intervention solutions are lacking. Trial participants were 351 men and women, aged 21–65 years, with a BMI of 30.0–44.9 and the aforementioned diagnoses (captured via ICD-9 codes). Additional inclusion criteria were as follows: at least two visits to the health center in the last 12 months, English fluency, ownership of a mobile phone, and willingness to send/receive three to nine text messages per week. Exclusion criteria included pregnancy or ≤ 12 months postpartum, cohabitation with another participant, participation in a related trial, or plans to move outside of the region within 2 years. The trial also excluded participants with a cardiovascular event in ≤ 6 months; a condition/medication that would affect weight; profound cognitive, developmental, or psychiatric disorders; or psychiatric hospitalization in ≤ 12 months.

Measures

Piedmont Health's EHR was used to identify potentially eligible participants. Staff then sent invitation letters and study brochures via postal mail. Individuals could opt out of additional contact by dialing a toll-free number; none utilized this option. After 1 week, study staff performed an eligibility assessment by phone and scheduled a screening study visit. Patients provided their informed consent at the screening visit and returned for a baseline study visit, at which randomization occurred. The trial employed a covariate adaptive randomization method, specifically minimization, which allocated participants equally (one to one) across treatment arms, after minimizing differences for health center, gender, race, and ethnicity. An algorithm checked the balance of previously allocated participants according to these characteristics. If the groups were imbalanced, the participant was randomly assigned to a group with equal probability. The group was assigned by the computer during the randomization process and revealed to the staff and participant at that time. The trial design precluded blinding either patients or study coaches to treatment assignment.

Anthropometric and blood pressure data were collected at baseline, 6, and 12 months. Weight was measured (with participants in gowns) to the nearest 0.1 kg using an electronic scale (Seca 876), height to the nearest 0.1 cm using a calibrated wall-mounted stadiometer (Seca 222), and waist circumference to the nearest 0.1 cm using a vinyl tape measure (AccuFitness Myo-Tape). After 1−2 minutes of quiet sitting, blood pressure was measured three times at 1-minute intervals using an oscillometric device (Omron HEM 907XL); the average of the second and third measurements were used in analysis. At baseline and 12 months, participants fasted for >8 hours before researchers assessed glucose; lipids (Cholestech LDX); and HbA1c (Siemens DCA Vantage Hemoglobin A1C Analyzer).

Statistical Analysis

Using data from previous work, mean weight was estimated at 81 kg with a standard deviation of 8 kg. Twelve months post-intervention, the authors hypothesized that there would be no change in the usual care group and a 2.6-kg reduction in the treatment group and that there will be an autocorrelation between baseline and follow-up weight values of 0.55. From these values, using a two-tailed test of differences at the $\alpha = 0.05$ level, it was estimated 80% power to detect a difference of 2.36 kg with 140 complete cases per group. From previous trials,[4,15] the sample was inflated by 20% to accommodate projected attrition. All calculations were conducted in PASS, version 11.

The intervention is described in additional detail elsewhere.[14] Track was fully integrated into the health system's operations. Piedmont staff delivered all human intervention content. Track's back-end infrastructure facilitated integration of intervention data in the Piedmont EHR. Given the translational focus of the trial, this design ensured ease of use, cost containment, and maximized the potential for scalability and reimbursement.

Track utilized the interactive obesity treatment approach (described in detail elsewhere),[14,15] which prescribes personally tailored, weight-related behavior change goals.[14–17] This approach has several advantages among medically vulnerable patients: (1) it minimizes the high resource, literacy, and numeracy requirements inherent to many in-person behavioral treatments; and (2) it produces high rates of intervention engagement.[18] Participants used the Track app to self-monitor four behavior change goals each week. To lower development and operational costs and minimize numeracy burdens, the Track app used interactive voice response or text messaging to facilitate self-monitoring. After entering their data, the Track app immediately delivered a personalized feedback message with a short skills training tip, tailored to the participant's progress. Algorithms changed patients' assigned goals bimonthly to promote novelty and prevent habituation. Patients were asked to weigh themselves daily[19] using a cellular connected scale. The app used patients' weight data to personalize feedback about their weight loss progress.

A Piedmont Health staff dietitian or student delivered 18 coaching calls (10–15 minutes) over 12 months: weekly for Calls 1–4, biweekly for Calls 5–10, and monthly for calls 11–18. Calls were focused on motivational enhancement, behavioral skills training, and providing social support. Dietitian coaches scheduled counseling calls at times that would be convenient for the participant, including on evenings and weekends. Participants could call or text their coach to reschedule calls. When participants did not answer scheduled

counseling calls, the technology platform activated a retry protocol, which involved making several follow-up calls over the next week, at different times of day, and with varying voicemail messages. To minimize coach burden, these calls and their resolution were tracked automatically in the technology platform. Coaches were trained at baseline[20] and received biannual refresher instruction.

Clinicians were asked to counsel intervention participants at all medical visits over 12 months. Counseling was guided by a patient progress report that included recommendations that could be delivered within 2 minutes. The report was generated using aggregated patient data, delivered through the EHR, and was updated after each coaching call to ensure its relevance. Clinicians were asked to document any trial-related counseling in the EHR.

Participants received the current standard of care offered by Piedmont Health. Study staff offered annual in-service trainings at medical staff meetings to heighten awareness of obesity treatment guidelines. Staff provided patients with self-help materials (National Heart, Lung, and Blood Institute's *Aim for a Healthy Weight*); quarterly newsletters; and a list of community resources for weight loss at 6 months.

The primary intent-to-treat analyses used linear mixed effects modeling to examine 12-month changes in weight. The primary outcomes model included time as a main effect, treatment X time interaction, and fixed effects to control for gender, site, and race/ethnicity. Baseline weight was controlled for by retaining it as part of the response vector; the authors omitted a treatment main effect to constrain groups to a common intercept that reflects the baseline equality of groups assumed by randomization. An unstructured covariance matrix was used to account for the within-patient correlation between measures over time. Participants with missing visits were treated as missing at random and addressed using maximum likelihood methods. Model assumptions were checked with residuals diagnostics. Similar methods were used to analyze secondary outcomes (BMI, waist circumference, blood pressure). Poisson regression with a robust error variance was used to compare the probability of obtaining percentage weight-loss thresholds between treatment groups and estimate RRs with adjustment for gender, race/ethnicity, and site. Analysis of lipids and HbA1c outcomes used ANCOVA, controlling for gender, race/ethnicity, and site. All analyses were conducted using SAS, version 9.4, and assumed a two-tailed α of 0.05.

Participants with missing visits were treated as missing at random and addressed using intent-to-treat principles and maximum likelihood methods. Sensitivity analyses compared per protocol models, limited to data collected within window (2 weeks before and 4 weeks after the 6- and 12-month visits), with models including data collected outside the protocol window. Outcomes from these models were in line with the primary analyses.

RESULTS

The trial randomized 351 patients to either the intervention (n = 176) or usual care (n = 175) treatment arms (Table 1). Almost one third (32%) of the sample was male. Participants averaged age 50.7 (SD = 8.9) years and had a mean BMI of 35.9 (SD = 3.9). More than half (52%) of participants self-identified as black and 13% as Hispanic. Participants were mostly

employed either full-or part-time (67%) and were low-income (67% reported a total combined annual household income <$35,000). Nineteen percent of participants reported symptoms consistent with major depression (score of *10 or more* on the Patient Health Questionnaire–8) and 21% had all three of the comorbidities required for eligibility (hyperlipidemia, diabetes, and hypertension).

Fourteen participants became ineligible during the trial (Figure 1); eight in usual care and six in the intervention arm. Of the remaining 337 participants, 96% of intervention participants and 92% of those in usual care completed the 12-month visit; 90% completed all three study visits. Participant attrition did not differ by treatment arm.

Intervention participants completed a median 93.2% (IQR, 54%–100%) of weekly self-monitoring and a median 89% (IQR, 50%–100%) of coaching calls. Participants weighed themselves a median 2.8 (IQR, 1.2–4.5) days/week or 42.9% (SD = 28.4%) of expected days of weighing.

Over 12 months, participants had a median 3 visits (IQR, 1−4) to their healthcare provider. Among this group, 81% of intervention and 73% of usual-care participants reported being counseled about their weight. Whereas among intervention participants, 69% reported receiving Track-specific counseling (i.e., using the Track EHR progress report) at least once during the 12-month intervention.

In intent-to-treat analyses (Figure 2), the authors observed significantly greater mean 6-month weight change in the intervention arm (−4.1 kg, 95% CI = −4.8, −3.3 kg, $p < 0.001$), relative to usual care (0.3 kg, 95% CI = −0.4, 1.1 kg, $p = 0.41$, mean difference = −4.4 kg, 95% CI = −5.5, −3.3 kg, $p < 0.001$). These differences persisted at 12 months, with an estimated −4.0 kg (95% CI = −4.9, −3.0 kg) weight change in the intervention arm, compared with −0.1 kg (95% CI = −1.0, 0.8 kg) weight change in usual care (adjusted mean difference =−3.8 kg, 95% CI = −5.1, −2.5 kg, $p < 0.001$). Mean 6- and 12-month BMI change followed similar patterns. At both 6 and 12 months, a significantly larger proportion of intervention participants lost >5% of their initial weight, compared with usual care, at 6 (43% vs 6%, estimated RR = 6.8, 95% CI = 3.6, 12.7, $p < 0.001$) and 12 months (40.4% vs 16.7%, estimated RR = 2.4, 95% CI = 1.6, 3.5, $p < 0.001$). Similarly, a significantly larger proportion of intervention participants lost >3% of their initial weight, relative to usual care (6 months: 56% vs 15%, estimated RR = 3.8, 95% CI = 2.5, 5.6, $p < 0.001$, 12 months: 55% vs 30%, estimated RR = 1.8, 95% CI = 1.4, 2.4, $p < 0.001$).

As shown in Table 2, there were improvements in waist circumference among intervention participants, with no change among usual-care participants. There were significant reductions in blood pressure within both study arms at all timepoints; however, levels did not differ between treatment arms. There were no between-group differences in glucose, HbA1c, and blood lipids at 12 months, with the exception of high-density lipoprotein cholesterol. Between-group changes in cardiometabolic risk were consistently larger for patients with a baseline diagnosis of hyperlipidemia (Appendix Table 2, available online).

At 12 months, intervention participants who completed >80% of their expected self-monitoring episodes, counseling calls, or self-weighing days lost significantly more weight

than participants who were less engaged with the respective intervention activities (Appendix Table 1, available online).

During the trial, there were 19 adverse events. In the usual-care group, there were four types of events: cardiovascular (n=6); cancer diagnoses (n=2); musculoskeletal injury (n=1); and hospitalization because of other causes (n=1). Intervention participants experienced five types of events: cardiovascular (n=5); cancer diagnoses (n=1); death from an indeterminate cause (n=1); musculoskeletal injury (n=1); and hospitalization because of other causes (n=11). None of the events appeared to be related to trial participation.

DISCUSSION

These findings demonstrate that clinically meaningful levels of weight loss can be achieved among profoundly vulnerable patients in primary care practice, using a largely digital obesity treatment. More than 40% of intervention participants lost at least 5% of their baseline weight, a threshold that has consistently been associated with myriad health benefits. These outcomes were likely produced by patients' high levels of intervention engagement.

This trial is most directly comparable to other primary care–based effectiveness investigations, particularly the National Heart, Lung, and Blood Institute–funded Practice-based Opportunities for Weight Reduction (POWER) trials. These findings compare favorably to the POWER trial by Appel et al.,[21] which found 12-month outcomes of −4.5 kg when comparing a call center–directed intervention (which included web-based skills training modules and self-monitoring) to a self-directed treatment arm. Patient engagement was strong in both trials, particularly with respect to individual counseling. This trial observed higher rates of engagement with the technology components; this is likely attributable to the use of telephonic technologies, which have the advantage of near-constant user proximity, relative to other technology channels. In contrast to Appel et al.[21] and many other trials of behavioral weight-loss treatments, this study's sample had lower household income, Medicaid-eligibility or uninsured status, and elevated cardiovascular disease risk. These findings improve on the POWER trial by Bennett and colleagues,[22] which found that a nonmobile web-based app, combined with telephone counseling, produced approximately −1 kg over 24 months in a community health center population, relative to usual care. Indeed, the current 6- and 12-month findings generally exceed those observed in both efficacy and effectiveness trials conducted among socioeconomically disadvantaged patients.

The accumulated evidence suggests that digital obesity treatments are not yet ideally suited as replacements for individual or group therapeutic encounters. At present, they are arguably best used to ease the challenge of long-term self-monitoring, deliver educational materials, offer tailored feedback, and facilitate encounters with clinicians. A formal cost analysis is forthcoming, but the present intervention intentionally adopted low-cost digital modalities—interactive voice response and text messaging—which can highly engage patients, but cost significantly less to develop, maintain, and scale relative to in-person treatments.[23] Evidence suggests that digital health interventions produce maximal outcomes only when combined with human counseling.[8] Accordingly, the intervention employed algorithms to present

patient data for maximal utility—short EHR counseling reports for clinicians, rich data dashboards for dietitians, and tailored feedback for participants. Situating the app at the nexus of the patient and their providers, while using features that matched each party's respective needs, likely produced high rates of engagement.

Participants engaged with the intervention technologies at a level that is greater than what has been commonly observed.[16,24] This is particularly notable given the largely rural and socioeconomically disadvantaged nature of the patient population.[13] Although the drivers of the engagement findings are uncertain, one might first speculate that use of mobile and telephonic technology channels were critical elements. Socioeconomically disadvantaged populations are disproportionately mobile dependent,[25] often using their phones as the primary—and sole—Internet connection. The population's familiarity with mobile phones creates advantages for interventions like the present one that required frequent patient interaction. Second, the app provided individually tailored feedback in a one-to-one ratio with user self-monitoring; every time a user provided data, the system returned tailored feedback. Third, the app used interactive obesity treatment approach, a behavioral intervention approach designed to minimize the inherent numeracy requirements that are inherent in most evidence-based weight-loss approaches.[4] Finally, full data integration with patients' dietitian and primary care provider amplified accountability and ensured that reinforcements were offered through multiple sources.

The intervention's use of telephonic technology promotes scalability. Significant time and technical expertise were necessary to build the underlying technical platform, but once built, adding 10- or 100-fold more participants is both possible, and significantly less expensive relative to other digital health channels. The lack of a downloadable app package, graphical user interface, and deployment of cellular connected scales (versus those that connect using Wi-Fi or Bluetooth) eases the apps' reach and limits the patient-level technical and customer service needs. The intervention employed these design features—which maximizes ease, cost efficiencies, and scalability—in an attempt to facilitate translation.

Limitations

Several considerations impact the interpretation of these findings. This was a multicomponent intervention, combining both digital and clinician-delivered counseling activities. Given the design, the authors are unable to determine the extent to which these outcomes are attributable to a particular intervention component. Weight losses were greater in the first 6 months of intervention, and stable thereafter. The reasons for this pattern are unclear, but similar long-term stability in weight change has been observed previously when using this approach.[4,15] One can speculate that although the intervention approach does not produce extremely large initial weight losses, it teaches behavioral skills that facilitate long-term maintenance.[15] There were improvements in cardiovascular risk factors within each arm; as such, there were few between-group differences. These results may have been influenced by a quality improvement initiative (including a focus on chronic disease self-management) that was implemented at the health system during the trial or differences in medication management and adherence by group. Clinicians in the trial counseled patients at levels much higher than the national average. Although the reasons for their counseling

behaviors are unclear, the low rate of weight loss in the usual-care arm suggests that patient-directed interventions are necessary to produce meaningful weight loss outcomes. The effectiveness trial design did not limit participation for those traditionally excluded in weight loss trials (e.g., diabetes, uncontrolled hypertension). Trial ineligibility was largely attributable to language and non−health-related considerations (Figure 1). Intervention disinterest is expected in this population, which has low weight loss motivation,[26] and sociocultural norms that are tolerant of heavier body weight, relative to more advantaged populations.[27] It is unclear how these considerations affect external validity; the authors suspect that they enhance the sample's representativeness, relative to efficacy trial samples, which often include healthier volunteers with high weight loss motivation.

CONCLUSIONS

These findings demonstrate that clinically meaningful weight loss can be achieved among patients in medically vulnerable circumstances and with heightened cardiovascular risk— a group in which such outcomes have been rarely demonstrated. With rapidly increasing uptake of digital technologies, these approaches might have beneficial health impacts for patients, including those who have been historically challenging for the health system to reach and treat.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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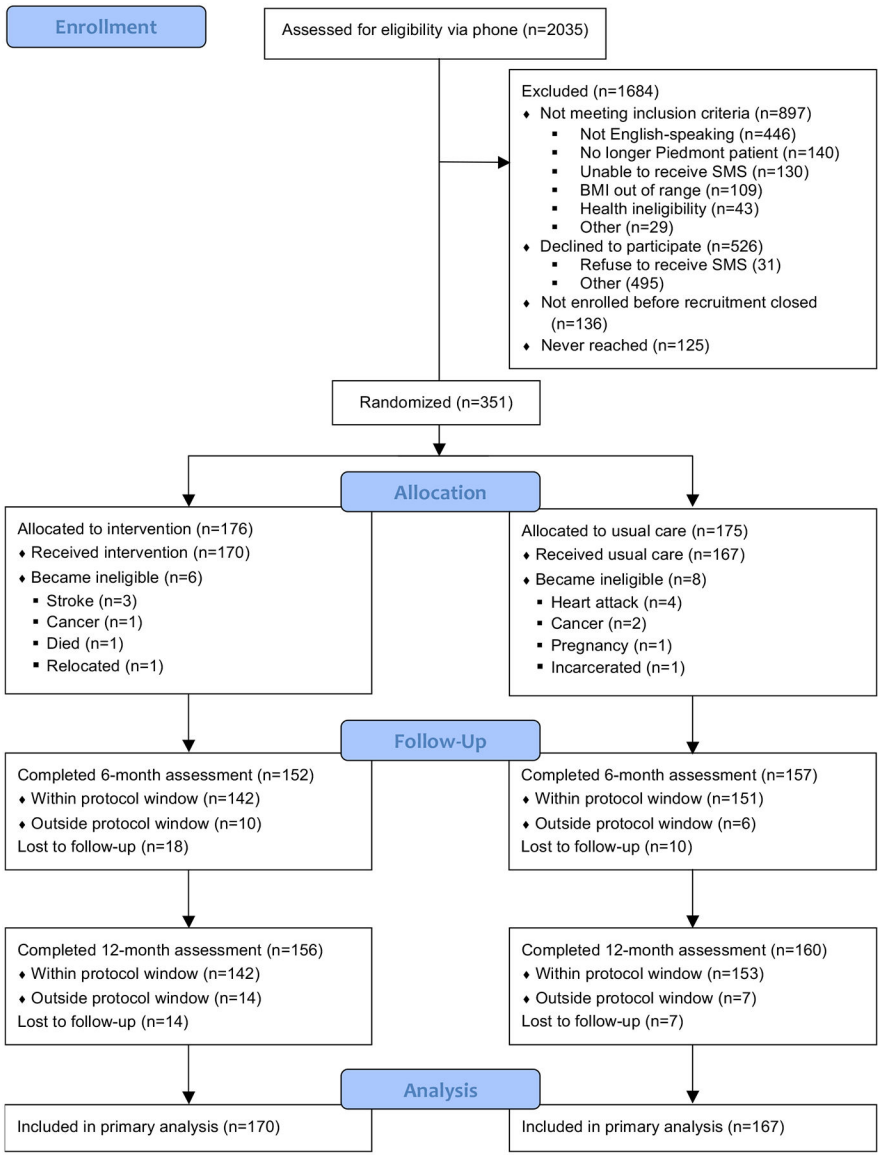

Figure 1.

CONSORT 2010 flow diagram.

SMS, text messaging.

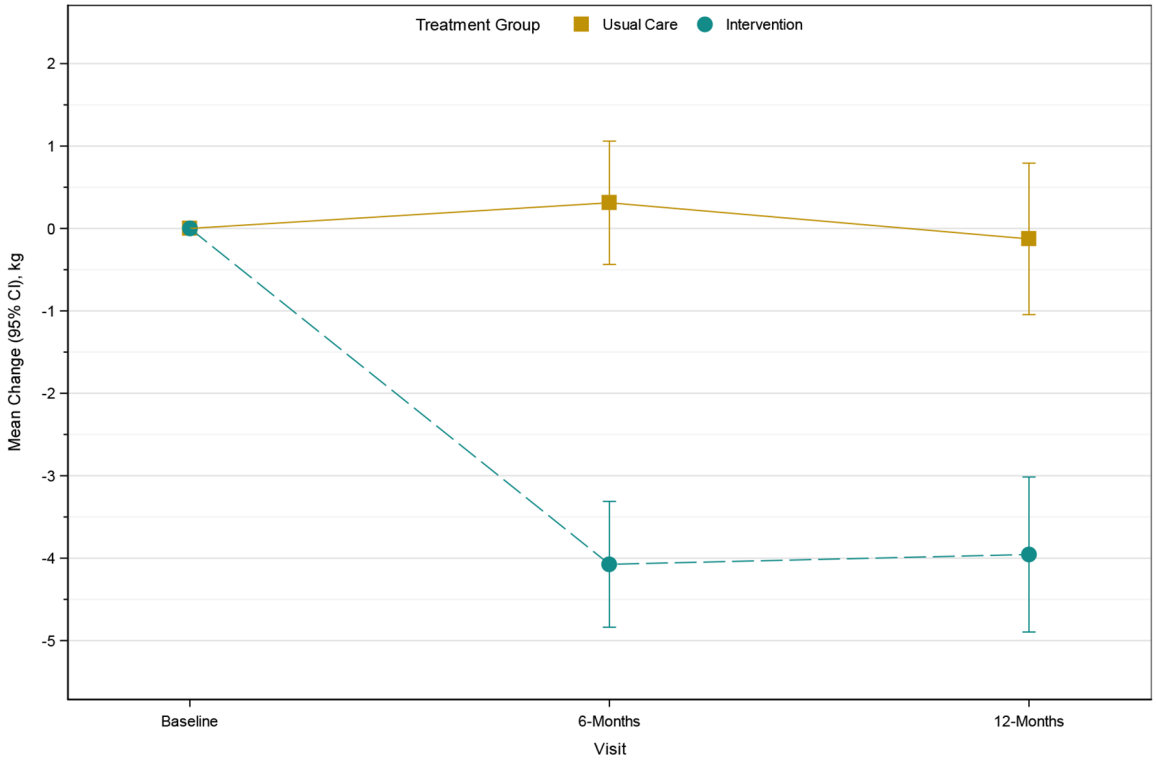

Figure 2.
Average weight change by treatment group.

Table 1.

Participant Characteristics

Characteristic	Total (N = 351)	Intervention (*n* = 176)	Usual care (*n* = 175)
Gender			
Female	239 (68)	120 (68)	119 (68)
Male	112 (32)	56 (32)	56 (32)
Race/ethnicity			
Non-Hispanic black	183 (52)	94 (53)	89 (51)
Non-Hispanic white	102 (29)	51 (29)	54 (31)
Hispanic (all races)	44 (13)	23 (13)	21 (12)
Non-Hispanic other/unreported	19 (5)	8 (5)	11 (6)
Education			
Less than high school graduate	51 (15)	23 (13)	28 (16)
High school graduate or GED	125 (36)	70 (40)	55 (31)
Some college or vocational/trade school	139 (40)	70 (40)	69 (39)
4-year college degree or higher	36 (10)	13 (7)	23 (13)
Annual household income			
0–$11,999	70 (20)	28 (16)	42 (24)
$12,000–$24,999	110 (31)	66 (38)	44 (25)
$25,000–$34,999	56 (16)	34 (19)	22 (13)
$35,000–$49,999	46 (13)	25 (14)	21 (12)
≥ $50,000	26(7)	10 (6)	16 (9)
Unknown or unreported	43 (12)	13 (7)	30 (17)
Living under 2014 U.S. Census poverty threshold			
Below	104 (30)	49 (28)	55 (31)
Borderline	56 (16)	31 (18)	25 (14)
Above	144 (41)	81 (46)	63 (36)
Unknown	47 (13)	15 (9)	32 (18)
Marital status			
Not married or living with partner	178 (51)	88 (50)	90 (51)
Married or living with partner	172 (49)	88 (50)	84 (48)

Characteristic	Total (N = 351)	Intervention (*n* = 176)	Usual care (*n* = 175)
Unreported	1(0)	0 (0)	1 (1)
Current employment			
Yes, full- or part-time	234 (67)	123 (70)	111 (63)
No	110 (31)	50 (28)	60 (34)
Unreported	7 (2)	3 (2)	4 (2)
Health insurance			
Yes	176 (50)	89 (51)	87 (50)
No	175 (50)	87 (49)	88 (50)
Current smoker			
No	257 (73)	128 (73)	129 (74)
Yes	93 (26)	48 (27)	45 (26)
Unreported	1 (0)	0 (0)	1 (1)
Diagnosis			
Diabetes only	12 (3)	6 (3)	6 (3)
Hypertension only	103 (29)	52 (30)	51 (29)
Hyperlipidemia only	32 (9)	19 (11)	13 (7)
Diabetes and hypertension	42 (12)	19 (11)	23 (13)
Diabetes and hyperlipidemia	20 (6)	9 (5)	11 (6)
Hypertension and hyperlipidemia	69 (20)	31 (18)	38 (22)
Diabetes, hypertension, and hyperlipidemia	73 (21)	40 (23)	33 (19)
Depression			
PHQ-8 score less than 10	282 (80)	153 (87)	129 (74)
PHQ-8 score 10 or greater	67 (19)	23 (13)	44 (25)
Unknown	2 (1)	0 (0)	2 (1)
Age, M (SD), years	50.7 (8.9)	50.9 (9.1)	50.5 (8.7)
Weight, M (SD), kg	99.3 (14.1)	98.9 (14.4)	99.7 (13.8)
BMI, M (SD)	35.9 (3.9)	35.9 (4.1)	35.9 (3.7)
Waist circumference, M (SD), cm	114.7 (10.2)	114.4 (10.2)	115.0 (10.2)
Blood pressure, M (SD), mm Hg			
Systolic	130.0 (17.5)	130.1 (17.4)	130.0 (17.6)
Diastolic	82.0 (11.7)	82.1 (11.6)	81.9 (11.8)

Characteristic	Total (N = 351)	Intervention (*n* = 176)	Usual care (*n* = 175)
Fasting lipid profile, M (SD) [*n*], mg/dL			
Triglycerides	160.8 (101.2) [340]	157.4 (96.7) [169]	164.0 (105.7) [171]
LDL	110.8 (33.9) [323]	109.8 (31.7) [161]	111.7 (34.1) [162]
HDL	44.1 (14.0) [340]	44.7 (14.1) [169]	43.6 (13.8) [171]
Total cholesterol	187.2 (38.0) [343]	185.9 (35.0) [172]	188.6 (40.9) [171]
Fasting glucose	117.5 (49.1) [344]	119.4 (52.1) [172]	115.7 (46.0) [172]
HbAlc, M (SD) [*n*], %	6.6 (1.6) [333]	6.6 (1.7) [165]	6.5 (1.6) [168]

Note: Data presented as *n* (%) unless otherwise indicated. SI conversion factors: To convert cholesterol to mmol/L, multiply values by 0.0259; triglycerides to mmol/L, multiply values by 0.0113; fasting glucose to mmol/L, multiply values by 0.0555.

HDL, high-density lipoprotein; LDL, low-density lipoprotein; PHQ, Patient Health Questionnaire; SI, International System of Units.

Table 2.

Secondary Outcomes

	Intervention		Usual care			
Variable	**N**	**Adjusted mean change (95% CI) from baseline**	**N**	**Adjusted mean change (95% CI) from baseline**	**Between-groups difference, Adjusted mean difference (95% CI)**	***p*-value**
BMI						
6 months	170	−1.4 (−1.7, −1.1)	167	0.2 (−0.07, 0.5)	−1.6 (−2.0, −1.2)	<0.0001
12 months	170	−1.4 (−1.7, −1.0)	167	−0.01 (−0.3, 0.3)	−1.4 (−1.8, −0.9)	<0.0001
Waist circumference, cm						
6 months	170	−3.4 (−4.3, −2.4)	167	0.1 (−0.8, 1.1)	−3.5 (−4.8, −2.2)	<0.0001
12 months	170	−2.9 (−4.0, −1.9)	167	0.6 (−0.4, 1.6)	−3.6 (−5.0, −2.1)	<0.0001
SBP, mm Hg						
6 months	170	−4.6 (−7.5, −1.7)	167	−3.4 (−6.3, −0.6)	−1.2 (−5.0, 2.6)	0.54
12 months	170	−8.4 (−11.4, −5.3)	167	−7.5 (−10.4, −4.5)	−0.9 (−4.9, 3.1)	0.65
DBP, mm Hg						
6 months	170	−4.1 (−5.9, −2.4)	167	−2.5 (−4.2, −0.8)	−1.6 (−3.9, 0.7)	0.16
12 months	170	−5.2 (−7.1, −3.3)	167	−4.2 (−6.1, −2.4)	−1.0 (−3.5, 1.5)	0.43
Total cholesterol, mg/dL						
12 months	136	−3.5 (−10.5, 3.5)	149	−6.6 (−13.2, 0.1)	3.1 (−4.7, 10.9)	0.44
LDL, mg/dL						
12 months	119	−5.0 (−11.8,1.7)	133	−1.8 (−8.3, 4.6)	−3.2 (−10.5, 4.1)	0.39
HDL, mg/dL						
12 months	133	3.2 (1.0, 5.3)	148	−0.3 (−2.3, 1.7)	3.5 (1.1, 5.9)	0.005
Triglycerides, mg/dL						
12 months	129	−6.4 (−25.1, 12.3)	143	−13.2 (−30.6, 4.2)	6.8 (−14.0, 27.6)	0.52
Glucose, mg/dL						
12 months	136	−4.9 (−13.0, 3.2)	151	3.2 (−4.4, 10.9)	−8.1 (−17.1, 0.9)	0.08
HbA1c, %						
12 months	129	−0.3 (−0.5, −0.2)	146	−0.2 (−0.04, −0.001)	−0.2 (−0.4, 0.04)	0.11

Note: SI conversion factors: To convert cholesterol to mmol/L, multiply values by 0.0259; triglycerides to mmol/L, multiply values by 0.0113; fasting glucose to mmol/L, multiply values by 0.0555.

DBP, diastolic blood pressure; HDL, high density lipoprotein; LDL, low density lipoprotein; SBP, systolic blood pressure.