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Track: A randomized controlled trial of a digital health obesity treatment intervention for medically vulnerable primary care patients

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Trial Registration

The trial is registered with clinicaltrials.gov NCT01827800.

AUTHORS' CONTRIBUTIONS

PF managed study design and execution and drafted the manuscript for publication. EL and DS coordinated intervention design and contributed to drafting of the manuscript. BB consulted on data safety and execution of the study. EP and SA participated in study design and conducted statistical analysis. LS, HB, HM, and AD participated in study conceptualization and design. GB conceived of the study, acquired study funding, led study design and supervised its coordination and drafted the manuscript for publication. All authors read and approved the final manuscript.

DECLARATION OF CONFLICTING INTERESTS

DS and GGB have equity in Scale Down, LLC that produces mobile applications for weight loss. GGB serves on the scientific advisory board of Nutrisystem. The remaining authors declare that they have no conflicting interests.

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Abstract

Introduction—Obesity continues to disproportionately affect medically vulnerable populations. Digital health interventions may be effective for delivering obesity treatment in low-resource primary care settings.

Methods—Track is a 12-month randomized controlled trial of a digital health weight loss intervention in a community health center system. Participants are 351 obese men and women aged 21 to 65 years with an obesity-related comorbidity. Track participants are randomized to usual primary care or to a 12-month intervention consisting of algorithm-generated tailored behavior change goals, self-monitoring via mobile technologies, daily self-weighing using a network-connected scale, skills training materials, 18 counseling phone calls with a Track coach, and primary care provider counseling. Participants are followed over 12 months, with study visits at baseline, 6, and 12 months. Anthropometric data, blood pressure, fasting lipids, glucose and HbA1C and self-administered surveys are collected. Follow-up data will be collected from the medical record at 24 months.

Results—Participants are 68% female and on average 50.7 years old with a mean BMI of 35.9 kg/m^2. Participants are mainly black (54%) or white (33%); 12.5% are Hispanic. Participants are mostly employed and low-income. Over 20% of the sample has hypertension, diabetes and hyperlipidemia. Almost 27% of participants currently smoke and almost 20% score above the clinical threshold for depression.

Conclusions—Track utilizes an innovative, digital health approach to reduce obesity and chronic disease risk among medically vulnerable adults in the primary care setting. Baseline characteristics reflect a socioeconomically disadvantaged, high-risk patient population in need of evidence-based obesity treatment.

Keywords

Obesity; weight loss; mobile health; minority health; rural health; primary care; digital health

INTRODUCTION

Obesity continues to exact a considerable toll among medically vulnerable populations. Socioeconomic factors strongly pattern exposure to obesogenic environments, the adoption of obesogenic risk behaviors,[1] and the limited availability of weight management resources.[2,3] Racial/ethnic minority populations are overrepresented among the socioeconomically disadvantaged and these groups disproportionately bear the nation's obesity burden.[4] Obesity increases risk of cardiovascular diseases, type 2 diabetes, some cancers, and several other chronic conditions.[5-7] Racial/ethnic minority populations exhibit

greater rates of adulthood weight gain[8,9] and extreme obesity,[1] both of which increase obesity-associated chronic disease risk[7,10,11] and subsequent premature mortality.[12,13]

Extant clinical trial evidence shows that even modest weight losses (3-5%) reduce blood pressure, blood glucose, HbA1C, triglycerides, and LDL cholesterol,[14-17] and prevent both diabetes and hypertension in predisposed individuals.[18-20] Despite a greater need in medically vulnerable populations, obesity is often recalcitrant to treatment.[21,22] Medically vulnerable populations are underrepresented in weight loss trials[23,24] and most studies – even landmark trials – find smaller weight loss outcomes for socioeconomically disadvantaged and racial/ethnic minority participants.[23] For example, blacks in the Diabetes Prevention Program (DPP) were less likely than whites to meet the trial's weight loss goals.[25] Larger weight losses were observed for racial/ethnic minority participants in the Weight Loss Maintenance trial than in the DPP, but weight losses were smaller for racial/ethnic minority participants than for white participants.[26]

Moreover, the challenges of impacting obesity have limited the translation of efficacious behavioral treatments for obesity in the primary care setting. Nationally, only 20% of obese patients receive primary care provider (PCP) counseling for weight management.[3] Racial/ethnic minorities are less likely than whites to be counseled.[27-29] This is unfortunate because PCPs can be helpful agents of behavior change,[15] particularly when PCP counseling is delivered with other behavioral weight management strategies, including social support and behavioral skills training.[30,31]

As such, there is a need for obesity treatment strategies integrated into primary care and aimed at those with highest risk – low-income, racial/ethnic minority adults with obesity and related comorbidities. We designed Track, a digital health approach to obesity treatment among this patient population. Designed to be integrated at low cost and with minimal additional effort by primary care clinics, our findings might inform obesity counseling reimbursement policies and clinical guidelines in primary care settings with high-risk patient populations.

METHODS/DESIGN

Track is a randomized controlled trial of a 12-month weight loss intervention for obese (BMI: 30.0-44.9 kg/m^2) community health center patients with a diagnosis of hypertension, diabetes and/or hyperlipidemia. The primary outcome is weight change over 12 months; secondary outcomes include achievement of ≥ 3% weight loss over 12 months (based on the new obesity guidelines suggesting that a 3% weight loss is clinically meaningful[14]), changes in diet and physical activity and cardiometabolic risk factors, such as waist circumference, blood pressure, fasting lipids, glucose and HbA1C. We will also examine weight and blood pressure change at 24 months post randomization (Figure 1). All study procedures were approved by the Duke University Institutional Review Board (protocol #B0033) and the Piedmont Health Board of Advisors.

Setting

Track is conducted in four federally-qualified community health centers (CHCs) of Piedmont Health Services, Inc. (Piedmont). Piedmont is a private, non-profit community health system that operates health centers with Level 3 Patient-Centered Medical Home designation in a seven-county service area in central North Carolina. The four CHCs participating in Track are located in Carrboro, Burlington, and Prospect Hill, North Carolina. Patients are predominately racial/ethnic minority (70%), impoverished (96% with income <200% of the federal poverty level), and most are either uninsured, underinsured, or hold public insurance (45% uninsured, 32% Medicaid/S-CHIP, 6% Medicare). Registered dietitians are based at each health center. A meaningful use-compliant GE Centricity (CPS 12) electronic health record (EHR) is available at all Piedmont Health centers.

Participants

Participants include 351 men and women, aged 21 to 65 years, with a BMI of 30.0-44.9 kg/m^2 and a weight ≤ 330 pounds (the weight limit for the digital scales used in the intervention) and a current diagnosis of hypertension, type 2 diabetes, and/or hyperlipidemia. Additional inclusion criteria are: at least two visits to a participating Piedmont center in the prior 12 months, North Carolina residency, and the ability to read and write in English. Participants must also have a mobile phone and be willing and able to send/receive 3-9 text messages per week. Exclusion criteria include: current pregnancy, being ≤ 12 months postpartum, cohabitation with another study participant, current employment by Piedmont, current participation in another obesity treatment study or a study involving physical activity, high blood pressure, diabetes, or high cholesterol, or plans to move outside of the study region within the next two years. Participants must not have had a cardiovascular event in the prior 6 months or a diagnosis of coronary obstructive pulmonary disease, congestive heart failure or tachycardia. Patients with history of a condition (e.g., cancer, schizophrenia, end stage renal disease) or medication (e.g., lithium, steroids, anti-psychotics) that would affect body weight, for which weight loss is contraindicated, or that might impact treatment are not eligible. Patients who have profound cognitive, developmental or psychiatric disorders or who have been hospitalized in a psychiatric facility in the prior 12 months are not eligible to participate.

Participant screening and recruitment

Recruitment of participants occurred between June 2013 and September 2014. Piedmont Health staff used electronic health record (EHR) data to generate lists of potentially eligible patients. Study staff then abstracted patients' heights and weights from electronic health records to assess BMI eligibility and reviewed other information from the medical record to confirm eligibility. In order to best reflect the Piedmont patient population, we aimed to recruit a sample that was 25% male and 10% Hispanic.

Potentially eligible participants were sent invitation letters (signed by the health center medical director and the study principal investigator) and study brochures via postal mail. Patients could opt out of the study by calling the toll-free number provided in the recruitment letter. After one week, study staff called potentially eligible patients to invite participation, perform an initial eligibility assessment, and schedule a screening evaluation

visit. Patients completed the informed consent process at the screening visit and eligible participants were then scheduled for a baseline study visit.

Randomization

Randomization occurred at the baseline visit, using a computer-based algorithm. The randomization algorithm allocated participants equally (1:1) across treatment arms, after accounting for CHC, gender and ethnicity (Hispanic vs. non-Hispanic) in order to ensure the equal representation of these characteristics across arms. The intervention design precluded blinding either patients or study coaches to treatment assignment.

Sample size

We hypothesize that there will be no change in the usual care group and a 2.6 kg reduction in weight in the intervention group, and that there will be an auto-correlation between baseline and follow up weight values of 0.55. Based on these values, using a 2-tailed test of differences at the alpha<0.05 level, we would have a power of 80% to detect a difference of 2.36 kg in weight with 140 complete cases per group. Based on our previous studies,[32,33] we expect that 80% of all patients invited to participate in the study will complete the full protocol. Thus, we inflated the study sample to accommodate 20% attrition and aimed to enroll approximately 350 patients. All sample size calculations were conducted in PASS Version 11.

Treatment arms

Usual care—Usual care participants receive the current standard of care offered by their primary care providers. In order to optimize best practice, our team provides in-service trainings on obesity treatment at Piedmont provider meetings at least annually. These include trainings on counseling for weight loss, evidence for obesity treatment among medically vulnerable populations and the use of motivational interviewing during counseling. We provide self-help materials (NHLBI “Aim for a Healthy Weight”) to participants in the usual care arm at baseline and provide them with a collated list of community resources for healthful eating, physical activity, and weight management at 6-months post baseline. Control participants also receive quarterly newsletters that include seasonal-related health tips, and financial and safety information.

Weight loss intervention

Theoretical framework—Social Cognitive Theory (SCT)[34,35] informed the intervention's design. From SCT, self-efficacy was selected as the primary psychosocial mediator that all aspects of the intervention were designed to target. There is strong and consistent evidence that self-efficacy is positively associated with weight loss intentions, initiation, and maintenance.[36-38] Social Cognitive Theory also indicates that self-regulation can be facilitated through a number of processes that were built into the intervention, including self-monitoring,[39-41] goal setting,[38,42] and social support.[43]

Intervention design—The Track intervention contains five components (Table 1): 1) tailored behavioral goals (e.g., walk 10,000 steps/day, no sugary drinks, no fast food); 2)

self-monitoring of these goals via interactive voice response (IVR) phone calls and SMS text messages; 3) daily self-weighing via a cellular-connected scale; 4) skills training materials in print and video; 5) 18 weight loss counseling coaching calls with a Piedmont registered dietitian; and 6) brief PCP-delivered weight loss counseling at medical visits.

Behavior Change Goals: The intervention utilizes the interactive obesity treatment approach (iOTA), which aims to create an energy deficit for weight loss through the modification of routine obesogenic lifestyle behaviors.[32,33,44-47] The iOTA goal library contains two dozen obesogenic behavior change goals (e.g., no fast food, no sugary drinks, eat at least 5 fruits and vegetables a day) that were selected based on their: 1) empirical support; 2) population relevance; 3) ease of self-monitoring; and 4) concreteness. At the baseline study visit, each intervention participant completes a short self-administered survey to assess level of engagement in various dietary, physical activity, and other weight control behaviors. A computer algorithm then uses this information to create a personalized ranking of all the goals in the library based on each participant's need to change each behavior, readiness and self-efficacy to change each behavior, and the potential caloric deficit promoted by the specific behavior change. The algorithm rank orders the goals and participants are asked to self-monitor their adherence to the top 3 goals for the first 8 weeks of the study. Then, starting at week 9, participants self-monitor the next 3 goals on their list in order to maintain motivation and facilitate goal mastery. Goals change every 8 weeks throughout the 12-month intervention period. At the 6-month study visit, participants complete the obesogenic behavior survey again to update their goal list.

All participants also receive a universal 4th goal that rotates at 8-week intervals. In the first interval, we assign a "*no red zone foods*" goal. To determine the "red zone foods," we ask participants to select the foods they consume regularly (at least 3 days per week) from a list of commonly eaten, high-calorie foods and beverages (e.g., sodas, sweet tea, desserts, potato chips, pizza, hamburgers). This goal encourages participants to reduce the highest-calorie foods in their diet and maximize the caloric deficit. We provide all intervention participants with a list of "green zone" foods that they can substitute for their red zone foods. The other universal goals are: "*practice portion control"* and "*walk 7-10,000 steps per day."* We provide all intervention participants with pedometers (Yamax SW-650/651 Digi-Walker) and a worksheet that includes both their current weight and their goal weight after 12 months. Their goal weight is 7% less than their current weight.

Self-monitoring: Regular self-monitoring is a robust predictor of weight loss,[39,41,48] although adherence wanes over time.[49] To enhance engagement potential,[50] Track intervention participants self-monitor their behavior change progress weekly via interactive voice response (IVR) or SMS text messaging throughout the intervention period. The Track IVR system calls intervention participants weekly, requests self-monitoring data (by keypad) on participants' 4 goals (e.g., How many days did you drink number sugary drinks last week?), then immediately provides automated tailored feedback (e.g., "You are doing better than last week. This week, try drinking flavored seltzer water instead of soda to save calories."). Feedback messages describe trends in progress, reinforce successes, offer motivational strategies, and provide short skills training tips. We have hundreds of hours of

audio content (recorded by professional actors) that the automated system pieces together seamlessly during the call.[51] This means that participants hear a human voice (not a digitized voice) that invites self-monitoring and immediately delivers tailored feedback. The weekly IVR calls are 2-3 minutes in duration. Participants who do not respond to IVR attempts are sent a SMS message and are prompted to communicate their weekly tracking data via SMS. Participants who provide self-monitoring data via SMS also receive tailored feedback and a brief skills training message (Figure 2). We have a robust retry protocol that attempts to reach participants if the first IVR call or SMS text goes unanswered.

Regular self-monitoring of body weight is supported by emerging evidence.[40,52] As in our previous studies,[53] we provide intervention participants with scales from BodyTrace, (BodyTrace, New York, NY) which transmit weight data directly to our systems through cellular networks; they do not need a computer, smartphone, or Internet connection. We ask participants to weigh themselves daily and we provide materials and weekly feedback sent via SMS to help participants interpret their daily weight fluctuations and to maintain progress towards their weight loss goal of 7% of initial body weight. Weights received from these scales are available for the coaches to review and to use in providing feedback to participants.

Skills training materials: After randomization and goal assignment at the baseline visit, intervention participants watch a 10-minute video that introduces the Track intervention components. Participants receive a binder and a DVD with additional videos that include descriptive and skills training materials specific to each Track goal. We give participants DVD players if they do not already own one. As participants' goals change every 8 weeks, they can refer to these materials for continual skills training and behavior change tips.

Telephone counseling calls: Track coaches include 3 Piedmont registered dietitians (RDs) and 2 psychology graduate students. Intervention participants are assigned one coach at baseline and stay with that coach for the duration of the study. Coaches deliver a total of 18 counseling calls over the 12-month intervention period: weekly for calls 1-4, every two weeks for calls 5-10, and monthly for calls 11-18. Each counseling call lasts 20-30 minutes and is designed to enhance/sustain participant motivation, deliver in-depth behavioral skills training (e.g., a lesson on how to read a food label), and provide social support. The coaching calls favor a directive approach, but coaches are trained in the principles of motivational interviewing (MI)[54] to counsel participants through any behaviors that they are ambivalent about changing.[54] On each call, coaches: (1) review self-monitoring data (behavioral goals and daily weights) and reinforce its importance; (2) discuss barrier reduction strategies; (3) deliver skills training content and; (4) discuss community resources. In later sessions, coaches and patients collaboratively develop weight maintenance plans.

Coaches use a web-based application that presents data on each participant, allows for note taking, and provides access to the self-monitoring data for behavioral goals and a graph of daily weights over time. The system can record coaching and IVR calls and automatically stores process data (e.g., date/time, call disposition, duration). Track coaches participated in a 2-day training session at study start-up and receive biannual refresher trainings. They are trained to detect clinical information (emergent diagnoses, acute symptoms) that requires

referral to the provider. Coach supervisors review coaching calls for adherence to protocol and deliver weekly coach supervision.

PCP-delivered weight counseling: Primary Care Providers (PCPs) in participating sites are asked to counsel Track intervention participants at all medical visits during the 12-month study period. All Piedmont PCPs received annual in-service trainings on weight loss counseling from study staff. To address the three major barriers to PCP weight counseling - insufficient training, provider confidence, and provider time - the Track intervention includes regular participant progress reports (called “Track Updates”) delivered to PCPs through the Piedmont EHR (Figure 3). The reports include participant status on his/her behavior change goals, weight change data (from BodyTrace scales) and feedback regarding the participant's adherence to self-monitoring. Providers are alerted to these updates through “pop-ups” that display upon opening an intervention participant's electronic medical record.

These recommendations are structured to take no more than 2 minutes for delivery. Variation in the quality of PCP counseling is expected, but there is a minimum expectation that PCPs will reinforce the need for behavior change and endorse intervention participation at each visit. PCPs are asked to document episodes of study-related counseling in the Piedmont EHR. To determine frequency of PCP counseling, we will abstract counseling-relevant data from the visit notes at the conclusion of the intervention period.

We also provide PCPs with Track quarterly reports. These reports provide the PCPs with clinic-level data and feedback on their individual Track counseling rates. The study team reinforces PCP participation in Track by periodically presenting at medical staff meetings throughout the study period. We will determine PCP counseling through a variety of measures. We collect self-report survey data from all participants about their experiences with provider weight counseling over the past year. We also assess provider counseling during the 24-month EHR review after the intervention is complete. We will review visit notes from both intervention and control participants about weight counseling (both related to the Track study and general weight counseling) in order to determine provider adherence to patient counseling recommendations. We will also conduct key informant interviews at the end of the trial with providers and Piedmont Health leadership to further ascertain counseling adherence and to assess adoption potential.

Data collection—At the screening visit, which on average takes 1.5 hours to complete, research assistants orient participants to the study, gather informed consent, and collect anthropometric data to confirm BMI eligibility. As such, research assistants are not blinded to study allocation. Waist circumference, blood pressure, lipid panel, glucose and HbA1C measurements are also collected at this screening visit. Anthropometric and blood pressure data collection activities are conducted again at both the 6 and 12 month follow-up visits and finger prick blood samples for lipids, glucose and HbA1C measures are taken again at 12 months. Surveys are administered at the baseline visit and again at 6 and 12 months post-baseline. We will collect weight, blood pressure and lab data from the EHR at 24 months post-baseline. Participants were reimbursed $35 each at baseline, 6, and 12 months for their time.

Anthropometric data: After changing into hospital gowns, body height is measured to the nearest 0.1 cm using a calibrated wall-mounted stadiometer (Seca 222)[55] and body weight is measured to the nearest 0.1 kg using a portable electronic scale (Seca Model 876).[55] Waist circumference is measured to the nearest 0.1 cm using a vinyl, retractable tape measure (AccuFitness MyoTape) where circumference is measured horizontally from the highest point of the iliac crest at minimal respiration. Approximately 5% of the baseline waist circumference measurements were repeated by a second research assistant for quality assurance purposes, although the first measure is used in analysis.

Blood Pressure: The Omron HEM 907XL, a microprocessor controlled, noninvasive device that automatically measures systolic pressure, diastolic pressure, and pulse rate for adults, is used to measure blood pressure three times at 1-minute intervals after 1-2 minutes of quiet sitting. Participants are advised not to smoke or to consume any caffeine within 30 minutes prior to their study visits.

Cardiometabolic biomarkers: Participants are instructed to fast for at least eight hours prior to their screening and 12-month study visits. At the screening and at 12-month visits, we measure fasting glucose, lipid panels (Cholestech LDX; Cholestech Corporation, Hayward, CA, USA) and hemoglobin A1C (Siemens DCA Vantage Hemoglobin A1C Analyzer, Tarrytown, NY) using fingerstick blood specimens.

Survey data: Surveys are administered in English via computer using an online survey tool. Demographic variables collected at baseline include age, gender, race/ethnicity, nativity, marital status, parity, child height/weight, socioeconomic status, insurance status, occupational status, and educational attainment. We administered validated measures to assess a range of relevant constructs, described in Table 2.

Data analysis

The study is a patient-randomized two-arm parallel group, longitudinal trial. The primary analysis will be based on intention-to-treat principles. We will model observed data vs. time plots for all participants to discern general trends in study outcomes.

Linear mixed modeling will be used to test the primary hypothesis.[76] A linear mixed-effects modeling approach will be used to estimate changes in weight over time, adjusted for site, and test the primary hypothesis.[76] The variables in the model will include a time main effect term, a treatment-by-time interaction term, and may include a fixed effect parameter to account for differences by site. Baseline weight will be retained as part of the response vector and the treatment groups will be constrained to a common intercept to reflect baseline equality of groups assumed by randomization. We will test for significant violation of this assumption before modeling. For the primary outcome, we will test the null hypothesis that the parameter on the interaction between treatment and 12-month change for the intervention is 0. Most additional outcomes are continuous and longitudinal and will be analyzed using similar models and assumptions, as described above. We plan to model binary, longitudinal outcomes using generalized estimating equation models. We will collect EHR data on weight and cardiometabolic risk marker data between 12-24 months post randomization. In

order to optimize the quality of weight data collected in the health centers, we conducted a quality improvement initiative at Piedmont, conducting comprehensive training, and instituting a calibration protocol. Weights between 22-24 months will be used to examine long-term weight change outcomes. We will also model longitudinal data using all weight data available to examine weight change trajectories over time. Given that not all patients will have a visit exactly at 24 months, we will include weights collected between 22-24 months when analyzing weights one-year post intervention.

We used descriptive statistics examining both the frequency and average value for various measures to help characterize the sample (Table 3). For the cardiometabolic panel, measurements that were above or below the measuring range of the Cholestech LDX or the DCA Vantage Analyzer produced a range error upon reading. As such, we imputed either the highest or lowest possible readable value for those measurements of total cholesterol (n = 1), HDL cholesterol (n = 3), triglycerides (n = 4) and HbA1c (n = 2).

Track will also be evaluated using the RE-AIM planning and evaluation framework[77] (Table 4). The RE-AIM framework addresses five issues related to both internal and external validity by comprehensively evaluating the success of interventions on issues key for translation from research to practice and dissemination: 1) Reach and representativeness of individuals who participate; 2) Effectiveness/Efficacy of the intervention on the primary outcomes at the individual level; 3) Adoption at the organizational/CHC level; 4) Implementation measured at the CHC provider/staff level; and 5) Maintenance at both the individual participant and provider level. Additionally, we collect intervention cost data for cost effectiveness analyses.

RESULTS

Baseline characteristics

We randomized 351 patients to either the intervention (n=176) or to usual care (n=175) treatment arms (Figure 1). At baseline, almost one-third (31.9%) of the sample is male (Table 4). Participants are an average of 50.7 (SD=8.9) years old with an average BMI of 35.9 (SD=3.9) kg/m^2. Over half (53.6%) of participants self-identify as black and 12.5% as Hispanic. Participants are mostly employed either full- or part-time (68.0%) and are low-income – 66.3% have a total combined annual household income < $35,000; 29.6% live beneath the 2014 U.S. Census Bureau poverty threshold and 34.3% had received support from the Supplemental Nutrition Assistance Program (SNAP) (data not presented in table). Including themselves, participants report supporting an average of 2.8 (SD=1.5) persons with their household income. One-half (50.1%) of participants do not live with household partners. Similarly, one-half (50.1%) of the sample have a high school diploma, GED or less and only 10% have completed a 4-year college degree or higher. Half (49.9%) of study participants are uninsured.

One-fifth (20.8%) of the sample have all three diagnoses required for enrollment (hypertension, diabetes, and hyperlipidemia). Over one quarter (26.6%) of participants are current smokers. Almost one-fifth (19.4%) score above the PHQ clinical threshold for depression. Mean blood pressure measurements are in the prehypertensive range, while

mean lipid levels are normal. Mean fasting blood glucose and hemoglobin A1c levels are elevated.

DISCUSSION

Few obesity treatment interventions have been successful in producing long-term, clinically meaningful outcomes among adults in primary care who are low-income, racially and ethnically diverse and who have obesity and related comorbidities. This is, at least in part, because the current “gold standard” for weight loss treatment consists of components (in-person coaching or group sessions, verbose skills training materials, copious diet logs) that are not readily testable in populations that face barriers to access and have low literacy and numeracy rates.

Track was designed to preserve the multi-component approach to obesity treatment in primary care, while overcoming many of the barriers to delivering the gold standard. For example, Track utilizes digital health technologies to facilitate self-monitoring, provide tailored feedback on progress, and integrate providers (both primary care providers and coaches), while increasing the scalability and, potentially, the cost effectiveness of treatment delivery.

We were successful in recruiting a sample that is composed of rural, middle-aged adults with obesity who are exceedingly socioeconomically disadvantaged. These patients are already exhibiting signs of significant cardiovascular disease risk; all were diagnosed with at least one obesity-related comorbidity and one-fifth of the sample already has hypertension, diabetes and hyperlipidemia. At baseline, many participants in our sample are current smokers (26.6%) and score above the clinical threshold for depression (19.4%). This group's exposure to adverse clinical, behavioral, and social determinants portends considerable risk for future cardiometabolic dysfunction. Notably, this is a group for which we have few evidence-based intervention approaches.

During the past decade, there has been increasing interest in determining how best to treat obesity in the primary care setting.[78] These efforts have been promising, but their findings do not yet extend to medically vulnerable populations, who have the highest risk of obesity and related chronic disease. Progress in treating obesity in these groups has been slow, and the reliably smaller weight losses often observed in these populations suggest that more intensive approaches are necessary. However, new treatment approaches must also be cost efficient. Moreover, there is great opportunity for new treatments, given greater recognition of the need to treat obesity in primary care[14] as well as the rapid expansion of federal, state, and private payer attention to obesity treatment. In Track, we have developed an innovative intervention approach specifically designed for medically vulnerable populations - one that incorporates several types of care providers in a manner in which they are most effective and links them with patients using a common digital health platform. Our model is designed to be scalable, sustainable, and cost effective, while improving obesity and related outcomes in a population that desperately needs effective treatment solutions.

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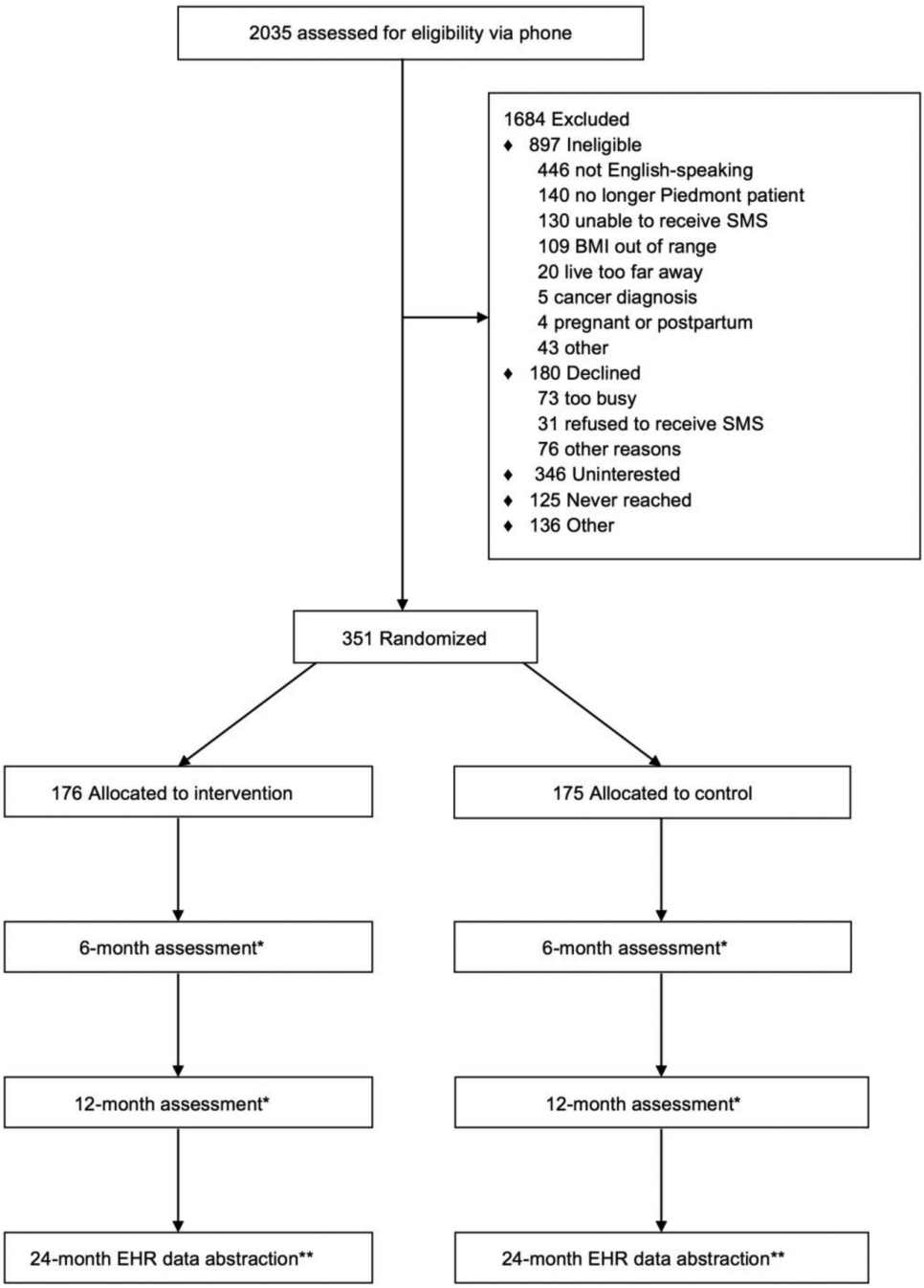

Figure 1.
CONSORT diagram for Track Study

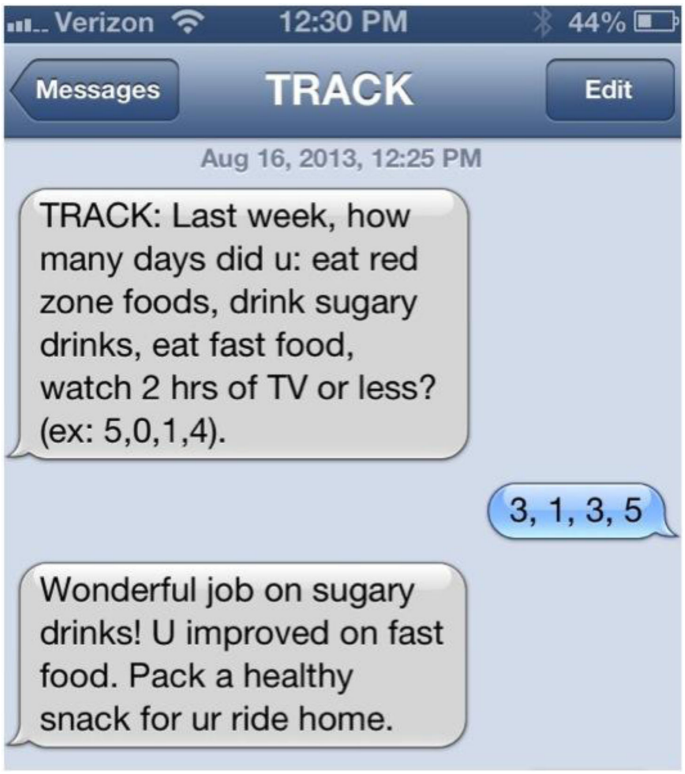

Figure 2.
Example of Track text message

Track update: 8/31/14

Jim Smith is in the Track study. He has lost 10.7 lbs. since 05-15-14. Jim's goal is to lose 15.7 pounds to be at his goal weight of 168.1 pounds by 05-15-15. He is doing well taking the automated Track self-monitoring calls. He is doing well on walking 7,000 steps every day and avoiding sugary drinks. Please reinforce eating more fruits and vegetables and strength training. Please encourage him to keep participating in Track.

Figure 3.
Sample Track Update sent to PCPs via the EHR

Table 1

Intervention Design

Component	**Mode of delivery**	**Frequency of engagement (over 12-month period)**
Self-monitoring of obesity behavior change goals	IVR calls and text messages	Weekly
Behavior change goal feedback	IVR calls and text messages	Weekly
Self-weighing	Cellular network-connected scales	Daily
Self-weighing feedback	Text messages with weight loss progress	Weekly
Tailored skills training	Printed goal information Videos	As desired, but we suggest review every 8 weeks as goals change
Interpersonal counseling	Coaching calls	18/year (weekly for calls 1-4, biweekly for calls 5-10, and monthly for calls 11-18)
PCP-delivered weight counseling	Weight counseling using updates integrated into EHR	Variable; at each PHS medical visit

Table 2

Survey measures and descriptions administered in the Track Study

Construct	Survey description
Health-related quality of life[56]	The 5-item EuroQol (EQ-5D) instrument assesses mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EuroQol visual analog scale (EQ-VAS) is similar to a health thermometer and is designed to measure self-rated health quality of life.
Physical activity[57]	WHO's 18-item Global Physical Activity Questionnaire measures three domains in which physical activity is performed (occupational, transport-related, and leisure-time) assessing intensity, duration, and frequency.
Dietary intake[58]	The 110-item Block Food Frequency Questionnaire is designed to estimate the usual and customary intake of a wide array of nutrients and food groups.
Self-reported medical conditions[59]	The NHANES diabetes and hypertension tools measures self-reported experience with diabetes, and hypertension awareness and treatment, and control of high blood pressure and high cholesterol.
Tobacco use[28]	A 3-item questionnaire from the National Health Interview Survey evaluates current smoking behaviors and previous quit attempts.
Sleep quality[60,61]	The Pittsburgh Sleep Quality Index assesses sleep behaviors and disturbances in the previous month.
Depression[63]	The 8-item Patient Health Questionnaire was designed to evaluate the presence of depressive symptoms with scores ranging from 0-24. Scores above 10 indicate moderate depression.
Negative live events[62]	A 16-item questionnaire measures frequency of stressful life events.
Provider communication[63-65]	This measures questions assess the nature of weight management counseling at previous doctor visit.
Medication adherence[66]	A short, modified version of the Morisky Medication Adherence Scale measures medication adherence for diabetes or hypertension management.
Perceived risk modification[67]	A three-item scale is used to analyze participant assessment of the risk-lowering effect of losing weight, improving diet and improving exercise on chronic disease.
Attitudes toward mental health treatment[68]	Four items from the Collaborative Psychiatric Epidemiology Surveys (CPES) are used to determine willingness to engage in professional treatment for mental health or substance abuse issues.
Food security[69]	A 6-item short form from the U.S. Household Food Security Survey determines household food security.
Perceived stress[70]	The Jackson Heart Study measure is used to assess perceptions of stress experienced in the past 12 months.
Health literacy[71]	The Newest Vital Sign health literacy tool is a 6-item questionnaire that measures participant health literacy
Self-weighing[53]	Participants are asked how often they weighed themselves in the past month with seven response options ranging from never to more than once a day.
Technology use[72]	As 15-item scale adapted from the Pew Research Center's Internet and American Life Project assessing the on use of and access to the internet and mobile technologies.
Importance of race/ethnicity to identity[73]	The 4-item Importance to Identity subscale of the Collective Self Esteem-Race Specific scale is used to understand the importance of one's race or ethnicity to his/her sense of identity.
Identity-based health promotion[74]	Survey items are adapted from the Oserman et al study used to assess identity-based motivation for a variety of health-related behaviors.
Medication use[75]	The Morisky Medication-Taking Adherence Scale-MMAS is a 4-item generic, self-reported scale that measures medication-taking behaviors.

Table 3

Baseline characteristics of the Track analytic sample (n=351)

Variable	N (percent)
Gender	
Female	239 (68.1)
Male	112 (31.9)
Race	
Black or African American	188 (53.6)
White	115 (32.8)
American Indian or Native American	9 (2.6)
Asian	4 (1.1)
Unreported	27 (7.7)
More than 1 race	8 (2.3)
Ethnicity	
Hispanic or Latino	44 (12.5)
Not Hispanic or Latino	305 (86.9)
Unreported	2 (0.6)
Education	
Less than high school graduate	51 (14.5)
High school graduate or GED	125 (35.6)
Some college or vocational/trade school	97 (27.6)
Associate degree	42 (12.0)
College graduate or post grad degree	36 (10.3)
Annual household income	
0 - $24,999	180 (51.3)
$25,000 - $34,999	56 (16.0)
$35,000 - $49,999	46 (13.1)
Over $50,000	26 (7.4)
Unknown or unreported	43 (12.3)
People supported by this income: mean (SD)	2.8 (1.5)
Living under 2014 U.S. Census poverty threshold	
Below	104 (29.6)
Borderline	56 (16.0)
Above	144 (41.0)
Unknown	47 (13.4)
Marital status	
Married or living with partner	172 (49.0)
Not married or living with partner	178 (50.7)
Unreported	1 (0.3)
Current employment	

Variable	N (percent)
Yes, full- or part-time	234 (66.7)
No	110 (31.3)
Unreported	7 (2.0)
Health insurance	
Yes	176 (50.1)
No	175 (49.9)
Current smoker	
Yes	93 (26.5)
No	257 (73.2)
Unreported	1 (0.3)
Eligibility diagnosis	
Diabetes only	12 (3.4)
Hypertension only	103 (29.3)
Hyperlipidemia only	32 (9.1)
Diabetes and hypertension	42 (12.0)
Diabetes and hyperlipidemia	20 (5.7)
Hypertension and hyperlipidemia	69 (19.7)
Diabetes, hypertension and hyperlipidemia	73 (20.8)
*Depression	
Yes	67 (19.1)
No	282 (80.3)
Unknown	2 (0.6)
	Mean (SD)
Age (yrs)	50.7 (8.9)
Weight (kg)	99.3 (14.1)
BMI (kg/m^2)	35.9 (3.9)
Waist circumference (cm)	114.7 (10.2)
Blood pressure: systolic (mmHg)	130.0 (17.5)
Blood pressure: diastolic (mmHg)	82.0 (11.7)
**Cardiometabolic markers	
Triglycerides (mg/dL), n=344	161.2 (104.6)
LDL (mg/dL), n=323	110.8 (32.9)
HDL (mg/dL), n=343	44.6 (14.9)
Total cholesterol (mg/dL), n=344	187.0 (38.3)
Fasting glucose (mg/dL), n=344	117.5 (49.1)
HbA1C (%, NGSP units), n=335	6.60 (1.7)

* Using the PHQ-8 scale with scores ranging from 0-24. Scores ≥ 10 are indicative of moderate depression

** Using imputed values for measurements read outside the possible range.

Table 4

RE-AIM Measures and how they are applied in the Track Study.

Domain	Description	Measure	Data Source(s)
Reach	Degree to which target population is reached by study activities	1. % Eligible population contacted 2. % Who respond to contact 3. % Who participate/are excluded 4. Representativeness of study sample to target population	1-4. Study database 1-4. PHS EHR
Efficacy	Improvement in study outcomes	1. Change in weight and secondary outcomes measures	1. In-person measurement
Adoption	Potential organizational uptake	1. Patient intervention satisfaction 2. Intervention satisfaction among PHS PCPs, dietitians and administrators	1. Survey 2. Qualitative key informant interviews among randomly selected patients (n=15), PCPs/dieticians (n=10), administrators (n=5)
Implementation	Degree to which intervention is implemented as intended	1. Interventionist adherence to counseling protocol 2. PCP weight loss counseling 3. Secular trends in PCP counseling 4. Participant adherence to intervention	1. Study database 2. PHS EHR 3. Patient survey (baseline, 6, 12mo) 4. Survey for all PCPs (12mo)
Maintenance	Can program outcomes be sustained over time?	1. Weight change at 24 months	1. PHS EHR (after QI initiative to improve clinic weight measurements)