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A Weight Loss Intervention Delivered by Peer Coaches in Primary Care: Rationale and Study Design of the PROMISE Trial

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Abstract

Primary care offers a familiar and accessible clinical venue for patients with obesity to receive evidence-based lifestyle interventions for weight management. However, there are numerous barriers to the implementation of such programs in primary care, and previous primary care weight loss interventions demonstrate modest and temporary effects. Weight loss treatment delivered within primary care by peer coaches may offer a viable and effective alternative. The purpose of this trial is to test the effects of weight loss treatment that includes ongoing support from a peer coach (i.e., trained, salaried community health workers) as compared to self-directed treatment. Peer coach treatment will be delivered over 18 months and includes a combination of in-person, group-based office visits and individual telephone contacts. This weight loss trial will include 375 adults with obesity (BMI=30–50 kg/m²) randomized from 10 primary care practices. The primary outcome will be changes in body weight at month 18. Secondary outcomes will include key patient-centered outcomes, including quality-of-life, physical and social functioning, mood, and treatment satisfaction. The cost-effectiveness of the peer coach intervention will also be evaluated. If this novel intervention is effective, it could offer a practical and sustainable approach for the delivery of weight loss treatment in primary care that has the potential to improve clinical outcomes for patients, increase treatment options for primary care providers, and reduce obesity-related healthcare utilization and costs.

Keywords

obesity; weight loss; primary care; peer coach; lifestyle intervention

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Introduction

Behavioral interventions for obesity produce clinically meaningful weight loss.¹⁻⁷ However, translation of evidence-based interventions to primary care has been limited, despite the potential for widespread reach to patients with obesity and calls for greater involvement of primary care providers in weight management.^{6,8} In fact, weight loss counseling infrequently occurs in primary care⁹⁻¹¹ given numerous barriers, including time constraints, insufficient reimbursement, perceptions of ineffective treatment, and physician discomfort.¹²⁻¹⁶

To date, primary care obesity treatments typically demonstrate modest, variable, and short-lived effects.¹⁷⁻²² A review reported effects ranging from 0.1 to 2.3 kg of weight loss with physician obesity counseling.¹⁷ Programs including treatment delivered by non-physicians may achieve better outcomes.^{17,23} However, primary care interventions relying on delivery by other trained healthcare professionals, such as nurses or certified diabetes educators,^{19,24-28} may be impractical for many clinical settings given the limited availability of some specialties and other clinical demands placed on these providers.

To address some of the limitations of previous primary care interventions, obesity treatment delivered by peer coaches may provide an innovative, effective, and practical alternative. Peer coaches, also referred to as community health workers (CHWs) or lay health educators, are typically defined as individuals who: 1) participate in some capacity in health promotion, 2) receive training for intervention delivery but have no formal professional healthcare training, and 3) have an existing relationship or other connection with the population receiving care.²⁹ Peer coaches have successfully delivered obesity interventions in other community settings,³⁰⁻³³ and preliminary work highlights the feasibility and potential effectiveness of peer-delivered weight management programs in primary care as well.³⁴

This alternative approach holds great promise for improving clinical outcomes for at-risk, patients with obesity, including racial/ethnic minorities who are disproportionately impacted by obesity, diabetes, and other weight-related conditions.^{35,36} Adapting an effective evidence-based weight management intervention that is both practical and sustainable in primary care could: 1) improve patients' clinical and psychosocial outcomes, 2) provide currently lacking management options for primary care clinicians seeking to reduce obesity and weight-related conditions among patients, 3) reduce obesity-related healthcare costs, and 4) offer promising public health strategies to address obesity and its associated illnesses. The purpose of the current trial, Partnership Optimizes Weight Management In the SouthEast (PROMISE), is to test the effectiveness of primary care obesity treatment that includes in-person and telephone-based support provided by peer coaches.

Methods

Overview of Study Design

This effectiveness trial compares 18-month outcomes between two conditions: 1) an intensive, behavioral weight loss intervention delivered by peer coaches (i.e., community health workers) through primary care, and 2) self-directed treatment that includes the same

weight loss materials without peer coach support. While both conditions have contact with their primary care provider for routine medical care, the peer coach intervention also includes a mHealth tool reporting patients' progress to physicians. This trial will ultimately include 375 patients from 10 primary care practices in and around Birmingham, AL. Assessments occur every six months, including baseline, month 6, month 12, and month 18. The protocol has been approved by the institutional review board (IRB) at the University of Alabama at Birmingham (UAB), and the trial has been registered at clinicaltrials.gov (NCT02959021).

Aims and Hypotheses

The primary aim of PROMISE is to compare the effects of peer coach treatment on changes in body weight at months 6, 12, and 18. It is hypothesized that treatment delivered by peer coaches will produce greater initial and long-term weight loss compared to self-directed treatment. The secondary aim is to compare the effects of treatment on changes in a variety of patient-reported outcomes at months 6, 12, and 18. It is hypothesized that peer coach treatment will produce greater improvements in quality-of-life, physical functioning, mood, and treatment satisfaction compared to self-directed treatment. A final aim is to evaluate the cost-effectiveness of peer coach treatment compared to the self-directed condition from the perspective of patients, 3rd party payers, and society. It is hypothesized that peer coach treatment for weight management will be cost-effective compared to self-directed treatment.

Setting and Participants

The trial includes 10 primary care practices in and around Birmingham, Alabama. Participating practices include a mix of those affiliated with the university health system, other area health systems, and independent private practices. The practices provide a racially-diverse sample of patients, including >50% African Americans. Participants include women and men aged 21–75 years with obesity (body mass index; BMI=30–50 kg/m²). To be eligible, they must receive care from one of the participating primary care practices. Individuals are ineligible for any of the following reasons: 1) presence of certain medical conditions, including uncontrolled hypertension (blood pressure >160/100 mm Hg at screening); myocardial infarction or cerebrovascular accident within the last six months; unstable angina within the past six months; NYHA Class III or IV congestive heart failure; type 1 diabetes; cancer requiring treatment in past five years (exception: non-melanoma skin cancer); and chronic lung diseases that limit physical activity; 2) current use of any of the following medications: antipsychotic agents, monoamine oxidase inhibitors, systemic corticosteroids, or chemotherapeutic drugs; prescription weight loss medications in the past six months; 3) unwilling or unable to do any of the following: give informed consent; read/understand English; accept random assignment; travel to the intervention site; 4) likely to relocate out of the area in the next 2 years; 5) weight loss ≥10 pounds in past six months; or 6) history of bariatric surgery.

Recruitment

Participants are recruited through a variety of methods utilizing a staged approach beginning with less intensive strategies followed by more directive methods as needed. Initial strategies include: 1) placing flyers in accessible, high-traffic areas (e.g., waiting room, exam rooms);

2) providing practice staff with simple and brief forms to refer patients; and 3) direct mailings to patient practice lists that include postcards providing a brief study description and contact information. Periodic ‘lunch and learn’ seminars for practice staff are conducted to facilitate referrals. If it is determined that more intensive recruitment strategies are needed in a participating practice, then subsequent efforts include more frequent visits to the practice by the study’s recruitment coordinator to meet with staff to identify potential participants and direct recruitment of patients from waiting rooms. Once 30–40 patients in a primary care practice have been recruited into the trial (depending on practice size), then treatment is initiated with that cohort of participants.

Screening

Referred patients are contacted by telephone by a trained research interviewer to determine basic eligibility criteria and assess patient’s interest and availability. Those meeting preliminary eligibility are scheduled for an in-person meeting to provide study details. After receiving a detailed study description and providing informed consent, an in-person screening visit is completed to confirm eligibility (i.e., objective measures of weight, height, and blood pressure). Individuals meeting eligibility criteria then complete the baseline assessment (including repeated anthropometry measures). Study-related visits are conducted in the primary care practice.

Randomization and Blinding

Randomization occurs at the patient (rather than practice) level since there is minimal concern for treatment contamination within practice sites because treatment is delivered to individuals by peer coaches rather than physicians. However, planned analyses conservatively account for clinic site as random effects in models (see Statistical Analyses section). Participants are randomized to the peer coach or self-directed intervention. Randomization is prepared by PROC PLAN in SAS. Ver. 9.3, and a unique randomization number is generated for each participant. Assignment uses a permuted-block randomization scheme with block sizes of 2 and 4 within each practice to maintain balance and prevent predictability. Randomization assignments are prepared as numbered, sealed envelopes. While it is impossible for practices, coaches, or participants to be blinded to treatment assignment, research staff completing assessments are blinded to assignment.

Treatment Conditions

Peer coach intervention.—Treatment includes a combination of in-person, group-based sessions and individual, telephone contacts. Group-based sessions are typically conducted onsite within the primary care practice. The treatment protocol includes 24 in-person group contacts and 34 telephone contacts distributed over 18 months (Table 1). Contacts are more intensive initially and decrease in frequency over time, consistent with other behavioral weight loss interventions.^{37–40} This is also consistent with current clinical guidelines that recommend intensive contact over the first 6–12 months of treatment followed by additional but less frequent extended care contacts to promote weight loss maintenance.⁶ A shift toward telephone contacts during extended care is included to reduce participant burden (i.e., travel) and is based on findings that telephone-based contacts are effective for weight loss

maintenance.⁴¹ In-person and telephone contacts are conducted by the peer coaches (described in greater detail below).

Initial group-based treatment sessions (months 1–6) focus on dietary modification, increases in moderate-intensity physical activity, and behavioral strategies designed to promote adherence to lifestyle changes, including self-monitoring, problem-solving, stimulus control, relapse prevention, social support, and cognitive restructuring.^{37–40} Goals for energy intake include 1200, 1500, and 1800 calories/day for individuals weighing <250, 250–300, and >300 lbs at baseline, respectively. For physical activity goals, participants are encouraged to gradually increase to 200 minutes/week of moderate-intensity physical activity. Participants are encouraged to self-monitor caloric intake, minutes of physical activity, and body weight daily. Extended care sessions (months 7–18) reinforce concepts and promote sustained adherence to weight management behaviors.³⁷ Session content is based on the Look AHEAD lifestyle intervention and the Diabetes Prevention Program (DPP).^{3,40} Groups are held in the primary care practice, space permitting. Alternative locations (e.g., local libraries, community centers) are utilized depending on space constraints and preferences of patients and coaches. Groups include 8–12 participants plus the peer coach facilitator.

The 60-minute in-person sessions include individual, private weigh-ins followed by a combination of didactic presentation of content and interactive group discussions facilitated by a peer coach. Weigh-ins are conducted by peer coaches prior to the start of group sessions. Didactic content, including recommendations for dietary changes, physical activity, and other behavioral strategies, is presented via engaging brief videos created by the research team that are available for viewing on DVDs or an internet site. Videos were created with iterative feedback provided by content experts and stakeholders represented by former and current weight loss program participants. Video content is presented by weight loss ‘experts’ from a variety of professional backgrounds (e.g., nutrition, exercise, psychology) and includes individuals representing diverse demographic characteristics (e.g., racial minorities, men and women). Video content also includes participant ‘testimonials’.

Pre-recorded videos ensure that intervention content is evidence-based and standardized across practices, coaches, and groups. This also minimizes the content expertise required of coaches, as our previous work indicates coaches are less comfortable in the role of “content expert”.⁴² Providing content via DVDs or web-based videos (e.g., posted on YouTube) offers flexibility depending on individuals’ preferences and access to DVD players and internet. This innovative feature of the intervention also offers greater potential for future dissemination and implementation. Pre-recorded content is accompanied by interactive group discussions facilitated by the peer coach (following a structured session outline) to discuss strategies for implementing behavioral changes and problem-solve anticipated adherence barriers.

Participants receive DVDs and/or web links for the videos along with corresponding written treatment materials. This allows participants to independently ‘make-up’ missed group sessions and follow-up with their peer coach to discuss content. Peer coaches also contact participants who missed group-based sessions within 24 hours to review content covered in the session. To assist with self-monitoring of food intake and physical activity, each

participant receives a booklet summarizing macronutrient contents of foods, sets of measuring cups and spoons, a food scale, a bathroom scale, and a pedometer.

In addition to in-person, group-based contacts, individual telephone contacts between participants and a peer coach are provided to enhance participants' motivation and commitment to weight-related behavior change. Calls provide opportunities to enhance individual social support beyond that provided in the group. Each call is intended to last approximately 15 minutes and follows a semi-structured format in which coaches review participant's progress and challenges as well as assist with goal-setting and problem-solving. Phone calls also allow coaches to review missed group sessions with participants.

Depending on practice size and number of patients enrolled at the site, each primary care practice has 1–3 peer coaches assigned to the practice to work directly with enrolled patients. Coaches provide brief progress reports to the physicians of participants in the peer coach intervention via a mHealth tool, which summarizes participants' progress (i.e., attendance to group sessions, completion of telephone calls, weight change). The specific method for including these reports in the medical chart varies across practice sites, depending on availability of an electronic health record and physician/staff preferences for receipt of notes. In some practices, notes are imbedded within the electronic health record. In other practices, a note is faxed to the practice and scanned into the medical chart. Progress notes are provided every six months (i.e., months 6, 12, and 18).

Self-directed intervention.—Self-directed participants receive the same written and prerecorded intervention materials (i.e., DVDs, online videos) as provided to those in the peer-led condition. Self-directed participants are instructed to work through the materials independently at their own pace. Like patients assigned to peer coaching, they also continue to have physician contact as needed for routine medical care. Physicians are not asked to change their practice behaviors with self-directed participants nor are they provided with feedback on their progress, since feedback provided in the peer coach condition is based on progress through the program (e.g., completion of group sessions, telephone contacts).

Peer Coach Training and Supervision

Peer coaches are individuals identified and hired through a community partner organization that has extensive experience training community health workers to provide behavior change counseling, healthcare navigation, and related health support services with a diverse population of patients and chronic conditions. This organization contracts with local health systems and academic groups to deliver health coaching and patient navigation services. Peer coaches are required to have at least a high school diploma or its equivalent, must have successfully completed a structured training program provided by the organization, be compassionate and empathetic, have basic computer skills, community connectedness, good communication skills, and good interpersonal skills. Coaches come from a variety of backgrounds and professional experiences, and they are recruited primarily through various community partners and organizations and referrals by current or past coaches and trainees. Coaches are assigned to primary care sites based on their familiarity with and engagement in the local communities in which specific sites are located. Coaches are not required to have

achieved or maintained significant weight loss themselves, as our experiences and the findings of others⁴³ suggest that other characteristics (e.g., communication skills, support provided) may be more relevant for success in this role. Peer coaches are reimbursed at a rate of \$18.50/hour (including salary plus fringe benefits). Coaches may work full-time or part-time depending on their availability and preferences. Each primary care practice has 1–3 peer coaches assigned to it (depending on patient volume and time availability of coaches), such that each coach follows approximately 10–20 participants per site. Once coaches complete training and treatment delivery at a site, then they have the opportunity to engage with a new practice and a new cohort of participants at subsequent time points.

Prior to intervention delivery, peer coaches undergo standardized training and certification conducted by a multi-disciplinary team of interventionists with extensive experience delivering evidence-based behavioral weight loss programs. Training includes didactic presentations and experiential learning activities (i.e., role-plays with feedback) on patient-centered communication, problem-solving, and goal-setting. Principles from motivational interviewing⁴⁴ are integrated throughout training. Peer coaches also receive detailed information on the weight loss protocol and its behavioral strategies. Initial training is provided to 4–8 coaches at a time (to ensure adequate hands-on experience and feedback) and includes 36 hours of contact delivered over a 2-week period, which is consistent with previous peer coach training protocols.^{30,31,45} Certification involves direct observation of the coaches' use of behavioral counseling skills in structured role-play encounters, and trainers utilize standardized checklists to ensure the completion of specific techniques during the observed encounter. In addition to this initial training, peer coaches receive weekly group supervision conducted by teleconference with a peer coach coordinator who is a trained interventionist experienced in the delivery of structured lifestyle programs for weight management. These ongoing calls provide support, address concerns, and ensure consistent intervention delivery.

Measures

Assessments occur at months 0, 6, 12, and 18 and include a combination of data collection by telephone and in-person. Telephone-based assessments are designed to reduce participant burden and maximize data collection. To minimize practice staff burden and maximize standardization of procedures, data are collected by centrally-trained research staff blinded to randomization. The primary outcome is body weight, which is measured at baseline and months 6, 12, and 18 during in-person visits. Secondary patient-reported outcomes are also measured on the same schedule, although these are collected in-person or by telephone depending on participant preference and convenience.

Anthropometry.—Weight (kg) is measured using a calibrated electronic scale to the nearest 0.1 kg. Height is measured using a wall-mounted stadiometer to the nearest 0.1 cm. Both measurements are performed in the primary care practice following standard techniques with participants' shoes removed.

Quality of life.—Quality of life is assessed through the validated Short-Form 12 (SF-12), which provides measures of health-related quality of life for physical and mental health.⁴⁶

Assessments also include the EuroQOL to measure Quality Adjusted Life Years (QALYs) for cost-effectiveness analyses.⁴⁷

Physical & social functioning.—Items from the Patient Reported Outcome Measurement Information System (PROMIS)⁴⁸ are administered, including the 8-item short forms for physical and social functioning.⁴⁹

Mood.—The Patient Health Questionnaire-8 (PHQ-8) measures self-reported depressive symptoms experienced over the past two weeks.^{50,51}

Physical activity.—Leisure-time physical activity is assessed with the Paffenbarger Physical Activity Questionnaire,^{52,53} which includes items about daily walking, stair climbing, and participation in recreational activities.

Healthcare utilization.—Self-reported utilization of health care services (hospitalizations, ER/physician office visits, prescription drugs, etc.) and out-of-pocket costs are collected using survey questions administered in previous behavioral intervention trials, including Look AHEAD.⁵⁴

Treatment implementation costs.—Implementation costs of peer coach treatment consist of the costs of: i) training peer coaches, including time of trainer and trainees; ii) time spent by peer coaches and participants on intervention activities, including scheduling contacts and documenting contacts/progress; iii) travel or phone charges; and iv) other supply costs (e.g., printed materials, DVDs). These costs are collected prospectively using project records. Salaries are valued using wage rates for peer coaches and other gender/age specific wage information from the Bureau of Labor Statistics.⁵⁵ Room rental costs are not included, because the goal of this program is to utilize primary care clinic space when available or no-cost alternative options when necessary (e.g., local libraries).

Costs of medical care.—These costs are obtained combining the utilization of hospitalizations, emergency department and physician office visits, and prescription drugs reported by participants along with data on the unit costs of these events. For the patient perspective analysis, these unit costs are obtained from self-reported, out-of-pocket costs. For the 3rd party payer perspective analysis, the unit costs are obtained from published data and other data sources available. Specifically, we use the data sources used in the Look AHEAD study, i.e., the Nationwide Inpatient Sample for average reimbursements of hospital admissions, the Medicare physician fee schedule, and other similar fee schedules available from Medicare.⁵⁴ Moreover, Medicare claims data for a 5% random sample of the Medicare population 65 years-old are available at the university. Reuse of the data will be requested to examine average payments of hospitalizations, outpatient visits, and other service utilization, and prescriptions. For the societal perspective analysis, costs of medical care include costs of participants and 3rd party payers.

Treatment satisfaction.—Participants complete a modified version of the Treatment Satisfaction Questionnaire for Medication (TSQM⁵⁶) and an additional single-item measure to assess attitudes and satisfaction regarding the weight loss intervention.⁵⁷

Treatment burden.—A modified version of the Treatment Burden Questionnaire (TBQ) includes 15 items measuring the behavioral burden of self-monitoring, dietary changes, and maintaining physical activity.⁵⁸ Participants also answer two items about the amount of time and effort spent on weight loss treatment.⁵⁷

Side effects.—A symptom checklist including minor (e.g., constipation, dry mouth) and more severe adverse events (e.g., cardiovascular events) is administered to assess side effects associated with treatment.^{59,60}

Other psychosocial constructs.—Other patient-centered outcomes include self-efficacy for healthy eating and physical activity⁶¹; social support^{48,62–64}; and perceived stress.^{65,66}

Physician and practice measures.—Physician characteristics (e.g., demographics, years in practice) and practice characteristics (i.e., number of weekly encounters, number/type of clinicians/staff, predominant payer status) are collected via brief surveys completed by appropriate practice staff.^{67,68} To assess program feasibility and sustainability, semi-structured interviews with physicians and clinic managers are conducted upon completion of the intervention. Topics will include facilitators and barriers to program implementation, including costs, time commitments, and other logistical considerations for program implementation and future refinements.^{67,68}

Process measures.—Participants' attendance to group sessions and telephone call completion are recorded to track adherence to the treatment protocol. The length of calls are documented by peer coaches as well as the number of call attempts, which also provides information for program cost estimates. Participants are asked about interactions with their physician and practice staff, including whether they offered any weight loss counseling or reinforcement of program participation during regularly-scheduled office visits. Finally, treatment fidelity is monitored by peer coaches completion of structured checklists of topics covered in each telephone contact. For group-based sessions, the peer coach coordinator directly observes 20% of sessions and rates fidelity using a standardized checklist. Feedback and retraining are provided as needed.

Retention

Practices.—To promote meaningful and sustained engagement of practice staff, the research team has worked with each participating practice in the development of the study protocol so that each clinical partner has a sense of involvement and investment. By randomizing patients within each practice to treatment conditions, some patients at all practices have access to the peer coach intervention, which should also boost practice retention. Further, efforts have been made to minimize physician and staff burden by providing a convenient referral procedure and by having research staff conduct eligibility screenings and data collection. Finally, practices receive a previously-lacking resource to help them manage their at-risk patients affected by obesity, which is a high priority for primary care practices.

If clinic drop outs occur during recruitment, we propose to first recruit additional participants from the remaining practices to achieve the desired sample size, which is feasible since 10 practices are included and randomization occurs at the patient rather than clinic-level. Secondly, we may enroll additional practices if needed. Participants already randomized and enrolled from practices that subsequently discontinue involvement will still complete the peer-delivered intervention and provide follow-up data.

Modest financial compensation is provided to practices to offset costs associated with losses in revenue and/or efficiency due to study-related activities, which is consistent with reimbursement strategies adopted in other primary care studies.^{20,69} Compensation includes a \$750 flat rate for start-up costs (e.g., attendance at an initial orientation session, clinic staff training) and \$25 per enrolled participant to minimize costs associated with providing medical clearance, referrals, and working with peer coaches and research staff. With each practice recruiting ~37–38 participants, this totals ~\$1,700/practice.

Participants.—A variety of retention strategies are employed in this trial. First, participants receive an intensive, state-of-the-art weight loss intervention at no-cost to them, including a variety of free treatment-related materials (e.g., food scale, pedometer). By including a combination of in-person and telephone-based treatment contacts (nearly 60% are by phone) and a considerable amount of data collection that can be completed by telephone, this protocol is more convenient for participants than programs relying entirely on in-person contacts. Birthday cards, holiday cards, and participant newsletters are mailed to participants during the study. Participants receive monetary incentives when completing follow-up assessments, including \$50 (month 6), \$75 (month 12), and \$100 (month 18). An escalating scale of reimbursement is designed to maximize data acquisition at follow-up.

Statistical Analyses

The primary aim of PROMISE is to compare the effects of peer coach treatment on changes in body weight at months 6, 12, and 18, while the secondary aim is to compare the effects of treatment on changes in a variety of patient-reported outcomes at the same time points. Since each aim compares changes in outcomes over time between groups, the structure of the respective analyses is parallel. Thus, only the analytic plan for Aim 1 is described in detail with the understanding that the analyses for Aim 2 will be similar. All primary analyses will be done with the participant as the unit of analysis and within the intention-to-treat structure; all tests will be considered to be statistically significant at the $p < 0.05$ level. All analyses will begin with an examination of summary statistics and graphs for all variables to ensure data quality and identify potentially spurious values and bivariate testing for differences in baseline characteristics between treatment groups.

For randomized controlled trials, the standard test for an intervention effect is an unadjusted comparison of the primary outcome measure between treatment groups, in this case, a comparison of mean percent weight change. As a trial including multiple primary care sites, current practice suggests that clinic sites should be included in models as random effects even when randomization occurs at the patient level.⁷⁰ While not strictly necessary for a balanced study in the absence of variability in intervention effects among sites, this is a more

conservative and generalizable approach. Accordingly, our main hypothesis test will use linear mixed effects regression with percent weight change as the dependent variable and treatment group assignment as the independent variable accounting for variability among sites with random effects. In the event that we observe imbalances in characteristics between groups at baseline (e.g. BMI, educational status), the imbalanced variables will be controlled for in the regression model. The hypothesis for Aim #1 is that the percent weight change will differ between groups at each of three time points: 6, 12, and 18 months. Thus, separate analyses will be done for each time point. We will also perform a secondary longitudinal analysis of weight change trends over all three time points using mixed models to account for both practices and repeated observations of each participant. If graphical summaries suggest that trends over time are non-linear, we will use generalized additive mixed models to adaptively fit trends over time as penalized splines.

While we do not expect a large amount of missing data, recent work^{71,72} demonstrates that multiple imputation (MI) is superior to other methods for handling missing data in obesity trials. MI imputes plausible values for missing data by generating several datasets with imputed values, which provides a set of parameter estimates that are combined and used for inferential testing. A sensitivity analysis may be performed utilizing alternative methods for handling missing data (e.g., maximum likelihood) to assess the most appropriate approach depending on the amount of missing data and effect sizes observed.⁷² In the event of significant attrition, baseline characteristics of participants lost to follow-up will be compared between groups and analyses will adjust for imbalanced characteristics. Further sensitivity analyses may also examine a range of assumptions related to the outcomes of patients lost to follow-up and how they affect estimates of the effect size. As noted above, analyses for the secondary outcomes in Aim 2 will proceed similarly, substituting those outcomes in place of weight change. All analyses will be done using SAS ver. 9.3 and R ver. 3.1.1 or later.⁷³

Cost Analyses

For Aim 3, cost-effectiveness of the peer coach treatment will be compared to self-directed treatment. Following established methods guidelines,^{74,75} we will conduct a within-trial cost-utility analysis from the perspectives of patients, 3rd party payers, and society. To conduct the analysis, we will determine intervention implementation costs and costs of medical care (described in Methods) for participants that may be affected by the interventions. Effectiveness will be measured by the change in percent weight and in QALYs. All costs will be expressed in 2015 US dollars. Discounting will be applied using an annual 3% discount rate.

The impact of the intervention on participants' health care costs will be determined using a regression model where costs will be the dependent variable, and a binary variable indicating study arm will be the independent variable. If data are skewed, non-parametric bootstrap techniques will be used to determine the difference in arithmetic means between the two groups, and Generalized Linear Models to control for confounding variables if necessary.^{76,77} Similar analyses will be used to determine the impact of the intervention on QALYs. We will then determine the: 1) net cost of peer coach treatment; e.g., total cost of

peer coach treatment (intervention implementation plus medical costs) minus total cost of self-directed treatment (implementation plus medical costs), and 2) effectiveness (e.g., the difference in percent weight or QALYs between trial arms).

If peer coach treatment is less costly and more effective than self-directed treatment, then it will be considered cost-saving. If peer coach treatment is more expensive and more effective, then we will calculate Incremental Cost Effectiveness Ratios (ICERs) as the ratios of the net implementation cost and effectiveness measures. Cost-effectiveness will be determined by comparing ICERs to those of other similar interventions. To examine uncertainty, we will sample with replacement costs and outcomes from the two trial arms and calculate mean costs and outcomes for each bootstrap sample, repeating the procedure 1000 times.^{78,79} Differences in costs and outcomes between groups from each sample will be plotted in a cost-effectiveness plane. ICERs will be obtained for each sample and confidence limits around the ICER will be obtained taking the values at the 5th and 95th percentile of the distribution. Analyses will be done separately for each perspective and repeated to examine the uncertainty around data inputs, such as peer coaches time value, and out-of-pocket and 3rd party payer costs. In addition, we will construct an acceptability curve by considering the proportion of bootstrap replications for which the ICER falls below possible thresholds of cost per QALY, including the commonly used \$50,000/QALY and \$100,000/QALY.

Sample Size and Power

Sample sizes were calculated requiring 80% power to detect the hypothesized difference in percent weight change between groups assuming a two-sided test with type-one error rate of 5%. A patient-level standard deviation of 8.0% was used,⁸⁰ which is conservative compared to the variance observed in other primary care interventions.^{22,67,68} Based on previous work of this research team and the outcomes from other primary care and peer-based interventions,^{22,31,33,67,68} we estimated a range of potential 18-month weight changes. Because participants will be recruited from 10 practice sites, we included sample size estimates both for treating the sites as a fixed effect and treating them as random effects (Table 2). This latter approach conservatively accounts for variability in each site's observed treatment effect. Power for random effects was calculated using the Optimal Design software.^{81,82} We have adopted a conservative scenario (i.e., -3.5% weight loss for peer treatment and influence of practice site on outcomes). Importantly, this level of weight loss is clinically significant.⁶ In fact, weight losses as small as 2–3% are associated with modest but clinically meaningful improvements in a number of cardiometabolic outcomes.^{6,83–85}

Based on these estimates, we require 150 participants/arm (total N=300). To additionally allow for 20% attrition, we will enroll N=375. However, we anticipate that retention will be better than this conservative estimate, as we achieved retention rates of 85–92% ranging from six months to 10 years in other lifestyle intervention trials, and other primary care and peer-based trials have achieved retention of 86%–92% at 2-year follow-ups.^{22,67,68,86} A sample of 375 equates to approximately 37–38 participants recruited per practice.

Discussion

This effectiveness trial will test a novel approach to weight loss treatment in primary care by utilizing peer coaches to deliver an adapted, evidence-based lifestyle intervention for obesity. Such work is particularly needed given the high prevalence of obesity observed in the U.S. population, the limited availability of evidence-based lifestyle interventions for weight management, and the disappointing uptake of efficacious obesity interventions into primary care. Existing obesity interventions implemented in primary care typically demonstrate only modest and temporary improvements in weight and other clinical outcomes. Thus, alternative models for managing obesity in primary care are urgently needed.

Weight loss treatment delivered by peer coaches is an innovative approach that may be effective and sustainable for integration into primary care. Peer coaches have several potential advantages, including familiarity with the community and/or condition, ability to provide ongoing collaborative support to patients, greater accessibility to patients, and potentially greater cost-effectiveness than healthcare providers.^{29,45,87} Peer coaches have successfully assisted in the management of diabetes⁸⁸ and physical activity promotion,⁸⁹ and recent studies show promise for the use of peer coaches in weight management as well.^{30–32,43} However, previous studies have not examined the effects of weight loss treatment delivered by peer coaches in primary care. To address this, a pilot study of a primary care weight management program that included group-based visits and telephone contacts with peer coaches was recently conducted.³⁴ This 6-month program achieved significant weight reductions and provides support for the rationale and methods of this longer-term, full-scale primary care weight loss trial.³⁴

The current trial will provide important information on the effects of this peer coach intervention for weight loss as well as a variety of patient-reported outcomes, such as mobility, mood, and quality-of-life. Cost effectiveness of the novel intervention will also be examined. Importantly, data on utilization and acceptability of the intervention will be gathered from the perspective of patients as well as physicians and primary care staff, which is particularly important for future refinements and potential dissemination of this protocol into applied clinical settings.

Several potential limitations and methodological decisions should be considered in evaluating this protocol. First, in the event that peer coaches permanently or temporarily discontinue involvement in the project (e.g., vacation, illness), we plan to pair coaches for backup coverage and will train new coaches throughout the protocol as needed. We will redistribute a coach's client load among other coaches until a replacement is trained and certified. Second, the intervention targets all adult patients with obesity regardless of presence (or absence) of an additional cardiometabolic risk factor (e.g., pre-diabetes). This decision was made in consultation with our primary care practice partners who expressed a strong preference to make treatment available to all patients with obesity. This is also consistent with current obesity treatment guidelines.⁶ Third, in addition to weight, the trial's outcomes primarily include patient-reported outcomes. While inclusion of other clinical outcomes (e.g., glucose, lipids) was considered, weight-related improvements in these

outcomes are well-documented.⁶ Thus, a streamlined and efficient assessment battery was retained. Finally, there could be concern that the number of treatment contacts will be burdensome for participants. However, more than half of contacts will be conducted by telephone and missed in-person sessions can be made up by telephone. Other peer-based interventions have utilized similar (or more intensive) levels of in-person and phone contacts while still maintaining high retention at extended follow-up.^{30,33} Additionally, low-intensity interventions are minimally effective for promoting weight loss.^{6,17}

If this weight management program proves effective for implementation in primary care, it would be well-positioned for future uptake by health systems, insurance providers, or individual practices. In fact, the Patient Protection and Affordable Care Act recognizes community health workers as an integral part of the health care team, they are becoming increasingly integrated into patient-centered medical homes, and the Centers for Medicare and Medicaid Services (CMS) now reimburses community health worker organizations for certain services (e.g. diabetes prevention programs).^{90–93} Potential program dissemination is also facilitated by the structured training and certification program for peer coaches that has been developed for this project, which has potential for widespread dissemination through online and/or DVD-delivered programs. There also will be a packaged treatment program, including pre-recorded video content and structured intervention materials, which could be readily disseminated into clinical settings as well.

Clinically, these findings may offer a practical, sustainable, and effective approach for the delivery of weight loss treatment in primary care, which could have significant public health reach for the management of obesity and the reduction of weight-related health conditions. Additionally, future work could adapt and evaluate the peer coach treatment model for the prevention or management of other chronic conditions in primary care.

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Table 1.

Schedule of treatment contacts for peer coach intervention

GROUP SESSIONS	PHONE CONTACTS *
Initial Treatment (months 1–6)	
12 weekly (months 1–3)	8 weekly (month 1–2)
2 bi-weekly (month 4)	8 bi-weekly (months 3–6)
2 monthly (months 5–6)	
16 groups	16 calls
Extended Care (months 7–18)	
4 monthly (months 7–10)	12 bi-weekly (months 7–12)
4 bi-monthly (months 11–18)	6 monthly (months 13–18)
8 groups	18 calls

* After month 3, telephone contacts will occur during weeks when no group sessions are scheduled to distribute contacts over time.

Table 2.

Sample size per group based on estimated mean changes in body weight (%) at 18- month follow-up

Between group difference	Peer treatment	Self- directed	SD	Power	Fixed effect ^a	Random effect ^b
−4.0%	−4.5%	−0.5%	8.0	0.8	n=64	n=70
−3.5%	−4.0%	−0.5%	8.0	0.8	n=83	n=100
−3.0%	−3.5%	−0.5%	8.0	0.8	n=113	n=150

^a
n per group with practice site as fixed effect^b
n per group with practice site as random effect