

Testing a Health Coaching Program to Help Patients with Obesity Lose Weight—The PROPEL Study

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TABLE OF CONTENTS

ABSTRACT	4
BACKGROUND	6
PATIENT AND STAKEHOLDER ENGAGEMENT	9
Stakeholder Engagement	9
Patient Engagement	9
Community Member Engagement	11
METHODS.....	12
Study Overview and Design.....	12
Study Setting	12
Participants.....	13
Table 1. Inclusion and Exclusion Criteria for the PROPEL Trial	15
Interventions and Comparators	16
Figure 1. Example of a Personal Weight Loss Graph for a Single ILI Participant Followed for 24 Months.....	19
Study Outcomes	21
Table 2. Data Measurement and Collection Schedule for Patient Data	22
Assessment Data Monitoring and Quality Assurance	26
Sample Size Calculations and Power	27
Time Frame for the Study.....	27
Figure 2. Overview of the PROPEL Data Collection Period	29
Data Collection and Sources.....	30
Analytical and Statistical Approaches.....	31
Changes to the Original Study Protocol	35
Focus Group Methods	38
RESULTS	41
Focus Group Results	41
Table 3. Patient Responses: What Has Your Doctor or Other Health Care Professional Done to Try to Help You Lose Weight?	43
Table 4. Health Care Provider (n = 6) Responses: What Are the Main Things That You Have Done to Help Patients Lose Weight?.....	45
Intervention Study Results	45
Figure 3. Patient Flow Through the PROPEL Trial.....	46

Table 5. Clinic and Participant Characteristics at Baseline	48
Table 6. Changes From Baseline in Weight Loss Variables Over 2 Years, Shown as Mean (95% CI) ^a	52
Figure 4. Percentage of Patients Achieving ≥5% and ≥10% Weight Loss From Baseline at 6 Months (A), 12 Months (B), 18 Months (C), and 24 Months (D) ^a	53
Table 7. Changes From Baseline in Patient-Reported Outcomes Over 2 Years, Shown as Mean (95% CI) ^a	55
Table 8. Changes From Baseline in Cardiometabolic Disease Risk Factors Over 2 Years, Shown as Mean (95% CI) ^a	58
Table 9. Relationships Between Intervention Components (Columns) and Corresponding Changes in Body Weight and Secondary Outcomes From Baseline to 24 Months (Rows) Among Patients in the ILI Group ^a	61
Table 10. Change in Patient Satisfaction With Their PCP From Baseline to 24 Months, Shown as Mean (95% CI) ^a	62
Figure 5. Mean Percentage Change in Weight From Baseline ^a in African American and Other Races (A), Women and Men (B), and Younger, Middle, and Older Adults (C)	64
Table 11. SAEs by Study Group ^a	65
DISCUSSION	66
Context for Study Results	66
Subgroup Considerations	71
Generalizability and Implementation of Results	72
Study Limitations	74
Future Research	75
CONCLUSIONS	77
REFERENCES	78
RELATED PUBLICATIONS	88
ACKNOWLEDGMENTS	89
APPENDICES	92
Appendix A. Supplementary Tables/Figures	92
Appendix B. Intervention Fidelity and Sustainability	106
Appendix C. Data Management Plan	111

ABSTRACT

Background: Louisiana currently has one of the highest rates of obesity in the United States. Obesity accounts for \$2.4 billion in yearly health care expenditures in Louisiana, 42.5% of which is financed by the Centers for Medicare & Medicaid Services (CMS). Obesity disproportionately affects underserved populations, and Louisiana is characterized by high levels of poverty, low health literacy, and food insecurity. The US Preventive Services Task Force recommended that physicians offer intensive multicomponent behavioral interventions to individuals with obesity, and CMS covers intensive behavioral therapy for obesity delivered by a qualified primary care provider (PCP). However, the reliance on PCPs to deliver intensive behavioral therapy for obesity has limitations, creating a critical need to test models that incorporate the 2013 American Heart Association/American College of Cardiology/The Obesity Society guidelines for the management of overweight and obesity in adults in real-life settings for obesity treatment in primary care clinics.

Objectives: The primary aim of this trial was to develop and test the effectiveness of a 24-month, patient-centered, pragmatic, and scalable obesity treatment program delivered within primary care in an underserved population. We hypothesized that relative to patients who received usual care (UC) from their PCP, patients who received an intensive lifestyle intervention (ILI) delivered by health coaches embedded in a primary care setting would have (1) greater percentage reductions in body weight and (2) significant improvements in quality of life (QOL), functional capacity, medical care satisfaction, and obesity comorbidities. Additionally, 3 secondary aims (1) evaluated the relationships between adherence to intervention components and corresponding changes in body weight and secondary outcomes; (2) examined the effects of the intervention on system-level practices and patient satisfaction with care; and (3) tested the heterogeneity of treatment effects (HTE) across clinics and subgroups of patients by sex, age, and race.

Methods: We conducted a cluster randomized controlled trial in which 18 Louisiana primary care clinics were randomized equally to either the ILI or UC group. A total of 803 (452 UC, 351 ILI) adults (67% African American; 65.5% with annual household income of <\$40 000) with obesity were enrolled. The UC group received their normal care from their primary care team. The ILI group received a program consisting of weekly sessions in the first 6 months (which represented an active weight loss period), followed by monthly sessions for the remaining 18 months (which represented a weight loss maintenance period), all delivered by health coaches embedded in the clinics. The multicomponent ILI included the provision of portion-controlled foods for the first 4 weeks, shared goal setting for diet and physical activity, and daily weighing on an electric scale with weight loss feedback to the coaches and patients through a computer tracking system. A “toolbox” approach provided specific nutritional, physical activity, and behavioral strategies to choose from depending on the needs of each patient.

The primary outcome was percentage weight loss at 24 months. Secondary outcomes included changes in cardiometabolic disease risk factors, QOL, functional capacity, medical care satisfaction, obesity comorbidities, and HTE across age, sex, and race subgroups. Changes in

outcome measurements from baseline to 24 months were analyzed in the context of repeated-measures linear mixed-effects models, which included random cluster (clinic) effects.

Results: Eighteen clinics (9 ILI, 9 UC) enrolled a median of 40.5 (range, 2-89) patients per clinic. Of the enrolled patients, 83.4% completed the 24-month trial. Percentage weight loss at 24 months was significantly greater in the ILI group (-4.99% [95% CI, -6.02% to -3.96%]) than in the UC group (-0.48% [95% CI, -1.57% to 0.61%]), with a mean difference of -4.51% (95% CI, -5.92% to -3.10%) between the groups ($P < .0001$). Compared with the UC group, significant improvements at 24 months were found in the ILI group for total and high-density lipoprotein cholesterol but not for other cardiometabolic risk factors. Weight-related QOL at 24 months was significantly greater in the ILI group than in the UC group for numerous subscales. Patient satisfaction with medical care did not significantly change within either group.

Conclusions: A high-intensity lifestyle-based obesity treatment program delivered in an underserved primary care population produced clinically significant weight loss and improvements in cardiometabolic risk factors and weight-related QOL over 24 months.

Limitations: Recruitment was lower than originally anticipated (sample size estimates ensured adequate power for all analyses). The sample was composed primarily of women (84.4%), which limited our ability to examine differences in weight loss across sex-by-race subgroups.

BACKGROUND

Obesity is a highly prevalent and serious medical condition in the United States, and Louisiana ranks highest among the states in the prevalence of obesity.¹ Obesity increases the risk of type 2 diabetes, heart disease, poor quality of life (QOL), and several cancers.² Indeed, Louisiana sits firmly in the “chronic disease belt,” characterized by a high prevalence of cancer,³ cardiovascular disease,^{4,5} diabetes,⁶ and obesity.⁷ Louisiana’s population is uniquely vulnerable, as 32% of the population is African American,⁸ 19% of residents live in poverty,⁸ and Louisiana is ranked 49th among the states for low levels of health literacy.⁹ Given that African Americans and other underserved populations have a disproportionately high obesity prevalence,^{10,11} identifying strategies to reduce obesity in these populations is imperative for achieving national public health goals to reduce health inequities.¹²

While the high obesity rates are concerning, it is equally concerning that health care systems have not delivered medical interventions capable of producing even modest weight loss.¹³ With primary care providers (PCPs) being the cornerstone of medical care in the United States, the US Preventive Services Task Force (USPSTF) recommends that physicians offer intensive multicomponent behavioral interventions to individuals with obesity.¹⁴ Further, the Centers for Medicare & Medicaid Services (CMS) covers intensive behavioral therapy for obesity delivered by a PCP.¹⁵ However, relying on PCPs to deliver intensive behavioral therapy for obesity has limitations, in part due to time constraints during a typical primary care visit and lack of training among PCPs in nutrition education and behavioral therapy.^{13,16} A narrative review of obesity management in primary care indicated that obesity treatment options delivered in primary care have limited success, demonstrating only a 1- to 3-kg weight loss over 6 to 24 months.¹³ As most studies only employed monthly or quarterly visits of 10 to 15 minutes in duration, this low weight loss was likely due to the low intervention intensity.¹³ Indeed, there is evidence that higher-intensity interventions delivered by trained interventionists in primary care can produce greater weight loss.¹⁷

The 2013 American Heart Association (AHA)/American College of Cardiology (ACC)/The Obesity Society (TOS) guidelines for the management of overweight and obesity in adults^{18,19}

assert that an intensive comprehensive lifestyle intervention is the centerpiece to effectively promoting weight loss and improving health. The guidelines' recommendation for comprehensive lifestyle interventions was based on a systematic review of the results from 51 trials to promote weight loss and weight loss maintenance. The guidelines emphasize the gold standard of onsite, high-intensity (ie, ≥ 14 sessions in 6 months) comprehensive interventions delivered by a trained interventionist. Interventionists include mainly health professionals with various specialties (eg, registered dietitians, psychologists, health counselors, exercise specialists) trained to follow weight management protocols. Obesity treatment models based on the AHA/ACC/TOS guidelines that are adaptable to real-life primary care settings are needed.

The primary aim of the PROMoting Successful Weight Loss in Primary Care in Louisiana (PROPEL) trial was to test the effectiveness of a pragmatic, high-intensity lifestyle-based obesity treatment program delivered within primary care clinics. PROPEL was designed to scale to large patient populations and directly address the “translation gap” between current evidence-based obesity treatment models and primary care practice to impact the way in which CMS reimburses for obesity treatment in the future. We hypothesized the following:

- Relative to patients who receive usual care (UC), patients who receive a high-intensity, health literacy-appropriate, and culturally appropriate intensive lifestyle intervention (ILI) delivered by trained health coaches embedded in a primary care setting will have greater percentage reductions in body weight; and
- relative to patients in UC, patients who receive the ILI will have significant improvements in health-related QOL (HRQOL), satisfaction with medical care, and improved obesity comorbidities.

The 3 secondary aims of the PROPEL trial were to (1) evaluate relationships between adherence to intervention components (physical activity, diet, sessions, etc) and corresponding changes in body weight and secondary outcomes; (2) examine the effects of the intervention on system-level practices and patient satisfaction with care; and (3) test the heterogeneity of treatment effects (HTE) across clinics and across subgroups of patients (men vs women, White vs African American, older vs younger adults).

PROPEL was a cluster randomized controlled trial (RCT) in which primary care practices were randomized into either an ILI or UC group, which differs from a traditional RCT in which individual patients are randomly assigned to intervention groups. The cluster randomized design helped reduce contamination or spillover effects between the 2 intervention groups. While the unit of randomization was the clinic, the main study outcomes were measured at the individual patient level.

PATIENT AND STAKEHOLDER ENGAGEMENT

The design of PROPEL was guided by extensive stakeholder, community, and patient engagement, as explained in Katzmarzyk et al²⁰ and below.

Stakeholder Engagement

Stakeholders (eg, leadership and clinicians of federally qualified health centers [FQHCs]) were recruited by the study co-investigators. Stakeholder engagement was initiated before the trial's inception and continued throughout the study period via email, phone, and in-person meetings. Stakeholders identified clinics to participate in the study, assisted study investigators in obtaining the proper approvals to collect data within the clinics, identified other clinic staff members to assist study staff within each clinic, provided clinic-level statistics to be included in analyses, and recruited members of our patient engagement teams among other vital roles. Additionally, stakeholders met periodically with study investigators to discuss and solve issues as they arose, such as slow recruitment or logistical challenges within the clinics (eg, lack of space for coaches or assessment technicians within the clinics).

Patient Engagement

A series of focus groups conducted early in the trial design phase captured perceptions about obesity treatment options among health care providers and patients with low income.²¹ These focus groups were vital to selecting the patient-reported outcomes (eg, QOL, obesity comorbidities, etc) and designing the intervention curriculum. Three patient advisory boards (PABs; located in North Louisiana [n = 8], South Louisiana [n = 8], and New Orleans [n = 18]) that met quarterly (in person or via teleconference) throughout the study period were also instrumental in trial design and conduct. PAB members were recruited with assistance from PROPEL stakeholders and co-investigators. The PAB members were representative of the anticipated study population; most members were African American, were middle aged, and had personal experience with obesity and weight loss. The PAB members also resided in similar communities as the study participants.

The PABs provided significant input on patient recruitment and retention strategies, reviewed PCP educational materials, and provided feedback on disseminating the results to the community. PAB meetings were generally informal, with a short presentation on a topic of interest during which members interacted through questions, comments, and recommendations. The initial PAB meeting included a presentation on the basics of research, which provided a foundation for future meetings. In addition to choosing the study name and acronym, PAB members provided feedback on the study protocol and conduct, including the intervention curriculum (examples of modifications made based on PAB feedback include making edits to the literacy level, as well as adding content about eating at social events/family functions, stress, and QOL), recruitment methods (editing language on recruitment flyers to better reflect patients' interests), UC newsletter (providing community health events to include), and patient retention (helping choose visit attendance incentives, emphasizing the altruistic aspect of research participation). As the study neared completion, the PAB meetings included presentations and discussions of basic research statistics so that PAB members were better able to both understand and comment on the study's results. PAB members provided feedback and context for preliminary study results, which were presented during the final PAB meeting members will continue to be an important avenue for disseminating the study's results to the community.

Finally, 2 patient representatives met with study investigators and staff during monthly study project management committee meetings to provide feedback and oversight on the study's conduct, contribute to and approve study materials, and help troubleshoot issues with recruitment, retention, and intervention delivery. Although the project management committee patient representatives were less representative of the study's patient population than were the PAB members, their experiences with weight management as well as their work in the community enabled them to provide invaluable feedback for the study's conduct. For example, these members provided topics, content, authorship, and edits to the UC newsletters, contributed to results dissemination through edits to conference abstracts, solved logistical challenges during the study's initial protocol development and trial initiation, and represented the trial at annual conference meetings.

Community Member Engagement

A community monitoring board (CMB), composed of 6 individuals representing community organizations (university agricultural center, health education center, community health organizations), met in person yearly to provide feedback on the trial's overall direction and helped disseminate the results to the community through their networks. CMB members were recruited through participating clinics, stakeholders, and study investigators. To solicit their feedback, during the annual meetings, we gave CMB members a status update on the trial's progress and an overview of the current issues the trial was experiencing. CMB members helped identify PAB members, suggested new retention techniques, and provided publication ideas and results interpretations based on their experiences (eg, an article on retention methods has been published).

METHODS

Detailed methods were previously published by our group, and the information in this section is derived from these publications.²⁰⁻²²

Study Overview and Design

PROPEL was a 2-group (ILI or UC) cluster RCT in which the clusters were primary care clinics in 3 geographic areas of Louisiana (New Orleans, North LA, and South LA). A total of 18 Louisiana primary care clinics inclusive of low-income populations with a high percentage of African Americans were randomized to either the (1) ILI or (2) UC group. Outcomes were assessed at baseline and 6-, 12-, 18-, and 24-month visits. The primary aim was to develop and test the effectiveness of a 24-month obesity treatment intervention delivered within primary care. The intervention was developed, in part, using information gathered from patients and health care providers through a series of focus groups²¹ (detailed methods are described at the end of this section). We hypothesized that relative to patients who received UC, patients who received a health literacy– and culturally appropriate ILI delivered by trained health coaches embedded in a primary care setting would have (1) greater percentage reductions in body weight and (2) significant improvements in HRQOL, satisfaction with medical care, and obesity comorbidities. The 3 secondary aims were to (1) evaluate relationships between adherence to intervention components and corresponding changes in body weight and secondary outcomes, (2) examine the intervention’s effects on system-level practices and patient satisfaction with care, and (3) test HTE across clinics and across patient subgroups.

Study Setting

Primary care clinics were chosen as the study’s setting in accordance with the USPSTF’s recommendation that physicians offer behavioral treatment for obesity and to address the translation gap between treatment recommendations and implementation in primary care. Eighteen primary care clinics were randomized by the study statistician to either the ILI or UC group after stratification by health system. The 18 clinics were from 5 health systems (4 FQHC systems [14 clinics] and 1 large, nonprofit academic health care delivery system [4 clinics]).

Randomization to the ILI or UC group was stratified by health system to ensure adequate staffing of ILI clinics and representation from all regions of the state and types of health systems in both groups of the trial. The study statistician revealed the clinics' randomization group to investigators once completed so that the ILI clinics could be properly staffed with health coaches and supplied with ILI materials. The health coaches were hired, trained, and paid by the Pennington Biomedical Research Center, the primary academic center that conducted the study. Given that this trial was randomized at the clinic level and the interventions were very distinct, as the ILI included a health coach, PROPEL patients knew their group assignment, as did clinic and study staff. However, the patients did not know any details of the other group assignment, and every effort was made to blind the study staff responsible for patient assessments (eg, assessment technicians) to patients' intervention status; all health coaches were blinded to the patients' official study measurements.

According to Federal Office of Rural Health Policy classification,²³ 14 of the participating clinics were in urban areas, while 4 were in rural areas. The size of the clinics (patients served) during study recruitment ranged from 1100 to 35 000.

Participants

Following the clinics' randomization, patients were recruited within the 18 primary care clinics using a variety of approaches, including (1) interactions with their PCPs, (2) searches of electronic medical records (EMRs), (3) responses to emails sent through their clinic's patient portal, (4) responses to flyers in clinic waiting areas, and (5) interactions with PROPEL staff in the clinic. Given that clinics were randomized rather than patients, all patients were recruited with specific information about the group to which their clinic was assigned; that is, patients were informed a priori about their group assignment rather than being randomized after recruitment.

A trained recruiter followed up with each patient to assess their interest in participating in the study. During this prescreening, eligibility was assessed based on self-reported responses to questions related to the inclusion/exclusion criteria provided in Table 1. An in-person screening visit was scheduled if the patient was eligible based on the prescreening criteria.

Study staff read and reviewed the consent documents with all patients, and written informed consent was obtained before participation in the screening visit, which was conducted by study staff at the patient's primary care clinic. At this screening visit, a patient's height and weight were measured, and patients answered several questionnaires to determine their eligibility. The body mass index (BMI) measured at the screening visit was used to determine eligibility, which may have differed from the baseline BMI used for analysis; however, the mean BMI at the screening visit (37.4) did not differ significantly from the mean baseline BMI (37.2; $P = .575$).

Following the screening visit, eligible patients' PCPs reviewed their medical records alongside the PROPEL inclusion and exclusion criteria and provided medical clearance if there were no contraindications to participation. Eligible patients with medical clearance were enrolled in the trial once they completed their baseline visit, which was conducted by study staff in the primary care clinic. Patients received the intervention (ILI or UC) to which their clinic was assigned as outlined in the recruitment materials and consent forms, and patients were only told details about the intervention to which they were assigned. Intervention group assignment was not blinded because researchers and study staff needed to logistically prepare for implementation in ILI clinics differently than in UC clinics. In addition, there were various measures taken to ensure intervention fidelity, defined as the extent to which the ILI was delivered according to the protocol, including monitoring health coaches in session, which further unblinded investigators. The assessors were unblinded to group assignment simply due to the health coach's presence in certain clinics but not in others. However, patients did not know details of the other intervention assignment (separate consent forms were used for the UC and ILI groups), assessment technicians were blinded to the details of patients' intervention participation during data collection, and both investigators and health coaches were blinded to the assessment data until all data collection was complete. The Pennington Biomedical Research Center IRB reviewed and approved the study protocol and all research materials.

Table 1. Inclusion and Exclusion Criteria for the PROPEL Trial

Inclusion criteria	• Age 20.0-75.0 y • BMI 30.0-50.0 • Able to provide written informed consent^a • Willing to change diet, physical activity, and weight^b • Patient of a participating clinic • Able to participate in scheduled sessions
Exclusion criteria	• Currently participating in a weight loss program • Current use of weight loss medication or recent weight loss (>10 lb in last 6 mo) • Plans to move from the area within 2 y • Given birth within the past year, is currently pregnant, or plans to become pregnant within 2 y • Past bariatric surgery or plans for bariatric surgery within 2 y • Current major depression • History of suicidal behavior or diagnosed eating disorder (bulimia, anorexia nervosa) • Hospitalization for mental disorder or substance abuse in the previous year • Active cancer (except prostate, skin, and thyroid if approved by physician) • Serious arrhythmias or cardiomyopathy • Severe congestive heart failure • Stroke or heart attack in previous 6 mo • Chronic inflammatory conditions, including but not limited to severe arthritis, lupus, or inflammatory bowel disease (ie, Crohn's disease or ulcerative colitis) • Disease that is life threatening or that can interfere with or be aggravated by exercise or weight loss • Discretion of PCP or PI^c

Abbreviations: BMI, body mass index; PCP, primary care provider; PI, principal investigator; PROPEL, PROMoting Successful Weight Loss in Primary Care in Louisiana.

^aPartly operationalized as inability to read the 2 test words (*flu* and *pill*) on the Rapid Estimate of Adult Literacy in Medicine–Short Form (REALM-SF) health literacy assessment (n = 6).

^bDetermined by self-report to the question: “Are you willing to change your diet and physical activity?”

^cAn example of exclusion by the PI (n = 1) was verbal abuse of study staff by the patient. Examples of discretion of the PCP (n = 9) included denying patients' medical clearance for reasons including degenerative activity-limiting arthritis, recent major depression diagnosis, or uncontrolled diabetes and hypertension.

Interventions and Comparators

ILI Group

Trained health coaches, who were employed by Pennington Biomedical Research Center and embedded in the primary care clinics, delivered a comprehensive, high-intensity intervention program (ILI) as recommended by the 2013 AHA/ACC/TOS obesity guidelines.¹⁹ This intervention program was designed based on the Diabetes Prevention Program (DPP),²⁴ Look AHEAD (Action for Health in Diabetes),²⁵ and Comprehensive Assessment of the Long-term Effects of Reducing Energy Intake (CALERIE)²⁶ studies. However, given the prevalence of low health literacy in Louisiana,⁹ all intervention materials and approaches were adapted to be health literacy appropriate through extensive consultation with PABs and health literacy experts (T.C.D. and C.L.A.). Health coaches were trained in principles of health literacy and motivational interviewing techniques to enhance patient communication and encourage patient activation.^{27,28} Health coaches had earned at least a bachelor's degree in nutrition, physical activity, or behavioral medicine. Of the 8 health coaches, 6 had master's degrees in nutrition, dietetics, exercise physiology, or counseling, and 5 were registered dietitian nutritionists. Fifty percent of the health coaches (n = 4) were African American and 50% were White, and all health coaches resided in the Louisiana community in which they coached.

Enrolled patients in ILI clinics attended weekly sessions in the first 6 months; 16 of these were completed in person in individual or small-group sessions and 6 via phone sessions (1 phone session per month). Sessions then occurred at least monthly and alternated between in-person (individual or small groups of 2-3 patients) and phone sessions for the remaining 18 months, though increased contact with the health coach via in-person or phone sessions was an option that was used if patients were struggling to meet their goals. In addition to the session attendance frequency defined by the protocol (weekly for 6 months, monthly for 18 months), patients met with their coach as often as they wished, assuming that the coach's schedule could accommodate it and there were no contraindications identified by the intervention team. There were 43 intervention session topics, which included the use of portion-controlled foods and meal replacements, increasing physical activity, calorie balancing, self-monitoring, and

dealing with stress, among other topics. The session topics were delivered in order as shown in Appendix A, Supplementary Table S1; however, coaches were encouraged to review additional session materials on topics with which the patient needed more support (ie, upcoming family functions with food often necessitated the “Stay on track at family events” session material; healthy snacking, fast food, and dealing with stress were other sessions often reviewed multiple times with patients). Coaches tracked additional contacts that were in excess of the 43 scheduled intervention sessions. Additional contacts occurred via various methods, such as additional in-person meetings, simple text messages reminding the patient to weigh themselves, a phone conversation to help the patient choose a healthy lunch option, etc.

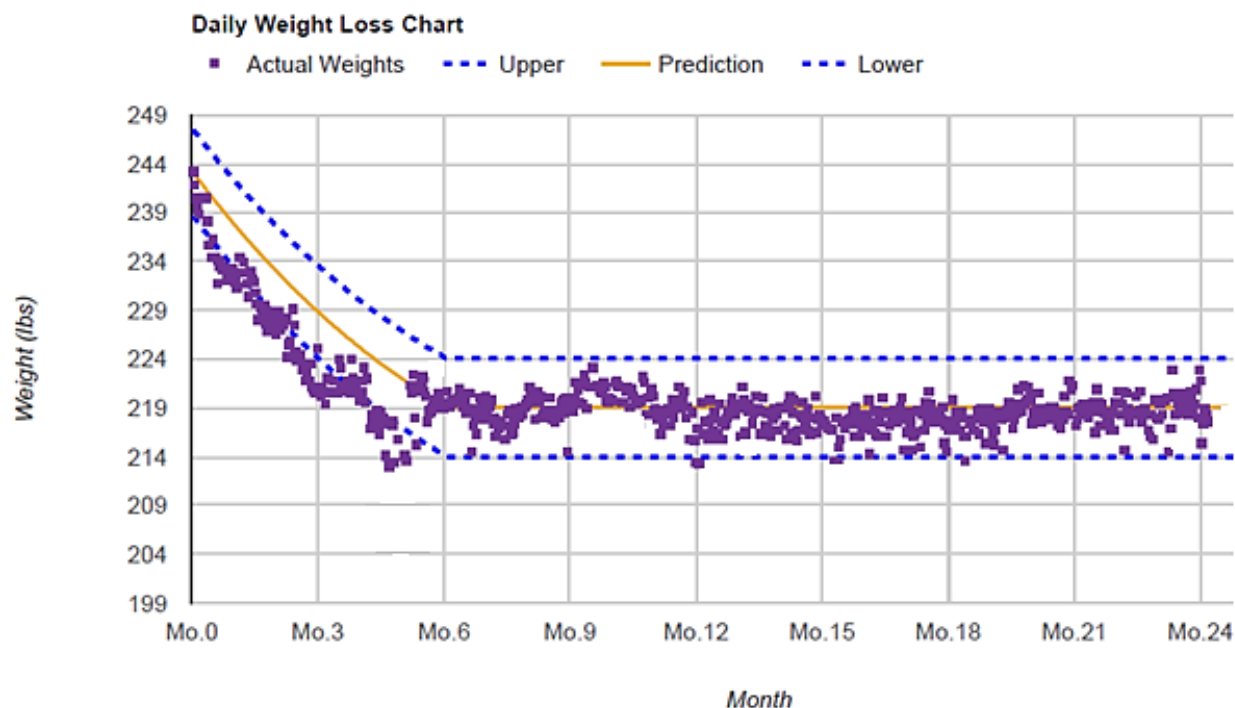
Given that greater initial weight loss is associated with long-term weight loss and weight loss maintenance,^{29,30} a strong focus of the intervention was on maximizing initial (3-month) weight loss. The meal plan for weeks 1 to 4 included portion-controlled foods, including easily available and affordable items. Prepackaged portion-controlled foods and meal-replacement shakes were provided to all ILI participants free of charge as a component of the ILI during weeks 1 to 4 and were available as part of our “toolbox” approach after week 5. Meal plans became less structured over time as participants learned to manage portion size and energy intake. Prepackaged foods were distributed as a toolbox option if it was clear that the participant might benefit and if attempts to secure similar foods failed. These foods were provided on a time-limited scale, usually 1 to 2 weeks, while solutions to the participant’s food access problem were identified. Participants were also provided measuring cups and portion-appropriate plates to help attain their dietary goals. Meal plans were consistent with dietary guidelines (eg, ~55% carbohydrate, ~15% protein, and ~30% fat),³¹ included nutrient-dense foods (eg, whole grains, fruits, lean protein), and were formatted for easy dissemination through clinics. Given Louisiana’s unique culinary environment, the ILI curriculum and coaching sessions also included ways in which to incorporate common Southern food staples (eg, red beans and rice, gumbo) in a healthier way.

An important component of the ILI was shared short-term goal setting between the health coach and participant to reach the broader study goals. A personal goal of 10% weight

loss was set for participants, and they were coached to set their own goals and develop eating and physical activity action plans to meet that goal. Given the importance of physical activity for successful weight loss and weight loss maintenance, the second target for this trial was for patients to achieve at least 175 minutes per week of moderate-to-vigorous physical activity. A major focus of the physical activity intervention was on increasing lifestyle activities, such as taking the stairs instead of the elevator, parking further away, actively commuting (walking or riding a bicycle), and replacing sedentary activities with more-active options. A pedometer (New Lifestyles model SW200) was provided to all ILI participants along with directions on how to increase their daily step counts.

A novel aspect of the PROPEL intervention was the addition of a computer tracking system (CTS), which facilitated tailoring the intervention to the individual participant and promoting intervention fidelity among clinics, health coaches, and participants.²⁶ A weight loss calculator was used to (1) calculate personalized daily energy intake targets for each participant that, if met, would result in 10% weight loss over 6 months; and (2) create a weight graph that would display each participant's predicted weight loss over time. This weight graph included a zone that reflected being adherent to the diet; plotting the participant's weight over time in relation to the zone determined if they met their energy intake target and lost weight at the rate expected (see Figure 1).³²⁻³⁵ The zone included a 10% weight loss target represented by a line in the middle of the zone, with lower and upper bounds that represent ~7.5% and ~12.5% weight loss, respectively. The upper and lower bounds of the graph accommodated biological variation and error in the prediction model. Participants were encouraged to weigh themselves daily with a study-provided electronic scale (BodyTrace). The scale uploaded data to the CTS in real time. In turn, the data were plotted onto the personal weight graph, which was available in real time to both the coach and the participant via any internet-connected device and thus provided a platform to intervene quickly (eg, between sessions) should the participant need additional support. Health coaches used the weight graphs to identify participants struggling to meet their weight loss goals (those whose weights plotted above the target zone), which triggered the health coach to deploy strategies from the toolbox.

Figure 1. Example of a Personal Weight Loss Graph for a Single ILI Participant Followed for 24 Months



Abbreviation: ILI, intensive lifestyle intervention.

In addition to the health coaching sessions, CTS, and the provision of portion-controlled foods, the ILI also included a toolbox of additional strategies. The toolbox approach was successfully deployed in previous clinical trials and led to improvements in intervention efficacy.²⁴⁻²⁶ Additionally, the toolbox enabled health coaches to tailor treatment to address patient preferences and lifestyles, as well as regional and cultural differences among patients. Supplementary Table S2 in Appendix A provides all toolbox options as well as their respective frequencies of use. This approach was highly individualized, and the health coach worked with the participant to develop acceptable strategies, including how long they would be deployed and how to evaluate their effectiveness.

As previously noted, intervention fidelity was facilitated by hiring coaches residing in the communities where the clinics are located, providing health coaches with extensive initial training and yearly updated training sessions, and using the CTS and toolbox to help standardize treatment delivery. In addition to formal monitoring sessions, the health coaches regularly

audio-recorded sessions that were reviewed by the intervention team to ensure that they were delivering the intervention similarly across clinics and using the CTS and toolbox as intended. Finally, a weekly case conferencing meeting was held via webinar for coaches to discuss participants with the research team and to share feedback on intervention strategies. All health coaches were required to attend these meetings. See Appendix B for more details on the trial's intervention fidelity measures.

In addition to the patient-centered ILI program itself, PCPs of patients in the ILI group received an obesity science education program. This education included information on the management of obesity, the co-management of morbidities such as type 2 diabetes and hypertension, minimizing bias and stigma related to obesity, and principles of health literacy. The PCP education program was delivered in a series of webinars and face-to-face seminars conducted in the clinics by experts in obesity, patient engagement, and health literacy. PCPs in the ILI clinics also received access to the webinar series via a password-protected website.

UC Group

Enrolled patients in UC clinics received their UC from their primary care team throughout the 24-month period. Although patients in the UC group were not required to see their PCP for weight management counseling, they were provided a series of health-related newsletters, and their PCPs were provided with a webinar related to weight management in primary care. To maintain contact and aid in the retention of patients in the UC group, we sent them 3 newsletters per year on selected topics, along with a listing of health promotion events offered in their community. Newsletter topics included the importance of reducing sedentary behavior, sleep hygiene, brain and memory health, smoking cessation, etc. The care received by patients in the UC group was measured with a patient-provider relationship survey; this survey was completed by patients in both groups at the baseline and 24-month assessment visits.

The PCPs in UC clinics received a baseline presentation that described weight management in primary care settings and the current CMS approach to reimbursement for obesity treatment.¹⁵ Additionally, an informational brochure on the current CMS approach to

reimbursement for obesity treatment was sent to the PCPs at least once per year throughout the trial. PCPs in UC clinics also had access to the baseline webinar presentation and the informational brochure throughout the study via a password-protected website.

Study Outcomes

Study outcome data were collected from patients or their PCPs by trained assessment technicians within the primary care clinics.

Primary Outcome Measure

The primary outcome measure of the PROPEL trial was the percentage change in body weight from baseline to month 24. Body weight was measured in duplicate with the patient in light clothing without shoes to the nearest 0.1 kg using a digital scale (Seca Model 876) at each assessment visit. The patient was instructed to stand still in the middle of the scale with head erect and eyes looking straight ahead.

Secondary Outcome Measures

Secondary outcome measures included absolute 24-month changes in body weight, waist circumference, blood pressure, fasting glucose and lipids, and QOL measures. Assessments were conducted by trained technicians with no involvement in intervention delivery. Table 2 provides an overview of the data measurement and collection schedule for PROPEL, as described below.

Anthropometric measurements. Standing height was measured with a portable stadiometer (Seca Model 213) at the baseline visit. Patients were asked to remove their shoes and have their heels, buttocks, and upper part of the back remain in contact with the stadiometer. The patient was asked to inhale and hold their breath, while 1 technician applied traction to the patient's head to maintain alignment with the Frankfort Plane. The slide was lowered until it reached the vertex of the skull. Waist circumference was measured at all assessment visits using a nonelastic anthropometric tape (Graham-Field model 1340-2). The

measurement was made by 1 technician, while a second maintained a parallel position of the tape midway between the lower rib margin and the iliac crest, at the end of gentle expiration.

Table 2. Data Measurement and Collection Schedule for Patient Data

Measurement	Screening visit	Baseline visit	6 mo	12 mo	18 mo	24 mo
Anthropometry						
Weight	X	X	X	X	X	X
Height	X	X				
Waist circumference		X	X	X	X	X
Risk factors						
Blood pressure and pulse		X	X	X	X	X
Fasting finger-stick sample		X		X		X
Patient-reported outcomes						
Demographics and health history	X					
Change in health history			X	X	X	X
REALM-SF	X					
Food security		X		X		X
Eating inventory		X	X	X		X
PROMIS-29		X	X	X		X
IWQOL-Lite		X	X	X		X
IPAQ-SF		X	X	X		X
Dietary intake questionnaire		X	X	X		X
Concomitant medications		X	X	X	X	X
Adverse event form			X	X	X	X
Patient-provider survey		X				X
Intervention satisfaction survey ^a			X			X
PCP-reported outcomes						
Provider demographics and knowledge		X				X

Abbreviations: IPAQ-SF, International Physical Activity Questionnaire–Short Form; IWQOL, Impact of Weight on Quality of Life; PCP, primary care provider; PROMIS, Patient-Reported Outcomes Measurement Information System; REALM-SF, Rapid Estimate of Adult Literacy in Medicine–Short Form.

^aCompleted by patients in the intensive lifestyle intervention (ILI) group only.

Blood pressure and pulse measurements. Resting systolic and diastolic blood pressures were measured using a validated automated Omron device (HEM-907XL digital blood pressure monitor) at baseline and all follow-up visits. After the patient sat quietly alone for at least 5 minutes, 2 sitting measurements were made 1 minute apart.

Fasting glucose and lipids. Finger-stick blood samples were obtained to measure fasting levels of lipids (total cholesterol, high-density lipoprotein [HDL] cholesterol, low-density lipoprotein [LDL] cholesterol, triglycerides) and glucose using a validated Alere Cholestech LDX Analyzer at the baseline, 12-month, and 24-month visits. The patients were asked to fast for at least 10 hours before their visit. The Cholestech Analyzer was checked for accuracy using standard controls each day before it was used to analyze patient blood samples.

Concomitant medications. Patients were asked to bring their medications or a list from their pharmacist/PCP to the screening visit and all subsequent assessment visits. A concomitant medications form was completed at each visit to track changes in the patient's medications and dosages throughout the trial.

Adverse events. An adverse event (AE) surveillance form was used to screen for AEs and serious AEs (SAEs) at each assessment visit. All SAEs were recorded, and those that were unexpected and related or possibly related to the study were reported to the IRB in accordance with their requirements.

Health literacy. The Rapid Estimate of Adult Literacy in Medicine–Short Form (REALM-SF) is a 7-item health literacy assessment that was administered at the screening visit.³⁶ The patient was asked to read health-related words aloud. Two words (*flu* and *pill*) were not scored but were used to identify patients who were ineligible due to their inability to read and comprehend the informed consent documents. The score ranges from 0 to 7. Those scoring below 7 were considered to have low health literacy (reading below a ninth grade level), and those scoring below 4 were considered to have very low health literacy (reading below a third grade level).¹⁹ Patients scoring 0 to 3 on the REALM-SF were provided assistance in completing

the other questionnaires using a semistructured interview. Patients scoring 4 to 7 on the REALM-SF completed the other questionnaires on their own, but assistance was provided as requested.

Demographics and health history. A self-report demographic and health history questionnaire was administered at the screening visit, which collected information about age, sex, race/ethnicity, use of cigarettes and alcohol, health insurance status, postmenopausal status, income and employment, education level, and history of chronic diseases. Changes in health status were captured by self-report at the 6-, 12-, 18-, and 24-month assessment visits.

Food security. Household food security was measured at baseline and at the 12- and 24-month assessment visits using a 6-item subscale of the 12-month Food Security Scale Questionnaire.³⁷ Scores range from 0 to 6, and a score of 2 or higher indicates food insecurity.

Provider demographics and knowledge (PCP survey). Each patient's PCP was asked to complete a survey before the trial began and at the trial's end. The provider survey was adapted from the Hopkins Practice-based Opportunities for Weight Reduction (POWER) trial.³⁸ The questionnaire assessed the PCP's demographic information and knowledge about weight management practices.

Physical activity. Physical activity levels were self-reported at baseline and at the 6-, 12-, and 24-month assessment visits using the International Physical Activity Questionnaire–Short Form (IPAQ-SF),³⁹ which asks questions related to physical activity performed over the previous 7 days. The IPAQ-SF has acceptable reliability³⁹ and is sensitive to change within the context of a weight loss intervention.⁴⁰

Dietary intake. A dietary fat, fruit, vegetable and alcohol intake questionnaire was administered at baseline and at the 6-, 12-, and 24-month assessment visits. The questionnaire contained scales derived from several sources: the National Cancer Institute (NCI) fat screener,⁴¹ the NCI and National 5 a Day Program fruit and vegetable screener,^{42,43} and the Brief Questionnaire to Assess Habitual Beverage Intake (BEVQ-15).⁴⁴ The questionnaire asked

patients to report the frequency of consuming specific foods and beverages over the past 12 months. Two scores were created in addition to the percentage energy from fat: number of times per day a fruit or vegetable (fruit, fruit juices, vegetables, salad, and potatoes) was consumed and number of times per day any type of alcohol was consumed.

Eating attitudes and behaviors. The Three-Factor Eating Inventory measures dimensions of eating attitudes and behaviors. Three factor-analyzed subscales (cognitive restraint, disinhibition, and hunger) are derived from the questionnaire.⁴⁵ For the purpose of the PROPEL trial, only the cognitive restraint and disinhibition subscales were administered to patients. This questionnaire was administered at baseline and at the 6-, 12-, and 24-month assessment visits.

Patient-provider relationships. A patient-provider relationship survey was completed by each patient at the baseline visit and at the 24-month assessment visit. This 11-item instrument was adapted from the POWER trial.³⁸ POWER investigators compiled the patient-provider survey from several sources, including the validated Consumer Assessment of Healthcare Providers and Systems (CAHPS) 2.0 Adult Core Survey.⁴⁶ A CAHPS global rating of the provider (rating from 0-10) was also included. Finally, a question was included to address patient centeredness or the perception of “being known as a person.”⁴⁷ The framing of all questions in the survey was adapted by asking patients about their care over the past 2 years given that both the POWER and PROPEL trials were 2 years in duration. A summary patient-provider relationship score (8-32) was computed by adding the total responses from the 8 questions (after reversing the 2 opposite scales).

Intervention satisfaction. A self-report questionnaire that asked about personal experience and satisfaction with the intervention was administered to patients enrolled in the ILL group at the 6- and 24-month assessment visits. This questionnaire was developed by the Rural Engagement in Primary Care for Optimizing Weight Reduction (RE-POWER) study⁴⁸ and included questions obtained from the Veterans Affairs Diabetes Prevention Program (VA DPP), Rural Lifestyle Eating and Activity Program (Rural LEAP), and POWER trials. It asked questions

about the convenience of the clinic's location and appointment times, feelings about the health coach, and the perceived effectiveness and organization of the intervention curriculum and delivery.

Generic HRQOL. Generic HRQOL was measured using the 29-item Patient-Reported Outcomes Measurement Information System (PROMIS-29) instrument.^{49,50} The questionnaire includes health-related domains of physical function/functional capacity, anxiety, depression, fatigue, sleep disturbance, ability to participate in social roles and activities, pain interference, and pain intensity. PROMIS surveys were designed and tested to be easy to understand and navigate. The PROMIS-29 was administered at the baseline visit and at the 6-, 12-, and 24-month visits.

Weight-related QOL. The Impact of Weight on Quality of Life–Lite (IWQOL-Lite) is a 31-item questionnaire designed to measure obesity-specific aspects of QOL, which produces a total score and separate scores for physical function/functional capacity, self-esteem, sexual life, public distress, and work or daily activities.^{51,52} The IWQOL-Lite was administered at baseline and at the 6-, 12-, and 24-month assessment visits.

Assessment Data Monitoring and Quality Assurance

The PROPEL trial implemented a data monitoring plan to ensure that data in the electronic data capture system accurately reflected the patients' responses, which confers greater confidence to the conclusions of the trial's effectiveness. Assessment technicians were trained on the study protocol and assessment procedures in an initial training session upon hire and annually at refresher training sessions. The assessment technicians' adherence to the study protocol and source document verification, verifying that the paper data collection form completed by the patient matched what data were entered, was monitored by study management during visits to each clinic 1 to 2 times per year. Additionally, study staff performed source document verification on 100% of the assessment data. Data entry errors and inconsistencies were corrected upon detection. Finally, the data manager and trial biostatistician conducted thorough data cleaning to identify any remaining inconsistencies once

all data were collected. See Appendix C for more information on the PROPEL Data Management Plan.

Sample Size Calculations and Power

As 3% to 5% weight loss is likely to result in clinically meaningful health outcomes for adults who are overweight or have obesity,¹⁹ the sample size calculations for the primary outcome were powered to detect differences in mean percentage of baseline weight loss in the ILI group of 3.5% at 24 months, relative to UC. Power calculations used a nominal $\alpha = .05$ significance level with a 2-tailed test, with minimal power of 80% for the planned subgroup analyses (men vs women; White vs African American; older vs younger adults). Based on the Louisiana Obese Subjects Study (LOSS) study,⁵³ the SD for percentage weight change for patients nested within clinics was 8.4%. For the subgroup analyses, a net sample size of 184 patients (92/group) was sufficient for detecting a 3.5% weight loss with 80% power when randomization was performed at the patient level. After accounting for the design effect (estimated to be 1.8 from the LOSS study⁵³), at least 134 patients per group were required to realize 80% power in a trial randomized at the clinic level. Allowing for 30% attrition, at least 192 patients per group were needed, with a total (2 groups) enrollment of at least 384 patients per subgroup analysis; this translated into a total sample size of at least 768 patients, providing at least 97% power to detect a mean weight loss in the ILI group of 3.5% at 24 months, relative to UC in the total sample.

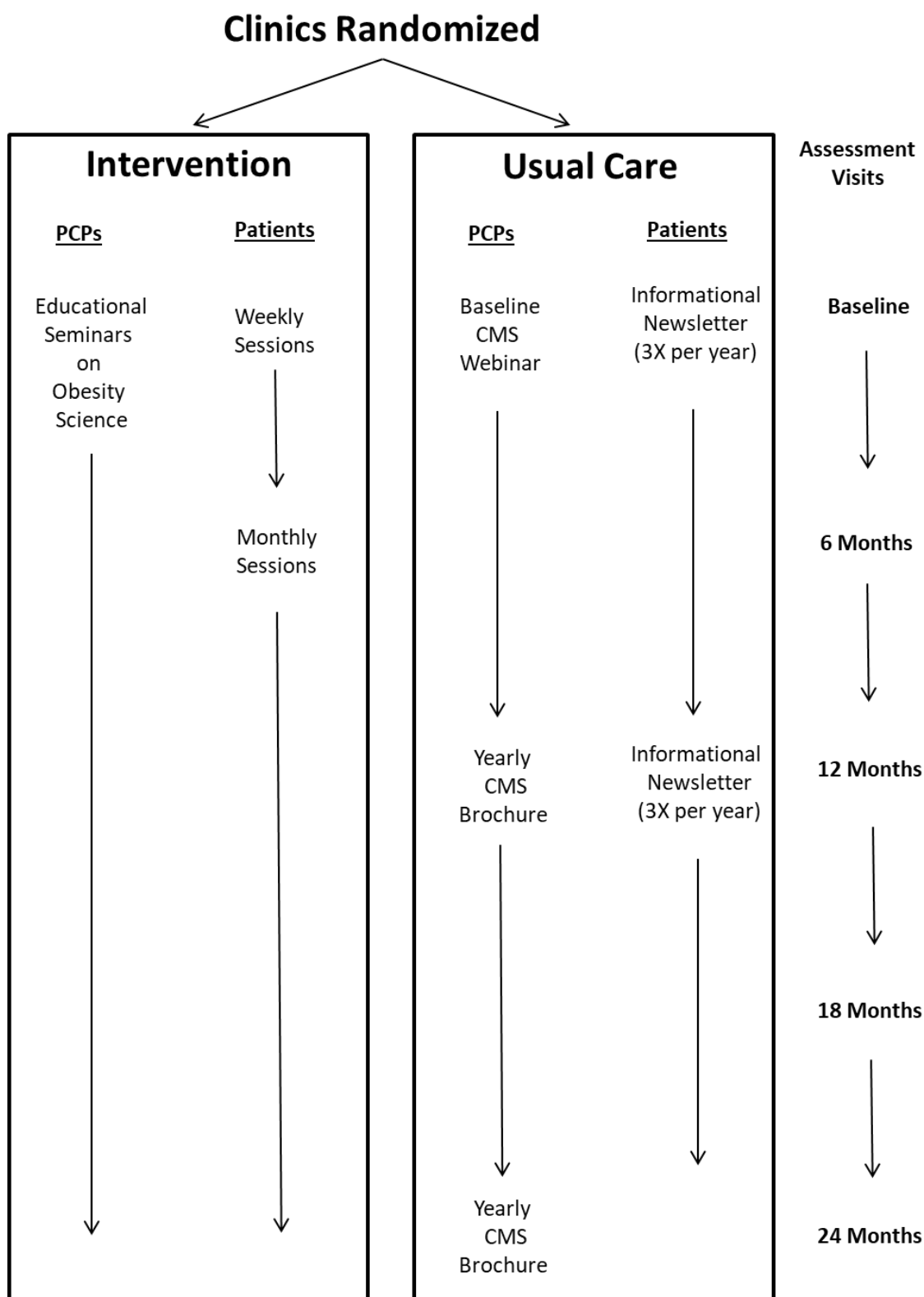
Time Frame for the Study

The study was organized into 3 periods: (1) study planning, (2) data collection, and (3) analysis. During the study planning period, which occurred from January 2015 to April 2016, the intervention and assessment materials were adapted, focus groups were conducted, IRB approvals were obtained, and study staff were hired. Data were collected from April 2016 through September 2019, during which time patients and PCPs received the intervention or educational program to which their clinic was assigned (Figure 2). Data analysis began in September 2019 when the final patient completed their 24-month assessment visit and

continued through the end of the grant period in December 2020. Additionally, data analysis of secondary manuscripts will continue beyond 2020.

The 18 participating clinics began recruitment in 2 phases. Phase 1 recruitment (10 clinics) began in April 2016, and phase 2 recruitment (8 clinics) began in October 2016. Patients were recruited between April 2016 and September 2017 and participated in either the UC or ILI group for 24 months. The intervention length was chosen to examine both an active weight loss period hypothesized to occur mostly in the first 6 months and a weight maintenance period during the final 18 months. Assessment time points were selected to capture initial weight loss (eg, at 6 months) and whether effects were sustained over time (eg, at 12, 18, and 24 months). The final patient completed their 24-month assessment visit in September 2019, at which time data analysis and manuscript preparation began.

Figure 2. Overview of the PROPEL Data Collection Period



Abbreviations: CMS, Centers for Medicare & Medicaid Services; PCP, primary care provider; PROPEL, PROMoting Successful Weight Loss in Primary CarE in Louisiana.

Data Collection and Sources

Patients completed the screening, baseline, and all follow-up assessment visits within their primary care clinic with assistance as needed from research study staff embedded in the clinic. The same level of assistance completing assessment visit materials was provided to both ILI and UC patients. All participants were given a \$75 stipend electronically loaded onto ClinCards (Greenphire) at the completion of the baseline visit and each follow-up visit as compensation for their time and travel. Patient follow-up data were collected, regardless of whether or not patients attended intervention sessions. We defined the ideal follow-up visit window as ± 2 weeks from the exact projected follow-up visit date (ie, exactly 6 months after the baseline visit date ± 2 weeks); however, patients could be seen up to 3 months past the exact projected follow-up visit date (ie, exactly 9 months after the baseline visit date for a 6-month visit).

Rigorous methods were used to maximize patient retention at each assessment visit. Retention procedures focused on increasing the number of contacts between study staff and patients and tailoring strategies to each individual, as these approaches are commonly used in studies with high retention rates.⁵⁴ Briefly, the next follow-up visit was scheduled at the end of the current visit, and patients were given an appointment reminder card listing the visit's date and time. Patients were contacted approximately 1 month before their follow-up visit to confirm or change the appointment. If the confirmation attempt was unsuccessful, staff contacted patients multiple times using various provided contact methods (eg, phone calls, emails, text messages) beginning with a patient's preferred method(s) and at different times of day/days of the week, depending on the patient's schedule. A similar process was used to schedule follow-up visits with patients who had not yet scheduled their next visit. Patients were reminded of their appointment approximately 1 to 4 days before their visit. Immediately upon a patient not arriving for their scheduled follow-up visit, staff contacted them multiple times using the process previously described. For patients who were difficult to reach or for whom we had outdated contact information, several strategies were used: (1) clinic personnel were asked for updated contact information or assistance locating the patient; (2) the patient's alternate

contact was used; and (3) a series of letters from the study's coordinating center were mailed to the patient's current home address.

To further increase contact, patients were mailed birthday and holiday cards each year as well as personalized "thinking of you" cards if the patient reported difficult life circumstances. The previously mentioned newsletters also served to maintain contact and aid in the retention of patients in the UC group, who interacted less with study staff than did those in the ILI group.²⁰ Finally, annual training sessions stressed the importance of retention, and staff members shared ways in which they were able to retain and reengage patients who were not regularly attending visits.²⁰

Patients who withdrew from the study were asked to provide the reason they did so, and common reasons included no longer being interested, time commitment, dissatisfied with group assignment, moved/relocated, change in health status, pregnancy, and personal issues. Additionally, several patients did not provide a reason for their wish to withdraw. Clinic personnel assisted with ascertaining reasons for patients who became lost to follow-up.

Analytical and Statistical Approaches

Primary Aim

To test the effectiveness of a pragmatic, high-intensity lifestyle-based obesity treatment program (ILI) delivered within primary care clinics.

The primary aim consisted of 2 hypotheses that we analyzed using the same approach. The first hypothesis was that the ILI group would have greater percentage reductions in body weight (primary outcome) than would the UC group. The second hypothesis was that the ILI group would have significant improvements in the secondary outcomes (QOL, functional capacity, satisfaction with medical care, and obesity comorbidities) compared with the UC group. To address the primary aim for hypothesis 1, we analyzed weight loss as the mean percentage of baseline weight change at months 6, 12, 18, and 24 in the context of linear mixed-effects multilevel models, which included random cluster (clinic) effects.

In addition to study group (ILI or UC), clinic, assessment time point, and a study group-by-time interaction term, the primary analytic model included patient-level (age, sex, race) variables as explanatory covariates. Clinic-level (clinic size, % African American, % Medicaid/Medicare) variables were explored as potential covariates but were not included in the main model, as they were not statistically significant. Preliminary analytical findings were used to choose the most plausible and efficient repeated-measures covariance structure (eg, compound symmetric, autoregressive, unstructured), at which point the unstructured covariance structure was selected. Although substantial effort was employed to minimize missing data, it was inevitable that some missing data occurred (additional details below). An intention-to-treat analysis that included all randomized patients, regardless of the number of assessments obtained, was conducted. The primary analysis used the mixed-effects model mentioned above and employed restricted maximum likelihood using all available data.

To address the primary aim's second hypothesis, the same analytic methodology was applied to each outcome variable (ie, changes in body weight in kilograms, waist circumference, systolic blood pressure, diastolic blood pressure, total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides, blood glucose, IWQOL total and scale scores, PROMIS-29 scale scores, and patient satisfaction with PCP). Estimates are presented as adjusted least-squares mean changes in each outcome variable within the intervention groups and the difference in adjusted least-squares means between the UC and ILI groups, with estimate precision represented by the 95% CI.

In addition to the main model to address the primary aim, we conducted several sensitivity analyses to examine (1) clinic-level covariates (clinic size, % African American, % enrolled in Medicaid), (2) unadjusted models and models adjusted for patient- and clinic-level covariates, and (3) the effect of combining 2 UC clinics with low enrollment with a UC clinic in close geographic proximity. The sensitivity analyses were conducted using the same analytic strategy used for all primary aim analyses.

Additional Analyses to Test the Secondary Aims

Secondary aim 1. Evaluate relationships between adherence to intervention components (physical activity, diet, sessions, etc) and corresponding changes in body weight and secondary outcomes.

The first secondary aim was accomplished by conducting correlation analyses of changes in body weight percentage and patient-reported outcomes with the percentage of intervention material received, changes in daily minutes of physical activity, and changes in fat intake from baseline to 24 months. The results are presented as correlation coefficients and their associated *P* values (see Table 9). Additionally, changes in daily minutes of physical activity and percentage dietary fat intake at 6, 12, and 24 months were analyzed in the context of linear mixed-effects (fixed and random) multilevel models using the same analytic approach described for the primary aim. The results are presented as adjusted least-squares mean changes in physical activity and fat intake within the intervention groups and the difference in adjusted least-square means between the UC and ILI groups with estimate precision represented by the 95% CI (see Appendix A, Supplementary Table S5). Subanalyses in different adherent groups, such as among patients who received at least 80% of intervention materials, were also conducted to inform this secondary aim (see Appendix A, Supplementary Table S6). The effect of the number of intervention session materials received on percentage weight loss at 24 months was assessed by analyzing subgroups of ILI participants who received <80% of materials and $\geq 80\%$ of intervention materials. This analysis was conducted using linear mixed-effects multilevel models using a similar analytic approach as the primary aim; however, these analyses were conducted within the ILI group only. The results are shown as 24-month least-squares mean changes in percentage body weight, body weight in kilograms, and waist circumference between ILI participants who received <80% of materials and $\geq 80\%$ of intervention materials and the associated 95% CI. Finally, categorical weight loss was analyzed by comparing the percentage of patients achieving $\geq 5\%$ and $\geq 10\%$ weight loss at each assessment time using generalized linear mixed models. The results are shown graphically along with the 95% CI (see Figure 4).

Secondary aim 2. Examine the effects of the intervention on system-level practices and patient satisfaction with care.

The second secondary aim was accomplished using a similar strategy as the primary aim, with patient satisfaction with care as the outcome variable of interest in linear mixed-effects multilevel models. The results are presented as the adjusted least-squares mean changes in patient satisfaction with their PCP at 24 months within the UC and ILI groups, as well as adjusted least-squares mean differences between the UC and ILI groups in patient satisfaction with their PCP (see Table 10). Estimate precision is represented by the 95% CI. Due to low survey completion rates among PCPs (see the Results section for details), analyses of system-level practices (ie, PCP weight management practices) were not conducted.

Secondary aim 3. Test the HTE across clinics and across subgroups of patients (men vs women, White vs African American, older vs younger adults).

Analyses of HTE were an important aspect of this study, as the identification of systematic differences in response to the intervention is important for broad dissemination of our weight loss model and for further tailoring the intervention to specific subgroups. We conducted 3 confirmatory HTE analyses within 3 subgroups: (1) African American and other races; (2) men and women; and (3) younger (21-42 years), middle-aged (43-56 years), and older (57-74 years) adults. Age categories were determined by separating the sample into 3 equal groups based on age. The intervention effect on weight loss in each of the subgroups was investigated using a subgroup variable in linear mixed-effects multilevel models analogous to the primary aim analysis with a focus on intervention-by-subgroup interactions. Changes in percentage weight loss at 6, 12, 18, and 24 months within each subgroup are presented graphically as adjusted least-squares means (see Figure 5). HTE results are also shown as the differences in adjusted least-squares means between the UC and ILI groups for 24-month changes in percentage weight loss, body weight expressed in kilograms, and waist circumference within each subgroup, along with the 95% CI.

Adverse events. Chi-square tests conducted overall and at each time point were used to compare SAEs between groups. All tests were 2 sided, and $P < .05$ was used as the cutoff for statistical significance for the primary outcome. All analyses were conducted using SAS version 9.4 (SAS Institute, Inc).

Handling of missing data. Missing data were expected due to dropouts and missed visits. Weight loss was a subject-level variable, and missing assessments would influence tests relative to treatment-by-time interactions. The analyses described above employed restricted maximum likelihood using all data on each participant (ie, data were not deleted in a case-wise manner if they were missing an observation). The model assumes that missing values are missing at random, and all parameters presented in the tables and figures are model-based estimates. To assess the robustness of the results and how sensitive they were to how missing data were handled, we analyzed weight loss using (1) all patients irrespective of missing data to perform analysis of variance (ANOVA) using mixed-effects multilevel models with repeated measures; (2) only patients who completed all assessment visits and had no missing data, to perform ANOVA employing mixed-effects multilevel models with repeated measures; (3) all patients, irrespective of missing data, to conduct analyses using mixed-effects multilevel time trend models with random coefficients to capture individual time trends (does not require complete data across time); and (4) multiple imputation. The results did not appreciably differ according to how the data were analyzed under these 4 different scenarios; thus, the final analyses included all patients irrespective of missing data.

Changes to the Original Study Protocol

Several changes to the original study protocol were made during the study period due to various challenges. All changes were reviewed and approved by Pennington Biomedical's IRB and by PCORI, with formal contract modifications executed as necessary.

Changes to Inclusion/Exclusion Criteria

In December 2016 (8 months into recruitment), the following changes were made to the inclusion criteria:

- The BMI upper range for the trial was increased from 45.0 to 50.0.
- The “recent weight loss” criterion was changed from “within last year” to “within the last 6 months.”
- The blood pressure exclusion criterion of stage 2 or 3 hypertension (systolic ≥ 160 mm Hg or diastolic ≥ 100 mm Hg) was removed.

These changes were made because we were excluding many potential patients, which impeded the study’s recruitment and made it difficult for PCPs referring patients to the trial. Additionally, patients who were being excluded based on the previous criteria could potentially benefit from the intervention, given that the low-income patient population did not have access to other weight loss options, such as bariatric surgery or pharmacological interventions. These changes removed a significant barrier to recruitment and allowed more patients to participate in the study.

Before recruitment, we also clarified in the protocol that patients who were unable to correctly read 1 or both of the REALM health literacy assessment’s practice words (*flu* and *pill*) would be deemed ineligible for PROPEL due to an inability to provide written informed consent and the intervention’s reliance on written materials. Six patients (3 ILI, 3 UC) were unable to correctly read the REALM’s practice words (*flu* and *pill*) and were excluded from participation.

Change in Sample Size

In April 2017 (1 year into recruitment), the study’s target sample size was reduced from 1080 to 800 patients to meet recruitment targets and reduce the burden on study staff and the patient population. Initially, the trial was powered at 90% power for the subgroup analyses (weight loss by age, sex, and race). We recalculated the sample size estimates based on a traditional level of 80% power for the subgroup analyses, which ensured at least 97% power for the primary analysis if we enrolled 768 patients. This change was approved by the data and safety monitoring board (DSMB) and by PCORI before we made the change in the protocol.

Changes to Assessment Procedures

Before the start of recruitment, several changes were made to the assessment procedures, and these changes are reflected in the revised protocol. Several of these changes were informed by a pilot study conducted during the PROPEL study's development to determine patient acceptability of tablet technology and questionnaires. The pilot study involved 30 patients and was conducted in a primary care clinic that served a population similar to that in the main study. The patients in the pilot study completed several questionnaires on a tablet computer with assistance from study staff as needed.

Based on the feedback obtained in the pilot study, we omitted the Subjective Numeracy Questionnaire, which assessed the ability to perform various mathematical tasks and preference for the use of numeric vs prose information. The questionnaire was removed following our pilot study in which patients responded negatively to the survey. The PROPEL pilot also determined that direct data entry using tablet computers was not suitable for the patient population; thus, this method of data collection was removed from the original protocol. The physical activity assessment tool was changed from the Modifiable Activity Questionnaire to the IPAQ-SF, as investigators determined that this survey was better suited to the anticipated study population.

Logistical Changes

Logistical challenges required changing the data measurement and collection schedule. The original protocol specified that assessment scales and stadiometers would be calibrated monthly by study staff, but the calibration frequency was changed to occur at periodic site monitoring visits. Additionally, remote intervention session monitoring for quality assurance was added in lieu of strictly in-person monitoring. Originally, we planned to collect a finger-stick blood sample for cardiovascular disease risk factor measurement at baseline and all follow-up visits, but due to cost challenges, we limited the finger stick to baseline and the 12- and 24-month visits. These time points were chosen so that the measurements would be evenly spaced in time across the 24-month trial. Several questionnaires were administered at the screening visit rather than the baseline visit to reduce the patient's burden at baseline, and the Food

Security Scale Questionnaire was removed from the 6-month assessment to reduce the patient's burden at that visit. The waist circumference measurement directions were changed from taking the measurement with the patient's arm resting at their sides to their arms slightly forward at a 45° angle. This change allowed assessment technicians to more easily read the measurement. The timing of blood pressure measurements was altered slightly, from the patient sitting for 5 to 10 minutes before the first reading to sitting for at least 5 minutes. Originally, patients in the UC group were presented with information on various topics of interest through a series of social meetings, but attendance at these meetings was poor. Therefore, the social meetings were stopped in favor of informational newsletters delivered to UC patients by email or postal mail.

Patient Protection

Several changes were made to the original protocol to ensure proper patient protection against risks. With approval from PROPEL's DSMB, several categories of AEs viewed as expected and unrelated to the study were excluded from AE reporting (unless they met the definition of an SAE), including constipation, joint/muscle pain, and fall-related injuries (other than those related to a secondary condition such as vertigo). Further, a protocol section was added specific to the handling of patients who became pregnant or developed a serious condition during the course of the trial. Finally, blood pressure and blood glucose alert and emergency values were changed in accordance with recognized standards (which changed midway through the trial), and instructions were added.

Focus Group Methods

Study Overview

Before completing the study protocol or intervention curriculum for the analytical aims of the PROPEL study, we conducted a series of focus groups to inform development of the intervention and patient-reported outcomes. Detailed focus group methods and results were previously published by our group, and the information in this section is derived from the publication.²¹

Participants

Patients as well as physicians or nurse practitioners (here referred to as *health care providers*) aged 20 years or older, willing to provide written informed consent, and able to speak and understand English were eligible to participate in 1 of 5 structured focus groups held across Louisiana. We solicited participants with an interest in discussing weight loss and weight management strategies. Individuals with a cognitive impairment that would interfere with participation in a group discussion were not eligible.

Convenience sampling was employed, and participants were recruited by word of mouth or from flyers posted within primary care clinics. Written informed consent was obtained before the start of each focus group discussion. Each participant received a \$50 gift card. The focus group study protocol, procedures, and consent form were reviewed and approved by the Pennington Biomedical Research Center IRB.

Design and Procedures

The nominal group technique (NGT), a qualitative method of data collection, was used within the focus groups to engage patients and health care providers to obtain their perspective on potential obesity treatment strategies.⁵⁵⁻⁶⁰

The multistep NGT design is useful for systematically stimulating meaningful statements among participants by gathering equally weighted responses to a specific question that tends to offer a valid representation of group views.⁶¹⁻⁶⁴ The NGT method eliminates the need for audio recording and transcription because verbatim responses are written on a flipchart. Before conducting NGT sessions, the investigative team articulated the specific question and pilot-tested it with individuals desiring to lose weight to ensure that it would capture the responses intended.

Primary care patients residing in 4 communities (Franklin, Bossier City, New Orleans, and Shreveport, LA) and health care providers in Baton Rouge, Louisiana, participated in 1 of 5 NGT focus groups. All sessions were conducted during July 2015. Each group consisted of 6 to 8

participants and included both men and women. Each group session lasted approximately 90 minutes.

Demographic information was collected using survey instruments that included age, race/ethnicity, sex, education, employment, annual household income, and marital and health status. In addition, height and weight were self-reported, and health care providers selected the number of years in their primary occupation as a health care provider.

Preliminary probing questions included, “How do you define overweight?” “What are the main reasons that you would want to lose weight?” “What are the best ways to lose weight?” “What are the major things stopping people from losing weight in your community?” and, “If researchers were successful in designing a weight management program, what would that look like?” The facilitator, accompanied by a cofacilitator, then posed the main question to patients: “What has your doctor or other health care professional done to try to help you lose weight?” Similarly, the health care providers were asked, “What are the main things that you have done to help patients lose weight?”

Participants worked independently to write down as many responses to the question as possible in short phrases that represented their individual views. Participants were then asked to share their answers while the cofacilitator wrote each response verbatim on a flipchart without discussion. Each recorded response was then discussed for the sole purpose of clarification and not for evaluation or debate as to its relative importance. Finally, during the voting phase, participants privately selected what they considered to be the top 3 responses likely to have the greatest impact on losing weight and the top 3 responses that would be the easiest to implement for weight management. A ranking of 3 was given to the most impactful/easiest to implement, and a ranking of 1 was given to the least impactful/most challenging. The facilitator recorded the votes on the flipchart and tallied the votes for each response. The primary results were the top 3 strategies identified in each group; the secondary results were all other ideas. Through an iterative process, the facilitators categorized responses into common themes until consensus was obtained.

RESULTS

Focus Group Results

A series of 5 focus groups (4 for patients, 1 for health care providers) was held to inform the intervention's development; the results were previously published.²¹ Selected demographic characteristics of the 34 focus group participants (28 patients, 6 health care providers) are shown in Appendix A, Supplementary Table S3. The average BMI was 46.5 for patients and 26.9 for health care providers.²¹ Eighty-three percent of the health care providers were physicians, and 67% had been in their profession more than 10 years.²¹

When patients were asked how they defined *overweight*, they responded that it meant having low self-esteem, and the main reasons patients said they want to lose weight are because they are concerned about their health, have family history issues, and want to have enough energy to keep up with their grandchildren. Patients stated that the best ways to lose weight are controlling portions, planning meals, keeping healthy choices available, keeping a food and exercise diary, and joining a social support group. In addition, patients perceived that a lifestyle change is needed to lose weight, because many had taken diet pills and know they work only temporarily. The most common weight loss barrier cited was the cost of healthy foods, especially for patients with limited incomes. Patients reported that effective weight loss programs should be structured and based on individual needs, because one size does not fit all.

The most consistent things health care providers reported doing to help patients lose weight were counseling them on appropriate portion size, advising them to consume fewer calorie-dense foods, encouraging them to read labels, and discussing comorbidities of excess weight. Health care providers perceived the major barriers to losing weight to be the influence of family members, seeing discouraging results, lack of access to healthy foods, staying at different homes, and consuming fast food. Health care providers perceived successful weight management programs to be multidisciplinary, structured, and easily adaptable, as one size does not fit all. They reported not having enough time to spend with patients; 15-minute visits are not conducive to combating the obesity problem.

Four NGT focus group sessions were conducted with patients at 4 clinical sites. Patients generated responses to the question, “What has your doctor or other health care professional done to try to help you lose weight?” Four themes were identified in response to this question. Patients reported that their doctors referred them to exercise more often, referred them to a nutritionist, referred them to take medication, and provided advice only. Table 3 lists the themes, with patient responses from each clinical site given under each theme.

Referred to nutritionist, referred to medication, and referred to exercise were chosen as the ideas most likely to have the greatest impact on losing weight. As the easiest method to implement, patients chose *support group, medication referrals, and nutritionist referrals* in Bossier City, Franklin, Shreveport, and New Orleans, respectively.

In the fifth NGT focus group session, health care providers generated responses to the question, “What are the main things that you have done to help patients lose weight?” Four themes were identified: *referred to nutritionist, referred to metabolic medications, referred to exercise, and referred to weight loss programs*. In Table 4, the themes are listed in bold, with provider responses listed under each theme.

The top 3 themes that health care providers identified as having the greatest impact on patients losing weight were (1) *referred to nutritionist* (chosen as easiest to implement), (2) *referred to metabolic medications*, and (3) *referred to exercise*.²¹

Table 3. Patient Responses: What Has Your Doctor or Other Health Care Professional Done to Try to Help You Lose Weight?

Clinical site	Total votes	Sum of ranks ^a
Franklin, LA (n = 8 patients)		
Theme 1: Referred to exercise		
“Do exercise.”	8	24
Theme 2: Referred to nutritionist		
“Diet plan, juice plus, less salt and sugar.”	4	12
“Gave me diet sheets.”	2	6
Theme 3: Referred to medication		
“Diet pills.”	6	12
Theme 4: Provided advice only		
“Preached at me with no advice how to do it; told me the risk of being overweight.”	4	0
“Everything that is wrong with you is because you are obese.”	2	0
Shreveport, LA (n = 6 patients)		
Theme 1: Referred to nutritionist		
“Encouraged to change portion size, type of food.”	4	12
“Drink more water before meals.”	2	6
Theme 2: Referred to medication		
“Said there will be additional medications.”	5	10
“Prescribed Invokana (canagliflozin).”	2	4
Theme 3: Referred to exercise		
“Walk 30 minutes after eating.”	3	9
Theme 4: Provided advice only		
“Hear the same things about what to avoid; education doesn’t help.”	1	0
“Talked to me about losing weight and getting off some medications.”	1	0
Bossier City, LA (n = 6 patients)		
Theme 1: Referred to nutritionist		
“Nutritionist.”	5	15
“Diets.”	3	9

Clinical site	Total votes	Sum of ranks^a
Theme 2: Referred to exercise		
“Exercise, walking.”	4	8
“Physical therapy.”	2	4
Theme 3: Referred to medication		
“Appetite suppressants; fat burners.”	3	6
“Diet pills.”	3	3
Theme 4: Provided advice only		
“Told me what would happen if I don’t lose weight.”	2	0
“Encouraged me with motivation on how well my health will be and how the changes will improve my life.”	1	0
New Orleans, LA (n = 8 patients)		
Theme 1: Referred to nutritionist		
“Combination of portion control, diet and exercise, and visit with dietitian.”	8	24
“Recommended to track my weight and what I eat.”	4	12
Theme 2: Referred to exercise		
“Advised me to exercise more; showed me exercises for the pool.”	4	12
“Improve fitness level.”	2	6
Theme 3: Referred to medication		
“Prescribed diet pills.”	5	10
“Approved bariatric surgery.”	1	3
Theme 4: Provided advice only		
“Just said how overweight is detrimental to health.”	1	0
“Encouraged me to do something.”	1	0

^aCalculated by summing the ranks of responses (3 = most important, 2 = second most important, and 1 = least important). A higher score equals greater perceived importance.

Table 4. Health Care Provider (n = 6) Responses: What Are the Main Things That You Have Done to Help Patients Lose Weight?

	Total votes	Sum of ranks^a
Theme 1: Referred to nutritionist		
“Talk to them about appropriate portion size, and portion control.”	6	18
“Reduce and/or omit sugary drinks.”	4	11
“Eat more fruits and vegetables and fewer calorie-dense foods.”	5	10
Theme 2: Referred to metabolic medications		
“Diet pills.”	5	13
“Insulin.”	4	8
Theme 3: Referred to exercise		
“Discuss exercise and diet.”	6	11
Theme 4: Referred to weight loss programs		
“Comprehensive and/or commercial weight loss programs.”	4	10
“Counseling, set goals, motivate.”	4	9
“Discuss comorbidities.”	5	8

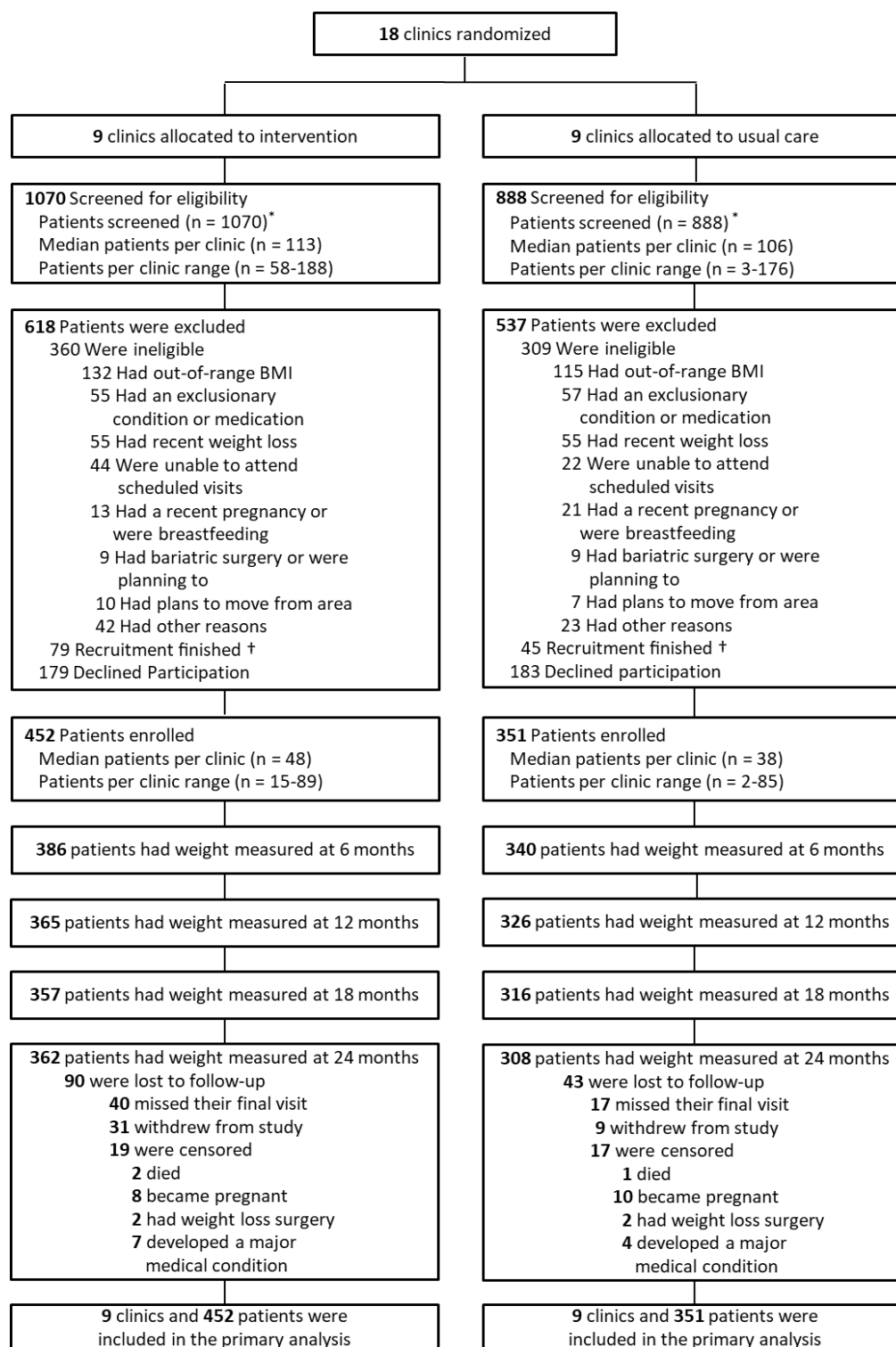
^aCalculated by summing the ranks of responses (3 = most important, 2 = second most important, and 1 = least important). A higher score equals greater perceived importance.

Intervention Study Results

Recruitment and Retention

Detailed information on recruitment²⁰ and retention²² was described previously. The flow of participants from initial screening to enrollment (at baseline) is shown in Figure 3.²⁰ A total of 1958 patients were screened for initial eligibility at the 18 randomized clinics. Of those patients, 362 declined participation, 669 did not meet the inclusion/exclusion criteria, and 124 were not enrolled, as their screening visit had not been completed at the time recruitment ended. Further, 102 patients were deemed ineligible and not allocated to a study group due to not having a PCP at a participating clinic. The final sample size was 803 (452 ILI, 351 UC). The final number of patients enrolled per clinic ranged from 2 to 89, with a median of 40.5 patients per clinic.²²

Figure 3. Patient Flow Through the PROPEL Trial



Abbreviations: BMI, body mass index; PROPEL, PROmoting Successful Weight Loss in Primary CarE in Louisiana.

*An additional 102 patients were ineligible due to not having a primary care provider at a participating clinic and were not allocated to a study group.

†A total of 124 patients were not enrolled because their visits were pending when recruitment ended.

All clinics completed participation between April 2016 and September 2019.²² Eighty-three percent of the sample (80.1% of ILI, 87.7% of UC) had body weight data available at the 24-month visit (Figure 3). Thirty-six patients (n = 19 in ILI, n = 17 in UC) became pregnant, had weight loss surgery, developed a major medical condition, or died during the trial, and their data were censored at a prior visit. The exclusion of these patients resulted in 87.4% (83.6% of ILI, 92.2% of UC) of the sample having weight measured at 24 months.²²

Descriptive Characteristics

Table 5 provides the descriptive characteristics of the sample at baseline. Approximately 67% of the sample was African American, and 41.2% reported an annual household income below \$20 000.²² The mean age of the sample was 49.4 years, with a range of 21 to 74 years. The mean BMI was 37.2.²⁰ A total of 30.8% of the sample had low literacy, and 30.8% had food insecurity.²² The 2 cluster randomized groups were well balanced with respect to baseline characteristics; however, there was a greater proportion of African American patients and women in the ILI group, and a greater proportion of patients with diabetes in the UC group (Table 5).²⁰

Table 5. Clinic and Participant Characteristics at Baseline

	UC	ILI	Total
Clinics			
No. of clinics	9	9	18
Clinic size, No.	7994	5184	6589
Clinic type, no. of clinics (%)			
FQHC	7 (77.8)	7 (77.8)	14 (77.8)
Other	2 (22.2)	2 (22.2)	4 (22.2)
Race, %			
African American	49.7	62.9	56.3
Other	50.3	37.1	43.7
Medicaid, %	27.7	24.5	26.1
Participants			
No. of patients (%)	351 (43.7)	452 (56.3)	803
Race, No. (%)			
African American	208 (59.3)	332 (73.5)	540 (67.3)
White	113 (32.2)	95 (21.0)	208 (25.9)
Other	30 (8.5)	25 (5.5)	55 (6.8)
Ethnicity, No. (%)			
Hispanic	14 (4.0)	18 (4.0)	32 (4.0)
Non-Hispanic	337 (96.0)	433 (96.0)	770 (96.0)
Sex, No. (%)			
Male	71 (20.2)	54 (11.9)	125 (15.6)
Female	280 (79.8)	398 (88.1)	678 (84.4)
Annual family income, No. (%) ^a			
<\$10 000	70 (20.5)	86 (19.3)	156 (19.8)
\$10 000-\$19 999	73 (21.4)	95 (21.3)	168 (21.4)
\$20 000-\$39 999	79 (23.2)	112 (25.2)	191 (24.3)
\$40 000-\$59 999	48 (14.1)	69 (15.5)	117 (14.9)
≥\$60 000	71 (20.8)	83 (18.7)	154 (19.6)

	UC	ILI	Total
Health literacy, No. (%)			
≤Eighth grade	106 (30.2)	141 (31.2)	247 (30.8)
≥Ninth grade	245 (69.8)	311 (68.8)	556 (69.2)
Household food insecurity, No. (%)			
Food secure	233 (66.4)	323 (71.5)	556 (69.2)
Food insecure	118 (33.6)	129 (28.5)	247 (30.8)
Diabetes, No. (%)	104 (29.6)	103 (22.8)	207 (25.8)
Age, mean ± SD, y	50.1 ± 13.6	48.8 ± 12.7	49.4 ± 13.1
Body weight, mean ± SD, kg	102.7 ± 17.0	101.6 ± 16.4	102.1 ± 16.7
BMI, mean ± SD	37.2 ± 4.8	37.3 ± 4.6	37.2 ± 4.7
Waist circumference, mean ± SD, cm	113.9 ± 12.6	113.1 ± 12.4	113.4 ± 12.5
Systolic blood pressure, mean ± SD, mm Hg	122.6 ± 16.5	123.1 ± 16.3	122.9 ± 16.4
Diastolic blood pressure, mean ± SD, mm Hg	78.4 ± 10.6	79.7 ± 10.6	79.1 ± 10.6
Fasting glucose, mean ± SD, mg/dL	112.3 ± 40.2	106.4 ± 31.9	109.0 ± 35.8
Total cholesterol, mean ± SD, mg/dL	180.0 ± 36.7	179.6 ± 37.5	179.8 ± 37.1
HDL cholesterol, mean ± SD, mg/dL	47.7 ± 14.4	50.5 ± 14.4	49.3 ± 14.4
Triglycerides, mean ± SD, mg/dL	131.6 ± 69.4	125.2 ± 72.8	128.0 ± 71.3
LDL cholesterol, mean ± SD, mg/dL	106.7 ± 31.5	105.7 ± 32.8	106.2 ± 32.2
Weight-related QOL (IWQOL), mean ± SD ^b			
Total	75.3 ± 18.3	72.8 ± 19.5	73.9 ± 19.0
Physical function	71.3 ± 20.9	68.4 ± 22.3	69.7 ± 21.7
Public distress	87.3 ± 20.7	86.5 ± 20.0	86.9 ± 20.3
Self-esteem	64.9 ± 28.1	62.2 ± 27.6	63.4 ± 27.8
Work/daily activities	86.3 ± 18.7	85.7 ± 19.4	85.9 ± 19.1
Sexual life	79.0 ± 28.6	72.8 ± 31.1	75.5 ± 30.1
HRQOL (PROMIS), mean ± SD ^c			
Anxiety	52.2 ± 10.1	51.7 ± 9.7	51.9 ± 9.9
Fatigue	50.9 ± 10.4	49.4 ± 9.8	50.1 ± 10.1
Pain Interference	52.5 ± 9.4	51.5 ± 9.7	51.9 ± 9.6

	UC	ILI	Total
Pain Intensity ^d	3.2 ± 2.7	2.9 ± 2.7	3.0 ± 2.7
Physical Functioning	48.1 ± 8.1	48.9 ± 7.9	48.6 ± 8.0
Depression	48.1 ± 8.7	47.0 ± 8.5	47.5 ± 8.6
Sleep Disturbance	51.5 ± 9.5	50.2 ± 9.2	50.7 ± 9.4
Social Functioning	54.3 ± 9.1	55.2 ± 8.9	54.8 ± 9.0
Satisfaction with PCP	29.1 ± 4.2	29.3 ± 4.1	29.2 ± 4.1

Abbreviations: BMI, body mass index; FQHC, federally qualified health center; HDL, high-density lipoprotein; HRQOL, health-related quality of life; ILI, intensive lifestyle intervention; IWQOL, Impact of Weight on Quality of Life; LDL, low-density lipoprotein; PCP, primary care provider; PROMIS, Patient-Reported Outcomes Measurement Information System; QOL, quality of life; UC, usual care.

^aDue to missing values, the denominators for income are 341, 445, and 786 for the UC group, the ILI group, and the total sample, respectively.

^bTransformed scores were calculated for the total and each IWQOL domain so that the score ranges from 0 to 100, with higher scores indicating more of that domain (ie, a higher score for physical functioning indicates better physical functioning, while a higher score for public distress indicates more distress).

^cNorm-based scores were calculated for each domain on the PROMIS measures, so that a score of 50 represents the mean or average of the reference population. The T score rescaled the raw score into a standardized T score with a mean of 50 and an SD of 10. Therefore, a person with a T score of 40 is 1 SD below the mean.

^dScale of 0 to 10, in which a higher score reflects more pain.

Primary Aim

To develop and test the effectiveness of a 24-month, patient-centered, pragmatic, and scalable obesity treatment program delivered within primary care in an underserved population.

Hypothesis 1. Relative to patients who receive UC, patients who receive the ILI will have greater percentage reductions in body weight.

Percentage weight loss at 24 months was significantly greater in the ILI group (−4.99% [95% CI, −6.02% to −3.96%]) than in the UC group (−0.48% [95% CI, −1.57% to 0.61%]), with a mean difference of −4.51 percentage points (95% CI, −5.93 to −3.10) between the groups ($P < .0001$).²² The greatest weight loss occurred at 6 months; however, clinically significant weight loss was maintained at 24 months (Table 6). The ILI group regained an average of 30% of their initial 6-month adjusted weight loss (2.38 of 7.81 kg) by month 24, and approximately 51% of ILI participants maintained at least 5% weight loss at 24 months. Similar results were obtained for changes in absolute weight and waist circumference. Age, sex, and race were included as

covariates in all models. Clinic-level covariates (clinic size, % African American, % enrolled in Medicaid) were not significant covariates and were not included in the final models.

Appendix A, Supplementary Table S4 provides the results from unadjusted models and models adjusted for patient- and clinic-level covariates. The results from all models were similar.²² The

intraclass correlation coefficient (ICC) was calculated as $\frac{\sigma_{clinics}^2}{(\sigma_{clinics}^2 + \sigma_{\epsilon}^2)}$. For percentage weight loss at 24 months, the calculated ICC was 0.14.

Categorical weight loss results at 6, 12, 18, and 24 months are presented in Figure 4.²² At 24 months, 19.62% (95% CI, 12.92%-28.66%) and 4.74% (95% CI, 2.61%-8.45%) of the UC group experienced $\geq 5\%$ and $\geq 10\%$ weight loss, respectively, while 50.70% (95% CI, 39.79%-61.55%) and 23.25% (95% CI, 16.52%-31.67%) of the ILI group experienced $\geq 5\%$ and $\geq 10\%$ weight loss, respectively.²²

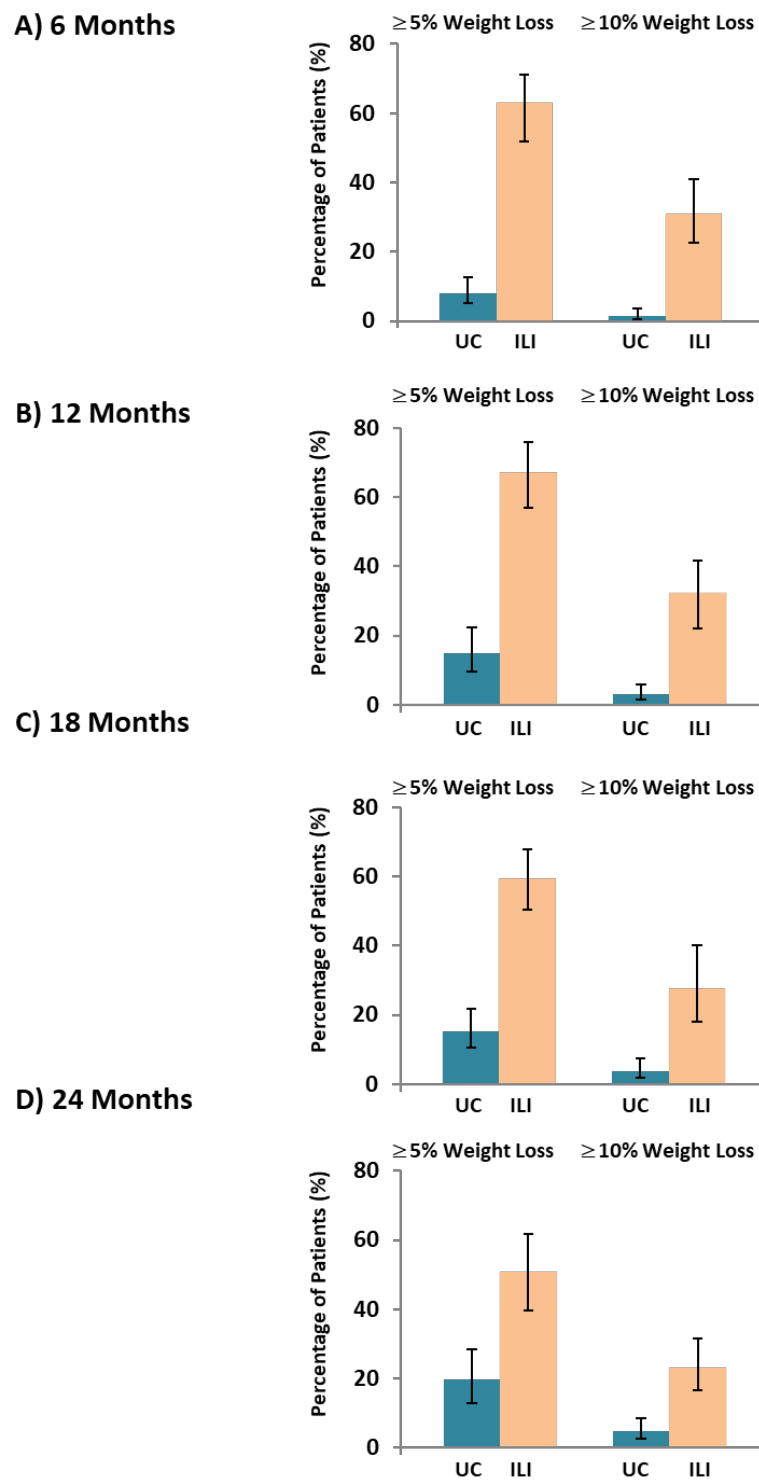
Table 6. Changes From Baseline in Weight Loss Variables Over 2 Years, Shown as Mean (95% CI)^a

Variable	UC	ILI	Difference
Change in body weight, %			
6 mo	-0.47 (-1.40 to 0.46)	-7.34 (-8.23 to -6.45)	-6.86 (-8.05 to -5.68)
12 mo	-0.59 (-1.61 to 0.43)	-6.75 (-7.72 to -5.78)	-6.16 (-7.47 to -4.85)
18 mo	-0.40 (-1.44 to 0.64)	-5.62 (-6.61 to -4.63)	-5.22 (-6.57 to -3.88)
24 mo	-0.48 (-1.57 to 0.61)	-4.99 (-6.02 to -3.96)	-4.51 (-5.93 to -3.10)
Change in body weight, kg			
6 mo	-0.83 (-1.82 to 0.17)	-7.81 (-8.77 to -6.85)	-6.98 (-8.26 to -5.71)
12 mo	-0.99 (-2.08 to 0.09)	-7.22 (-8.25 to -6.19)	-6.23 (-7.63 to -4.83)
18 mo	-0.82 (-1.92 to 0.29)	-6.07 (-7.12 to -5.02)	-5.26 (-6.69 to -3.82)
24 mo	-0.91 (-2.07 to 0.24)	-5.43 (-6.52 to -4.34)	-4.51 (-6.01 to -3.02)
Change in waist circumference, cm			
6 mo	-0.99 (-1.93 to -0.05)	-6.84 (-7.75 to -5.93)	-5.85 (-7.04 to -4.66)
12 mo	-0.68 (-1.70 to 0.33)	-6.63 (-7.61 to -5.66)	-5.95 (-7.25 to -4.65)
18 mo	0.21 (-0.82 to 1.24)	-5.33 (-6.32 to -4.34)	-5.54 (-6.86 to -4.22)
24 mo	0.71 (-0.35 to 1.78)	-4.42 (-5.44 to -3.41)	-5.13 (-6.50 to -3.77)

Abbreviations: ILI, intensive lifestyle intervention; UC, usual care.

^aAnalyzed using multilevel mixed-effects linear regression. All models included age, sex, and race as covariates; age and race were significant covariates at $P < .05$. The 95% CIs that do not include 0 indicate a statistically significant result. Missing observations were as follows: *change in body weight* (% and kg): month 6 = 66 missing observations, month 12 = 88 observations, month 18 = 100 observations, month 24 = 97 observations; *change in waist circumference*: month 6 = 69 missing observations, month 12 = 93 observations, month 18 = 103 observations, month 24 = 100 observations.

Figure 4. Percentage of Patients Achieving $\geq 5\%$ and $\geq 10\%$ Weight Loss From Baseline at 6 Months (A), 12 Months (B), 18 Months (C), and 24 Months (D)^a



Abbreviations: ILI, intensive lifestyle intervention; UC, usual care.

^aError bars represent 95% CIs.

Hypothesis 2. Relative to patients in UC, patients in the ILI group will have significant improvements in HRQOL, functional capacity, satisfaction with medical care, and improved obesity comorbidities.

Table 7 describes changes in patient-reported outcomes (QOL and satisfaction with medical care) over 2 years.²² The ILI group showed significant improvements across all 5 weight-related QOL scales and the total score measured by the IWQOL at 6, 12, and 24 months. Changes in the total weight-related QOL score and 4 of the 5 scales (physical function, self-esteem, sexual life, and work) were significantly greater in the ILI group than in the UC group at 6, 12, and 24 months (mean differences $P < .05$). The mean difference in total weight-related QOL between the 2 groups was 7.53 (95% CI, 5.18-9.88) at 6 months, 7.59 (95% CI, 5.15-10.03) at 12 months, and 6.66 (95% CI, 4.10-9.21) at 24 months, all in favor of the ILI group.

Of the 8 generic HRQOL scales measured by the PROMIS instrument, fatigue, sleep, and social functioning significantly improved in the ILI group at 24 months. There was no change in any of the subscales in the UC group at 24 months. The mean difference between the UC and ILI groups was statistically significant in favor of the ILI for 6 generic QOL scales (Anxiety, Fatigue, Pain Interference, Physical Functioning, Sleep Disturbance, Social Functioning) at 6 months, 3 scales (Pain Interference, Physical Functioning, Social Functioning) at 12 months, and 2 scales (Fatigue, Social Functioning) at 24 months. No significant differences between the 2 groups were identified for the pain intensity or depression scales at any time point. There was no significant difference in patient satisfaction with their PCP between or within the 2 groups at 24 months.

Table 7. Changes From Baseline in Patient-Reported Outcomes Over 2 Years, Shown as Mean (95% CI)^a

Variable	UC	ILI	Difference
Change in PROMIS-29 Physical Functioning ^b			
6 mo	-0.17 (-1.12 to 0.78)	1.96 (1.02-2.90)	2.13 (0.94-3.32)
12 mo	-0.33 (-1.30 to 0.65)	1.23 (0.26-2.19)	1.55 (0.32-2.78)
24 mo	-0.39 (-1.39 to 0.62)	0.82 (-0.16 to 1.79)	1.20 (-0.06 to 2.46)
Change in PROMIS-29 Anxiety ^c			
6 mo	0.39 (-0.96 to 1.74)	-1.51 (-2.84 to -0.19)	-1.90 (-3.61 to -0.19)
12 mo	-0.29 (-1.62 to 1.04)	-0.89 (-2.20 to 0.41)	-0.60 (-2.28 to 1.07)
24 mo	-0.53 (-1.95 to 0.89)	-0.92 (-2.29 to 0.46)	-0.39 (-2.18 to 1.41)
Change in PROMIS-29 Depression ^c			
6 mo	0.73 (-0.19 to 1.65)	-0.06 (-1.00 to 0.87)	-0.79 (-1.93 to 0.35)
12 mo	0.80 (-0.13 to 1.74)	0.29 (-0.67 to 1.24)	-0.52 (-1.69 to 0.66)
24 mo	0.64 (-0.34 to 1.63)	-0.18 (-1.17 to 0.81)	-0.82 (-2.07 to 0.42)
Change in PROMIS-29 Fatigue ^c			
6 mo	-0.98 (-2.13 to 0.17)	-3.49 (-4.64 to -2.33)	-2.51 (-3.94 to -1.07)
12 mo	-1.23 (-2.43 to -0.04)	-2.60 (-3.80 to -1.40)	-1.36 (-2.87 to 0.15)
24 mo	-1.03 (-2.28 to 0.22)	-2.82 (-4.06 to -1.59)	-1.80 (-3.37 to -0.22)
Change in PROMIS-29 Sleep Disturbance ^c			
6 mo	0.23 (-0.93 to 1.39)	-2.01 (-3.15 to -0.87)	-2.24 (-3.69 to -0.78)
12 mo	-0.02 (-1.25 to 1.21)	-0.88 (-2.08 to 0.32)	-0.86 (-2.42 to 0.70)
24 mo	-0.35 (-1.59 to 0.89)	-1.25 (-2.45 to -0.05)	-0.90 (-2.47 to 0.67)
Change in PROMIS-29 Social Functioning ^b			
6 mo	0.05 (-0.87 to 0.98)	2.14 (1.19-3.08)	2.08 (0.95-3.22)
12 mo	0.46 (-0.52 to 1.45)	1.97 (0.96-2.97)	1.50 (0.27-2.74)
24 mo	0.15 (-0.87 to 1.17)	1.57 (0.55-2.60)	1.42 (0.14-2.71)
Change in PROMIS-29 Pain Interference ^c			
6 mo	-0.04 (-1.07 to 0.98)	-1.58 (-2.63 to -0.53)	-1.54 (-2.80 to -0.28)
12 mo	0.46 (-0.63 to 1.55)	-0.95 (-2.06 to 0.16)	-1.41 (-2.78 to -0.05)
24 mo	0.21 (-0.95 to 1.37)	-1.06 (-2.22 to 0.10)	-1.27 (-2.72 to 0.19)
Change in PROMIS-29 Pain Intensity ^{c,d}			
6 mo	0.02 (-0.28 to 0.31)	-0.26 (-0.56 to 0.05)	-0.27 (-0.64 to 0.10)
12 mo	0.07 (-0.25 to 0.40)	-0.01 (-0.33 to 0.32)	-0.08 (-0.49 to 0.33)
24 mo	0.21 (-0.12 to 0.53)	-0.02 (-0.35 to 0.30)	-0.23 (-0.64 to 0.18)
Change in weight-related QOL (IWQOL-L total score) ^e			
6 mo	3.02 (1.14-4.90)	10.55 (8.69-12.41)	7.53 (5.18-9.88)
12 mo	3.56 (1.61-5.50)	11.14 (9.23-13.06)	7.59 (5.15-10.03)

Variable	UC	ILI	Difference
24 mo	4.36 (2.34-6.39)	11.02 (9.04-13.00)	6.66 (4.10-9.21)
Change in IWQOL-L physical function ^e			
6 mo	2.71 (−0.03 to 5.45)	13.35 (10.70-16.00)	10.64 (7.17-14.10)
12 mo	3.20 (0.44-5.96)	13.59 (10.92-16.27)	10.39 (6.89-13.89)
24 mo	4.11 (1.24-6.97)	12.31 (9.55-15.06)	8.20 (4.56-11.84)
Change in IWQOL-L self-esteem ^e			
6 mo	4.69 (2.20-7.17)	12.20 (9.67-14.72)	7.51 (4.44-10.58)
12 mo	5.86 (3.21-8.50)	13.74 (11.07-16.40)	7.88 (4.57-11.19)
24 mo	7.62 (4.88-10.36)	14.39 (11.66-17.12)	6.77 (3.32-10.21)
Change in IWQOL-L sexual life ^e			
6 mo	2.02 (−1.05 to 5.08)	12.19 (9.05-15.33)	10.18 (6.37-13.98)
12 mo	3.19 (0.12-6.27)	12.20 (9.04-15.36)	9.01 (5.18-12.84)
24 mo	4.49 (1.18-7.80)	14.32 (11.00-17.65)	9.83 (5.68-13.99)
Change in IWQOL-L public distress ^e			
6 mo	2.42 (−0.12 to 4.96)	4.76 (2.29-7.22)	2.33 (−0.88 to 5.54)
12 mo	2.39 (−0.19 to 4.96)	5.95 (3.46-8.44)	3.56 (0.31-6.82)
24 mo	2.41 (−0.20 to 5.02)	5.38 (2.86-7.89)	2.97 (−0.34 to 6.27)
Change in IWQOL-L work/daily activity ^e			
6 mo	2.69 (0.57-4.82)	5.41 (3.29-7.53)	2.72 (0.07-5.37)
12 mo	1.83 (−0.38 to 4.03)	5.67 (3.48-7.86)	3.84 (1.08-6.60)
24 mo	1.47 (−0.83 to 3.76)	5.48 (3.22-7.75)	4.02 (1.12-6.91)

Abbreviations: ILI, intensive lifestyle intervention; IWQOL-L, Impact of Weight on Quality of Life–Lite; PROMIS, Patient-Reported Outcomes Measurement Information System; QOL, quality of life; UC, usual care.

^aAnalyzed using multilevel mixed-effects linear regression. All models included age, sex, and race as covariates. The 95% CIs that do not include 0 indicate a statistically significant result.

^bA positive change score indicates improvement, while a negative change score indicates worsening from baseline.

^cA negative change score indicates improvement, while a positive change score indicates worsening from baseline.

^dOn a scale of 0 to 10, in which a higher score reflects more pain.

^eHigher change scores indicate greater improvement from baseline.

Table 8 describes changes in cardiometabolic risk factors over 2 years.²² In the ILI group, fasting glucose levels decreased significantly from baseline to 12 months but did not change significantly from baseline to 24 months, leading to a mean difference of -7.14 mg/dL (95% CI, -12.12 to -2.16 mg/dL) at 12 months and -0.91 mg/dL (95% CI, -6.28 to 4.45 mg/dL) at 24 months in favor of the ILI group. HDL cholesterol levels increased significantly in the ILI group by 4.54 mg/dL (95% CI, 3.21 - 5.87 mg/dL) at 12 months and 4.16 mg/dL (95% CI, 2.78 - 5.54 mg/dL) at 24 months; they did not change in the UC group at 12 or 24 months. The mean difference in HDL cholesterol between the 2 groups was 4.04 mg/dL (95% CI, 2.41 - 5.68 mg/dL) at 12 months and 4.60 mg/dL (95% CI, 2.88 - 6.32 mg/dL) at 24 months, both in favor of the ILI group. There were no significant differences in systolic or diastolic blood pressure, LDL cholesterol, or triglycerides between the 2 groups at any time point.

Table 8. Changes From Baseline in Cardiometabolic Disease Risk Factors Over 2 Years, Shown as Mean (95% CI)^a

Variable	UC	ILI	Difference
Change in systolic blood pressure, mm Hg			
6 mo	1.35 (−1.33 to 4.03)	−0.01 (−2.57 to 2.54)	−1.36 (−4.82 to 2.09)
12 mo	2.11 (−0.63 to 4.85)	0.52 (−2.09 to 3.13)	−1.59 (−5.13 to 1.95)
18 mo	1.08 (−1.73 to 3.89)	−0.08 (−2.76 to 2.59)	−1.16 (−4.81 to 2.48)
24 mo	0.41 (−2.43 to 3.26)	1.94 (−0.75 to 4.63)	1.53 (−2.15 to 5.21)
Change in diastolic blood pressure, mm Hg			
6 mo	0.23 (−1.56 to 2.03)	−0.88 (−2.59 to 0.82)	−1.12 (−3.44 to 1.20)
12 mo	0.13 (−1.70 to 1.97)	−1.28 (−3.02 to 0.46)	−1.41 (−3.79 to 0.97)
18 mo	−0.84 (−2.70 to 1.02)	−1.83 (−3.60 to −0.06)	−0.99 (−3.41 to 1.43)
24 mo	−0.64 (−2.53 to 1.24)	−0.61 (−2.39 to 1.17)	0.03 (−2.41 to 2.48)
Change in total cholesterol, mg/dL			
12 mo	0.58 (−3.09 to 4.26)	3.06 (−0.79 to 6.91)	2.48 (−2.10 to 7.05)
24 mo	−1.26 (−5.38 to 2.87)	4.64 (0.45-8.82)	5.89 (0.68-11.10)
Change in HDL cholesterol, mg/dL			
12 mo	0.50 (−0.81 to 1.81)	4.54 (3.21-5.87)	4.04 (2.41-5.68)
24 mo	−0.44 (−1.81 to 0.94)	4.16 (2.78-5.54)	4.60 (2.88-6.32)
Change in LDL cholesterol, mg/dL			
12 mo	0.81 (−2.74 to 4.35)	1.58 (−2.19 to 5.34)	0.77 (−3.69 to 5.23)
24 mo	−0.17 (−4.17 to 3.83)	3.22 (−0.85 to 7.29)	3.39 (−1.69 to 8.47)
Change in triglycerides, mg/dL			
12 mo	−1.56 (−12.40 to 9.29)	−9.45 (−20.39 to 1.49)	−7.89 (−21.62 to 5.84)
24 mo	−5.58 (−16.39 to 5.23)	−11.23 (−22.02 to −0.44)	−5.65 (−19.23 to 7.92)
Change in glucose levels, mg/dL			
12 mo	2.30 (−1.70 to 6.29)	−4.84 (−9.04 to −0.64)	−7.14 (−12.12 to −2.16)
24 mo	−0.33 (−4.61 to 3.94)	−1.25 (−5.65 to 3.15)	−0.91 (−6.28 to 4.45)

Abbreviations: HDL, high-density lipoprotein; ILI, intensive lifestyle intervention; LDL, low-density lipoprotein; UC, usual care.

^aAnalyzed using multilevel mixed-effects linear regression. All models included age, sex, and race as covariates. The 95% CIs that do not include 0 indicate a statistically significant result.

Secondary Aims

Secondary aim 1. Evaluate relationships between adherence to intervention components (physical activity, diet, session attendance) and corresponding changes in body weight and secondary outcomes.

Correlations between adherence to intervention components and changes in outcomes at 24 months are presented in Table 9. Overall, weak correlations were identified between weight change at 24 months and intervention components (24-month changes in daily physical activity, change in percentage fat intake, and units of session material received). Change in total daily minutes of physical activity was significantly negatively correlated with percentage weight change, such that increases in physical activity were associated with greater weight loss. Also, the ILI group significantly increased their total daily physical activity at 6 and 12 months, although participants engaged in significantly more activity than did those in the UC group only at 6 months (19.64 minutes/day; 95% CI, 5.76-33.51 minutes/day; Appendix A, Supplementary Table S5). Change in percentage energy from fat was significantly positively correlated with percentage weight change and change in waist circumference and glucose levels, and it was negatively correlated with select metrics of weight-related QOL. Further, the ILI group significantly decreased their percentage energy from fat compared with the UC group at all time points (24 month difference: -2.09%; 95% CI, -3.31% to -0.87%; Appendix A, Supplementary Table S5). The percentage weight change in ILI participants who received $\geq 80\%$ of the intervention session materials was -7.07% (95% CI, -8.58% to -5.56%) at 24 months, compared with -1.93% (95% CI, -3.81% to -0.06%) among those who received $< 80\%$ of the sessions (Appendix A, Supplementary Table S6).

Additionally, a greater number of units of intervention session material received was associated with lower waist circumference and higher HDL cholesterol at 24 months. The relationships between the number of intervention session materials received and generic QOL metrics were mixed, while significant positive correlations were found for the overall and subscales of weight-related QOL. Health coaches also tracked their intervention-related contacts with ILI participants outside the 43 sessions included in the intervention curriculum

(Appendix A, Supplementary Table S7). Outside the scheduled sessions, coaches had nearly 8000 additional contacts with their patients during the trial. Additional contacts occurred via a variety of communication methods, with text messages being the most used (n = 6852).

Table 9. Relationships Between Intervention Components (Columns) and Corresponding Changes in Body Weight and Secondary Outcomes From Baseline to 24 Months (Rows) Among Patients in the ILI Group^a

	Change in daily physical activity		Change in % fat intake		Session material received	
	r ^b	P value ^c	r ^b	P value ^c	r ^b	P value ^c
% weight change	−0.174	.018	0.229	.002	−0.278	.000
Weight change, kg	−0.174	.018	0.205	.005	−0.291	<.0001
Waist circumference, cm	−0.064	.386	0.210	.004	−0.215	.003
Systolic blood pressure, mm Hg	−0.082	.267	−0.032	.666	−0.055	.458
Diastolic blood pressure, mm Hg	−0.084	.257	0.025	.740	−0.153	.037
Glucose, mg/dL	−0.088	.233	0.180	.014	−0.113	.125
Total cholesterol, mg/dL	0.010	.889	0.110	.136	−0.042	.567
HDL cholesterol, mg/dL	0.014	.852	−0.109	.140	0.090	.222
LDL cholesterol, mg/dL	0.009	.907	0.135	.066	−0.069	.350
Triglycerides, mg/dL	−0.006	.934	0.027	.714	−0.007	.922
PROMIS-29 scales						
Physical Functioning	0.137	.063	−0.059	.425	0.245	.001
Anxiety	0.034	.644	−0.007	.928	0.083	.264
Depression	0.047	.523	0.049	.509	0.065	.379
Fatigue	−0.089	.230	−0.045	.547	−0.185	.012
Sleep	−0.019	.797	0.031	.672	−0.079	.284
Social	0.084	.255	0.036	.625	0.224	.002
Pain Interference	−0.086	.244	−0.089	.230	−0.151	.040
Pain Intensity	−0.084	.257	0.065	.378	−0.126	.087
IWQOL-Lite scales						
Total score	0.086	.243	−0.258	.000	0.186	.011
Physical function	0.131	.076	−0.225	.002	0.204	.005
Self-esteem	0.087	.241	−0.259	.000	0.115	.118
Sexual life	−0.091	.216	−0.065	.377	0.079	.288
Public distress	0.072	.329	−0.196	.008	0.129	.080
Work	0.086	.243	−0.192	.009	0.127	.085
Satisfaction with PCP	−0.135	.068	0.065	.380	0.096	.191

Abbreviations: HDL, high-density lipoprotein; ILI, intensive lifestyle intervention; IWQOL, Impact of Weight on Quality of Life; LDL, low-density lipoprotein; PCP, primary care provider; PROMIS, Patient-Reported Outcomes Measurement Information System.

^aILI group only (n = 452).

^bValues are partial correlation coefficients adjusted for age, sex, and race.

^cP < .05 indicates a statistically significant relationship.

Secondary aim 2. Examine the effects of the intervention on system-level practices and patient satisfaction with care.

Patient satisfaction with their PCP did not significantly change within the UC or ILI groups at 24 months relative to baseline (Table 10). Furthermore, there was no significant difference in patient satisfaction with care between the UC and ILI groups at 24 months. In total, 79 PCPs across the 18 clinics enrolled at least 1 patient in the PROPEL trial. Low PCP completion rates of 51.9% (n = 41) and 22.8% (n = 18) were observed for surveys administered at the start and end of the trial, respectively. These modest completion rates precluded multilevel modeling of intervention effects on system-level practice.

Table 10. Change in Patient Satisfaction With Their PCP From Baseline to 24 Months, Shown as Mean (95% CI)^a

	UC		ILI		Difference		P value
24 mo	-0.09	(-0.09 to 0.7)	-0.40	(-1.2 to 0.4)	-0.30	(-1.3 to 0.7)	.55

Abbreviations: ILI, intensive lifestyle intervention; PCP, primary care provider; UC, usual care.

^aAnalyzed using multilevel mixed-effects linear regression. Model includes age, sex, and race as covariates. The 95% CIs that do not include 0 or have $P < .05$ indicate a statistically significant result.

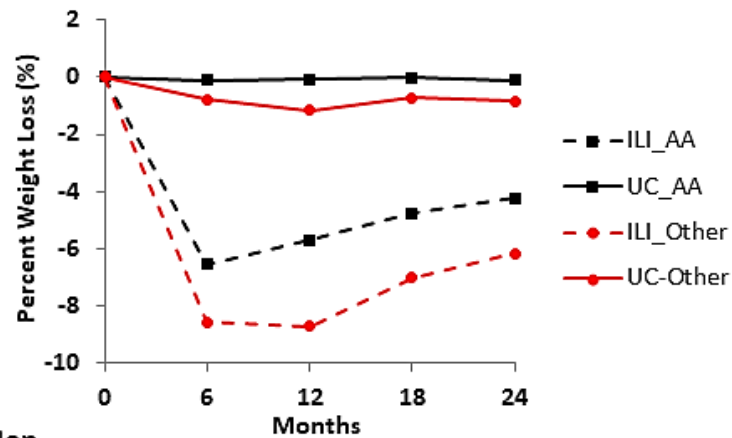
Secondary aim 3. Test the HTE across clinics and across subgroups (age, sex, race) of patients.

The results of the 3 planned HTE subgroup analyses are presented in Figure 5 and in Appendix A. The percentage weight loss in the ILI group tended to be lower in African American participants than in those in the “other” race category, and the difference between the ILI and UC groups across all outcomes was at least 1% less at 24 months in African American participants than were outcomes in other races (Appendix A, Supplementary Table S8). Women and men responded similarly to the intervention (Appendix A, Supplementary Table S9); however, differences were observed across age groups. There appeared to be a dose-response association with age, with younger adults experiencing less weight loss in the ILI group than did older adults (Figure 5), although the differences in weight loss between the UC and ILI groups were similar across age groups (Appendix A, Supplementary Table S10).

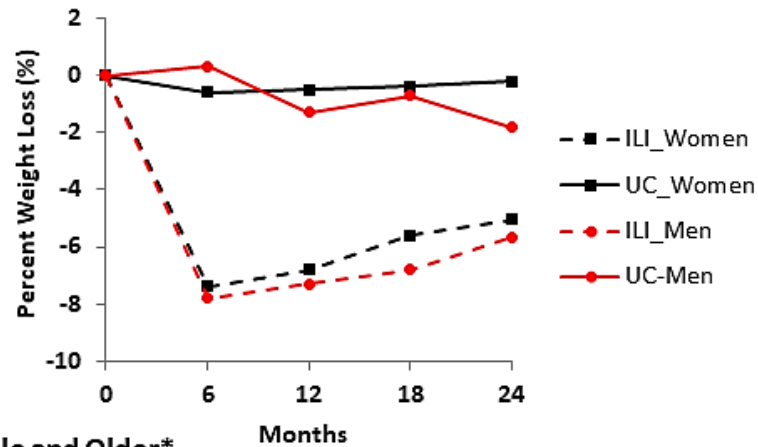
Two UC clinics failed to enroll more than 4 patients each, and patients at these clinics gained more weight than did those at other UC clinics (Appendix A, Supplementary Figure S1). Therefore, a sensitivity analysis was conducted whereby these patients were combined with those from a UC clinic in close geographic proximity (Appendix A, Supplementary Table S11). The results were similar, with an estimated 24-month weight loss difference of -4.43 (95% CI, -5.86 to -3.00) percentage points between the groups.

Figure 5. Mean Percentage Change in Weight From Baseline^a in African American and Other Races (A), Women and Men (B), and Younger, Middle, and Older Adults (C)

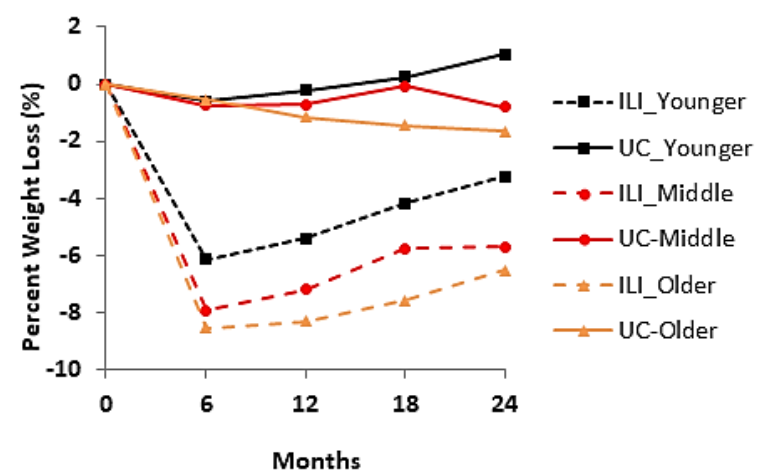
A) African American and Other Races



B) Women and Men



C) Younger, Middle and Older*



Abbreviations: AA, African American; ILI, intensive lifestyle intervention; UC, usual care.

^aAnalyzed using multilevel mixed-effects linear regression.

*Younger = 21 to 42 years; middle = 43 to 56 years; older = 57 to 74 years.

Adverse Events

A total of 86 patients had at least 1 SAE during the 24-month intervention (Table 11); 83 patients reported hospitalizations or other life-threatening conditions, and there were 3 deaths. None of the SAEs were related to the intervention. There were no significant differences in SAEs between the groups overall or at any time point.

Table 11. SAEs by Study Group^a

SAE	Baseline-6 mo	>6-12 mo	>12-18 mo	>18-24 mo	Total ^b
Hospitalization/life threatening					
UC	8	10	11	10	35
ILI	9	19	21	8	48
Death					
UC	1	0	0	0	1
ILI	0	0	1	1	2

Abbreviations: ILI, intensive lifestyle intervention; SAEs, serious adverse events; UC, usual care.

^aData are presented as total patients with at least 1 AE at each time point. Analyzed using chi-square tests.

^bThe number of patients does not sum to equal the total patients column, as several patients had an SAE at more than 1 time point.

DISCUSSION

Context for Study Results

A high-intensity patient-centered lifestyle–based obesity treatment program (ILI) inclusive of 43 sessions and customizable toolbox options delivered by a trained health coach in an underserved primary care population produced clinically significant weight loss over 24 months. A series of focus groups with input from both patients and health care providers contributed to this patient-centered intervention. Patients and health care providers both perceived that the best way to lose weight was to follow a specific plan that included eating healthy foods, exercising, and tracking food consumption. These similarities coincide with previous research in which fruits and vegetables were provided along with a nutrition education component; participants lost an average of 2.0 kg of weight by the end of the study.⁶⁵

A major hindrance to losing weight perceived by both patients and health care providers was a lack of access to healthy food choices or the associated costs. Despite US supermarkets stocking an average of 28,000 foods, allowing vast food choice,^{66,67} focus group participants stressed the realities of living on a limited budget with limited access to healthy foods given that fast foods and highly processed foods are less expensive and more readily available than are fresh fruits and vegetables.⁶⁶ Indeed, approximately 13.5 million people in the United States live in food deserts, which are low-income communities lacking supermarkets or grocery stores that sell affordable, healthy foods.⁶⁸ In accordance with these findings, the PROPEL ILI group provided meal plans specific to various caloric intake targets and provided food-tracking logs. The intervention was also tailored to be appropriate for both food-secure and food-insecure individuals in various ways. For example, patients were provided handouts depicting low-cost food items appropriate for their meal plan, and health coaches were knowledgeable about budget-friendly food stores in their patients' neighborhoods that stocked these healthy foods.

Patients and health care providers commonly reported that successful weight management programs must be easily adaptable to individual needs because “one size does not fit all.” Weight loss programs often adopt a one-size-fits-all behavioral model that

subscribes to the culture of the dominant majority without considering the cultural attitudes and preferences of nonmajority members.⁶⁹⁻⁷² As such, PROPEL implemented a toolbox approach in which the intervention was adapted according to individual patient needs. Toolbox options included keeping a food diary, increasing coach contact, incorporating meal replacements, and wearing a step tracker; these options were decided on via shared decision-making between patients and their health coach.

Finally, patients and health care providers cited referrals to a nutritionist as having the greatest impact on losing weight. Research shows that dietary consultation is one of the most useful services available for weight management; however, health care professionals report their lack of training in nutrition and counseling as a major barrier to offering weight management services to patients with obesity.⁷³⁻⁷⁵ In a recent review of strategies to increase obesity management in primary care and overcome such barriers, authors cited the need for health care professions not to “go it alone” but instead to incorporate a multidisciplinary team approach inclusive of nutrition professionals and health coaches.⁷⁵ The PROPEL trial emphasized this multidisciplinary approach and focus on dietary counseling as an effective weight management strategy, as trained health coaches were embedded within the primary care clinic. Additionally, most PROPEL health coaches had advanced degrees and/or certifications in nutrition, and the intervention relied heavily on nutrition-based information and practices.

Although patients agreed with some of the ideas generated by the health care providers, they indicated that only providing advice does not tangibly assist them in losing weight. Previous research indicated that patients prefer health care providers to give specific recommendations for weight loss, including exercise and dietary instructions.^{76,77} However, as confirmed by our focus groups, many health care providers feel that they cannot devote adequate clinical time to weight management when faced with acute and chronic demands to manage disease states and illnesses.^{78,79} Thus, primary care patients may not always feel that their weight concerns are being thoroughly addressed, necessitating a different approach for weight management in primary care.⁷⁷

Our trial demonstrated the effectiveness of implementing a high-intensity lifestyle–based obesity treatment program that targeted increasing physical activity and reducing dietary intake, consistent with the 2013 AHA/ACC/TOS guidelines, in an underserved primary care population.²² The ILI group experienced an average of 5% weight loss, and approximately 51% of ILI patients maintained at least 5% weight loss at 24 months. Our results are comparable with those from studies conducted in academic health centers, such as the DPP⁸⁰ and Look AHEAD⁸¹ trials, which demonstrated 5.8% and 6.4% weight loss at 24 months, respectively, in their lifestyle intervention groups. Weight loss interventions delivered by PCPs, which have typically been low to moderate intensity, have produced only modest weight loss (1-2 kg).^{13,82} However, there is mounting evidence that high-intensity lifestyle interventions conducted in primary care can produce greater weight loss (4-7 kg).⁸² Weight loss percentages in behavioral lifestyle interventions conducted in the POWER trials in primary care clinics in Baltimore, MD; Boston, MA; and Philadelphia, PA, were 5.2%, 1.7%, and 4.7%, respectively, at 24 months.⁸³⁻⁸⁵

The PROPEL intervention also led to significant improvements in weight-related QOL in the ILI group compared with UC, reflecting the importance of weight loss to better QOL. There was significant improvement in all subscales and total weight-related QOL at every time point within the ILI group. Additionally, the mean difference between change in scores from the UC and ILI groups was analyzed, and 5 of 6 scales (total weight-related QOL, physical function, self-esteem, sexual life, and work) showed that, relative to baseline, participants in the ILI group had significantly improved QOL compared with those in the UC group at 6, 12, and 24 months. While differences in mean weight loss from baseline between the UC and ILI groups were slightly attenuated at 24 months (–4.5 percentage points) compared with that at 6 months (–6.9 percentage points), little attenuation was observed for weight-related QOL improvements (total score: +7.5 at 6 months vs +6.7 at 24 months), suggesting that QOL changes may be long-lasting. These weight-related QOL changes are clinically meaningful, as represented by the minimal clinically important difference (MCID), which is the smallest difference in a health-related outcome that patients perceive to be beneficial.⁸⁶ The MCID for the IWQOL-Lite total score was determined to be between 7.7 and 12 in a cohort of patients with severe obesity.⁸⁶ Our findings for change in total weight-related QOL within the ILI group at all time points, as

well as the difference between the ILI and UC groups at all time points except 24 months (difference = 6.6), fall within the aforementioned MCID point estimate range. Similar to our results, participants in the POWER-UP pragmatic weight loss trial reported significant improvements in weight-related QOL at 6 months, which were well maintained through 24 months.⁸⁹ Thus, lifestyle-based weight loss treatment delivered by a health coach in primary care may yield significant and persistent improvements in weight-related QOL.

Whereas weight-related QOL improved, results were mixed for generic HRQOL. For the PROMIS subscales, the ILI group improved on some scales but experienced no change on others, and improvements were often only at the 6-month time point. None of the generic QOL measures from the PROMIS-29 reached clinical significance at any time point, as defined by the MCIDs reported in samples of patients with chronic pain⁸⁷ or undergoing spinal surgery.⁸⁸ MCIDs for the PROMIS-29 QOL instrument have not yet been determined for a sample of patients with obesity in a weight management trial, so the lack of clinical significance for the PROMIS-29 scales should be interpreted with caution, as they were determined for patients with other ailments. However, these findings are consistent with a review of 34 weight loss RCTs that found that generic QOL measures were not consistently improved in weight loss trials, whereas obesity-specific QOL measures were more likely to show improvements within the intervention group.⁹⁰ Obesity-specific measures, such as the IWQOL, include domains most relevant to people with obesity; thus, they may be more sensitive to change in the context of a weight loss intervention. Our findings agree with this proposition, such that the ILI group had better weight-related QOL than did the UC group at 24 months, while the findings for generic QOL were mixed.

The PROPEL intervention also elicited significant improvements compared with UC in fasting glucose and HDL cholesterol, highlighting the clinical relevance of the 5% weight loss achieved in the ILI group compared with the UC group.²² Specifically, fasting glucose levels decreased in the ILI group at month 12, while fasting glucose did not change significantly in the UC group at either time point, leading to a significant mean difference between the 2 groups at 12 but not 24 months. Further, the ILI group showed beneficial increases in HDL cholesterol

compared with the UC group at 12 and 24 months. These changes could be attributed to the increases in physical activity observed in the ILI group. Improvements in HDL cholesterol in the ILI group likely contributed to the observed significant increase in total cholesterol compared with the UC group at 24 months, because LDL cholesterol levels did not change in either group.

Similar to our results, the POWER-UP trial found a significant difference in fasting glucose levels between the enhanced lifestyle intervention group and control group at 12 but not 24 months.⁸³ In contrast to the PROPEL results, POWER-UP found a decrease in fasting glucose levels at both time points in the intervention group, with relatively stable values in the control group, whereas we found the significant difference only at 12 months. The trend of relatively stable glucose values as observed for the ILI group in PROPEL is comparable to that in the DPP, which likewise did not find significant changes from baseline to 24 months in the lifestyle intervention group while showing an increase in the control group; however, the DPP found a significant mean difference in glucose values of approximately 5 mg/dL between the groups at 24 months.⁹¹ Look AHEAD found decreases in glucose levels at 12 months in both the lifestyle intervention group and control group, with a significantly greater decrease in the intervention group (approximately -14 mg/dL).⁹² Further, improvements in HDL cholesterol in the ILI group relative to the UC group in PROPEL were approximately twice as large as the increases in Look AHEAD at 12 and 24 months (approximately +2 mg/dL for both time points);^{92,93} the DPP and POWER-UP trials did not find a significant difference between the intervention and control group at any time point.^{83,94} Together, these findings demonstrate the cardiometabolic risk reduction achieved by PROPEL's high-intensity lifestyle intervention (ILI) compared with UC received by patients with obesity.

It is noteworthy that despite the clinically relevant weight loss and accompanying improvements in cardiometabolic parameters in PROPEL, there were no significant improvements in blood pressure at any time point. This differs from Look AHEAD^{92,93} and DPP,⁹⁴ which both showed significant reductions in systolic and diastolic blood pressure between the lifestyle intervention group and control group at both 12 and 24 months. Similar to our results, POWER-UP did not find significant changes in blood pressure between the intervention and

control groups. The specific reason for this lack of effect in PROPEL is conjecture; however, more than 50% of participants were prescribed antihypertensive medication at baseline and throughout the trial. The concurrent drug treatment along with relatively normal mean blood pressure values at baseline (123/80 mm Hg in the UC group, 123/79 mm Hg in the ILI group), indicating a predominantly well-controlled blood pressure that leaves little room for improvement through the lifestyle intervention, likely masked any blood pressure–lowering effect achieved by the PROPEL intervention.

Subgroup Considerations

We conducted stratified analyses to examine the HTE by race, sex, and age. The results demonstrated that African American participants experienced slightly less weight loss than did participants of other races. These results are consistent with evidence from several multicenter trials,⁹⁵ such as Look AHEAD, where White participants lost significantly more weight than did African American participants,⁸¹ and DPP, where African American women lost less weight than other sex-by-race/ethnicity groups.⁹⁶ Research has suggested that lower weight loss in African Americans may be mediated by less behavior change and lower engagement with intervention components.⁹⁷ Given this, and that the psychological predictors of weight loss appear to differ by race,⁹⁸ behavioral interventions may need to be tailored specifically to African American populations to maximize weight loss. Further, African Americans, especially African American women, experience obesity at a greater rate than do other race/ethnic groups.⁹⁹ African American cultural norms may influence these obesity rates. It has been documented that African American women tend to be more accepting of larger body sizes.¹⁰⁰ Obese African Americans tend to underestimate their actual weight¹⁰¹ and do not believe that health consequences of obesity exist until one is severely obese.¹⁰² In addition, African American women report that family members and significant others either do not comment on body weight or do not support weight loss.¹⁰³ There is also evidence of racial differences in body weight satisfaction/norms; African American women tend to “prefer” higher levels of body weight and have different perceptions of their body shape than do White women.^{104,105} Additional racial differences exist, with data showing that non-Hispanic White women perceive greater social pressure for weight loss than do African American women.¹⁰⁶ These race

differences may partially explain the differential response to obesity treatment vis a vis differences in perceived health risks associated with excess body weight and motivations for weight loss. This is an important area for future research.

Although previous studies have demonstrated greater weight loss in men than in women,¹⁰⁷ we did not identify any sex differences in our study. Indeed, the percentage weight loss experienced by patients in the ILI group was almost identical in men and women. These results also do not support those from the Look AHEAD study, where men experienced greater weight loss than did women at 2 years.⁸¹ The reasons for these disparate results are not clear.

Our results suggest that age may be an important factor in weight loss. Older adults experienced greater weight loss in the intervention group than did younger adults. In the DPP, older age was positively associated with meeting the 7% weight loss goal at the end of the 2-year intervention.¹⁰⁸ Similarly, a positive graded association was observed across age groups and weight loss at 2 years in the Look AHEAD lifestyle intervention group.⁸¹ In our study, the difference in weight loss between the UC and ILI groups did not differ by age (ie, older adults in the UC also lost more weight than did other age groups); therefore, it is possible that we may have observed some age-related weight loss in the overall cohort of patients.

Generalizability and Implementation of Results

The strengths of this trial warrant discussion.⁶⁴ A major strength is the diverse sample of clinics and patients from urban and rural regions of Louisiana, which represents a population typically underserved in clinical research. Thus, the results of this trial are broadly generalizable to the large, underserved, low-income population in the United States that faces significant barriers to receiving effective weight loss treatment. Another strength is the incorporation of a health coach into the collaborative care team, which represents a potential model for future weight loss programs in primary care settings. CMS covers intensive behavioral therapy for obesity delivered by a PCP¹⁵; however, the sole reliance on PCPs to deliver obesity treatment has limitations. Our results illustrate the effectiveness of a non-PCP (ie, a health coach) delivering obesity treatment based on current guidelines within the primary care setting. Last, our patient-centered approach to all facets of the trial and our detailed retention plan, inclusive

of phone calls, text messages, birthday cards, letters, etc, likely contributed to high patient retention rates (83% at 24 months). However, the \$75 stipend offered to patients on completion of the assessment visits may have also encouraged high retention, in which case future implementation of a similar program when such stipends are unavailable may lead to lower retention.

Although our program is likely broadly generalizable to primary care patients with obesity, there are potential barriers to future widespread implementation related to patients' lack of financial resources, program engagement, and current health care reimbursement structures. Patients may lack access to healthy, affordable foods, as noted by the high prevalence of food insecurity and low household income among patients in our study. Patients in the PROPEL trial were initially provided healthy food options at no cost, but this may not be an option for future implementation. PROPEL also provided patients with handouts of low-cost healthy food options available in local neighborhood stores along with estimated pricing, a strategy that can be implemented in the future; however, this is a difficult barrier to address fully. Further, underserved populations may have competing demands for their time, including a lack of childcare or transportation and the inability to take time off work to attend their weight management visits within the clinic. PROPEL experienced reasonable intervention engagement, with nearly 70% of ILI patients receiving at least 80% of the study materials; however, the more-engaged patients lost more weight. Therefore, future program success will need to address these barriers in various ways, such as providing transportation to and from the clinic for visits and occasionally providing program coaching sessions by phone or through a virtual platform, according to the patient's needs. Perhaps the largest barrier to widespread implementation is that the PROPEL model relies on a health coach with advanced nutrition knowledge to deliver the program, which is not currently reimbursable by CMS. Out-of-pocket costs are likely to prevent participation by most underserved patient populations. Thus, clinic administrators, PCPs and the collaborative care team, and health care payers all have a role to play in overcoming barriers to the successful implementation of weight management programs in primary care.

Study Limitations

A limitation of the study is that our sample was composed primarily of women (approximately 84%), which limits our ability to examine differences in weight loss across sex-by-race subgroups. However, our study is not unique in this regard, as women have made up an average of 73% of the samples in other lifestyle-based weight loss interventions.^{22,109} Our study encountered and addressed additional challenges and limitations in implementation that are likely unique to trials conducted in health care settings.

An overarching theme to the challenges incurred relates to the fact that patient care, not research, is the priority within primary care clinics, which necessitates adaptable study practices. Although we did not formally track instances in which the needs of the clinical practice created logistical challenges for the study, we observed this across all 18 clinics. It was essential to the study team, as well as future study teams in health care settings, to minimize the clinic's burden to participate in the research study by recognizing that clinical care is the priority and that study personnel are guests in the clinic. Related to this, we initially experienced slow patient recruitment, which necessitated a decrease in the study's sample size from 1080 to 800 patients. The one-size-fits-all recruitment approach, which relied too heavily on active participation of clinic PCPs and clinical staff, was problematic. Thus, we consulted with clinic personnel, stakeholders, and patient partners to develop clinic-specific recruitment strategies, such as EMR-based approaches and increasing study staff presence and efforts. After we customized the recruitment strategies, PROPEL successfully met the revised recruitment targets, which provided adequate statistical power to detect as little as a 3.5-percentage-point difference between the ILI and UC groups at 24 months.

Finally, low survey completion rates among PCPs (52% at baseline, 23% at 24 months) precluded our intended investigation of practice-level changes; in fact, the 50% baseline survey completion rate reflects the engagement level typically seen for PCPs who have many competing demands for their time.^{110,111} The low end-of-trial survey response reflects the high PCP turnover observed within the clinics, with the highest turnover observed within FQHCs. Nearly 30% of the PCPs with patients enrolled in PROPEL were no longer employed within the

clinic by the end of the trial and were thus lost to our attempts to follow-up with PCPs. The low survey completion rates may also reflect overall low engagement in the trial; however, all PCPs were involved in the recruitment process and provided medical clearance for all enrolled patients. Additionally, we tracked use of the password-protected PROPEL website on which all PCP webinars were posted; only PROPEL PCPs had access. The website indicates moderate engagement, with 140 page views from 40 unique visitors.

Future Research

Our results demonstrate the effectiveness of a high-intensity lifestyle-based obesity treatment program (ILI), consistent with the 2013 AHA/ACC/TOS guidelines, in an underserved primary care population. The ILI group experienced an average of 5% weight loss, and 51% of patients maintained at least 5% weight loss at 24 months. Treatment models based on the AHA/ACC/TOS guidelines that are adapted to real-life settings and that add effective delivery methods for obesity treatment in primary care are needed. The results from the PROPEL trial demonstrate that significant weight loss in primary care is possible by the addition of a health coach to the collaborative care team. These findings support the recommendation for a multidisciplinary approach to weight management in primary care.⁷⁵

CMS currently reimburses for obesity treatment delivered by a PCP¹⁵; however, our results provide support for expanding the eligibility for reimbursement to other members of a collaborative care team who can be trained in obesity treatment approaches such as the one used in this study. Novel reimbursement schemes for obesity treatment are needed to support the implementation of higher-intensity, evidence-based therapies more broadly across health systems. Innovative strategies to implement this approach across different health care settings should be explored using implementation science frameworks.¹¹² Further, given the proliferation of EMRs, electronic scales, and associated technologies in the last 5 years, there is a need to better understand the effectiveness of transitioning intervention delivery to new technologies, such as EMR patient portals, and using telemedicine to deliver virtual sessions.

PROPEL patients may not have accessed the online tools, such as the CTS, as frequently as intended due to various barriers that we did not systematically identify during our trial.

Therefore, there is also a need to understand and provide solutions to increase the use of online intervention delivery tools, including patient portals and other telemedicine approaches, among both underserved and older populations. The low survey completion rate among PCPs in our and previous studies elucidates the need for future research to increase PCP engagement in research studies.

Additional barriers to PCP engagement in research and weight management practices should also be explored, including potentially high turnover rates among PCPs in community clinics over time. The webinar series for PCPs in the UC group addressed 1 such barrier, that of biases and stigma associated with obesity. Specifically, the webinar aimed to explore the issue in an effort to improve clinicians' interactions with patients with obesity, which is essential to providing high-quality, equitable health care. Although we did not measure implicit bias in this trial, we recognize it as a major issue in obesity treatment and one that future research should address. Most health care providers do not openly discriminate against their patients with obesity, but their implicit attitudes may guide their behavior and decision-making, which, in turn, may cause their patients to feel disrespect and mistrust.¹¹³ These feelings may discourage patients from seeking future care, resulting in poor health outcomes.¹¹³ Indeed, a systematic review of 42 articles examining implicit bias in health care professionals revealed that 83% of studies (n = 35) found evidence of implicit biases on the basis of various patient characteristics, including weight.¹¹⁴ All studies that examined correlations found that greater implicit bias among health care professionals was related to lower quality of health care.¹¹⁴ Future trials on weight management in health care settings should use tools, such as the Implicit Associations Test,¹¹⁵ to measure the implicit biases health care professionals may have regarding obesity in an effort to better understand the impact of these biases on health-related outcomes for patients with obesity.

CONCLUSIONS

This study addressed the gap between present-day obesity management guidelines and what is currently implemented in primary care.²² Our approach was a treatment model based on the AHA/ACC/TOS guidelines but adapted to real-life settings and coupled with effective delivery methods for obesity treatment in the primary care setting. The results from this pragmatic trial demonstrate that clinically significant weight loss in primary care is possible. We believe that the keystone of this outcome is the addition of a trained health coach to the collaborative care team to administer a high-intensity lifestyle, patient-centered intervention program.

Percentage weight loss at 24 months was significantly greater in the ILI group (−4.99% [95% CI, −6.02% to −3.96%]) than in the UC group (−0.48% [95% CI, −1.57% to 0.61%]), with a mean difference of −4.51% (95% CI, −5.92% to −3.10%) between the groups. Peak weight loss occurred during the first 6 months of the trial; however, clinically significant weight loss was maintained through 24 months. Additionally, we found clinically significant improvements in weight-related QOL in the ILI group compared with the UC group. Although improvements in cardiometabolic risk factors were limited, ILI patients had significantly higher HDL cholesterol than did the UC group at 24 months. Relative to the UC group, the ILI group also had significantly lower blood glucose at 12 months, but this was not sustained at 24 months. In conclusion, in our trial, the implementation of a high-intensity lifestyle–based obesity treatment program consistent with the 2013 AHA/ACC/TOS guidelines produced clinically significant weight loss and improvements in cardiometabolic risk factors and QOL over 24 months in underserved patients in primary care clinics.²²

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APPENDICES

Appendix A. Supplementary Tables/Figures

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Table S1. Propel Intervention Curriculum Session Topics.

Table S2. Number of Patients and Individual Usage of Specific ILI Toolbox Options.

Table S3. Characteristics of Participants in the Focus Groups.

Table S4. Unadjusted and Adjusted Differences from Baseline between Usual Care and the Intensive Lifestyle Intervention Groups for Changes in Weight Loss Variables over Two Years.

Table S5. Change from Baseline in Physical Activity and Dietary Intake over Two Years.

Table S6. 24-Month Changes from Baseline in Weight Loss Variables in the Intensive Lifestyle Intervention among Patients who Received <80% and $\geq$ 80% of Session Materials.

Table S7. Additional Contacts¹ between Health Coaches and Patients in the Intensive Lifestyle Intervention.

Table S8. Differences between Usual Care and the Intensive Lifestyle Intervention Groups for Changes in Weight Loss Variables over Two Years in African Americans and Other Races.

Table S9. Differences from Baseline between Usual Care and the Intensive Lifestyle Intervention Groups for Changes in Weight Loss Variables over Two Years in Women and Men.

Table S10. Differences from Baseline between Usual Care and the Intensive Lifestyle Intervention Groups for Changes in Weight Loss Variables over Two Years in Younger, Middle, and Older Adults.

Figure S1. Percent Changes in Body Weight from Baseline to 24 Months by Clinic.

Table S11. Changes from Baseline in Weight Loss Variables from a Sensitivity Analysis Using Data from 16 Clusters Instead of all 18 Clinics.

Table S1. Propel Intervention Curriculum Session Topics.

Session	Week	Session Topic
1	1	Welcome to PROPEL
2	2	Weight Path, Plan for Eating, and Toolbox Tools
3	3	Weight Path Review and Energy Balance
4	4	Phone Session: How's it going?
5	5	Let's Move More
6	6	Food Labels and Cutting Portions
7	7	Swapping Fruits and Vegetables
8	8	Phone Session: How's it going?
9	9	Healthy Protein Choices
10	10	Healthy Carbs
11	11	Fast Food
12	12	Phone Session: How's it going?
13	13	Asking for Support & Eating Less During the Holidays & Special Events
14	14	Healthy Snacking
15	15	Eating foods that fill you up
16	16	Phone Session: How's it going?
17	17	Dealing with Stress
18	18	Skip the Extra Calories
19	19	Flavoring your food
20	20	Phone Session: How's it going?
21	21	Preparing for Monthly Meetings
22	22	Phone Session: How's it going?
23	24	Grocery shopping without breaking the bank
24	28	Phone Session: Stay Motivated
25	32	Setting and meeting your goals
26	36	Phone Session: Getting the most of your time
27	40	Easy Food Swaps
28	44	Phone Session: Mindfulness
29	48	Losing weight and keeping it off
30	52	Phone Session: Reward yourself for meeting your goals
31	56	Change the way you eat
32	60	Phone Session: Find time to keep moving!
33	64	Stay on track at family events
34	68	Phone Session: Can anyone help over here?
35	72	Making cues work for you
36	76	Phone Session: I've got to have it!
37	80	Avoid Added Sugar
38	84	Phone Session: Challenge yourself
39	88	Avoid High Calorie, Unhealthy Foods
40	92	Phone Session: Goal setting review
41	96	Have a plan for slip ups
42	100	Phone Session: Ending strong
43	104	Congratulations!

Table S2. Number of Patients and Individual Usage of Specific ILI Toolbox Options.

Toolbox option	Patients n (%) ^a	Uses n (%) ^b
Weigh yourself every day	441 (97.6)	5995 (41.6)
Use a meal replacement or single serving food for both lunch and dinner for 7 days	425 (94.0)	2633 (18.3)
Swap some of your foods for healthier ones	413 (91.4)	4958 (34.4)
Write down everything I eat	374 (82.7)	3280 (22.7)
Make an agreement with yourself that you will choose certain healthy foods or activities over unhealthy ones	363 (80.3)	2830 (19.6)
Make changes in the way I cook my meals	327 (72.3)	3335 (23.1)
Attend all of your sessions with your coach	309 (68.4)	1500 (10.4)
Keep track of what you are eating	299 (66.2)	1400 (9.7)
Use one serving sized foods ____ times a week / day ^c	296 (65.5)	2514 (17.4)
Control how much you eat by measuring your food ____ times a week / day ^c	283 (62.6)	1624 (11.3)
Remove the foods and cues that make you want to eat more and move less	281 (62.2)	1398 (9.7)
Use a meal replacement ____ times a week / day ^c	264 (58.4)	2018 (14.0)
Make an eating plan with your coach	253 (56.0)	1070 (7.4)
Write down how much activity you are doing	233 (51.5)	1408 (9.8)
Review what you've learned in your Make it Happen Book	217 (48.0)	670 (4.6)
Cook my meals at home ____ times this week ^c	163 (36.1)	1355 (9.4)
Plan to make healthy meals at home instead of eating out ____ times a week / day ^c	155 (34.3)	323 (2.2)
Your coach will contact you every few days	151 (33.4)	338 (2.3)
Eat the same breakfast, lunch and snacks each day ____ times a week / day ^c	150 (33.2)	383 (2.7)
Eat single serving foods ____ times a week / day ^c	132 (29.2)	613 (4.3)
Add ____ steps to what you are already doing each day ^c	74 (16.4)	165 (1.1)
Call my coach ____ times this week ^c	65 (14.4)	113 (0.8)
Wear a step tracker (pedometer, Fitbit)	0 (0)	0 (0)
Practice paying more attention to what, when, and how you feel when you eat	0 (0)	0 (0)

^aNumber and percentage of unique ILI patients who were assigned each toolbox option by their health coach during at least one intervention session. The same patient may be assigned the same toolbox option at multiple intervention sessions.

^bNumber and percentage of intervention sessions across all 452 intervention patients in which the health coach assigned each toolbox option.

^cSpecific number was determined through shared decision making between the health coach and patient.

Table S3. Characteristics of Participants in the Focus Groups

Characteristic	Patients	Healthcare Providers^a
Age, years	n=28, %	n=6; %
18-35	11	33
36-55	32	50
56-65	32	17
≥66	25	
Race		
White	36	67
African American	64	17
Asian	0	16
Sex		
Male	14	50
Female	86	50
Education		
0-8 grade	0	0
Some high school	14	0
High school	18	0
1-3 years college	36	0
College degree	11	0
Postgraduate degree	21	100
Employment		
Full time	14	100
Part time	0	0
Medical disability	25	0
Unemployed	21	0
Retired	40	0
Annual income, \$^b		
10,000	36	0
10-19,999	11	0
20-29,999	7	0
30-39,999	21	0
50-59,999	7	0
60-69,999	7	0
≥70,000	11	100

^aPhysicians and nurse practitioners.^bTotal household income.

Table S4. Unadjusted and Adjusted Differences from Baseline between Usual Care and the Intensive Lifestyle Intervention Groups for Changes in Weight Loss Variables over Two Years.

Variable	Unadjusted	Adjusted ¹	Adjusted ²
Change in Body Weight (%)			
At 6 months	-6.75 (-8.11, -5.39)	-6.86 (-8.05, -5.68)	-6.68 (-8.08, -5.28)
At 12 months	-6.02 (-7.51, -4.54)	-6.16 (-7.47, -4.85)	-5.98 (-7.49, -4.47)
At 18 months	-5.08 (-6.60, -3.57)	-5.22 (-6.57, -3.88)	-5.04 (-6.58, -3.50)
At 24 months	-4.37 (-5.95, -2.80)	-4.51 (-5.93, -3.10)	-4.33 (-5.93, -2.73)
Change in Body Weight (kg)			
At 6 months	-6.83 (-8.30, -5.36)	-6.98 (-8.26, -5.71)	-6.87 (-8.41, -5.32)
At 12 months	-6.05 (-7.63, -4.47)	-6.23 (-7.63, -4.83)	-6.11 (-7.76, -4.46)
At 18 months	-5.07 (-6.69, -3.46)	-5.26 (-6.69, -3.82)	-5.14 (-6.82, -3.46)
At 24 months	-4.33 (-6.00, -2.65)	-4.51 (-6.01, -3.02)	-4.39 (-6.13, -2.66)
Change in Waist Circumference (cm)			
At 6 months	-5.73 (-6.83, -4.63)	-5.85 (-7.04, -4.66)	-6.00 (-7.39, -4.60)
At 12 months	-5.83 (-7.05, -4.60)	-5.95 (-7.25, -4.65)	-6.10 (-7.60, -4.61)
At 18 months	-5.41 (-6.65, -4.16)	-5.54 (-6.86, -4.22)	-5.69 (-7.20, -4.18)
At 24 months	-5.00 (-6.29, -3.71)	-5.13 (-6.50, -3.77)	-5.28 (-6.83, -3.74)

Values are mean difference (95% C.I.)

¹Adjusted for age, race and sex

²Adjusted for age, race, sex, and clinic level variables (clinic size, %African American, %Medicaid)
95% confidence intervals which do not include zero indicate a statistically significant result.

Table S5. Changes from Baseline in Physical Activity and Dietary Intake over Two Years.

Variable	UC	ILI	Difference
Change in Total Daily PA (min/day)			
At 6 months	3.57 (-7.39, 14.53)	23.21 (11.98, 34.43)	19.64 (5.76, 33.51)
At 12 months	7.67 (-4.15, 19.50)	19.61 (7.59, 31.63)	11.94 (-3.25, 27.12)
At 24 months	3.82 (-7.64, 15.29)	10.91 (-0.76, 22.59)	7.09 (-7.55, 21.73)
Change in Percent Fat Intake			
At 6 months	-0.93 (-1.80, -0.07)	-3.31 (-4.17, -2.45)	-2.37 (-3.46, -1.29)
At 12 months	-0.89 (-1.77, -0.02)	-2.66 (-3.52, -1.79)	-1.76 (-2.85, -0.67)
At 24 months	-0.63 (-1.60, 0.33)	-2.73 (-3.67, -1.78)	-2.09 (-3.31, -0.87)

Values are mean changes (95% C.I.).

CI: Confidence interval; UC: Usual care; ILI: intensive lifestyle intervention; PA: Physical activity.

All models included age, sex and race as covariates.

95% confidence intervals which do not include zero indicate a statistically significant result.

Table S6. 24-Month Changes from Baseline in Weight Loss Variables in the Intensive Lifestyle Intervention among Patients who Received <80% and ≥80% of Session Materials.

Variable	<80% of Materials	≥80% of Materials
Change in Body Weight (%)	-1.93 (-3.81, -0.06)	-7.07 (-8.58, -5.56)
Change in Body Weight (kg)	-2.00 (-3.90, -0.11)	-7.39 (-8.92, -5.87)
Change in Waist Circumference (cm)	-1.87 (-3.71, -9.02)	-6.13 (-7.61, -4.65)

Values are mean changes (95% C.I.).

Results are from a linear mixed model including age, sex, race and baseline weight as covariates.

95% confidence intervals which do not include zero indicate a statistically significant result.

Table S7. Additional Contacts¹ between Health Coaches and Patients in the Intensive Lifestyle Intervention.

Contact Method	Total Number	Per Patient Mean (Range)
In Person	626	1.38 (0-23)
By E-mail	33	0.07 (0-4)
By Phone	306	0.68 (0-12)
By Text	6852	15.16 (0-91)
Other Method	2	0.004 (0-1)
Total (All Methods)	7819	17.29 (0-93)

Intensive Lifestyle Intervention patients only (n=452).

¹Additional contacts reflect contacts in which some type of intervention content (i.e., 'weigh yourself daily', coaches assisting patients choose a meal, etc.) was delivered to the patient above the 43 scheduled sessions (i.e., a phone session which was scheduled as part of the 43-session intervention curriculum was not considered an additional contact). Retention efforts were not considered as additional intervention contacts as no intervention content was delivered.

Table S8. Differences from Baseline between Usual Care and the Intensive Lifestyle Intervention Groups for Changes in Weight Loss Variables over Two Years in African Americans and Other Races.

Variable	African American	Other
Change in Body Weight (%)		
At 6 months	-6.45 (-7.66, -5.23)	-7.81 (-9.16, -6.46)
At 12 months	-5.64 (-7.00, -4.28)	-7.56 (-9.38, -5.75)
At 18 months	-4.78 (-6.18, -3.38)	-6.30 (-8.23, -4.37)
At 24 months	-4.16 (-5.61, -2.71)	-5.33 (-7.57, -3.10)
Change in Body Weight (kg)		
At 6 months	-6.58 (-7.78, -5.38)	-7.84 (-9.53, -6.15)
At 12 months	-5.74 (-7.08, -4.40)	-7.54 (-9.64, -5.45)
At 18 months	-4.83 (-6.22, -3.44)	-6.31 (-8.51, -4.11)
At 24 months	-4.20 (-5.65, -2.75)	-5.23 (-7.65, -2.80)
Change in Waist Circumference (cm)		
At 6 months	-5.07 (-6.50, -3.65)	-7.37 (-8.80, -5.93)
At 12 months	-5.26 (-6.82, -3.71)	-7.28 (-9.05, -5.51)
At 18 months	-5.15 (-6.71, -3.59)	-6.32 (-8.18, -4.45)
At 24 months	-4.55 (-6.13, -2.98)	-6.23 (-8.34, -4.12)

Values are mean difference (95% C.I.)

All models included age and sex as covariates.

95% confidence intervals which do not include zero indicate a statistically significant result.

Table S9. Differences from Baseline between Usual Care and the Intensive Lifestyle Intervention Groups for Changes in Weight Loss Variables over Two Years in Women and Men.

Variable	Women	Men
Change in Body Weight (%)		
At 6 months	-6.83 (-7.94, -5.72)	-7.47 (-10.13, -4.81)
At 12 months	-6.32 (-7.59, -5.05)	-6.01 (-9.03, -2.99)
At 18 months	-5.22 (-6.53, -3.91)	-6.09 (-9.21, -2.98)
At 24 months	-4.83 (-6.21, -3.45)	-3.85 (-7.38, -0.31)
Change in Body Weight (kg)		
At 6 months	-6.71 (-7.78, -5.64)	-9.00 (-12.44, -5.56)
At 12 months	-6.17 (-7.41, -4.94)	-7.25 (-11.02, -3.48)
At 18 months	-5.04 (-6.32, -3.76)	-7.31 (-11.16, -3.47)
At 24 months	-4.71 (-6.06, -3.36)	-4.51 (-8.70, -0.32)
Change in Waist Circumference (cm)		
At 6 months	-5.58 (-6.69, -4.47)	-7.43 (-10.55, -4.31)
At 12 months	-6.03 (-7.28, -4.78)	-5.49 (-8.96, -2.01)
At 18 months	-5.58 (-6.85, -4.31)	-5.42 (-8.91, -1.94)
At 24 months	-5.28 (-6.59, -3.96)	-4.51 (-8.30, -0.72)

Values are mean difference (95% C.I.)

All models included age and race as covariates.

95% confidence intervals which do not include zero indicate a statistically significant result.

Table S10. Differences from Baseline between Usual Care and the Intensive Lifestyle Intervention Groups for Changes in Weight Loss Variables over Two Years in Younger, Middle, and Older Adults.*

Variable	Younger	Middle	Older
Change in Body Weight (%)			
At 6 months	-5.55 (-7.12, -3.99)	-7.17 (-8.51, -5.83)	-8.03 (-9.48, -6.58)
At 12 months	-5.21 (-7.18, -3.25)	-6.48 (-7.98, -4.98)	-7.18 (-8.94, -5.41)
At 18 months	-4.44 (-6.47, -2.41)	-5.69 (-7.23, -4.15)	-6.13 (-7.97, -4.29)
At 24 months	-4.33 (-6.60, -2.05)	-4.90 (-6.67, -3.13)	-4.89 (-6.78, -3.00)
Change in Body Weight (kg)			
At 6 months	-5.77 (-7.49, -4.06)	-7.36 (-8.74, -5.97)	-8.01 (-9.48, -6.54)
At 12 months	-5.36 (-7.42, -3.30)	-6.60 (-8.15, -5.06)	-7.13 (-8.92, -5.35)
At 18 months	-4.55 (-6.71, -2.40)	-5.73 (-7.32, -4.14)	-6.10 (-7.96, -4.24)
At 24 months	-4.39 (-6.75, -2.02)	-4.83 (-6.63, -3.03)	-4.89 (-6.80, -2.97)
Change in Waist Circumference (cm)			
At 6 months	-4.49 (-6.07, -2.91)	-6.43 (-7.99, -4.88)	-6.60 (-8.43, -4.77)
At 12 months	-4.72 (-6.74, -2.71)	-6.62 (-8.27, -4.97)	-6.70 (-8.75, -4.66)
At 18 months	-3.70 (-5.79, -1.60)	-6.82 (-8.45, -5.20)	-6.26 (-8.34, -4.18)
At 24 months	-4.06 (-6.27, -1.85)	-4.99 (-6.75, -3.23)	-6.26 (-8.39, -4.12)

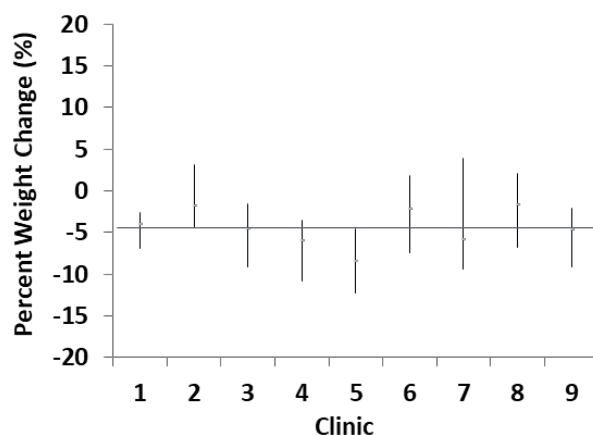
Values are mean difference (95% C.I.)

*Younger = 21-42 y; middle = 43-56 y; older = 57-74 y.

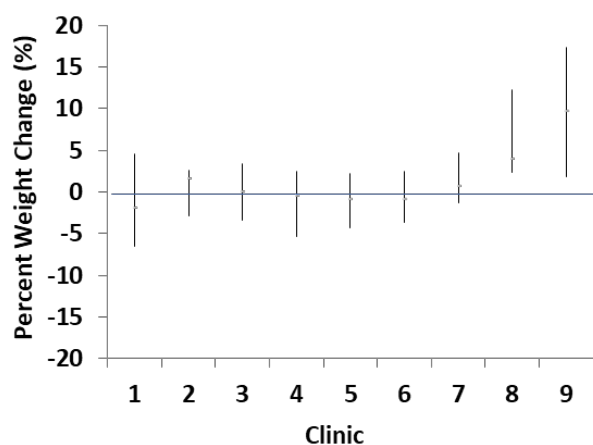
All models included sex and race as covariates.

95% confidence intervals which do not include zero indicate a statistically significant result.

A. 9 Intensive Lifestyle Intervention Clinics



B. 9 Usual Care Clinics



C. 7 Usual Care Clinics

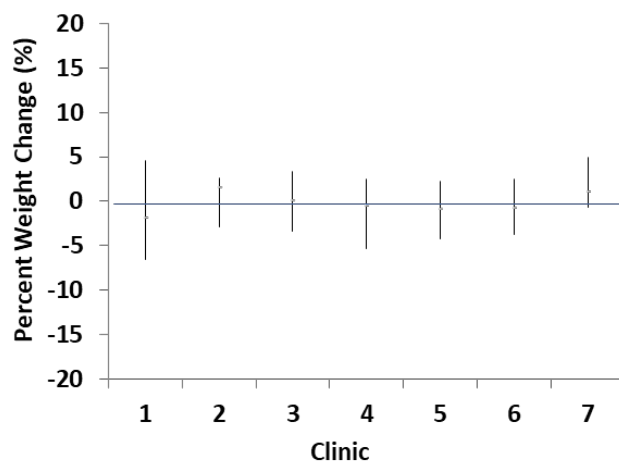


Figure S1. Percent Changes in Body Weight from Baseline to 24 Months by Clinic.

Shown are median percent weight loss changes in each clinic in the A) 9 Intensive Lifestyle Intervention (ILI) clinics, B) 9 Usual Care (UC) clinics, and C) 7 UC clinics (after combining 2 clinics that failed to recruit more than 4 patients with another UC clinic in close geographic proximity). The error bars represent the 25th and 75th percentiles of change. The blue lines indicate the median weight change in ILI or UC, respectively.

Table S11. Changes in Weight Loss Variables from a Sensitivity Analysis Using Data from 16 Clusters Instead of all 18 Clinics*

Variable	UC	ILI	Difference
Change in Body Weight (%)			
At 6 months	-0.55 (-1.50, 0.39)	-7.33 (-8.23, -6.44)	-6.78 (-7.98, -5.58)
At 12 months	-0.67 (-1.70, 0.36)	-6.75 (-7.72, -5.76)	-6.08 (-7.41, -4.75)
At 18 months	-0.49 (-1.55, 0.57)	-5.62 (-6.62, -4.63)	-5.13 (-6.49, -3.77)
At 24 months	-0.56 (-1.67, 0.55)	-4.99 (-6.03, -3.95)	-4.43 (-5.86, -3.00)
Change in Body Weight (kg)			
At 6 months	-0.91 (-1.93, 0.11)	-7.81 (-8.76, -6.85)	-6.90 (-8.19, -5.60)
At 12 months	-1.08 (-2.18, 0.02)	-7.22 (-8.25, -6.19)	-6.14 (-7.55, -4.73)
At 18 months	-0.91 (-2.04, 0.21)	-6.07 (-7.13, -5.02)	-5.16 (-6.61, -3.71)
At 24 months	-1.00 (-2.17, 0.17)	-5.42 (-6.52, -4.33)	-4.42 (-5.93, -2.91)
Change in Waist Circumference (cm)			
At 6 months	-1.04 (-1.99, -0.09)	-6.84 (-7.75, -5.93)	-5.80 (-6.99, -4.60)
At 12 months	-0.74 (-1.76, 0.29)	-6.63 (-7.61, -5.65)	-5.90 (-7.21, -4.59)
At 18 months	0.16 (-0.88, 1.20)	-5.33 (-6.32, -4.34)	-5.48 (-6.81, -4.16)
At 24 months	0.67 (-0.40, 1.74)	-4.42 (-5.44, -3.40)	-5.09 (-6.46, -3.72)

Values are mean changes (95% C.I.).

UC: Usual care; ILI: intensive lifestyle intervention; values are mean (95% C.I.)

All models included age, sex and race as covariates.

*2 clinics failed to recruit more than 4 patients (n=2; n=4) so data from these patients were combined with a usual care clinic in close geographic proximity to reduce the number of clusters from 18 to 16 for the sensitivity analysis.

95% confidence intervals which do not include zero indicate a statistically significant result.

Appendix B. Intervention Fidelity and Sustainability

Appendix B. Intervention Fidelity and Sustainability

Treatment or intervention fidelity was achieved first by relying on an experienced team of clinicians and clinical investigators to develop the intervention and supervise its delivery. The Intervention Team was led by Dr. Corby Martin, a Clinical Psychologist, and Dr. John Apolzan, who has a doctorate in Foods and Nutrition. Drs. Martin and Apolzan directly supervised a coordinator with a Master's of Science degree in psychology and extensive experience delivering interventions similar to the PROPEL intervention. The intervention coordinator managed the day-to-day delivery of the intervention and was the main liaison with the health coaches who delivered the intervention in their respective clinics throughout Louisiana. Further, the PROPEL intervention materials were designed based on the Diabetes Prevention Program (DPP),¹ Look AHEAD,² and CALERIE^{3,4} and were adapted for appropriate levels of health literacy via the guidance of Terry Davis, PhD and Connie Arnold, PhD. Drs. Davis and Arnold are health literacy and patient education experts and have extensive experience designing and delivering interventions that are health-literacy appropriate. Drs. Davis and Arnold provided guidance on the intervention materials and led integration of patient feedback about the intervention and its materials that was garnered from focus groups and Patient Advisory Board meetings. Finally, Drs. Davis and Arnold approved the intervention materials prior to study start.

The health coaches were also hired based on their training and clinical experience. Although it is difficult to identify and hire people with the desired credentials and level of clinical experience in rural locations, the health coaches who delivered the intervention throughout the study included Registered Dietitian Nutritionists and coaches with Master's degrees in counseling, health, exercise, or health promotion. To foster treatment fidelity, the coaches received two in-person multi-day training programs that were held at Pennington Biomedical. During this training, coaches learned the theoretical rationale for the intervention, observed experienced clinicians deliver mock sessions, and then conducted mock sessions under supervision and subsequently they practiced mock sessions with each other prior to seeing patients. In addition to the two initial training programs, coaches attend a re-training session at Pennington Biomedical once per year. The intervention coordinator also conducted

training sessions virtually, and these sessions were initiated by the Intervention Team when it was detected that a coach required additional training. Additionally, all coaches collected two audio recordings of patient sessions per month, and these sessions are reviewed by members of the Intervention Team and coaches were provided with feedback based on this review. The Intervention Team also attempted to conduct both announced and unannounced site visits to each clinic once per quarter, with each coach being directly observed delivering the intervention to enrolled patients. All coaches and the entire Intervention Team also participated in a weekly 1.5 hour virtual Intervention meeting that relied on the Computer Tracking System (CTS, described below). During this weekly meeting, each coach presented self-selected patient cases to the group to obtain help and suggestions on how to work with the patient, and the Intervention Team also selected cases to review based on the Team's review of the coach's patient data. Finally, for approximately the first year of the intervention, the Intervention Team conducted an additional weekly Regional Call with the coaches in each region to help the coaches address regional nuances that were affecting delivery of the intervention.

Intervention fidelity was further facilitated with the use of a Computer Tracking System (CTS) and toolbox that standardized intervention delivery over time, among patients, and among coaches. The CTS and toolbox were based on previous work and interventions,^{2,3,4} and the CTS provided different levels of data and access to the patients, coaches, and Intervention Team at Pennington Biomedical. It is password protected and Internet-based; hence, it is accessible via any Internet-enabled device. The patient materials (Lesson Materials, meal plans, etc.) were accessible in the CTS, and the coaches used the CTS as their sole source of patient management. Each patient's session materials were printed from the CTS, their meal plan was selected and printed from the CTS, and the coach kept their notes and attendance data in the CTS; thus, obviating the need for paper patient records. The CTS also houses a toolbox that helps standardize delivery of intervention components (e.g., the use of portion-controlled foods, increased contact with the coach, etc.) across patients. Specifically, the CTS tracks objectively if the patient is achieving their expected rate of weight loss and other goals (e.g., session attendance), and these data are used to prompt the coach and patient to utilize specific

intervention strategies based on the problem that the patient is experiencing. Hence, patients in different parts of Louisiana with different coaches were likely to receive the same treatment suggestions when they encountered the same problem, such as failing to lose weight at the expected rate. This method was used successfully in the Diabetes Prevention Program (DPP),¹ Look AHEAD,² and CALERIE.^{3,4} Dr. Martin led the intervention team, which included the same intervention coordinator, during CALERIE, and CALERIE relied on a very similar CTS. Finally, the CTS facilitated intervention fidelity by providing patient data at the patient level, coach level, clinic level, and study level. These data were summarized to identify if certain clinics or coaches were experiencing high or low levels of patient attendance or patient weight loss, for example, compared to other coaches or the overall study.

Intervention Sustainability

The PROPEL intervention provides a platform for a sustainable program. First, the intervention materials were created to have appropriate levels of health literacy and the materials were well-received by participants. Second, the intervention outlines strategies or tools to help people lose weight when they experience set-backs or challenges, and those tools can be deployed in programs that do or do not utilize a CTS. Third, the CTS can be used as a standalone program and integrated into Electronic Medical Records or other platforms that manage delivery of care. Further, the intervention and CTS can be adapted to meet the needs of other patient populations or to achieve different weight management goals.

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Appendix C. Data Management Plan

Quality Assurance and Control

Quality assurance and quality control is of utmost importance in a randomized clinical trial. Standardized protocols for all measurements were developed, and adherence to the written protocols was of paramount importance. All data collection personnel were certified as competent to make the required measurements by trained experts. The following provides an outline of the quality assurance and control program developed for PROPEL:

- Training and certification of all data collection personnel by experts
- Development of detailed manual of operations
- Retraining and recertification of all data collection personnel yearly
- Maintenance of logs of certified personnel
- Routine calibration of all equipment following manufacturers guidelines
- Maintenance of logs of calibrated equipment
- Performance of routine clinic site-visits and source document verification
- Setting realistic limits on data entry fields in REDCap
- Remote monitoring of data entry, missing data and lag times through REDCap
- Creating both real-time and subsequent executable data quality checks in REDCap
- Querying appropriate personnel regarding missing data
- Preparing quality control reports for personnel, investigators and Data and Safety

Monitoring Board

There were logistical issues that limited the research management staff's ability to perform site visits and monitor data collection readily at 18 remote clinics (budgetary restrictions, time constraints, limited staff, etc.). Therefore, consent was obtained from patients who were willing to have their intervention sessions audio and video recorded; consent status was data entered and tracked in REDCap. These recordings were used as a means of monitoring to ensure treatment fidelity. Participants who signed the consent to record their sessions were informed before each visit begins when the visit is being recorded.

Data Management

Assessment Data - REDCap

All data collected by the assessment team at SV, BV, and at month 6, 12, 18 and 24 assessment visits was transferred from paper form to the Research Electronic Data Capture (REDCap) system⁵ through data entry by study personnel. REDCap is a secure, HIPAA-compliant, web-based application that can be utilized for electronic collection and management of research and clinical trial data. Study data and electronic data capture tools are housed in a secure data center at Pennington Biomedical, and all web-based information transmission is encrypted. The server is backed up nightly and is protected by an enterprise network security firewall. REDCap was accessed through the Pennington Biomedical secure website, <https://redcap.pbrc.edu>, where research personnel were required to enter user ids and passwords previously approved and set up by the Pennington Biomedical REDCap Administrator.

The level of user access and privilege was determined on an individual basis and relied upon each user's role in the study and clinics they were associated with. Only select project management personnel were able to edit participant record IDs or export data; the data collection staff were only able to view, enter, and edit (not export) the participant data and run quality checks for the clinics with which they were associated. All data entered were run through multiple checks for internal consistency and biologic plausibility; these were conducted in REDCap with either real-time error messages and data stoppage rules or user-initiated query reports, as well as with study-specific SAS programs designed by the data manager. Missing or questionable data were assessed and corrected by research staff at the clinics or project management staff at Pennington Biomedical. All users were thoroughly trained in the use of the PROPEL REDCap data entry and validation system. Once it was determined that data collection, entry and verification was complete, the REDCap project was locked so that users were no longer be able to edit the data, but investigators were still able export and preserve the data. The trial data dictionary and associated metadata were developed by the data manager using the REDCap data dictionary functions.

Intervention Data – Computer Tracking System (CTS)

The internet-based Computer Tracking System (CTS) facilitated intervention delivery, treatment fidelity, scheduling of intervention visits with patients, and tracking of process measures for intervention delivery, such as attendance. The CTS allowed for tailoring the intervention to individual patients, and it was used by the intervention team to quantify process measures related to intervention delivery. Specifically, it was used to review participant session attendance, receipt of session materials, adherence to the diet based on the weight graph, and weight loss. These process data were provided in reports generated by the CTS, and these data were available at the study, clinic, counselor, and patient level. The CTS was housed on a HIPAA compliant server.

Assessment and Intervention Data Confidentiality

The assessment team, health coach, and project and data management staff had access to personally identifiable private information about human subjects. All volunteers were assured of their confidentiality both verbally and in the informed consent form. The facilities were strictly limited to the study staff, clinics and research volunteers. All study records were locked in a secure area in a locked filing cabinet. Access to these areas was limited to the clinical and research support staff and the study investigators. Study records were filed according to study identification numbers rather than by name. All forms in the chart, with the exception of the consent form and participant contact form, displayed only the ID number. Electronic data storage was similarly restricted in a password-protected, encrypted website.

Data Sharing

De-identified data and supporting documents will be made available upon request to the Principal Investigator: peter.katzmarzyk@pbrc.edu. Data availability will begin one year after publication of the primary outcomes paper.⁶ Data will be available to researchers whose proposed use of the data has been approved by the PROPEL Publications Committee for scientific publications. Data will be transferred with a signed data use agreement with the Pennington Biomedical Research Center.

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