Title

Tailored weight loss intervention in obese adults within primary care practice: Rationale, design, and methods of Choose to Lose

Journal

Contemporary Clinical Trials, 38(2)

ISSN

1551-7144

Authors

Hartman, Sheri J
Risica, Patricia M
Gans, Kim M
et al.

Publication Date

2014-07-01

DOI

10.1016/j.cct.2014.06.001

Peer reviewed

Published in final edited form as:
Contemp Clin Trials. 2014 July ; 38(2): 409–419. doi:10.1016/j.cct.2014.06.001.

Tailored weight loss intervention in obese adults within primary care practice: Rationale, design, and methods of Choose to Lose

Sheri J. Hartman[a,b,*], **Patricia M. Risica**[c,d], **Kim M. Gans**[c,e], **Bess H. Marcus**[a], and **Charles B. Eaton**[d,f,g]

[a] Program in Public Health, Department of Family and Preventive Medicine, University of California San Diego, San Diego, CA, USA

[b] Cancer Prevention and Control, University of California San Diego Moores Cancer Center, San Diego, CA, USA

[c] Institute for Community Health Promotion, Brown University School of Public Health, Providence, RI, USA

[d] Department of Epidemiology, School of Public Health, Brown University, Providence, RI, USA

[e] Department of Behavioral and Social Sciences, School of Public Health, Brown University, Providence, RI, USA

[f] Center for Primary Care and Prevention, Memorial Hospital of Rhode Island, Pawtucket, RI, USA

[g] Department of Family Medicine, Alpert Medical School of Brown University, Providence, RI, USA

Abstract

Although there are efficacious weight loss interventions that can improve health and delay onset of diabetes and hypertension, these interventions have not been translated into clinical practice. The primary objective of this study is to evaluate the effectiveness and cost effectiveness of a tailored lifestyle intervention in primary care patients. Patients were recruited by their primary care physicians and eligible participants were randomized to an enhanced intervention or augmented usual care. All participants met with a lifestyle counselor to set calorie and physical activity goals and to discuss behavioral strategies at baseline, 6 and 12 months. During the first year, enhanced intervention participants receive monthly counseling phone calls to assist in attaining and maintaining their goals. Enhanced intervention participants also receive weekly mailings consisting of tailored and non-tailored print materials and videos focusing on weight loss, physical activity promotion and healthy eating. The second year focuses on maintenance with enhanced intervention participants receiving tailored and non-tailored print materials and videos regularly throughout the year. Augmented usual care participants receive five informational handouts on weight loss across the two years. This enhanced intervention that consists of multiple modalities of print, telephone, and video with limited face-to-face counseling holds promise for

[*] Corresponding author at: Moores UCSD Cancer Center, 3855 Health Sciences Drive, La Jolla, CA 92093-0901, USA. Tel.: +1 858 534 9235; fax: +1 858 822 2399. sjhartman@ucsd.edu (S.J. Hartman)..

being effective for encouraging weight loss, increasing physical activity and healthy eating, and also for being cost effective and generalizable for wide clinical use. This study will fill an important gap in our knowledge regarding the translation and dissemination of research from efficacy studies to best practices in clinical settings.

Keywords

Weight loss; Primary care; Tailored intervention; Physical activity

1. Introduction

Obesity is a major public health problem that has reached epidemic proportions with 65% of the adult U.S. population overweight or obese [1]. Overweight individuals are at risk for developing co-morbid medical problems including hypertension, diabetes, and dyslipidemia. Many obese people already have these co-morbid medical problems, which along with obesity places them at increased mortality risk [2–4]. Primary care physicians (PCPs) are in a unique position to motivate patients to lose weight, improve their diet, and increase physical activity because they reach most segments of the population, and their expertise is highly regarded by patients [5]. Although interventions can produce weight reduction to improve health, and delay onset of diabetes and hypertension, existing research has not been translated into clinical practice. Most weight loss trials have been efficacy studies conducted on highly motivated participants led by teams of experts using multiple face-to-face encounters [6–11]. The expense and resource utilization involved in these efficacy trials make such an approach impractical and cost prohibitive in clinical practice. Most weight loss trials focusing on PCP counseling have been less intensive and have not demonstrated efficacy [12–18]. However, there is growing evidence that PCP referrals to weight loss programs and use of non-face-to-face interventions can be effective for weight loss [19–22]. Additionally, a recent, highly efficacious and less costly approach to the promotion of health behavior change has been the development of tailored interventions that match patient characteristics and treatment needs often delivered using computerized expert systems. Tailored interventions can be implemented by print, telephone, video or a combination of these media with limited face-to-face counseling [23–29]. They hold promise to be not only effective for encouraging weight loss, but also cost effective and generalizable for wide clinical use. These practical, innovative interventions can be easily replicated and sustained linking primary care practices with home-based programs supported by third party payers or employers. This study tests such an intervention in overweight or obese adults in a primary care setting using a randomized controlled trial.

The primary aim is to evaluate the effectiveness of a tailored lifestyle intervention in primary care patients: the Choose to Lose Study. First, we hypothesize that the enhanced intervention group would demonstrate greater reductions in their body mass index (BMI) and better maintenance of this change at 2 years compared to the augmented usual care group. Second, we hypothesize that the enhanced intervention group would engage in greater levels of physical activity and would demonstrate greater reductions in total calories

and maintain these changes at the 2 year follow-up compared to the augmented usual care group.

The study has two exploratory aims: 1. To evaluate the cost of the intervention for replication purposes and the cost effectiveness of the intervention per unit of BMI loss (as well as physical activity and dietary change). 2. To examine relationships among important mediating variables with changes in BMI, diet and physical activity. These variables include: self-efficacy, decision-making, processes of change, perceived barriers, perceived social support, behavioral capability, outcome expectations, and problem solving skills. We will examine whether these variables mediate the intervention's success. We anticipate that successful weight loss, physical activity and dietary change will be correlated with positive changes in many of the above variables.

2. Methods

2.1. Overview of study design

This study is testing a tailored lifestyle weight loss intervention in overweight/obese patients recruited from primary care practices. A total of 211 patients with a BMI above 25 kg/m^2 were recruited from 24 PCPs. Participants were randomized into either a tailored lifestyle intervention focused on weight loss, physical activity, and nutrition (Enhanced Intervention) or a non-tailored, less intensive weight loss intervention (Augmented Usual Care). The intervention lasted 24 months, with the first 12 months focused on weight loss and the second 12 months focused on maintenance. All study procedures and materials were approved by the Institutional Review Boards at Memorial Hospital of Rhode Island and Brown University.

2.2. Recruitment of primary care providers

In April 2010, 111 provider recruitment letters were sent out to Family and Internal Medicine physicians representing 86 practices in Rhode Island and southeastern Massachusetts. Of the letters sent, 41 providers showed interest in the Choose to Lose Study, 2 providers declined. Of the 41 interested providers, 17 providers were not approached due to the following reasons: only one PCP per practice eligible to participate; PCP leaving the area; the geographic location of the practice; time constraints on the practice; or their self-reported inability to recruit at least 20 overweight/obese patients into the study. In the fall of 2010, the eligible providers were contacted to schedule a visit with the Principal Investigator (CBE) to provide detailed information about the study. Between October 2010 and September 2011, 24 providers (representing 24 practices) were consented and formally enrolled.

2.3. Participant eligibility criteria

Inclusion criteria included: men and women at least 18 years of age and less than 80 years old whose BMI was ≥25 kg/m^2; available for the entire 24-month study period; able to read and speak English; able to provide informed consent; able to accept phone calls; able to attend study visits; and have access to a DVD player.

Exclusion criteria included: diagnosed or hospitalization for active CVD disease in the past 6 months; history of a significant orthopedic limitations or other conditions that make exercise dangerous or extremely difficult; limited physical ability to be active (e.g., unable to walk briskly); another family member in the study; unstable psychiatric co-morbidity; participant requesting surgical treatment of obesity; weighing over 400 lb; participating in another clinical trial with regard to obesity or physical activity; having poorly controlled diabetes mellitus (hospitalized for poor diabetes control in the past 6 months); limited prescribed diet (e.g. gluten free diet); present treatment for an eating disorder; taking over the counter diet aids or medications for weight loss for the previous 6 months; underwent treatment for cancer in the past 5 years; end stage renal disease requiring dialysis; chronic steroid therapy; major surgery in the past month; planning a pregnancy in the next two years or delivered a baby within the past six months; exercising ≥90 min/typical week of moderate intensity activity; unwilling or unable to complete study requirements.

2.4. Recruitment of participants

Patients were recruited through their PCPs. Recruitment occurred in two ways: 1) the provider obtained their patients' written authorization for them to be contacted by the research staff or 2) after discussing the study with their provider, patients initiated contact with the research staff.

Patients were screened over the phone for initial study eligibility. Final eligibility was determined at the baseline clinic visit, during which written informed consent was obtained. Participants were asked to perform specific tasks in order to qualify for randomization. Tasks included completing all procedures at the baseline clinic visit, including all questionnaires and filling out a food and exercise journal for seven days. Of the 610 people screened, 430 were eligible, interested, and scheduled for the in-person screening visit. Of those scheduled, 61 declined to continue in the study and 58 could not be contacted. The most common reasons for declining to participate in the study were related to the time commitment of participating in a research study of two years duration, having to attend multiple in person visits, the experimental nature of being randomized, and time commitment and intensity of self-recording (food and exercise journals) required to participate. 211 met all eligibility requirements and enrolled in the study. See Fig. 1 for breakdown of eligibility and randomization of participants.

2.5. Participant randomization

Participants were admitted to the study using rolling enrollment with participant as the unit of randomization. To insure balance between the two arms of the study, participant randomization occurred in blocks of 2 within practice and high/ low risk status based upon co-morbidities and behavioral risk factors. Successfully screened and eligible participants were assigned the first available randomization ID by practice and risk status. All randomizations were assigned using the random number generator within SPSS for Windows, version 11.0 (SPSS Inc., Chicago, IL). Of the 211 participants recruited, we had 105 participants in the ‘Enhanced Intervention’ arm of the study and 106 participants in the ‘Augmented Usual Care’ arm.

2.6. Design considerations

Several considerations were made when designing the current study. We chose using an 'Augmented Usual Care' arm, rather than a true control group for multiple reasons. First, we wanted to provide the control arm with care that is typically covered by health insurance plans. Second, many PCPs were unwilling to participate if their participants could be assigned to a group that received no intervention. Third, by providing the control arms with some intervention, we hoped to prevent PCPs from referring participants to other weight loss programs. Lastly, we wanted to limit loss to follow-up in the control arm.

We also considered randomizing by practice to prevent contamination within practice, but PCPs refused to participate if all of their patients would be in the control group. Therefore, we chose the risk of possible contamination within practice so that we would be able to work collectively with the PCPs and be responsive to their concerns. However since the intervention occurs outside of the PCP office, we expect contamination to be minimal or non-existent.

3. Intervention

See Fig. 2 for overview of intervention timeline.

3.1. Training of primary care physicians

PCPs and their relevant staff members participated in a training session to aid in their ability to successfully refer patients to the study. Providers were shown a 30-minute PowerPoint presentation that reviewed the relevant research upon which this study was founded, reviewed inclusion and exclusion criteria, the proposed intervention and outcomes to be measured including chart audits after completion of the study. PCPs were encouraged to capitalize on any teachable moment occurring in the appointment and provide a launch pad on which to promote weight loss and participation in the study. PCPs were also taught about a framework for successful weight loss that would be used for the study including setting reasonable weight loss and physical activity goals, limiting calories, and the importance of self-monitoring weight, diet, and physical activity. The PCPs primary role was to assess patient's motivation to lose weight and then refer appropriate patients to the current study, but the PCPs also received updates on participants' progress throughout the study. These updates served to support PCPs in management of related medical co-morbidities, and also provided participants with additional accountability to encourage adherence to the intervention.

3.2. Training of the lifestyle counselors and quality control

The face-to-face and phone intervention components were delivered by Lifestyle Counselors (LCs). All LCs were registered dietitians with significant nutrition counseling training, prior experience and training in using counseling for behavior change. For the study, the LCs received additional training on using motivational interviewing skills within the intervention protocol. They also received training on how to use motivational interviewing to promote dietary and physical activity changes and to set behavior change goals. All trainings were led by PhD level investigators with extensive experience in health behavior change and

motivational interviewing. All intervention sessions were recorded and 20% of the recordings were reviewed for consistency and use of motivational interviewing skills. The LCs also received ongoing supervision and feedback throughout the study from PhD level clinical psychologists.

3.3. Intervention components common to both arms

3.3.1. Formative research—To inform the development of intervention components, four focus groups were held with a total of 37 people in attendance. The groups reviewed newsletters and DVDs to provide feedback; debated the potential effectiveness/pros and cons of proposed study components; and discussed their overall experience with weight loss and weight loss programs, successful and less successful components, and other ideas and suggestions regarding weight loss programs. The information gathered from these focus groups was used to adapt the intervention.

3.3.2. Orientation visit—Prior to randomization, all participants had an orientation visit with the LC. Prior to this visit, participants were given a 7-day food and exercise journal, asked to complete and bring to this visit. At this visit participants were informed about the benefits of a 10% weight loss for their health. They were given a weight loss goal of 10% of their current weight over the next 6 months, but were able to set a personalized weight loss goal. All participants were asked to weigh themselves at least weekly. They discussed the benefits of regular weight checks and were instructed on how to record their weight on the journals. Participants were then given a calorie and fat gram goal that was calculated based on their current weight that has been shown to produce a 7–10% weight loss in 6 months [30]. Participants reviewed with their LC the previous week's food and exercise journals and the LCs guided them in calculating the number of calories and grams of fat they had for one day in their journal. Participants were also provided with a structured meal plan, based on their calorie goal, and instructed on how to use the meal plan. The meal plan provided guidance for the number of calories to eat at each meal and snack and provided examples of foods they could eat for each meal that totaled the recommended calories. Participants were given a Calorie King book and measuring cups and spoons to help them accurately record their calories. Using motivational interviewing techniques the LCs discussed the participants' perceived importance for meeting their calorie goal and their confidence in being able to meet the calorie goal.

Next the LCs focused on helping the participants increase their physical activity. Right before meeting with the LCs, study staff asked the participants to walk on a treadmill in the clinic at moderate intensity (3–4 mph) for 10 min to inform them of what moderate intensity activity felt like. The LCs discussed how the treadmill walk went and the benefits of engaging in moderate intensity physical activity for at least 10 min at a time. Participants were informed of the study's goal to eventually help them reach 300 min of moderate intensity of physical activity per week. They were provided with a suggested starting goal of adding 10 min of moderate intensity most days of the week to what they were currently doing, and then were asked to set their own specific exercise goal. Participants were asked to make a detailed plan of what activities they would do, what days and time they would do them, where they planned to be active, and for how long each time. The LCs discussed ways

to gradually increase the amount of exercise over time. The LCs reviewed several methods to assess exercise intensity and several information sheets on exercising safely. Participants were also instructed on how to record their exercise in the food and exercise journals. Then the LCs discussed the participants' perceived importance for meeting their exercise goal and their confidence in being able to meet the exercise goal.

At the end of the session participants unsealed an envelope that informed both the participant and the LC to which group the participant had been randomized. Randomization occurred after the baseline goal setting visit to help ensure that all participants received the same session regardless of group assignment. Each visit lasted about 90 min.

3.3.3. Feedback sent to PCP—As part of the PCP-led team-based approach to weight control, every six months, a summary report regarding weight, physical activity and dietary goals was sent to the PCPs about each of their patients in the study.

3.3.4. 6 and 12 month visits—All participants, regardless of group assignment (enhanced intervention or augmented usual care) met with the LCs at 6 and 12 months. At both sessions progress towards the weight loss goal was reviewed and if needed a new weight loss goal was set. They also discussed their progress in meeting their calorie and fat goal, set a dietary plan moving forward, and set a new calorie and fat goal if needed. Similarly they reviewed their progress in meeting their physical activity goal, set an exercise plan moving forward and set a new goal for minutes of exercise if needed. Participants discussed the role of self-monitoring in relation to weight loss, changing their diet, and physical activity. For each area, barriers to progress were identified and the LCs helped the participants to problem-solve around the barriers. LCs also helped participants to identify what was working well for them and to reinforce those behaviors. At the 6-month visit, all participants were provided with a pedometer and were encouraged to monitor the number of steps they took a day.

At the 12 month visit, the focus was on strategies for maintenance of behavior change. The LCs helped the participants to identify benefits they experienced, recognize their successes, discuss how to create a supportive environment, and ways to reward themselves. Barriers to maintenance of behaviors were identified and the LCs helped the participants to problem-solve around the barriers. At the 12-month visit participants were also encouraged to increase the amount of fruits and vegetables they were eating and to monitor their fruit and vegetable intake.

3.4. Intervention components for Enhanced Intervention group only

3.4.1. Feedback on self-monitoring—After randomization during the orientation visit, participants in the Enhanced Intervention group were instructed to mail their food and exercise journals in each week. For the first 6 months, LCs reviewed the journals, provided written feedback on the journals, and mailed them back to the participants each week with a new journal to complete. Data from the journals was entered into a computerized dashboard so that the information was easily accessible to the LCs for the intervention phone calls.

3.4.2. Intervention phone calls—Enhanced intervention participants received 20–30 minute counseling phone calls from their LC monthly for the first six months and every other month for the next 6 months. The purpose of the intervention calls was to provide support and assist the participants in attaining and maintaining their weight loss and physical activity goals. The LCs reviewed the progress towards the stated goals, helped participants identity barriers and problem-solve around the barriers, reinforce progress, or help set new goals as needed. The focus and topics discussed on the phone calls utilized were determined by the participants' needs.

Participants who had not met their weight loss goal at the 12-month face-to-face meeting were offered an additional counseling call at month 13. All participants were informed that even though there were no more planned calls they could call during the second year if they had questions or concerns they wanted to address with their LC.

3.4.3. Mailed print materials—Participants in the Enhanced Intervention group received weekly mailings for the first year, bi-weekly mailings for the first 6 months of the second year, and monthly mailings for the last 6 months of the second year. Participants received personally tailored and non-tailored materials about healthy food intake and physical activity based on constructs in the Social Cognitive Theory [31], Social Learning Theory [32] and the Transtheoretical Model [33].

The dietary feedback reports were tailored based on baseline surveys and information obtained by the LC through the dashboard (from participant submitted food and exercise journals) and from telephone counseling calls. These reports included content for participant self-regulation such as feedback on progress related to current amount of weight loss, meeting their calorie goal, and compliance with self-monitoring. This content reinforced participants' successes to bolster self-efficacy for behavior change. The LCs also chose several content areas to be included in the report reflecting topics that arose on the telephone counseling calls. These included topics to increase generative capacity about food such as, portion sizes, beverages, dining out, and junk food. Outcome expectancies were addressed through topics such as how dietary or behavior changes could improve health conditions such as, high blood pressure, diabetes, and heart disease. Facilitation was also addressed through attention to barriers to dietary change such as resistance of family members to healthy eating, perceptions of healthy food not tasting good, lack of motivation, and getting off track due to illness, vacation, etc. The counseling messages for each topic were written by Ph.D. level nutritionists.

Other non-tailored dietary content focused mainly on lower calorie eating choices and maintaining caloric restric tions during the first six months. During the second six months of the first year, transitioning off of the structured meal plan was emphasized including food preparation that emphasized lowering excess fat and other calories, increasing fruits and vegetables, portion control, eating out; behavioral changes such as building social support for healthy eating, stimulus control by changing one's physical environment, goal-setting, and overcoming barriers to healthier eating.

The exercise feedback reports were based on Social Cognitive Theory and Transtheoretical Model constructs in cluding decisional balance, self-efficacy, and outcome expec tancies. The reports were generated from a computer-based expert system in response to the participant's answers to monthly questionnaire items. These counseling messages were created by Ph.D. level psychologists. They provide feedback on: 1) how the participant compared to profiles of individuals who had successfully adopted and maintained physical activity (normative feedback); and 2) following the baseline assess ment, feedback regarding progress made on specific topic areas and changes in minutes of physical activity participation since the individual's prior assessment (progress feedback). Partic ipants also received booklets with messages matched to their current readiness (stage) for physical activity based on the Transtheoretical Model. These tailored materials have been efficacious in changing PA levels in previous studies [34–37].

Other non-tailored exercise content focused on various topics including exercising safely, getting social support for exercise, changing outcome expectations by making exercise fun, goal setting, and overcoming barriers to exercise.

All print materials were created targeting a fifth grade literacy level including the use of white space and limiting sentence length and large multi-syllable words. The materials also used visual images and grouped information into manageable “chunks”. Focus groups with the target population were conducted to review the materials and provide feedback on the look, feel and readability to ensure that the materials were appropriate in terms of health literacy.

3.4.4. Mailed DVDs—Participants in the enhanced intervention arm also received four DVDs across the first 18 months of the study, two about physical activity and two about dietary changes. At month 1, participants received a video that reviewed the definition of moderate intensity and the benefits of engaging in moderate intensity exercise. At month 3, participants received a commercial physical activity video that included easy workouts starting at 18 min long and worked up to more advanced workouts that were 60 min long. The video focused on brisk walking but also incorporated strength and flexibility exercise. Resistance stretch bands were also included so that they could be used during parts of the video. The last two videos were delivered during months 15 and 18, focusing on maintenance of weight loss after transitioning off of the calorie specific meal plan. These videos included three main segment types: testimonials from others who have struggled with weight loss offering many short vignettes of success; motivation by our narrator, who shared her personal story and encouragement from her experiences of successful weight loss and maintenance; food preparation segments with chef prepared food demonstrations of simple and easy ways to prepare nutritious foods without excess calories, and include more fruits and vegetables.

3.5. Intervention components for Augmented Usual Care group only

3.5.1. Self-monitoring—Participants in the Augmented Usual Care were given 6 weeks worth of food and exercise journals at the orientation visit, but were not asked to send them back and they did not receive any written feedback on their journals.

3.5.2. Mailed print materials—Participants in the comparison group received five pamphlets (three in year 1 and two in year 2) produced by the National Institute for Diabetes and Digestive and Kidney Diseases for healthy lifestyle, eating, and exercise through the mail across the first year. These pamphlets were on Weight Loss for Life, Active at Any Size, Healthy Eating and Physical Activity across Your Lifespan, Just Enough For You, and Weight-loss and Nutrition Myths.

4. Evaluation measures

Measures were obtained at baseline, 6, 12, 18, and 24. We chose to follow participants for 24 months to assess if weight loss could be maintained for the same time length of time as participants received the intense intervention (12 months). Measurement staff was blinded to group assignment to reduce measurement bias.

4.1. Body composition

4.1.1. BMI—Body weight (kg) and height (m) are measured and BMI is calculated as a measure of relative weight (weight/height^2). Height without shoes is measured to the nearest 0.1 cm using a calibrated stadiometer at research visits. Weight was measured to the nearest 0.1 kg using a calibrated and certified scale at baseline and during most visits.

4.1.2. Waist circumference—While the main focus of the intervention is change in weight or BMI, surrogate measures of intra-abdominal fat are also of secondary interest [38,39]. The waist measurement is the smallest girth between the rib cage and the iliac crest. The hip measurement is the largest horizontal girth between waist and thigh. Each circumference is obtained in the standing position at the end of normal expiration to the nearest 0.1 cm with a non-elastic plastic coated tape, using standard techniques [40]. Measures are obtained twice from each participant, and then averaged. If the difference between the first and second measurement is greater than 1.0 cm, a third and fourth measurement is obtained.

4.2. Physical activity

Seven-day Physical Activity Recall (PAR): The PAR is an interviewer-administered instrument that provides an esti mate of weekly minutes of physical activity [41,42]. The PAR uses multiple strategies for increasing accuracy of recall, such as breaking down the week into daily segments (i.e., morning, afternoon, evening) and asking about many types of activities, including time spent sleeping and in moderate, hard, and very hard activity. Participants completed a 10-minute treadmill walk prior to the PAR in order to simulate moderate intensity exercise defined as 3 to 4 mph, to further enhance recall accuracy for the PAR. This measure has consistently demonstrated acceptable reliability, internal consistency, and congruent validity with other more objec tive measures of activity levels [43–46], as well as sensitivity to changes in moderate intensity physical activity over time [47,48].

4.2.1. Actigraph motion monitors—Actigraph Motion Monitors (Actigraph, LLC) provide an objective validation of self-reported activity obtained through the PAR in a 20%

sub-sample. At the screening visit randomly selected participants were asked to wear activity monitors for a 7-day period. Previous studies have validated the Actigraph monitor against heart rate telemetry [49] and total energy expenditure [50]. Additionally, Freedson et al. [51] have established Actigraph ranges and cut-points that correspond to MET categories, which means that different physical activity counts generated by the Actigraph can be categorized into various activity intensity levels (e.g., light, moderate, hard, very hard). Consequently, the Actigraph measures both quantity and intensity of physical activity [49].

4.2.2. Physical activity — theoretical constructs—Stages of Change for Physical Activity were assessed using the measure developed by Marcus and colleagues [52]. The Kappa index of reliability over a 2-week period was 0.78 for this instrument [53], which also significantly correlates with the 7-day PAR questionnaire, demonstrating concurrent validity [52]. In addition, moving from an early stage of change (i.e., Precontemplation, Contemplation, or Preparation stage) to Action has been shown to be significantly associated with positive changes in estimated peak VO_2 [52].

4.2.2.1. Self-efficacy for physical activity: This 5-item measure examines the participant's confidence regarding participation in physical activity in five separate situations (e.g., vacation, bad weather). The scale has good internal consistency and test–retest reliability [53].

4.2.2.2. Decision making for physical activity: This 16-item instrument contains two sub-scales, one indicative of benefits (i.e., Pros) of exercise adoption and another of negative consequences (i.e., Cons). The two sub-scales have acceptable internal consistencies and concurrent validity with measures of Stages of Change for Exercise Adoption [54].

4.2.2.3. Processes of change: This 40-item measure assesses the cognitive and behavioral processes of change for exercise behavior [55]. The five behavioral subscales include Rewarding Yourself, Substituting Alternatives, Committing Yourself, Reminding Yourself, and Enlisting Social Support. The cognitive subscales include Being Aware of Risks, Increasing Knowledge, Comprehending Benefits, Increasing Healthy Opportunities, and Caring about Consequences to Others. The internal consistency of the Processes of Change scales averages 0.83.

4.2.3. Food and nutrition—*4.2.3.1. The Diet History Questionnaire (DHQ II)*. The DHQ-II is an updated version of the DHQ-I. The DHQ-I instrument was used in many previous research studies and has been validated/calibrated against other instruments and provides reasonable nutrient estimates [56,57]. The DHQ II has a food list that has been updated based on more recent dietary data and consists of 134 food items and 8 dietary supplement questions. The nutrient and food group database for the DHQ II is based on a compilation of national 24-hour dietary recall data from the National Health and Nutrition Examination Surveys (NHANES) conducted in 2001–02, 2003–04, and 2005–06 [58]. There have been no updated validation studies with the DHQ II, however, validation findings are unlikely to be greatly modified by the minimal modifications to the food list and the updated nutrient database.

4.2.3.2. The Three Factor Eating Questionnaire (TFEQ): Part I of the TFEQ, which consists of 36 true/false items assesses Cognitive Restraint, Disinhibition and Perceived Hunger [59].

4.2.3.3. Eating Behavior Inventory (EBI): The 26 item EBI queries behaviors done intentionally or not intentionally during weight loss. The EBI has been shown to be consistently sensitive to weight management interventions such that the change in the EBI score is generally consistent with changes in weight status [60].

4.2.4. Demographic and clinical variables—Resting heart rate and resting systolic and diastolic blood pressure are taken using a mercury sphygmomanometer with appropriate cuff size using standard methodology.

Sociodemographic information including age, sex, marital status, ethnicity, employment, occupation, years of education, and income range, was collected by questionnaire at baseline.

Medical information was obtained through self-report and verified by medical chart reviews. Self-report information is obtained using the Katz Co-morbidity Questionnaire [61]. The chart audit Charlson Index [62] is used to determine co-morbidities. An abbreviated 7-item version of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [63] is used to assess knee pain and stiffness.

4.2.5. Mental and physical health variables—Depressive Symptoms are assessed using the Centers for Epidemiologic Studies Depression Scale (CES-D) 20-item measure. Scores range from 0 to 60, with scores 16 or greater widely used as a threshold for clinical depression. Internal consistency for this measure in several different populations is relatively high, 0.85–0.90 [64].

To assess changes in mental health and physical health the SF-12® Health Survey (SF12), with minor formatting (non- substantive changes) is administered. SF12 contains 1 or 2 items that measure each of the eight concepts included in the SF-36 measures of eight domains of health, including physical functioning, role – physical, bodily pain, general health, vitality, social functioning, role – emotional, and mental health; and yields an eight scale profile of norm-based scores (one for each of the eight domains of health) as well as physical and mental health component summary scores [65].

The General Self-Efficacy Scale (GSE) is a 10-item measure designed to assess beliefs of personal competence to deal effectively with a variety of situations [66].

4.2.6. Primary care chart audit variables—Chart audits are being done by trained research abstrac tors unaware of the randomization status of the participants. Charts are reviewed for two years prior to the intervention and for the two year intervention time period. Number and type of office visits, medications, selected co-morbid conditions focusing on obesity related conditions, emergency room visits, consultations, hospitalizations, potential adverse events including orthopedic injuries, syncope, kidney stones, gall bladder attacks, gout, hypoglycemia; weight history and management, physical

activity assessment and counseling, dietary recommendations and counseling, vital signs includ ing height, weight, BMI, blood pressure; laboratory testing including lipids, liver function testing, kidney functioning, glucose, hemoglobin-A1c, and high sensitivity-c-reactive protein if measured are being abstracted.

4.2.7. Adverse events—Potential adverse events are gathered incidentally when LCs or research assistants contact participants regarding appointments or counseling calls and as part of the formal research protocol by the research assistants during research visits and recorded using a standard format. These are followed up by research nurses for more information from either patient, primary care provider, or specialist. All potential adverse events are reviewed by the PI and the patient is told to continue on the usual study protocol, placed on medical hold awaiting clearance by PCP or other medical provider. Patients continue to receive the intervention materials but are told to hold onto these materials until they are released from medical hold and then resume full intervention activities.

4.3. Data analysis

The primary aim is to evaluate the effectiveness of the tailored lifestyle intervention delivered in the enhanced intervention arm by comparing the change in BMI during the two years of intervention to an augmented usual care arm. The univariate analysis will be conducted at the patient levels. Two group t-test and Analysis of Variance (ANOVA) will then be used to test differences between the two arms and over time. The patient level analysis is a bivariate comparison of BMI at 6, 12, 18 and 24 months between enhanced intervention and augmented usual care arm. Additionally, multivariate analysis for with repeated measures will be used to test the independent association between the change of BMI and the interventions, while adjusting for clustering of patients at the provider level and important covariates if the randomization is unbalanced. Alternatively, we will also compare the percentage of participants who will be successful at achieving a 5% weight loss at each time period using both univariate and multivariate analyses. We will also calculate cluster coefficients of associations within practice and will be performing hierarchical modeling to adjust for within practice associations.

Missing data will be treated by several methods including complete case, last value carried forward, and multiple imputation.

The effectiveness of the tailored physical activity intervention will be evaluated by comparing the change in the 7-day Physical Activity Recall during the two years of intervention in the two arms of the trial. The outcomes of interests are the repeated measures of activity time (minute) change from baseline at 6, 12, 18 and 24 months after intervention respectively as measured by the PAR.

We will evaluate the effectiveness of the tailored nutrition intervention by comparing the change in total calories, percentage of calories from fat and servings of fruits and vegetables during the two years of intervention in the two arms of the trial. The outcomes of interests are the repeated measures of total calories, % energy from fat, and servings of fruits and vegetables change from baseline at 6, 12, 18 and 24 months after intervention respectively.

If the intervention is effective, we will perform a cost-effectiveness evaluation for replicating the intervention in clinical practice. Cost of screening participants, and costs associated with intervention itself-performing the face-to-face lifestyle counseling and implementing the structured meal plan, frequent tailored and untailored mailings, review and providing written feedback and mailing of food and exercise logs, monthly LC phone calls will be calculated and compared between the enhanced intervention and augmented usual care per unit of BMI loss.

4.4. Sample size consideration

A priori sample size calculations found that using a sample size of 72 in each group achieves 80% power to detect a 6% average difference in a design with 4 repeated measurements when the standard deviation is 6.000, assuming the correlation between observations on the same subject is 0.50, and the alpha level is 0.050. To over sample and account for attrition, we enrolled 105 into each arm of the study.

5. Discussion

If effective in demonstrating that a home based program with limited face-to-face contact is effective in promoting clinical significant levels of weight loss in obese primary care patients with multiple co-morbidities, this study will be an important contribution to the public health solution to the obesity epidemic.

While some recent studies have shown that PCPs or PCPs with co-located health coaches can effectively help obese primary care patients lose weight, they require extensive training of local staff and their ability to be disseminable and adopted by most primary care practices remains unknown [11,21,67,68]. This study focuses on a different role for the PCP, which has been efficacious previous studies [19,22], and utilizes the teachable moment in daily encounters to motivate obese patients to participate in a home based program located within the “medical neighborhood” and to manage medical co-morbidities. All face-to-face lifestyle counseling, mailings and phone calls can be performed by central located LCs and staff. All tailored mailing materials based upon computerized expert systems have been developed. All DVDs have been produced. These educational materials as well as the study manuals and materials for structured meal plans, goal setting, food and exercise logs, lifestyle counseling, LC training will be available for dissemination to third party payers, worksites or other organizations who could replicate the intervention in the future.

Having the PCPs serve as a motivator for weight loss, dietary and PA change and linking the patient to effective weight loss services is an important and appropriate role for the PCP [19,69,70]. Asking PCPs to counsel their patients on losing weight is not practical or sustainable on a large scale as evidenced by a national study where only 41% of obese patients reported that their physicians counseled them on losing weight [71]. In a busy primary care practice even PCPs with adequate insurance reimbursement, training in counseling skills and effective teaching materials will likely not be successful in providing the intensive lifestyle management needed for successful weight loss and its long term maintenance. However, it is our belief that primary care physicians lead the obesity-associated healthcare team, motivating patients to enter into behavioral focused weight loss

programs, providing ongoing medical care focusing on supporting attainment of weight loss and PA goals, prescribing and monitoring medications, and treating co-morbid conditions such as hyperlipidemia, hypertension, and diabetes mellitus. Therefore the current study utilized PCPs in this role to encourage enrollment in the weight loss intervention and by providing ongoing medical care.

The intervention has several innovative components to increase its likelihood of success, dissemination, and wide appeal. First, by having PCPs refer their obese patients to the study, we are capitalizing on a teachable moment when patients may be motivationally ready for behavioral change that could lead to successful weight loss, increased physical activity and healthier eating. PCPs also receive updates on their patients' progress in the study. These updates provide additional accountability and could lead to improved management of co-morbid conditions such as hypertension, hyperlipidemia, glucose intolerance or glycemic control in diabetics. Second, this intervention uses tailored materials that match patient characteristics with effective treatments. This tailoring is done using computerized expert systems which represent a novel, innovative and potentially cost-effective means of translating the best of behavioral science research into mainstream clinical practice. Third, this intervention combines weight loss, physical activity and healthy eating information using multiple delivery channels: face-to-face, print, telephone, and video. Although weight loss interventions using limited face-to-face interventions but frequent print have been shown to be effective [23,25,27], the use of video and telephone tailored components may be more effective than print alone in underserved populations who may have lower literacy levels. Many individuals, even those who can read, frequently depend on non-written means to obtain health-related information [72]. Unfortunately, while significant effort has focused on improving the quality, literacy levels and appropriateness of printed materials, high quality non-print health information sources are rare [73,74]. Targeted patient education programs, using more audiovisual material are sorely needed [73]. Video can demonstrate procedures and concepts that might be difficult to explain or translate in print (i.e., motivation, demonstrations, and modeling), and they can circumvent the problem of low literacy. Videos can increase learner interest, accommodate different learning styles and serve as useful adjuncts for clarification, support, and motivation. Thus, inclusion of non-print intervention components increases the potential to reach a wide range of patients, including underserved populations who have higher rates of obesity and are disproportionately burdened by obesity related health conditions. This intervention that consists of multiple modalities of print, telephone, and video with limited face-to-face counseling holds promise not only for being effective for encouraging weight loss, increasing physical activity and healthy eating but also for being cost effective and generalizable for wide clinical use. If this intervention is found to be effective, it could also be translated and adapted for other cultural and language groups.

By demonstrating the effectiveness and cost-effectiveness of a practical lifestyle intervention with limited face-to-face contact for participants recruited from primary care practices that produce clinically meaningful changes in BMI, physical activity, and diet, the results of the proposed trial will have direct relevance to clinical practice. This study will fill an important gap in our knowledge regarding the translation and dissemination of research from efficacy studies to best practices in the community settings.

Acknowledgments

This work was supported by the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health (5R18DK079880).

References

1. Ogden CL, Carroll MD, Curtin LR, McDowell MA, Tabak CJ, Flegal KM. Prevalence of overweight and obesity in the United States, 1999–2004. JAMA. 2006; 295(13):1549–55. [PubMed: 16595758]
2. Fontaine KR, Redden DT, Wang C, Westfall AO, Allison DB. Years of life lost due to obesity. JAMA. 2003; 289(2):187–93. [PubMed: 12517229]
3. Peeters A, Barendregt JJ, Willekens F, et al. Obesity in adulthood and its consequences for life expectancy: a life-table analysis. Ann Intern Med. 2003; 138(1):24–32. [PubMed: 12513041]
4. Roe DA, Eickwort KR. Relationships between obesity and associated health factors with unemployment among low income women. J Am Med Womens Assoc. May; 1976 31(5):193–4. 198–199, 203–194. [PubMed: 180078]
5. Hiddnick G, Hautvast J, Van Woerkum C, Fieren C, Van't Hof M. Consumers' expectations about nutrition guidance: the importance of the primary care physicians. Am J Clin Nutr. 1997; 65:1974S–9S. [PubMed: 9174506]
6. Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med. 2002; 346(6):393–403. [PubMed: 11832527]
7. Appel LJ, Champagne CM, Harsha DW, et al. Effects of comprehensive lifestyle modification on blood pressure control: main results of the PREMIER clinical trial. JAMA. Apr 23–30; 2003 289(16):2083–93. [PubMed: 12709466]
8. Stevens VJ, Obarzanek E, Cook NR, et al. Long-term weight loss and changes in blood pressure: results of the Trials of Hypertension Prevention, phase II. Ann Intern Med. 2001; 134(1):1–11. [PubMed: 11187414]
9. Howard BV, Manson JE, Stefanick ML, et al. Low-fat dietary pattern and weight change over 7 years: the Women's Health Initiative Dietary Modification Trial. JAMA. 2006; 295(1):39–49. [PubMed: 16391215]
10. Ryan DH, Johnson WD, Myers VH, et al. Nonsurgical weight loss for extreme obesity in primary care settings: results of the Louisiana Obese Subjects Study. Arch Intern Med. 2010; 170(2):146–54. [PubMed: 20101009]
11. Wadden TA, Volger S, Tsai AG, et al. Managing obesity in primary care practice: an overview with perspective from the POWER-UP study. Int J Obes (Lond). Aug; 2013 37(Suppl. 1):S3–S11. [PubMed: 23921779]
12. Logue E, Sutton K, Jarjoura D, Smucker W, Baughman K, Capers C. Transtheoretical model-chronic disease care for obesity in primary care: a randomized trial. Obes Res. May; 2005 13(5): 917–27. [PubMed: 15919846]
13. NHS Centre for Reviews and Dissemination, University of York. The prevention and treatment of obesity. Eff Health Care. 1997; 3:1–12.
14. Bowerman S, Bellman M, Saltsman P, et al. Implementation of a primary care physician network obesity management program. Obes Res. Nov; 2001 9(Suppl. 4):321S–5S. [PubMed: 11707560]
15. Wolf AM, Conaway MR, Crowther JQ, et al. Translating lifestyle intervention to practice in obese patients with type 2 diabetes: Improving Control with Activity and Nutrition (ICAN) study. Diabetes Care. Jul; 2004 27(7):1570–6. [PubMed: 15220230]
16. Read A, Ramwell H, Storer H, Webber J. A primary care intervention programme for obesity and coronary heart disease risk factor reduction. Br J Gen Pract. Apr; 2004 54(501):272–8. [PubMed: 15113494]
17. McQuigg M, Brown J, Broom J, et al. Empowering primary care to tackle the obesity epidemic: the counterweight programme. Eur J Clin Nutr. 2005; 59S:S93–S100. [PubMed: 16052202]
18. Moore H, Summerbell CD, Greenwood DC, et al. Improving management of obesity in primary care: cluster randomised trial. BMJ. Nov 8.2003 327(7423):1085. [PubMed: 14604931]

19. Appel LJ, Clark JM, Yeh HC, et al. Comparative effectiveness of weight-loss interventions in clinical practice. N Engl J Med. 2011; 365(21):1959–68. [PubMed: 22085317]
20. Bennett GG, Warner ET, Glasgow RE, et al. Obesity treatment for socioeconomically disadvantaged patients in primary care practice. Arch Intern Med. 2012; 172(7):565–74. [PubMed: 22412073]
21. Yeh HC, Clark JM, Emmons KE, et al. Independent but coordinated trials: insights from the practice-based Opportunities for Weight Reduction Trials Collaborative Research Group. Clin Trials. Aug; 2010 7(4):322–32. [PubMed: 20573639]
22. Mehring M, Haag M, Linde K, et al. Effects of a general practice guided web-based weight reduction program—results of a cluster-randomized controlled trial. BMC Fam Pract. 2013; 14:76. [PubMed: 23981507]
23. Campbell MK, DeVellis BM, Strecher VJ, Ammerman AS, DeVellis RF, Sandler RS. Improving dietary behavior: the effectiveness of tailored messages in primary care settings. Am J Public Health. May; 1994 84(5):783–7. [PubMed: 8179049]
24. Scisney-Matlock M, Glazewki L, McClerking C, Kachorek L. Development and evaluation of DASH diet tailored messages for hypertension treatment. Appl Nurs Res. May; 2006 19(2):78–87. [PubMed: 16728291]
25. Heimendinger J, O'Neill C, Marcus AC, et al. Multiple tailored messages are effective in increasing fruit and vegetable consumption among callers to the Cancer Information Service. J Health Commun. 2005; 10(Suppl. 1):65–82. [PubMed: 16377601]
26. Brug J, Campbell M, van Assema P. The application and impact of computer-generated personalized nutrition education: a review of the literature. Patient Educ Couns. Feb; 1999 36(2): 145–56. [PubMed: 10223019]
27. Campbell MK, Carbone E, Honess-Morreale L, Heisler-Mackinnon J, Demissie S, Farrell D. Randomized trial of a tailored nutrition education CD-ROM program for women receiving food assistance. J Nutr Educ Behav. Mar-Apr;2004 36(2):58–66. [PubMed: 15068753]
28. Clark M, Hampson SE, Avery L, Simpson R. Effects of a tailored lifestyle self-management intervention in patients with type 2 diabetes. Br J Health Psychol. Sep; 2004 9(Pt 3):365–79. [PubMed: 15296683]
29. Shin Y, Yun S, Jang H, Lim J. A tailored program for the promotion of physical exercise among Korean adults with chronic diseases. Appl Nurs Res. May; 2006 19(2):88–94. [PubMed: 16728292]
30. The Diabetes Prevention Program (DPP). description of lifestyle intervention. Diabetes Care. Dec; 2002 25(12):2165–71. [PubMed: 12453955]
31. Bandura, A. Social Foundations of Thoughts and Action: A Social–Cognitive Theory. Prentice Hall; Englewood Cliffs, NJ: 1986.
32. Rosenstock IM, Strecher VJ, Becker MH. Social learning theory and the Health Belief Model. Health Educ Q. 1988; 15(2):175–83. Summer. [PubMed: 3378902]
33. Prochaska JO, DiClemente CC. Stages and processes of self-change of smoking: toward an integrative model of change. J Consult Clin Psychol. Jun; 1983 51(3):390–5. [PubMed: 6863699]
34. Marcus BH, Napolitano MA, King AC, et al. Telephone versus print delivery of an individualized motivationally tailored physical activity intervention: Project STRIDE. Health Psychol. Jul; 2007 26(4):401–9. [PubMed: 17605559]
35. Bock BC, Marcus BH, Pinto BM, Forsyth LH. Maintenance of physical activity following an individualized motivationally tailored intervention. Ann Behav Med. 2001; 23(2):79–87. Spring. [PubMed: 11394558]
36. Marcus BH, Dunsiger SI, Pekmezi DW, et al. The Seamos Saludables study: a randomized controlled physical activity trial of Latinas. Am J Prev Med. Nov; 2013 45(5):598–605. [PubMed: 24139773]
37. Carr LJ, Dunsiger SI, Lewis B, et al. Randomized controlled trial testing an internet physical activity intervention for sedentary adults. Health Psychol. Mar; 2013 32(3):328–36. [PubMed: 22823069]
38. Jackson A, Pollock M. Practical assessment of body composition. Physician Sports Med. 1985; 13:76–90.

39. Houmard JA, Wheeler WS, McCammon MR, et al. An evaluation of waist to hip ratio measurement methods in relation to lipid and carbohydrate metabolism in men. Int J Obes. Mar; 1991 15(3):181–8. [PubMed: 2045211]
40. Callaway, CW.; Chumlea, WC.; Bouchard, C.; Himes, JH.; Lohman, TG.; Martin, AD.; Mitchell, CD.; Mueller, WH.; Roche, AF.; Seefeldt, VD. Circumferences.. In: Lohman, AFRPG.; Martorell, R., editors. Anthropometric standardization manual. Human Kinetics; Champagne, IL: 1988. p. 39-49.
41. Blair SN, Haskell WL, Ho P, et al. Assessment of habitual physical activity by a seven-day recall in a community survey and controlled experiments. Am J Epidemiol. Nov; 1985 122(5):794–804. [PubMed: 3876763]
42. Sallis JF, Haskell WL, Wood PD, et al. Physical activity assessment methodology in the Five-City Project. Am J Epidemiol. Jan; 1985 121(1):91–106. [PubMed: 3964995]
43. Hayden-Wade HA, Coleman KJ, Sallis JF, Armstrong C. Validation of the telephone and in-person interview versions of the 7-day PAR. Med Sci Sports Exerc. May; 2003 35(5):801–9. [PubMed: 12750590]
44. Pereira MA, FitzerGerald SJ, Gregg EW, et al. A collection of Physical Activity Questionnaires for health-related research. Med Sci Sports Exerc. Jun; 1997 29(6 Suppl.):S1–S205. [PubMed: 9243481]
45. Prince SA, Adamo KB, Hamel ME, Hardt J, Gorber SC, Tremblay M. A comparison of direct versus self-report measures for assessing physical activity in adults: a systematic review. Int J Behav Nutr Phys Activ. 2008; 5:56.
46. Sloane R, Snyder DC, Demark-Wahnefried W, Lobach D, Kraus WE. Comparing the 7-day physical activity recall with a triaxial accelerometer for measuring time in exercise. Med Sci Sports Exerc. Jun; 2009 41(6):1334–40. [PubMed: 19461530]
47. Dunn AL, Andersen RE, Jakicic JM. Lifestyle physical activity interventions. History, short- and long-term effects, and recommendations. Am J Prev Med. Nov; 1998 15(4):398–412. [PubMed: 9838980]
48. Dunn AL, Marcus BH, Kampert JB, Garcia ME, Kohl HW III, Blair SN. Comparison of lifestyle and structured interventions to increase physical activity and cardiorespiratory fitness: a randomized trial. JAMA. 1999; 281(4):327–34. [PubMed: 9929085]
49. Janz KF. Validation of the CSA accelerometer for assessing children's physical activity. Med Sci Sports Exerc. Mar; 1994 26(3):369–75. [PubMed: 8183103]
50. Melanson EL Jr, Freedson PS. Validity of the Computer Science and Applications, Inc. (CSA) activity monitor. Med Sci Sports Exerc. Jun; 1995 27(6):934–40. [PubMed: 7658958]
51. Freedson PS, Melanson E, Sirard J. Calibration of the Computer Science and Applications, Inc. accelerometer. Med Sci Sports Exerc. May; 1998 30(5):777–81. [PubMed: 9588623]
52. Marcus BH, Simkin LR. The stages of exercise behavior. J Sports Med Phys Fitness. Mar; 1993 33(1):83–8. [PubMed: 8350613]
53. Marcus BH, Selby VC, Niaura RS, Rossi JS. Self-efficacy and the stages of exercise behavior change. Res Q Exerc Sport. Mar; 1992 63(1):60–6. [PubMed: 1574662]
54. Marcus BH, Rakowski W, Rossi JS. Assessing motivational readiness and decision making for exercise. Health Psychol. 1992; 11(4):257–61. [PubMed: 1396494]
55. Marcus BH, Rossi JS, Selby VC, Niaura RS, Abrams DB. The stages and processes of exercise adoption and maintenance in a worksite sample. Health Psychol. 1992; 11(6):386–95. [PubMed: 1286658]
56. Thompson FE, Subar AF, Brown CC, et al. Cognitive research enhances accuracy of food frequency questionnaire reports: results of an experimental validation study. J Am Diet Assoc. Feb; 2002 102(2):212–25. [PubMed: 11846115]
57. Subar AF, Thompson FE, Kipnis V, et al. Comparative validation of the Block, Willett, and National Cancer Institute food frequency questionnaires: the Eating at America's Table Study. Am J Epidemiol. 2001; 154(12):1089–99. [PubMed: 11744511]
58. Diet History Questionnaire, Version 2.0. National Institutes of Health, Applied Research Program, National Cancer Institute; 2010.

59. Stunkard AJ, Messick S. The three-factor eating questionnaire to measure dietary restraint, disinhibition and hunger. J Psychosom Res. 1985; 29(1):71–83. [PubMed: 3981480]
60. O'Neil PM, Currey HS, Hirsch AA, et al. Development and validation of the Eating Behavior Inventory. J Behav Assess. 1979; 1(2):123–32.
61. Katz JN, Chang LC, Sangha O, Fossel AH, Bates DW. Can comorbidity be measured by questionnaire rather than medical record review? Med Care. Jan; 1996 34(1):73–84. [PubMed: 8551813]
62. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis. 1987; 40(5):373–83. [PubMed: 3558716]
63. Bellamy, N. WOMAC Osteoarthritis Index User Guide. Version V. Brisbane, Australia: 2002.
64. Radloff LS. The CES-D scale: a self-report depression scale for research in the general population. Appl Psychol Meas. Jun 1; 1977 1(3):385–401.
65. Ware J, Kosinski M, Keller S. A 12-item short-form health survey: construction of scales and preliminary tests of reliability and validity. Med Care. 1996; 34(3):220–33. [PubMed: 8628042]
66. Schwarzer, R.; Jerusalem, M. Generalized self-efficacy scale.. In: Weinman, SWJ.; Johnston, M., editors. Measures in health psychology: a user's portfolio. , Causal and control beliefs. NFER-NELSON; Windsor, England: 1995. p. 35-7.
67. Wadden TA, Volger S, Sarwer DB, et al. A two-year randomized trial of obesity treatment in primary care practice. N Engl J Med. 2011; 365(21):1969–79. [PubMed: 22082239]
68. Kumanyika SK, Fassbender JE, Sarwer DB, et al. One-year results of the Think Health! study of weight management in primary care practices. Obesity (Silver Spring). Jun; 2012 20(6):1249–57. [PubMed: 22051940]
69. Marvin NG. Patient education: effective methods in primary care practice. J Kans Med Soc. Mar; 1980 81(3):115–7. [PubMed: 7381287]
70. Michener JL. Nutrition, education, and family physicians. Arch Fam Med. Mar-Apr;1997 6(2): 146–7. [PubMed: 9075449]
71. Kraschnewski JL, Sciamanna CN, Stuckey HL, et al. A silent response to the obesity epidemic: decline in US physician weight counseling. Med Care. Feb; 2013 51(2):186–92. [PubMed: 23047128]
72. Meade CD, McKinney WP, Barnas GP. Educating patients with limited literacy skills: the effectiveness of printed and videotaped materials about colon cancer. Am J Public Health. Jan; 1994 84(1):119–21. [PubMed: 8279598]
73. Brown P, Ames N, Mettger W, et al. Closing the comprehension gap: low literacy and the Cancer Information Service. J Natl Cancer Inst Monogr. 1993; 14:157–63. [PubMed: 8123353]
74. Health literacy: report of the Council on Scientific Affairs. Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, American Medical Association. JAMA. Feb 10; 1999 281(6): 552–7. [PubMed: 10022112]

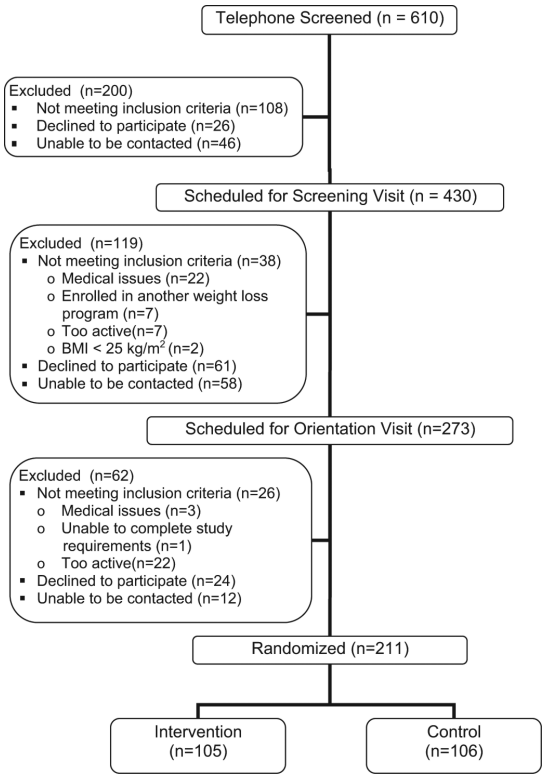

Fig. 1.
Study flow of eligible and randomized participants.

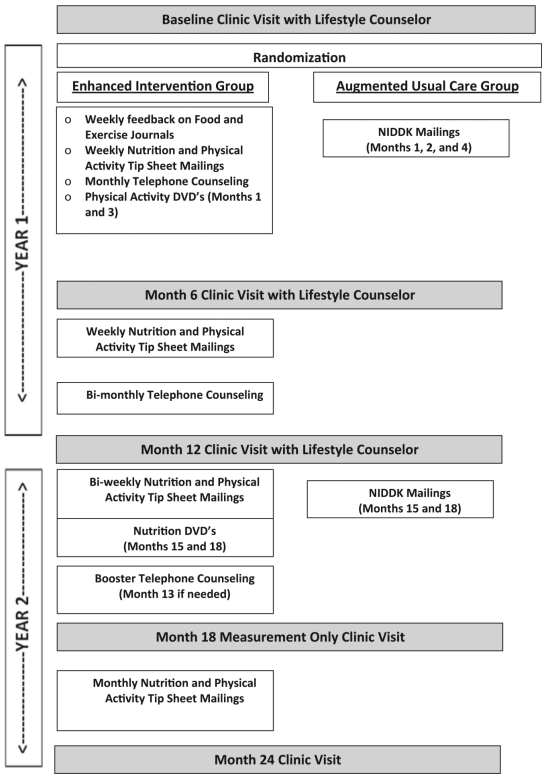

Fig. 2.