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PREFER study: A randomized clinical trial testing treatment preference and two dietary options in behavioral weight management — rationale, design and baseline characteristics☆

Lora E. Burke *, Jina Choo, Edvin Music, Melanie Warziski, Mindi A. Styn, Yookyung Kim, Mary Ann Sevick

University of Pittsburgh, Health and Community Systems, 3500 Victoria Street, 415 Victoria Building, 15261 Pittsburgh, PA, USA

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Abstract

Background: Obesity, a disorder associated with a myriad of comorbidities, is increasing at an alarming rate around the world. Given that pharmacotherapy has limited available options and that bariatric surgery is reserved for those who are morbidly obese or who have significant comorbidities, the most common approach to the treatment of obesity is standard behavioral treatment. This approach includes behavior modification related to eating and activity habits. The purpose of this paper is to describe the rationale, design, methods and baseline sample characteristics of a randomized controlled trial of a behavioral intervention in weight loss management, referred to as the PREFER study.
Methods: The PREFER study, using a four-group design, includes: (1) a randomization scheme that permits participants to indicate a preferred dietary treatment approach, and (2) two dietary options, one of which is a lacto-ovo-vegetarian diet that has demonstrated potential for long-term adherence. The intervention (32 treatment sessions) is delivered over 12 months and is followed by a 6-month maintenance phase; final assessment occurs at 18 months.
Results: We screened 932 individuals and randomized 197 to the study: Treatment Preference-Yes ($n=84$) and Treatment Preference-No ($n=98$). To maintain a balance across the four treatment groups, 15 subjects who preferred the standard diet had to be discarded from the Treatment Preference-Yes group. Retention at 18 months for the first of three cohorts was 82%.
Conclusions: The PREFER study is a single center study and is the first randomized controlled trial examining a lacto-ovo-vegetarian diet as part of weight loss treatment. The ethnically diverse sample includes males and females with a body mass index of 27 to 43. The study has the potential to make a contribution to understanding the role of treatment preference and the potential of a lacto-ovo-vegetarian diet for long-term weight loss.

Keywords: Obesity; Treatment preference; Lacto-ovo-vegetarian diet; Standard behavioral treatment of obesity; Randomized clinical trial; Research design; Two-factor analysis; Adherence

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* Corresponding author. Tel.: +1 412 624 2305; fax: +1 412 383 729.
E-mail address: lbu100@pitt.edu (L.E. Burke).

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1. Introduction and background

According to the 1999–2000 National Health and Nutrition Examination Survey (NHANES) estimates, obesity is increasing at an alarming rate [1]. In 1999, the prevalence of adult obesity was 18.9% and today it is 33%, while 31% of adults in the U.S. are overweight [http://www.cdc.gov, access Feb. 2, 2005]. Severe or morbid obesity affects 4.7% of U.S. adults [2]. Countries outside the U.S. are showing similar trends with developing countries reporting a faster increase in prevalence compared to developed countries, and increases occurring in the more affluent families. According to International Obesity Task Force estimates, 1 billion people are overweight and 300 million are obese [task force site http:www.iotf.org, access Feb. 2, 2005].

Obesity is associated with a myriad of medical conditions, including hypertension, dyslipidemia, gallstones, osteoarthritis, sleep apnea and certain cancers [1]. It is also associated with several of the risk factors for coronary heart disease (CHD), e.g., insulin resistance, metabolic syndrome, and inflammation [1,3–5]. However, weight loss is associated with reduced symptoms, improved function, and metabolic benefits are seen with a modest loss of 5% of initial weight [6].

Treatment for obesity includes pharmacotherapy, which is limited, and surgery, which is indicated only in those who are morbidly obese or have serious comorbidities [4]. The more common form of treatment is cognitive-behavioral therapy, which includes behavior modification, dietary intervention and physical activity and referred to as standard behavior treatment (SBT) [7]. Numerous dietary approaches have been studied but the standard approach is a low-fat diet (<25% of calories from fat) with a calorie deficit of 500 to 1000 kcal per day, which will result in an initial weight loss of 1 to 2 lb per week. Calorie prescription is usually based on the person's initial weight, e.g., a person weighing >200 lb would follow a 1500 kcal/day eating plan. In addition to restricting energy intake, physical activity goals, usually set at being physically active at least 30 min per day most days of the week, aim to increase energy expenditure. Various approaches to the behavioral treatment of obesity have been studied for over 20 years [8]. The most significant achievement in these two decades has been in substantial initial weight loss. However, maintaining weight loss in the long-term is problematic. Typically, individuals regain approximately 35% of their lost weight in the year following cessation of treatment, and return to their baseline weight within 3 to 5 years. Therefore, the greatest challenge in the treatment of this disorder is identifying strategies that can improve long-term maintenance of weight loss. With this challenge in mind, we designed the PREFER study.

The purpose of this paper is to describe the rationale, design, methods and baseline sample characteristics of the PREFER study, a randomized controlled trial of a behavioral intervention program in weight loss management. The PREFER study design includes: (1) a randomization scheme that permits participants to choose their preferred dietary treatment approach, and (2) a lacto-ovo-vegetarian (LOV) dietary option that has demonstrated, in the literature, potential for long-term adherence. The LOV diet is compared to a standard calorie and fat restricted diet.

The first factor in the PREFER study is effect of treatment preference or choice of outcome. An emerging body of empirically based literature focuses on patients' preference for treatment choice, involvement in decision-making, and satisfaction with medical care [9–14]. Three studies that used treatment choice in weight loss had methodological limitations, such as nonstandardized treatment groups, a small sample and high attrition rates, but showed promise for better adherence and weight loss and less regain among those who received their choice condition. However, Renjilian et al. [13] reported no significant effects for treatment preference or the interaction for treatment preference by type of therapy. More recently, the literature has gone beyond patients' preference for treatment and has addressed desire for involvement in decision-making and satisfaction with medical care.

Preference for decision-making is more common among younger, more educated persons [15]. Individuals born after World War II represent a cohort that has been part of a societal shift toward increased involvement in health-care decision-making [16]. Individuals who value control over their health care derive satisfaction from participating in health-related decision-making [17,18]. Not only is satisfaction an important attribute of quality care [19], but it is also associated with improved health status and therapeutic outcome [20]. These findings suggest that providing individuals their treatment preference and involving them in decision-making may result in improved outcomes. Thus, the PREFER study design, which has overcome the limitations of the previous studies that examined treatment preference, permits the investigators to explore the influence of dietary preference on weight loss and maintenance.

The second factor in the PREFER study is that some participants will be assigned to a lacto-ovo-vegetarian eating plan. As a group, vegetarians provide a striking contrast to the temporary adoption of lifestyle habits or "diets" common among the overweight and obese. Individuals who adopt a vegetarian meal plan report following it

for longer periods than those following weight loss diets [21–23]. Research has shown that a vegetarian eating plan can be followed for sustained periods [21,22]. In studies not focused on weight loss but rather on cardiovascular risk reduction, Singh reported significant weight loss at one year [24], and Ornish reported maintenance of that loss at five years [24–26].

Besides improved duration and long-term weight loss, it appears that there is also improved adherence to vegetarian diets [27,28]. In a review of 30 studies prescribing dietary modification for cardiovascular risk reduction, Barnard et al. noted that stricter dietary programs yielded greater dietary change. For example, the mean fat intake of those prescribed a vegetarian diet was 24% compared to 30% for those not prescribed a vegetarian diet. There was 100% compliance to the restricted fat goal in the two vegetarian studies while there was a reported 46% compliance to the restricted fat goal in the 28 non-vegetarian studies [27]. These studies suggested that it might be easier to achieve a lower fat intake when eating a vegetarian-eating plan.

2. Objectives of the PREFER study

The primary aim of the PREFER study is to test the effect of the interaction between treatment assignment (standard behavior treatment [SBT]+standard weight loss diet vs. standard behavior treatment–lacto-ovo-vegetarian diet [SBT+LOV]) and dietary treatment preference on weight loss at 18 months. Second, we are interested in the effect of the interaction between the two treatment assignment conditions and the two treatment preference conditions on weight loss. Our secondary aims include describing participants' preferences for weight loss treatment by individual characteristics; testing the interaction between treatment assignment and treatment preference on adherence to the diet and physical activity goals; and finally, to test the effect of the interaction between treatment assignment and treatment preference on serum lipids, glucose, and insulin.

3. Methods

3.1. Design

The PREFER study is a single-center, 18-month randomized controlled trial of adults seeking treatment for weight loss. A four-group design with two factors is being utilized for comparing the effects of SBT+standard weight loss diet and SBT+LOV diet by whether or not subjects received their preferred dietary treatment. See Fig. 1.

All study procedures are in accordance with the ethical research standards set by the Institutional Review Board of the University of Pittsburgh. Participants complete an oral consent for the initial phone screening and written consents for screening, baseline assessment, and the intervention.

3.2. Recruitment, screening and enrollment procedures

Participant recruitment from the community was performed in three waves or cohorts from September 2002 to May 2004. Three methods were used: a database of individuals seeking weight loss treatment at the Obesity Nutrition Research Center at the University of Pittsburgh, the university and medical center audix announcement system, and

	Factor 1 Treatment Preference	
	NO	**YES**
Factor 2 Treatment: Diet Condition		
	SBT	SBT
	SBT + LOV	SBT+LOV

Target sample size for each of the Treatment Preference-Yes groups was 38 (15% expected attrition); for each of the Treatment Preference-No groups 45 (expected attrition 25%), for a total sample of 168.

Fig. 1. PREFER study design.

direct mailing from purchased lists. Refer to Fig. 2 for number of participants at each stage. Eligibility screening took approximately six to eight weeks and included several steps. First, 931 responders to the audix or mailings were screened via a brief telephone interview that assessed basic inclusion criteria (e.g., age, height and weight to determine body mass index (BMI)). See Table 1 for full list of inclusion and exclusion criteria. Five hundred and seven individuals did not meet eligibility criteria for the following reasons: subject called back to report she was vegetarian ($n=1$, .2%), outside the age criteria ($n=26$, 5.1%), outside the BMI criteria ($n=199$, 39.4%), pregnant ($n=5$, 1%), currently or in past six months in weight loss program ($n=62$, 12.3%), taking weight loss medication ($n=12$, 2.4%), receiving medications or counseling for psychological problems ($n=155$, 24.7%), interfering medical problems such as diabetes ($n=20$, 4%), and not available the evenings of the treatment sessions ($n=423$, 83.59%). The cumulative total exceeds 100% since individuals may have not met criteria for more than one reason, but since we were not permitted to assign ID numbers at the phone screening stage, we could not track the data by individual subject.

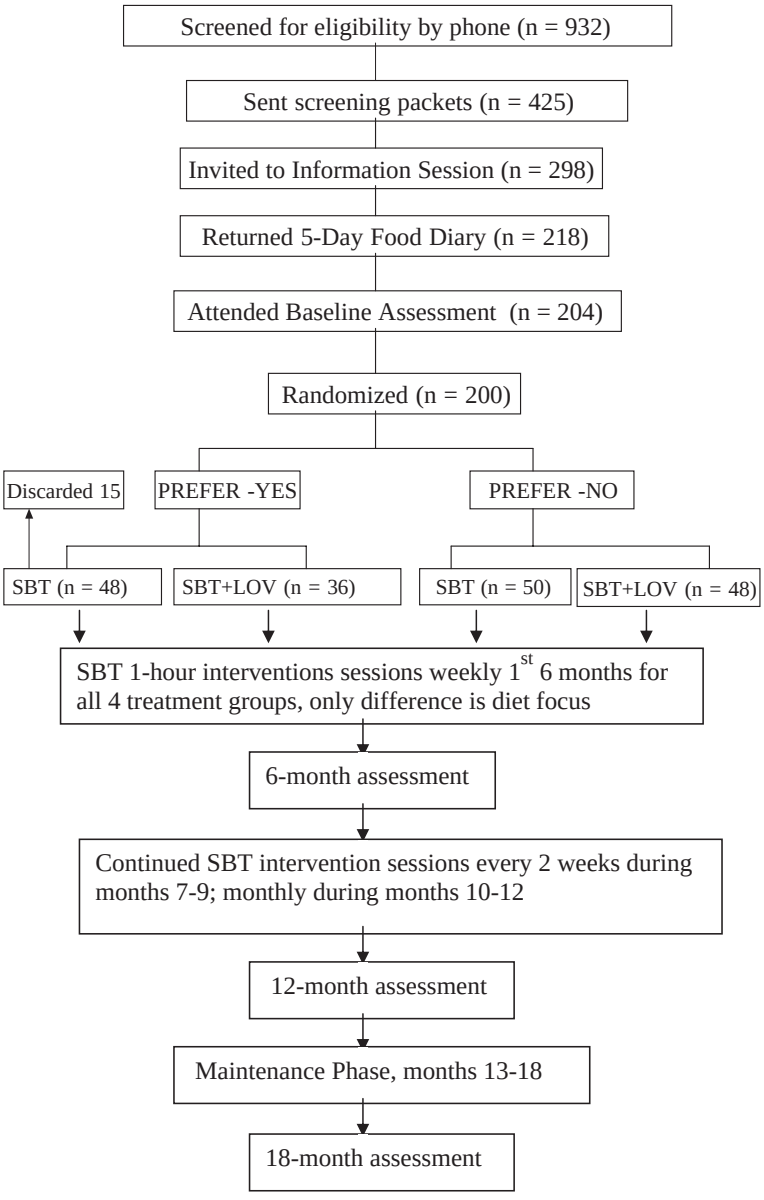

Fig. 2. Screening, enrollment, intervention and assessment in the PREFER study.

Table 1
Inclusion and exclusion criteria for the PREFER study

Inclusion criteria	Exclusion criteria
• 18 to 55 years of age	• Presence of current serious illness or unstable condition that requires physician supervision of diet or physical activity (e.g., diabetes, recent myocardial infarction)
• BMI of at least 27 but not >43	• Physical limitations precluding ability to exercise
• Willing to be randomized to one of 2 treatment preference conditions and one of the 2 dietary conditions	• Pregnancy or intention to become pregnant in next 18 months
• Successfully completed 5-day food diary	• Current treatment for a psychological disorder
• Willing and able to give informed consent	• Reported alcohol intake ≥4 drinks/day
	• Current or recent (past 6 months) participation in weight loss treatment program or use of weight loss medication
	• Reporting no regular intake of meat, fish, or poultry for past month

Individuals who met the eligibility criteria ($n=425$) were sent a packet of four questionnaires to assess socio-demographic data, medical history, presence of an eating disorder, and current dietary intake to rule out that the person was following a vegetarian diet. Individuals who remained eligible ($n=298$) were invited to an information session. Prior to the session, staff measured each attendee's height and weight to confirm the self-reported information and eligibility by BMI criteria (27 to 43). The Principal Investigator (PI) conducted the information sessions and provided a detailed overview of the study. At the end of the session attendees were provided a form summarizing the main points of each treatment condition and were asked to rate on a scale (*strongly*, *moderately*, *mildly*) their preference for SBT or for SBT+LOV. In order to be included in the study individuals had to indicate at least a moderate preference for one condition over the other (standard weight loss diet vs. LOV diet). Participants who consented to the next phase were given a paper diary to record their food intake for the next five days, and were told to return the diary after the fifth day in the postage, prepaid envelope that was provided. Diary completion ensured that individuals were appropriate for the intervention and served as a run-in to reduce later attrition. Individuals who returned a completed diary ($n=218$) were provided an appointment for the baseline assessment and were sent a packet

Table 2
Schedule of data collection activities

Measure	Screening 1 — phone	Screening 2 — mail	Information session	Baseline	6 months	12 months	18 months
Eligibility data	X						
Sociodemographic data		X					
Medical history		X					
Eating Habits Questionnaire		X					
Connor Diet Habit Survey		X					
BMI — (height and weight)			X	X			X
5-day food diary			X				
Treatment preference			X				
Lipid profile				X	X	X	X
Fasting glucose				X	X	X	X
Insulin				X	X	X	X
Waist circumference				X	X	X	X
Weight					X	X	
BP				X	X	X	X
3-day food record				X	X	X	X
Paffenbarger Activity Questionnaire				X	X	X	X
Barriers to healthy eating				X	X	X	X
Correlates of maintenance of low fat diet					X	X	X
Identity as a vegetarian					X	X	X
Beck Depression Index-II				X	X	X	X
Weight lifestyle self-efficacy				X	X	X	X
Hunger Satiety Scale				X	X	X	X
Symptom and Injury Survey					X	X	X

Adherence to treatment protocol (attendance, self-monitoring diaries, adherence to calorie, fat gram, and physical activity goals) — collected at each treatment session visit (weekly months 1–6, bi-weekly months 7–9, and monthly in months 10–12).

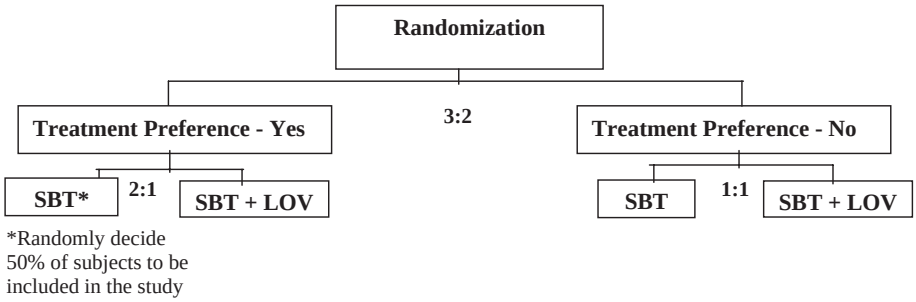

Fig. 3. Randomization scheme.

of questionnaires (see Table 2). The baseline appointment included a venipuncture for fasting blood work and anthropometric measurements, as well as review of the completed Three-day Food Record and packet of questionnaires, and was completed by 204 individuals.

3.3. Randomization

Randomization was conducted once baseline laboratory tests confirmed eligibility. See Fig. 3 for the randomization scheme. We based our estimates of the proportion of subjects who would select SBT vs. SBT+LOV on data collected from two previous weight loss studies [29,30]. These data revealed that 29% to 34% of the subjects would select the vegetarian option. Therefore, we projected that the ratio of subjects who would prefer the SBT to the SBT+LOV would be about 2:1. To ensure that an adequate number of subjects who preferred SBT+LOV would be in the Treatment Preference-Yes group, we randomized subjects to Treatment Preference-Yes vs. Treatment Preference-No in a 3:2 ratio.

Because participants in the Treatment Preference-Yes group could choose between the SBT and the SBT+LOV, we designed a two-stage randomization scheme (refer to Fig. 3). First, subjects were randomized to Treatment Preference-Yes or Treatment Preference-No with a 3:2 probability. In the next stage, subjects in the Treatment Preference-No group were randomized evenly to either the SBT or the SBT+LOV conditions. Subjects in the Treatment Preference-Yes group were not randomized but were treated according to the preference they indicated on the form at the orientation session. All subjects who preferred the SBT+LOV condition were assigned to that group. However, those who chose the SBT had to go through a random selection process with 50% probability of being included in the study. This was done to obtain a fair balance in size across the four groups. Because more subjects preferred the standard diet than the LOV diet, 15 subjects were discarded to prevent the Treatment Preference-Yes SBT group from being significantly larger than the Treatment Preference-Yes SBT+LOV group. We counseled individuals at each stage of screening that being discarded might occur but never disclosed why it would since that might influence their stated preferred choice. The discarded individuals were compensated for their time and referred to another study. We used Visual Basic 6.0 programs for the different randomization schemes (i.e. minimization, permuted blocks) and stratified subjects on gender, race, and preference.

4. Measurements

Measurements are conducted at baseline and at 6, 12, and 18 months at the General Clinical Research Center (GCRC) at the University of Pittsburgh. See Table 2 for details.

4.1. Biological and physical measures

Venipuncture for the collection of serum for the lipid profile (total cholesterol, high density lipoprotein, low density lipoprotein, and triglycerides), glucose and insulin is performed by a trained phlebotomist with the subject sitting upright following a 12-h fast and a brief resting period. A wall-mounted stadiometer is used to measure height and a Tanita scale and body fat analyzer is used for weight and percent fat mass, which is assessed via bioelectrical impedance analysis. BMI is calculated using the following formula: BMI=weight (kg)/height (m^2). Waist circumference is measured two

times with a Gullick II measuring tape and the two values, which need to be within 2 cm of each other, are averaged. Blood pressure is measured following the American Heart Association standard guidelines with the subject in a sitting position after at least a 5-min rest period, using a mercury sphygmomanometer and stethoscope.

4.2. Self-report measures

The self-report measures are sent to the subjects in advance of their assessment appointment and they are told to bring the completed materials to the appointment.

4.2.1. Measures of treatment adherence

Adherence to the dietary protocol is assessed through a Three-Day Food Record. Subjects are instructed to record one leisure day and two workdays, to record on days that are representative of their usual intake, and to bring recipes or food labels with them. At the appointment, a dietitian reviews the food record for completeness and clarifies any incomplete or unclear entries with the subject. Afterward, the food records are sent to the Obesity Nutrition Research Center for entry into the Nutrition Data System Research (NDS-R), a comprehensive nutrient calculation software program that is maintained by the Nutrition Coordinating Center at the University of Minnesota [31]. The NDS-R database contains over 18,000 foods, 8000 brand names and a number of ethnic foods. These data provide total calories, fat grams, and 172 other nutrients for our analysis.

The Paffenbarger Activity Questionnaire assesses daily and leisure activities and provides a measure of adherence to the physical activity protocol [32]. Other indicators of adherence include attendance to the treatment sessions and to self-monitoring by completing the food and physical activity diaries.

4.2.2. Measures of factors related to adherence

These measures include the Barriers to Healthy Eating scale, a 22-item questionnaire that asks the subject to rank various situations or conditions (e.g., feelings of deprivation, cost) on a scale of 1 (not at all a problem) to 5 (a very important problem) according to the extent to which they are barriers to healthy behavior [33]. A higher score on the scale indicates more barriers. Correlates of Maintenance to a Low-Fat Diet is a 25-item scale that assesses experiences thought to be related to diet maintenance, and thus not administered until the 6-month assessment. The scale has a total of 6 factors: wellness, distaste, cost, inconvenience, deprivation, and family [34]. The 6-item Hunger Satiety Scale measures hunger, satiety, and enjoyment because an individual's sense of hunger as well as satisfaction and enjoyment of food may influence one's ability to regulate eating. A higher score, measured on a seven-point Likert scale, reflects a more positive experience. Self-Efficacy in Weight Management, a 20-item questionnaire, is being used to measure self-efficacy as a potential mediator of adherence [35]. The scale assesses level of confidence in the capability to resist eating in varied situations or in different emotional states; responses are given on a scale of 0 (not confident) to 9 (very confident). The Beck Depression Inventory-II is being used to identify depressive symptomatology and to monitor emotional status throughout the 18-month study. Scores can range from 0 to 63; scores greater than 20 indicate moderate to severe depression. The Medical Outcomes Questionnaire, Short Form-36 (MOS-SF-36), a 36-item generic version of the Medical Outcomes Study Short Form questionnaire, is being used to measure general health-related quality of life, how it is affected by weight reduction, and its impact on adherence to the lifestyle change [36]. The SF-36 provides two summary scores, physical function and psychological function, which are transformed to a scale of 0 (lowest functioning) to 100 (highest functioning). All instruments have been used previously in this population and have adequate psychometric properties.

4.2.3. Identity as a vegetarian

This 20-item, investigator-developed questionnaire assesses on a 10-point scale how strongly subjects identify with being a vegetarian and if this identification makes it easier to adhere to the dietary guidelines. It is administered to subjects in the SBT+LOV groups at 6, 12, and 18 months.

4.3. Measurement quality control

Data are collected at the GCRC by trained and certified staff using standardized procedures and questionnaires. Equipment is standardized and routinely calibrated. Questionnaires are checked for accuracy and completeness prior

Table 3
Central features and strategies of the PREFER standard behavioral treatment intervention

The strategies are based on several models of motivation and behavioral change, such as social cognitive theory
Goal setting: Teach participants the importance of setting goals for behavior change, which can lead to enhancement of motivation. They are instructed to set daily and weekly goals for calorie and fat consumption, exercise time, and behavior change, e.g., to eat breakfast daily, alter the content of snacks.
Self-monitoring: A key technique of self-control, self-monitoring consists of systematically observing and recording one's behavior [45,46], and is positively related to successful weight control [47].
Self-evaluation: Individuals compare their behavior to a desired standard. A perceived discrepancy between one's current performance and the desired standard can prompt one into action. Satisfaction will occur if there is a close match between the performance criteria and feedback information [48].
Self-reinforcement: Occurs as the evaluation process is completed, comes from seeing personal change occur. As individuals observe their behavior change, they develop a strengthened sense of efficacy for maintaining those behaviors [48]. Thus, self-efficacy influences maintenance and self-regulation [49].
Feedback: Setting specific, daily goals and evaluating one's performance in achieving these goals, as well as receiving reinforcement on performance. Subjects are taught to use the information recorded in their diaries as a source of feedback on their progress in changing their behavior. The interventionists monitor the recorded behavior and provide feedback and guidance throughout the program.
Stimulus control: Refers to behavioral strategies designed to help participants to alter their environment, minimize cues that might trigger undesirable behaviors related to physical activity or eating, and add cues to increase activity [7]. Participants are taught to rearrange their environment for this purpose, e.g., remove counterproductive items from sight.
Problem solving: Participants learn skills to deal with situations that interfere with achieving their goals. Problem solving consists of 5 steps: identifying and defining the problem; brainstorming solutions; evaluating the pros and cons of potential solution; implementing the solution plan; and evaluating its success [50].
Social assertion: The skill of being assertive in social situations that threatens desirable eating and physical activity behaviors is essential to behavior change in weight loss. Participants are taught three communication styles (aggressive, passive, and assertive) and how to use assertive skills in situations that may threaten their ability to meet their eating and physical activity goals.
Cognitive strategies: Participants are taught how to recognize patterns of negative thought that can interfere with behavior change and weight control, such as perfectionism, all or none thinking, and self-doubt; to use cognitive techniques to counter these negative thoughts and to use positive self-statements.
Relapse prevention: Marlatt and Gordon's relapse prevention model is used to teach participants to recognize situations that place them at risk for lapses from their dietary behavior change program [51]. They learn how to use behavioral and cognitive strategies for handling these situations in the future.
Maintenance: Issues related to weight loss vs. maintenance are addressed during the latter months of the treatment program. Participants are instructed and encouraged to identify their own problems related to maintaining their new patterns of eating and exercising and to develop problem solving strategies to deal with these potential or real problems. Since research has consistently demonstrated that exercise is an important component of weight loss maintenance, emphasis on this increases later in the study [52].
Reinforcement: Participants in the SBT groups receive a subscription to the magazine *Cooking Light* to reinforce what they learn about modifying recipes to reduce fat and calories, and developing a healthier lifestyle; participants in the SBT+LOV groups receive a subscription to *Vegetarian Times*.
Cooking classes: A trained chef with a health background teaches a class on how to cook to accommodate the new eating pattern. Participants bring a modified dish to the next session for tasting.
Field experiences: A grocery shopping field trip is lead by a dietitian employed by a large, local supermarket to help subjects learn how to shop to accommodate their new eating patterns. Also, we mimic a restaurant and participants practice ordering from a variety of menus and under varying conditions. Tasting of low-calorie and low-fat foods occurs in this session.
Social support for dietary changes: For one session, we encourage participants to bring at least one significant other (relative, friend, co-worker), and we discuss the importance of support at home and at work.
Modeling: Several sessions use modeling, an effective strategy to enhance skills for changing behavior [53]. Examples are the cooking demonstration, and the exercise sessions in which the interventionist demonstrates exercises and has participants practice them with her. Also, in two sessions, successful former participants in a weight loss study or the PREFER trial are guest speakers and share strategies for making the transition to a healthier lifestyle and maintaining the new habits.
Portion size control: Learning to recognize and control portion size is crucial to reducing food consumption. We provide a group exercise in which subjects view portions of food (e.g., shredded cheese, cooked pasta, stir fried food) and estimate the amount; then are told the actual amount.
Ensuring dietary adequacy: The interventionists, including a dietitian, review all the food diaries for the behavior component as well as energy intake and expenditure and also for nutrient adequacy; participants are advised not to consume <1000 kcal/day or <10% fat.
Incentives: All subjects receive a magazine subscription, which they receive when they attend the session; parking expenses are covered for all treatment sessions and assessment appointments. Participants receive compensation for completing the paper-and-pencil instruments, Three-Day Food Record, and appointment for physical measures and phlebotomy at 6, 12, 18, and 24 months.

to the participant leaving the center. Each staff person who oversees or completes an assessment procedure records his or her initials on a form that documents each assessment procedure. The coordinator reviews the form prior to the participant's departure.

5. Intervention

Subjects in both dietary conditions receive 32 treatment sessions of standard cognitive-behavioral weight management treatment over 12 months; the main components of this approach include self-monitoring, goal setting, cognitive restructuring, stimulus control, demonstrations and skill development. See Table 3 for details. The only difference between the SBT and SBT+LOV groups is the content focused on the two dietary plans: a LOV diet and a diet that permits meat, fish, and poultry. Whether or not a participant received the preferred treatment condition is not addressed as part of the intervention.

Participants in all four groups are instructed to follow a calorie restriction (1200–1500 for women and 1500–1800 for men) and fat restriction (25% of total calories), and the same physical activity goals (walking at least 150 min per week). Prior to each session the subject is weighed in a private room and exchanges the completed paper food diary for a new one. The group size ranges from 12 to 18 and the sessions last 60 min. Sessions are held in the evening, weekly for the first six months, then every two weeks for months 7–9 and monthly for months 10–12. At 12 months subjects enter the maintenance phase and there is no contact until the 18-month assessment appointment.

5.1. Interventionists and protocol adherence

The interventionists are masters' prepared dietitians and exercise physiologists complimented by a multidisciplinary team that includes nurses and behavioral scientists. The interventionist, the evenings and the times for the four group sessions are rotated for each cohort to remove any potential influence of interventionist, day or time of session. Intervention manuals with detailed leader notes provide specific guidelines for the interventionist to follow to ensure integrity of the intervention protocol. To ensure uniformity of treatment procedures, the interventionists attend weekly meetings with the PI to review the previous sessions and plan for the next sessions, and meet monthly with a clinical psychologist with extensive experience in behavioral management of weight to discuss issues related to delivery of the intervention or to participants.

6. Data safety monitoring plan

Because this is a low risk study, a data safety monitoring committee was not required; however, a detailed plan and identified Data Safety Monitoring Officer (DSMO) was. The primary safety concerns are gastrointestinal, musculoskeletal, and psychological systems. A Symptom and Injury Survey was developed for the study and is administered at each assessment appointment. If the participant reports symptoms or injury, the individual completes a more detailed survey specific to that body system. Depressive symptomatology, measured by the BDI–II, is a secondary outcome in the study but is also addressed in safety monitoring. The scores for the BDI–II are reviewed immediately after each assessment and the participant's physician is notified in writing if the score (>20) indicates a concern about clinical depression. The participant is also informed and offered information about counseling resources. Biological measures are routinely collected and reviewed for safety monitoring, e.g., lipid profile, insulin, glucose and blood pressure. Results are reviewed by the PI and shared with the DSMO, a physician specialized in endocrinology with extensive experience in weight management. If any of these parameters are elevated, the participant is advised to inform his or her physician. All participants are provided a written report of the biological and physical measure results from each assessment.

7. Data management

The study uses a password protected centralized Oracle 9i database for storage of the outcome data, which is identified by subject identification number only. The outcome data are collected on forms designed to permit scanning using Teleform 6.1 software. Data are verified for accuracy after they are scanned into the database. A Visual Basic 6.0 program is used to clean all scanned data by employing logic for data correction, range checks, skip and fill,

coding missing values, and coding non-applicable questions. The progress of all subjects is tracked throughout the study in a Microsoft (MS) Access tracking program that permits staff to query the system and develop reports at any time. Process data (completion of weekly diary, achievement of dietary and physical activity goals, weights and attendance) are entered weekly in a MS Access database so retention and progress can be reviewed monthly. Status reports of screening, recruitment, and assessments are provided frequently. Only trained project staff are permitted to scan or clean the data and must first provide a logon name and password.

8. Analysis plan

The design of the study requires data collection at baseline, 6, 12, and 18 months. Therefore, missing data may present a problem in the data analyses. Analyses will follow the intention-to-treat model (ITT), that is, all randomized

Table 4
Baseline sample description ($N=182$)

Characteristic	% (n)	
Gender		
Female	87.4 (159)	
Race/ethnicity		
White	70.3 (128)	
Marital status		
Currently married	58.2 (106)	
Never married	19.2 (35)	
Divorced or separated	15.3 (28)	
Employment status		
Employed full time	80.8 (147)	
Employed part time	9.3 (17)	
Homemaker or student	4.9 (9)	
Gross household income		
>$50,000	56.0 (102)	
$30,000–$50,000	25.8 (47)	
$10,000–$30,000	17.0 (31)	
Co-morbid conditions		
Coronary heart disease	1.0 (2)	
Hypertension	26.4 (48)	
Elevated cholesterol	19.2 (35)	
History of emotional/psychological problems	6.0 (11)	
History of being overweight		
Pre-school period	9.3 (17)	
Elementary school period	23.6 (43)	
Junior high school period	29.7 (54)	
High school period	25.3 (46)	
Age 19–25 years	33.0 (60)	
Age 26–35 years	56.6 (103)	
Age 36–45 years	52.2 (95)	
Age 46–55 years	29.7 (54)	
Have intentionally lost:	10–19#	20–49#
Never	13.2% (24)	39.0% (71)
1–2 times	41.2% (75)	44.5% (81)
3–5 times	25.3% (46)	9.9% (18)
6–10 times	12.1% (22)	2.2% (4)
10+ times	6.6% (12)	1.6% (3)
	M ± SD	Range
Age (years)	44.1 ± 8.6	20–55
Education (years)	15.2 ± 2.5	11–23
BMI (kg/m^2)	34.2 ± 4.1	26.7–42.7

There were no significant differences between the groups at baseline.

subjects will be included in the analyses according to their original assignment [37]. For the primary hypotheses, the outcome variable is the weight change from baseline to 18 months. Individuals who withdraw or do not complete the final assessment will be included in the analysis by using the baseline weight as imputed values; in other words, no weight change will be assumed. The ITT approach will tend to bias the analyses in the direction of the null hypothesis of no difference between groups.

9. Preliminary results

9.1. Sample-baseline description

As of February 2004, when recruitment was closed, 200 individuals had been randomized to the PREFER study. From that sample, 15 were discarded in order to maintain a balance between the treatment groups (SBT and SBT+LOV) and three subjects were withdrawn because they no longer met the inclusion criteria (2 diagnosed with diabetes, 1 became pregnant). There were no significant differences in the sociodemographic variables including age, BMI and education between the 182 subjects who participated in the study and the 18 subjects who did not continue in the study. The sample ($N=182$) has a 29.7% minority representation; however, the sample is limited in its male representation (12.6%). At baseline, the mean age was 44.1 ± 8.6 years (range 20–55) and on average the sample had 15.19 years of education; 58.2% were married and 80% were employed full time. The clinical profile suggested a fairly healthy group. The average BMI was 33.94 with a range of 26.7–42.6. CHD risk factors were represented with 26.4% having hypertension and 19.2% having elevated cholesterol. A history of excessive body weight was common (see Table 4). Compared to the total screened sample ($N=932$), the sample that remained eligible and was randomized ($n=200$) was older (44.2 ± 8.6 vs. 34.3 ± 7.1 years) and had a lower mean BMI (33.9 ± 4.1 vs. 42.9 ± 9.6). The range

Table 5
Descriptive statistics for the baseline measures ($N=182$)

Scale	M ± SD
Low density lipoprotein (LDL) cholesterol (mg/dL)	124.38 ± 34.91
Females	124.45 ± 33.92
Males	123.87 ± 41.99
High density lipoprotein (HDL) cholesterol (mg/dL)	53.07 ± 12.23
Females	54.71 ± 11.82
Males	41.71 ± 8.63
Triglycerides (mg/dL)	133.82 ± 70.23
Females	125.86 ± 60.78
Males	188.87 ± 102.09
Glucose (mg/dL)	95.73 ± 8.26
Insulin (μU/mL)	18.68 ± 8.87
Blood pressure ($n=57$)* (mm Hg)	
Systolic	123.09 ± 14.44
Diastolic	79.93 ± 8.71
Waist circumference (cm)	
Females	104.1 ± 13.2
Males	112.5 ± 10.7
BMI (kg/m^2)	
Females	34.13 ± 4.17
Males	33.72 ± 3.60
Paffenbarger Activity Questionnaire (Kcal expended/week)	1942.20 ± 2291.78
Barriers to Health Eating (range: 0–110)	60.86 ± 14.50
Hunger Satiety Scale (range: 6–42)	25.44 ± 3.36
Weight Efficacy Lifestyle (range: 0–180)	109.36 ± 32.85
Beck Depression Inventory-II (range: 0–63)	7.95 ± 6.73
Medical outcomes (range: 0–100 for each)	
Physical function	51.48 ± 6.98
Psychological function	50.60 ± 8.10

* BP measures were not obtained on the first two cohorts at baseline.
There were no significant differences between the genders at baseline except for HDL-C and triglyceride levels ($P<.001$).

of BMI among those who were screened was 21.09 to 69.32, demonstrating the wide range in body weight among those seeking weight loss treatments. The four treatment groups were compared in terms of baseline characteristics, and the results showed that there were no significant differences across the four treatment groups. Therefore, descriptive statistics were reported for the entire sample, combining the four treatment groups, as listed in Table 5.

10. Issues encountered and how managed

10.1. Adverse events

Two participants developed cholelithiasis, the first one presented with acute symptoms at the 38th week of the intervention (following a 43 lb weight loss) and required hospitalization and surgical treatment. The second participant did not require acute treatment. The usual procedures for handling an adverse event were followed and the Institutional Review Board required two actions: a letter informing participants of the increased risk for gallstones that is associated with weight loss that participants needed to sign and return, and an information session on the risk of developing gallstones associated with being overweight and subsequent weight loss. It should be noted that the moderate dietary restrictions in place in this study helped reduce the risk of cholelithiasis.

10.2. Adherence to the treatment protocol

Although the frequency of treatment sessions is weekly for the first 24 weeks, we observed that self-monitoring and attendance at the treatment sessions began to decline over time and also varied across the four groups. Adherence to self-monitoring for the first three weeks by the full sample by treatment groups was 80% for the SBT group and 85% for the SBT+LOV group who received their preferred treatment group; for those who did not receive their preferred group, the adherence for SBT group was 86% and for the SBT+LOV group 84%. Attendance for the first cohort's four treatment groups at 16 weeks and at 25 weeks was as follows: Preference-Yes SBT 60% and 60%, SBT+LOV 45% and 33%; Preference-No SBT 82% and 65%, SBT+LOV 81% and 60%, at 16 and 25 weeks, respectively. Preliminary data analysis suggest there is no difference in adherence to the protocol by treatment preference groups. To reduce absenteeism, participants who miss a session are contacted by one of the interventionists; if the participant declines to come in for a weight and obtain the handout materials from the session, the materials are mailed to the participant. If a participant misses two consecutive sessions, a letter is sent offering a catch-up session and the individual is encouraged to resume attending the sessions. Once the frequency of the sessions is reduced to every two weeks, reminder phone calls are made to the participants the day before the session; when the sessions are monthly, a reminder letter is sent the week before and a reminder phone call is made the day before the session. Even though completion of a 5-day food and physical activity diary are part of the screening and run-in period prior to enrollment, we have observed that adherence to self-monitoring begins to decline immediately, with adherence ranging from 53% at 16 weeks to 33% at 24 weeks. We encourage participants to self-monitor regularly so they can be aware of their behavior on an ongoing basis and take corrective action to ensure that they are meeting the dietary and physical activity goals.

Participants were introduced to the LOV diet over the first six weeks beginning with a meatless breakfast and progressing to lunch and then dinner. A dietitian who is a vegetarian participated in four sessions and helped participants learn how to adapt to this diet and how to make adjustments for a family that did not wish to follow the same eating plan. After six weeks, participants were expected to follow a diet that excluded meat, fish, and poultry. At 24 weeks, participants reported consuming, on average, 0.44 servings of meat, fish or poultry per week.

10.3. Retention

The duration of the PREFER study makes retention a challenge. To maintain contact throughout the 18-month period, we send a birthday card to all participants and holiday cards in December. Approximately two months prior to the 18-month assessment, a letter is sent to the participants to remind them of the upcoming final assessment and to remind them of the importance of their completing the study regardless of how they feel they have done during the study, that their data are crucial to the successful outcome of the study. There is a common misperception among weight loss study participants that if they have regained any weight that they are "ruining the study" if they come in

for the assessment, so this letter attempts to dispel that myth. We are flexible in scheduling the follow-up appointments for time of day and day of week. We also compensate participants $50.00 for each assessment. Such financial incentives consistently have been shown to improve treatment compliance [38]. Using this approach we achieved 86.3% retention across the three cohorts at 6 months, and 82% retention at 18 months for the first cohort.

11. Discussion

The PREFER study is a single center study, and to the best of our knowledge, it is the first randomized controlled trial examining a lacto-ovo-vegetarian eating plan as part of a weight loss study. The sample includes males and females, adults across a wide BMI range (27 to 43), and has a 30% representation of minority groups. A limitation includes the small percent of males (12.6%), which may have been affected by the potential to be assigned to the lacto-ovo-vegetarian group, although this sample includes more males than is generally reported in weight loss studies. Males do not respond to weight loss studies in large numbers so a more concerted effort is needed to enroll more men in the future. Although we have maintained an acceptable retention rate so far, the six-month maintenance phase (months 13–18) with no contact is a challenge to prevent attrition when individuals are at risk to regain weight and may not want to come in for the final assessment. Considering the chronic nature of overweight and obesity, we would recommend maintaining some contact, if only in the form of a phone call every two months to provide ongoing support.

The design used in this weight loss treatment study represents the current state of science in standard behavioral weight loss treatment. Most studies have an 18-month to 24-month duration with group treatment sessions that begin at one-week intervals and are reduced over time to monthly intervals followed by a maintenance phase. The only major difference between the standard study design and the current study is the use of treatment preference and the restriction placed on meat, fish, and poultry consumption.

The literature supported the use of both treatment preference and a vegetarian diet as potential strategies to improve adherence. However, the literature supporting longer-term acceptance of a vegetarian diet includes primarily cross-sectional studies that rely on subject self-report [21,22]. In a recent report by Barnard et al. of a 14-week study that randomly assigned participants to either a low-fat vegan diet or to a fat-modified diet that included meat, participants reported that the vegan diet was easier to follow than their usual diet and that they could continue with the vegan diet at least most of the time in the future; the subjects in the low-fat meat containing diet thought that continuation of that diet would be more difficult to continue than their baseline diet [28].

It is difficult to compare adherence across most studies and weight studies are no different. First, few studies report adherence and many define and measure it differently. Those that do report adherence often report it only for the specific component of the standard behavioral treatment that was being manipulated. We found six studies that reported adherence to weight management programs. None reported on adherence to self-monitoring, and only one reported adherence to diet (fat intake) [39]. Three reported on adherence to physical activity prescription, [40–42] two on attendance, [40,43] and five on retention at varying points that ranged from 24 weeks to 30 months [40–44]. Our retention rates fall within the range of retention rates reported in the literature, while our attendance rates are somewhat lower than the two reports we identified.

As noted above, adherence to the treatment protocol continues to be a challenge, especially for the long-term. Self-monitoring is one of the core components of the behavioral intervention but adherence to this strategy began to decline early in the study. Observation of this decline prompted the PI to obtain additional funding for an ancillary study that is being conducted with participants in the third cohort to examine in detail the patterns of participants' self-monitoring patterns and to explore in depth with the participants, after the completion of the trial, their feelings about adherence to the protocol. The design and methods of this ancillary study are described in an accompanying paper [45].

In summary, we have learned several lessons from this trial. Participants need to be informed prior to study entry of the risk of developing gallstones as part of a weight loss program, a more concerted effort needs to be made to recruit men, and ongoing contact with participants is more consistent with the chronic disease model and should reduce attrition during the last six months of the study. The PREFER study has the potential to make a substantial contribution to understanding the role of treatment preference in long-term adherence to a study protocol as well as the potential of a diet that eliminates meat, fish, and poultry for long-term weight loss. Further work needs to be done to improve adherence to self-monitoring.

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