A Randomized Clinical Trial Testing Treatment Preference and Two Dietary Options in Behavioral Weight Management: Preliminary Results of the Impact of Diet at 6 Months—PREFER Study

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Abstract

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Objective: The PREFER study objectives were to examine potential differences in weight loss during a standard behavioral intervention between subjects assigned to one of two calorie- and fat-restricted diets [standard behavior treatment (SBT) and lacto-ovo-vegetarian ([SBT+LOV)], with or without regard to their preferred dietary treatment. This article reports the differences in outcomes between diet groups after the first 6 months of the intervention.

Research Methods and Procedures: The study used a four-group design. Subjects ($n = 182$) were randomized to a treatment preference group and then to a dietary treatment group. For this report, preference groups were combined to permit comparisons by dietary treatment only (SBT, $n = 98$; SBT+LOV, $n = 84$). Additional analyses compared SBT+LOV subjects who were 100% adherent (did not consume any meat, fish, or poultry, $n = 47$) to those who were <100% adherent ($n = 24$).

Results: Significant differences were seen in the baseline to 6-month change scores between the two groups for carbohydrate consumption ($p = 0.013$), protein consumption ($p < 0.001$), polyunsaturated-to-saturated fat ratio ($p = 0.009$), and low-density lipoprotein-cholesterol (LDL-C) level ($p = 0.013$). Among SBT+LOV subjects, those who were 100% adherent experienced greater reductions in weight ($p < 0.001$), total cholesterol ($p = 0.026$), LDL-C ($p = 0.034$), and glucose ($p = 0.002$) and consumed less fat ($p = 0.030$) compared with those who were <100% adherent.

Discussion: Differences between dietary treatment groups at 6 months were minimal, most likely because one-third of the SBT+LOV group did not follow the vegetarian diet and because both groups had the same calorie and fat restrictions. SBT+LOV subjects who were 100% adherent were more successful at both weight loss and cholesterol reduction than those who were <100% adherent, suggesting that vegetarian diets are efficacious for weight and cholesterol control.

Key words: weight loss, behavioral therapy, lacto-ovo-vegetarian, adherence, treatment preference

Introduction

Obesity has become a global epidemic contributing to a wide variety of medical conditions, including hypertension and cardiovascular disease, insulin resistance and type 2 diabetes, metabolic syndrome, dyslipidemia, gallstones, inflammation, osteoarthritis, respiratory problems such as asthma and sleep apnea, reproductive problems including infertility, and certain cancers (1–5). A commonly used treatment is a combination cognitive-behavioral therapy,

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referred to as standard behavior treatment (SBT),[1] which includes a low-calorie diet, increased physical activity, and behavioral therapy (3,6). The recommended dietary approach is a low-fat diet (<25% of calories from fat) with a calorie deficit of 500 to 1000 kcal/d, which will result in an initial weight loss of 1 to 2 lb/wk.

Behavioral therapy for obesity has been studied for more than 20 years. In general, investigators have succeeded in increasing initial weight loss but not in improving the long-term maintenance of that weight loss (7). Typically, within 1 year of completing weight loss therapy, individuals regain approximately 35% of their lost weight, and within 3 to 5 years, they return to their baseline weight (6,7). Currently, the greatest need in obesity treatment is to improve long-term maintenance of weight loss through permanent lifestyle change.

Individuals who adopt vegetarian diets seem to be more successful in achieving the goal of long-term lifestyle change than overweight and obese individuals who temporarily modify their eating habits to lose weight. They report following a vegetarian eating plan for longer periods than those following weight loss diets (8–10). They also report more satisfaction with the vegetarian eating plan and less desire to change their diet (10).

Vegetarians not only stay on their diets longer, but they also seem to adhere more closely to their eating plan than individuals on traditional weight loss diets (11,12). Barnard et al. (11) reviewed 30 studies that prescribed dietary modification for cardiovascular risk reduction and found that stricter dietary programs yielded greater dietary change. For example, those prescribed a vegetarian diet consumed a diet that, on average, contained 24% fat vs. those not prescribed a vegetarian diet, whose diets contained 30% fat. The two vegetarian studies reported 100% compliance to the restricted fat goal, whereas the 28 non-vegetarian studies reported 46% compliance to the restricted fat goal.

Studies not targeting weight loss but using vegetarian diets have resulted in significant weight loss. Moreover, the studies demonstrated maintenance of that loss (13–15). Subjects in the Multicenter Lifestyle Demonstration Project lost an average of 10.7 lb after 2 years and maintained a 7.4 lb average loss after 3 years (13).

The benefits of a vegetarian diet seem to extend beyond weight loss. Several studies have reported decreases in low-density lipoprotein-cholesterol (LDL-C) with a vegetarian diet (12,13,16). A recent study by Gardner et al. (16) reported significantly more reduction in both total cholesterol and LDL-C in a low-fat plant-based diet when compared with a standard low-fat diet. Similarly, in a study of a low-fat vegetarian diet vs. a placebo supplement, Barnard et al. (12) found that the low-fat vegetarian diet resulted in significant reductions in total cholesterol, LDL-C, and high-density lipoprotein-cholesterol (HDL-C). Szeto et al. (17) found that long-term vegetarians had a better antioxidant status and coronary heart disease profile than a group of age- and sex-matched controls when serum biomarkers were measured. These studies suggest that a vegetarian or plant-based diet may protect against coronary heart disease.

The PREFER trial was designed to evaluate the impact of the interaction between diet type [standard calorie- and fat-restricted weight loss diet (SBT) vs. calorie- and fat-restricted lacto-ovo-vegetarian diet (SBT+LOV)] as part of SBT and treatment preference [assigned to a preferred diet group (Treatment Preference–Yes) vs. randomly assigned to a diet group (Treatment Preference–No)] on weight loss at 18 months. The study also collected information on treatment adherence and biological measures. This report focuses on the impact of diet type on weight loss and on biological measures after the first 6 months of the intervention.

Research Methods and Procedures

Design

The PREFER study was a single-center, 18-month, randomized, controlled trial of SBT for weight loss in adults. A four-group design with two factors was used to compare the effects of dietary treatment (SBT vs. SBT+LOV) and treatment preference (Yes vs. No).

The Institutional Review Board of the University of Pittsburgh approved this study, and all subjects provided written informed consent.

Subjects

Figure 1 presents a subject flow diagram of the study. Subject recruitment from the community was performed in three waves, or cohorts, from September 2002 to May 2004. Recruitment methods included contacting individuals seeking weight loss treatment and listed in the University of Pittsburgh's Obesity Nutrition Research Center database; placing an audio advertisement on the University and Medical Center audix announcement systems; and mailing recruitment cards to individuals on purchased address lists.

Individuals were eligible if they were between 18 and 55 years of age, had a BMI between 27 and 43, were willing to be randomized to one of the two treatment preference groups and one of the two dietary groups, and successfully completed a 5-day food diary. A series of screening procedures was used to exclude individuals who had a serious illness or unstable condition for which physician supervision of diet and exercise prescription was needed; had a cardiovascular or orthopedic condition that would require physician clearance before participation; had limitations precluding ability to exercise; were pregnant or intended to

[1] Nonstandard abbreviations: SBT, standard behavior treatment; LOV, lacto-ovo-vegetarian; LDL-C, low-density lipoprotein-cholesterol; HDL-C, high-density lipoprotein-cholesterol.

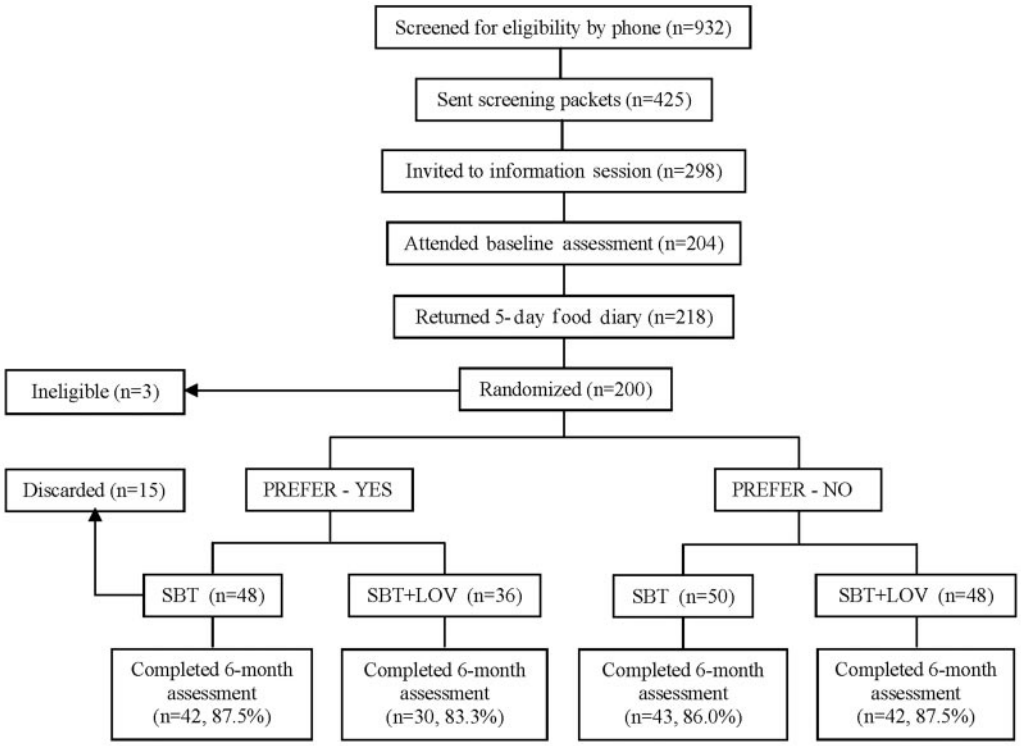

Figure 1: Subject flow diagram.

become pregnant in the next 18 months; were being treated for a psychological disorder; reported alcohol intake of ≥4 drinks/d; were participating or had recently participated in a weight loss treatment program or used weight loss medication; reported no regular intake of meat, fish, and fowl; had a serious binge eating problem; and did not at least moderately prefer one of the dietary treatments (SBT or SBT+LOV) over the other.

Randomization

Baseline laboratory tests were conducted to confirm eligibility before randomization. Of the 932 individuals who responded to the recruitment attempts, 200 were randomized. Three were excluded after randomization owing to subsequent events rendering them ineligible.

We used a two-stage scheme, first randomizing to treatment preference groups and then to dietary treatment groups. In the first stage, 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 condition. Subjects in the Treatment Preference–Yes group were not further randomized but were treated according to their diet preference. All subjects who preferred the SBT+LOV condition were assigned to that group. However, to obtain a fair balance in size across the four groups, only 50% of those who chose the SBT were randomly selected for inclusion. Fewer subjects preferred the SBT+LOV diet; therefore, 15 additional subjects who preferred the SBT diet were excluded to prevent the Treatment Preference–Yes SBT group from being significantly larger than the Treatment Preference–Yes SBT+LOV group.

Intervention

Subjects in both dietary conditions received 32 treatment sessions of standard cognitive-behavioral therapy for weight management over a period of 12 months; the main components of this approach included self-monitoring eating and exercise behaviors, goal setting, cognitive restructuring, stimulus control, demonstrations, and skill development. Treatment sessions were held separately for the two dietary treatment groups. The sessions were identical except for information on the two dietary plans: an SBT+LOV diet and an SBT diet that permitted meat, fish, and poultry. Treatment preference was not addressed as part of the intervention.

Physical activity consisted of a recommendation to increase the participants' activity to 150 min/d by the sixth week and thereafter to increase or at least maintain that goal. We recommended walking as the primary form of structured activity and encouraged all subjects to increase their daily activities, such as walking stairs instead of taking elevators and parking farther away from the store in large

parking lots. Four of the group sessions focused on exercise, e.g., aerobic training, weights, and resistance exercise. We monitored and provided feedback to subjects regarding their recorded activity in their weekly diaries.

Guiding participants in adopting the LOV diet took many forms. Subjects were instructed to eliminate meat, fish, and poultry over the first 6 weeks of the study, beginning with breakfast, then lunch, and, finally, dinner. We introduced several new foods to participants with tastings that followed a discussion of the food, e.g., vegetable protein substitutes such as soy products (tofu, veggie burgers), homemade dishes using legumes (Lentils Ole), and cheeses made of vegetable protein. Articles on adapting recipes and numerous recipes were provided on a regular basis. Subjects in both treatment groups participated in field trips to supermarkets that focused on teaching them how to select produce and navigate the large food markets, and also cooking demonstrations; however, the SBT+LOV subjects' excursions focused on a diet that excluded meat, fish, and poultry. We also addressed the issue that following an LOV diet did not guarantee a low-fat intake and that they needed to pay close attention to the fat content of the dairy products and other sources of protein they were using to replace meat. Finally, four of the sessions were led by a dietitian who was a vegetarian and who was able to discuss many of the everyday challenges one faces in adopting and implementing this type of diet.

All subjects were instructed to restrict consumption of calories (1200 to 1500 for women and 1500 to 1800 for men) and fat (25% of total calories) and to engage in physical activity (walking at least 150 min/wk). Subjects were instructed to record their daily food intake, the calorie and fat gram content, and the amount (in minutes) of physical activity that they performed in their weekly food and physical activity diaries. Subjects in the SBT+LOV group were told to also record in a specified column on the back cover of their weekly diaries the number of meat meals eaten every day.

Sessions were held weekly for the first 6 months, then every 2 weeks for Months 7 to 9 and monthly for Months 10 to 12. At 12 months, subjects entered the maintenance phase until the 18-month assessment appointment; during this phase, subjects did not have contact with the study except to plan the 18-month assessment appointment.

Subjects were weighed before each treatment session, and food and physical activity diaries were collected. The diary that was turned in at the previous session was returned to the subject with written feedback from the interventionist. If the subject did not attend the session, the diary and session materials were mailed to the subject.

We provided incentives to promote attendance at the sessions; e.g., the SBT group participants received the magazine *Cooking Light*, and the SBT+LOV participants received the magazine *Vegetarian Times*. Parking and/or public transportation costs were covered. Individuals who had high levels of attendance were recognized, and flowers were given to those who achieved 100% attendance.

Measures

Outcome variables were measured at baseline and at 6, 12, and 18 months. Laboratory assessments included a lipid profile (total cholesterol, HDL-C, LDL-C, and triglycerides), serum glucose, and insulin measurement. Physical measurements included height, weight, waist circumference, and blood pressure. BMI was calculated from height and weight measures.

Subjects also completed a battery of self-report measures. Measures of treatment adherence included a Three-Day Food Record and the Paffenbarger Activity Questionnaire. Measures of factors related to adherence included the Barriers to Healthy Eating scale, Correlates of Maintenance of a Low-Fat Diet, Hunger Satiety Scale, Self-Efficacy in Weight Management, Beck Depression Inventory-II, and the Medical Outcomes Questionnaire, Short Form-36. Indicators of adherence to the intervention protocol included the completion of the weekly food and physical activity diaries as well as attendance at the treatment sessions.

Subjects in the SBT+LOV groups were asked to complete the Identity as a Vegetarian Questionnaire at 6, 12, and 18 months. This 20-item investigator-developed questionnaire assessed on a 10-point scale how subjects felt about an LOV diet (e.g., that it was ethical, nutritional, enjoyable, easy, affordable) and how strongly subjects identified with being a vegetarian (feeling comfortable in social situations, selecting vegetarian options, overall identity).

Statistical Analysis

The current analysis focused only on the effect of the first 6 months of the intervention, using the data collected at baseline and at 6 months. Analyses followed the intention-to-treat model; that is, all randomized subjects were included in the analyses according to their original assignment (18). When possible, individuals who withdrew or did not complete the 6-month assessment were included in the analysis by using the baseline weight as imputed values; in other words, no weight change was assumed. The intention-to-treat approach tends to bias the analyses in the direction of the null hypothesis of no difference between groups. For measures that were not conducted at baseline, such as the Identity as a Vegetarian Questionnaire, individuals who did not complete the 6-month assessment were excluded from the analysis.

Preference groups were combined to allow for two-group comparisons of diet only (SBT vs. SBT+LOV). The two diet groups contained a similar proportion of subjects randomized to Treatment Preference–Yes (SBT = 49%, SBT+LOV = 43%). Categorical demographic data included sex (male vs. female), race (white vs. non-white),

Table 1. Demographic characteristics of the entire sample and comparisons of characteristics between the two diet groups.

	Sample n (%)	SBT n (%)	SBT+LOV n (%)	*p*
Total	182 (100.0)	98 (53.9)	84 (46.2)	
Sex: female	159 (87.4)	86 (87.8)	73 (86.9)	0.863
Race: white	128 (70.3)	69 (70.4)	59 (70.2)	0.980
Marital status ($n = 180$)				0.828
Never married	35 (19.4)	20 (20.6)	15 (18.1)	
Married/living with partner	115 (63.9)	60 (61.9)	55 (66.3)	
Separated/widowed/divorced	30 (16.7)	17 (17.5)	13 (15.7)	
Employment status ($n = 180$)				0.738
Full time	147 (81.7)	82 (83.7)	65 (79.3)	
Part time	17 (9.4)	8 (8.2)	9 (11.0)	
Other	16 (8.9)	8 (8.2)	8 (9.8)	
	Mean ± SD	Mean ± SD	Mean ± SD	*p*
Age (years)	44.1 ± 8.6	43.4 ± 8.9	45.0 ± 8.2	0.202
Education (years)	15.2 ± 2.5	15.3 ± 2.5	15.1 ± 2.5	0.581

SBT, standard behavior treatment; LOV, lacto-ovo-vegetarian; SD, standard deviation.

marital status (married vs. not married), and employment status (employed vs. not employed). Continuous demographic data included age at entry (years) and education (years). Continuous variables measured at both the baseline and 6-month visit included weight (kg) and waist circumference (cm). Continuous variables derived from Three-Day Food Records at both visits included mean daily intake of each of the following nutrients: energy (kcal), fat (g), saturated fat (g), monounsaturated fat (g), polyunsaturated fat (g), carbohydrates (g), and protein (g). The ratio of polyunsaturated fat to saturated fat was calculated from the Three-Day Food Record data. Change scores were calculated by subtracting the 6-month value from the baseline value. Additional analyses were restricted to the SBT+LOV group only, comparing those who were 100% adherent (had not consumed meat according to their Three-Day Food Record) to those who were not 100% adherent.

To assess differences between the dietary treatment groups and between SBT+LOV adherence groups, χ^2 tests were performed for categorical data. Exact tests were used when necessary. For continuous variables, *t* tests were used for normally distributed variables, and Mann-Whitney tests were used when the variables were not normally distributed. All analyses were performed using SPSS software (SPSS, Inc., Chicago, IL).

Results

No significant differences in demographic variables, including age, BMI, and education, existed between the 182 subjects who participated in the study and the 18 subjects who were removed or became ineligible. The sample had a 29.7% minority representation; however, the sample was limited in its male representation (12.6%). At baseline, the mean age was 44.1 ± 8.6 years (range, 20 to 55 years), and, on average, the subjects had 15.2 ± 2.5 years of education; 63.9% were married or living with a partner, and 81.7% were employed full-time. The two dietary treatment groups were compared in terms of demographic characteristics, and, as shown in Table 1, no significant differences existed between the two groups.

At baseline, subjects weighed an average of 94.86 ± 14.58 kg. Men had an average waist circumference of 112.52 ± 10.71 cm; women had an average waist circumference of 104.05 ± 10.71 cm. Subjects consumed an average of 2039.87 ± 652.12 calories/d; 35% of those calories were from fat. Average levels of serum total cholesterol, and specifically serum LDL-C, were higher than desired (5.29 ± 1.01 mM and 3.22 ± 0.90 mM, respectively). Ten subjects were on lipid-lowering drugs at baseline (eight in the SBT+LOV group, and two in the SBT group). At 6 months, three of the SBT+LOV group subjects and one of the SBT subjects were no longer on the drugs, and one in each group had initiated pharmacological treatment for hyperlipidemia. For the entire sample, significant changes were observed at 6 months in all measures except LDL-C and glucose. Subjects lost an average of 7.21 ± 6.28 kg (range, 3.15-kg gain to 29.79-kg loss).

Reported physical activity on the Paffenbarger questionnaire revealed no differences between the two groups at

Table 2. Baseline and 6-month measurements and comparisons of change scores by diet group*

	SBT (n = 98)			SBT±LOV (n = 84)			Change score† p
	Baseline	Six months	Change	Baseline	Six months	Change	
Body measurements							
Weight (kg)	95.25 ± 14.94	88.28 ± 15.66	−0.97 ± 6.53	94.40 ± 14.23	86.90 ± 15.55	−7.50 ± 6.00	0.321
BMI (kg/m^2)	34.08 ± 4.24	30.90 ± 4.64	−2.83 ± 2.07	34.09 ± 3.94	30.77 ± 4.32	−3.21 ± 2.06	0.125
Waist circumference (cm)							
Men	111.14 ± 11.12	99.35 ± 10.04	−11.78 ± 10.61	114.02 ± 10.57	104.65 ± 13.13	−9.37 ± 5.90	0.695
Women	103.96 ± 13.47	98.46 ± 13.31	−5.50 ± 6.31	104.16 ± 12.97	98.04 ± 13.08	−6.12 ± 7.34	0.799
Nutritional measurements							
Mean energy consumed (kcal)	2053.67 ± 647.79	1533.87 ± 581.08	−519.80 ± 533.15	2023.76 ± 660.66	1487.78 ± 475.23	−535.98 ± 511.81	0.836
Fat consumed (%kcal)	35.59 ± 6.75	27.08 ± 8.29	−8.51 ± 9.11	35.35 ± 6.84	25.76 ± 8.30	−9.59 ± 9.62	0.436
Saturated fat consumed (%kcal)	11.79 ± 2.81	8.68 ± 3.32	−3.12 ± 3.86	11.96 ± 3.27	8.20 ± 3.53	−3.76 ± 3.75	0.170
Monounsaturated fat consumed (%kcal)	13.66 ± 2.97	10.08 ± 3.56	−3.58 ± 3.80	13.42 ± 2.94	9.23 ± 3.54	−4.19 ± 4.30	0.312
Polyunsaturated fat consumed (%kcal)	7.30 ± 2.11	5.98 ± 2.04	−1.31 ± 2.64	7.20 ± 2.21	6.22 ± 2.30	−0.97 ± 2.93	0.412
Carbohydrates consumed (%kcal)	48.63 ± 7.85	55.74 ± 9.26	7.12 ± 10.58	50.31 ± 7.72	61.37 ± 9.25	11.06 ± 10.70	0.013
Protein consumed (%kcal)	15.73 ± 3.55	17.86 ± 4.37	2.14 ± 4.24	15.15 ± 3.41	15.07 ± 3.46	−0.08 ± 4.12	<0.001
PS ratio	0.71 ± 0.28	0.80 ± 0.29	0.10 ± 0.39	0.68 ± 0.31	0.95 ± 0.43	0.26 ± 0.45	0.009
Laboratory measures							
Total cholesterol (mM)	5.29 ± 0.97	5.20 ± 1.05	−0.09 ± 0.63	5.29 ± 1.06	5.07 ± 1.00	−0.22 ± 0.66	0.202
HDL (mM)	1.40 ± 0.32	1.34 ± 0.31	−0.06 ± 0.18	1.34 ± 0.31	1.31 ± 0.29	−0.04 ± 0.19	0.393
LDL (mM)	3.18 ± 0.88	3.23 ± 0.97	0.05 ± 0.55	3.27 ± 0.94	3.11 ± 0.86	−0.16 ± 0.54	0.013
Triglycerides (mM)	1.54 ± 0.86	1.36 ± 0.67	−0.17 ± 0.61	1.48 ± 0.71	1.43 ± 0.63	−0.05 ± 0.66	0.419
Glucose (mM)	5.28 ± 0.44	5.25 ± 0.44	−0.03 ± 0.40	5.35 ± 0.47	5.29 ± 0.54	−0.06 ± 0.54	0.332
Insulin (pM)	127.68 ± 63.60	105.68 ± 55.54	−22.00 ± 39.75	132.07 ± 59.46	102.41 ± 45.86	−29.67 ± 40.35	0.140

SBT, standard behavior treatment; LOV, lacto-ovo-vegetarian; PS ratio, polyunsaturated-to-saturated fat ratio.

* Mean ± standard deviation.

† Mean change scores from baseline to 6 months were calculated for each group. Means were compared using Student's t tests or Mann-Whitney tests, as appropriate.

Table 3. Demographic characteristics of SBT+LOV subjects and comparisons of characteristics between the two adherence groups

	All SBT+LOV with adherence data *n* (%)	100% adherent† *n* (%)	<100% adherent *n* (%)	*p*
Total*	71 (100.0)	47 (66.2)	24 (33.8)	
Sex: female	63 (88.7)	39 (83.0)	24 (100.0)	0.045
Race: white	49 (69.0)	36 (76.6)	13 (54.2)	0.053
Marital status				0.020
Never married	13 (18.3)	5 (10.6)	8 (33.3)	
Married/living with partner	50 (70.4)	38 (80.9)	12 (50.0)	
Separated/widowed/divorced	8 (11.3)	4 (8.5)	4 (16.7)	
Employment status ($n = 70$)				0.286
Full time	54 (77.1)	35 (76.1)	19 (79.2)	
Part time	8 (11.4)	7 (15.2)	1 (4.2)	
Other	8 (11.4)	4 (8.7)	4 (16.7)	
	Mean ± SD	Mean ± SD	Mean ± SD	*p*
Age (years)	45.5 ± 8.2	46.0 ± 7.1	44.4 ± 10.0	0.995
Education (years)	15.3 ± 2.5	15.4 ± 2.7	15.3 ± 2.3	0.858

SBT, standard behavior treatment; LOV, lacto-ovo-vegetarian.

*Adherence data were not available for 13 SBT+LOV participants.

† 100% adherent means that subjects did not consume any meat, fish, or poultry, according to the Three Day Food Record. <100% adherent means that subjects consumed meat, fish, or poultry for at least one meal, according to the Three Day Food record.

baseline (2109.92 kcal in the SBT group and 1746.53 kcal in the SBT+LOV group) and at 6 months (3123.95 kcal in the SBT group and 3100.94 kcal in the SBT+LOV group). Over time, both groups significantly increased their physical activity, by 983.73 kcal in the SBT group and 1252.62 kcal in the SBT+LOV group, but the differences in the increases between the two groups were not significant ($p = 0.619$).

Baseline and 6-month average measurements of the two diet groups are shown in Table 2. When the two diet groups (SBT vs. SBT+LOV) were compared, significant differences were seen in the change scores of carbohydrate consumption ($p = 0.013$), protein consumption ($p < 0.001$), polyunsaturated-to-saturated fat ratio ($p = 0.009$), and LDL-C ($p = 0.013$). The SBT+LOV participants had a greater increase in carbohydrate intake, maintained their protein intake, and increased their polyunsaturated-to-saturated fat ratio more than the SBT group.

Although the average number of meat meals consumed, according to the Three-Day Food Record, differed significantly between the two dietary treatment groups ($p < 0.001$), not all subjects in the SBT+LOV group adhered to the LOV restrictions. Subjects in the SBT+LOV group recorded consuming an average of 0.26 meat meals per day (range, 0 to 2.67 meat meals). To investigate whether poor adherence to the SBT+LOV diet reduced the observed effects of the vegetarian diet, we conducted a subgroup analysis of the SBT+LOV subjects, comparing those who were 100% adherent (no meat, fish, or poultry consumed) according to the Three-Day Food Record to those who were not 100% adherent (ate some meat, fish, or poultry).

Table 3 shows the demographic characteristics of the two SBT+LOV groups by adherence (100% adherent vs. <100% adherent). Employment status, age, and education did not differ significantly between groups. However, a significant difference was seen in sex ($p = 0.045$); none of the eight male subjects was <100% adherent to the LOV diet. Significant differences were also seen in race ($p = 0.053$) and marital status ($p = 0.020$) between the two adherence groups; a higher proportion of the 100% adherent subjects was white, and a higher proportion was married.

The mean values of the baseline and 6-month measurements for both of the SBT+LOV adherence groups (100% adherent vs. <100% adherent) are shown in Table 4. Compared with those who were <100% adherent, those who were 100% adherent lost more weight ($p < 0.001$), had a greater reduction in BMI ($p < 0.001$), consumed less fat

Table 4. Baseline and 6-month measurements and comparisons of change scores of the SBT+LOV participants by adherence group*

	100% adherent (n = 47)			<100% adherent (n = 24)			Change score‡ p
	Baseline	Six months	Change score	Baseline	Six months	Change score	
Body measurements							
Weight (kg)	94.05 ± 14.45	83.42 ± 14.57	−10.63 ± 5.39	90.45 ± 12.73	85.46 ± 13.84	−4.98 ± 3.95	<0.001
BMI (kg/m^2)	34.02 ± 4.02	30.15 ± 4.21	−3.87 ± 1.99	34.01 ± 4.20	32.10 ± 4.40	−1.91 ± 1.59	<0.001
Waist circumference (cm)							
Men	113.44 ± 11.04	101.84 ± 11.58	−11.60 ± 4.34				—
Women	105.14 ± 12.39	96.29 ± 11.96	−8.84 ± 8.21	101.86 ± 13.31	97.61 ± 13.39	−4.25 ± 4.96	0.018
Nutritional measurements							
Mean energy consumed (kcal)	2076.09 ± 614.95	1379.62 ± 336.68	−696.47 ± 481.29	1930.30 ± 709.75	1418.30 ± 326.76	−512.00 ± 516.13	0.141
Fat consumed (%kcal)	35.57 ± 7.15	22.49 ± 6.08	−13.08 ± 9.38	34.35 ± 6.39	26.40 ± 8.03	−7.95 ± 8.86	0.030
Saturated fat consumed (%kcal)	11.93 ± 2.92	7.00 ± 2.47	−4.93 ± 3.36	11.83 ± 3.38	8.31 ± 3.20	−3.52 ± 4.16	0.114
Monounsaturated fat consumed (%kcal)	13.47 ± 3.09	7.81 ± 2.65	−5.66 ± 4.08	13.34 ± 2.77	9.76 ± 3.56	−3.58 ± 4.33	0.051
Polyunsaturated fat consumed (%kcal)	7.41 ± 2.29	5.84 ± 2.17	−1.57 ± 3.42	6.40 ± 1.80	6.07 ± 2.20	−0.33 ± 2.46	0.120
Carbohydrates consumed (%kcal)	49.82 ± 7.80	65.35 ± 6.30	15.53 ± 9.14	51.50 ± 8.42	59.80 ± 9.97	8.3 ± 11.31	0.005
Protein consumed (%kcal)	15.40 ± 3.32	15.08 ± 3.46	−0.32 ± 4.74	14.73 ± 3.05	15.07 ± 2.98	−0.34 ± 4.01	0.560
PS ratio	0.68 ± 0.27	1.01 ± 0.44	0.33 ± 0.51	0.63 ± 0.32	0.91 ± 0.40	−0.28 ± 0.42	0.657
Laboratory measures							
Total cholesterol (mM)	5.29 ± 1.02	4.91 ± 0.88	−0.38 ± 0.76	5.25 ± 1.13	5.27 ± 1.10	0.02 ± 0.54	0.026
HDL (mM)	1.34 ± 0.31	1.29 ± 0.27	−0.05 ± 0.20	1.27 ± 0.27	1.25 ± 0.26	−0.02 ± 0.22	0.587
LDL (mM)	3.25 ± 0.96	2.97 ± 0.84	−0.28 ± 0.60	3.27 ± 0.94	3.30 ± 0.86	0.03 ± 0.49	0.034
Triglycerides (mM)	1.53 ± 0.77	1.42 ± 0.60	−0.10 ± 0.85	1.55 ± 0.67	1.58 ± 0.75	0.03 ± 0.35	0.359
Glucose (mM)	5.48 ± 0.47	5.26 ± 0.47	−0.22 ± 0.41	5.15 ± 0.43	5.35 ± 0.72	0.20 ± 0.78	0.002
Insulin (pM)	138.78 ± 64.55	100.21 ± 46.04	−38.57 ± 40.46	125.53 ± 51.35	98.30 ± 38.00	−27.23 ± 44.44	0.346

SBT, standard behavior treatment; LOV, lacto-ovo-vegetarian; PS ratio, polyunsaturated-to-saturated fat ratio.

* Mean ± standard deviation.

† Adherence data were available for 71 of 84 SBT+LOV subjects.

‡ Mean change scores from baseline to 6 months were calculated for each group. Means were compared using t tests or Mann-Whitney tests, as appropriate.

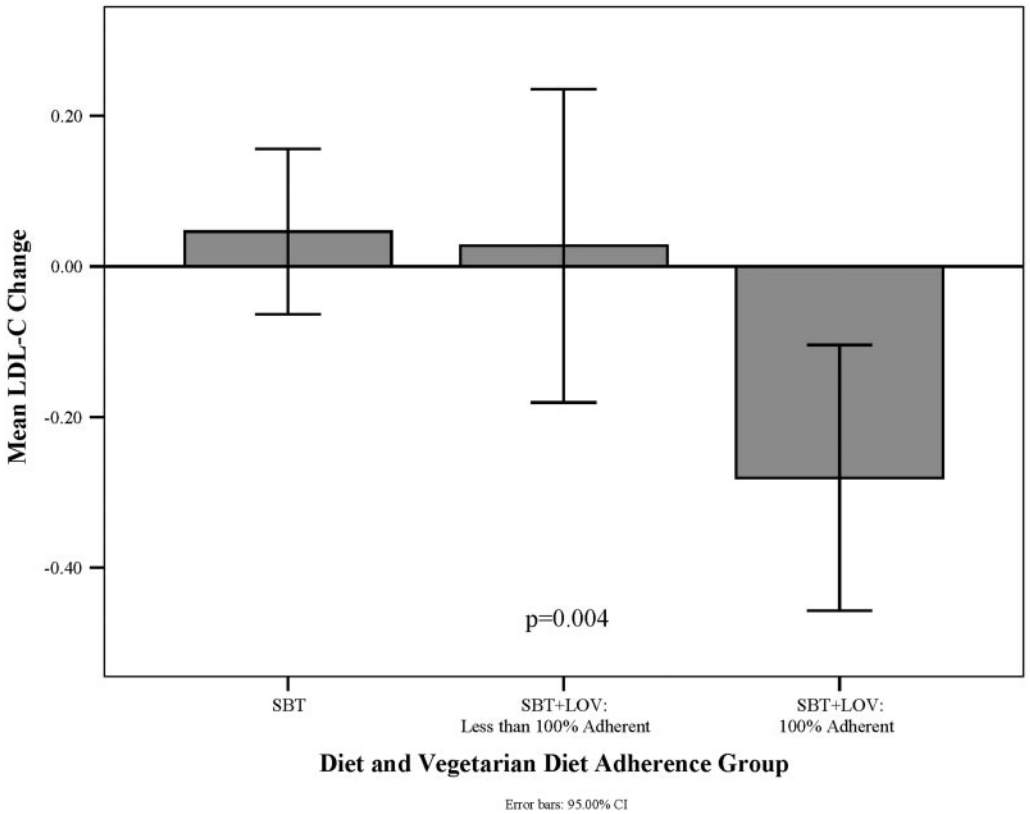

Figure 2: Comparison of LDL-C change scores from baseline to 6 months between the SBT diet group and the two SBT+LOV adherence groups. Error bars, 95% confidence intervals.

($p = 0.030$) and fewer carbohydrates ($p = 0.005$), and experienced greater reductions in total cholesterol ($p = 0.026$), LDL-C ($p = 0.034$), and glucose ($p = 0.002$). Figure 2 shows the LDL-C change scores for participants in the SBT, SBT+LOV 100% adherent, and SBT+LOV <100% adherent groups.

Compared with SBT+LOV subjects who continued to eat some meat, fish, or poultry meals, subjects who were 100% adherent to the vegetarian diet were significantly more likely to identify themselves as vegetarians ($p < 0.001$) on the Identity as a Vegetarian Questionnaire. Highly significant differences were found between SBT+LOV adherence groups in most questions (all except two questions regarding nutrition, one regarding affordability, one regarding ethics, and one regarding others' respect for the vegetarian diet). When the scores were averaged to provide an overall identity score, the subjects who were 100% adherent scored significantly higher than those who were <100% adherent (7.7 vs. 5.0 of 10 questions, $p < 0.001$).

Discussion

The PREFER study, to the best of our knowledge, is the first randomized controlled trial examining an LOV eating plan as part of a weight loss study. The sample included male and female adults across a wide BMI range (27 to 43) and had approximately a 30% representation of minority groups. Generally, men do not respond to weight loss studies in large numbers, and this study is no exception. The small percentage of male subjects may have been attributable to the potential to be prescribed an LOV diet. However, even at 12.6%, this sample included more men than are generally reported in weight loss studies, and the men in the SBT+LOV group were 100% adherent to the vegetarian diet. Nonetheless, because the obesity epidemic is not restricted to women, and a recent article reported increased prevalence among men (5), future weight loss studies need to consider recruitment strategies that will increase male representation.

Subjects in both diet groups benefited from the first 6 months of the behavioral intervention in that they reduced their weight by >7%, which results in clinically significant improvements, e.g., reduced risk of insulin resistance and type 2 diabetes, dyslipidemia, hypertension, and inflammation. In fact, many of these metabolic benefits occur with only 5% weight loss and continue to improve with increasing weight loss (4,19). These improvements over time with

weight loss were observed in both groups, e.g., reduced values in most of the biological variables from baseline to 6 months.

Nine percent of the SBT+LOV group was on lipid-lowering drug therapy at baseline, and the percentage was reduced to 7% at 6 months; at baseline and at 6 months, 2% of the SBT group was on lipid-lowering drug therapy. When we examined LDL-C over time, there was a significant difference between the two groups, with the SBT+LOV lowering their LDL and the SBT group showing a slight LDL increase. The fact that three fewer subjects in the SBT+LOV group were on drug therapy at 6 months and yet the mean LDL-C level was reduced might suggest that the dietary change contributed to the reduction.

Because the intervention was the same for both groups for all aspects of the study except for the elimination of meat, fish, and poultry, we did not expect to observe differences between the groups in their reported physical activity and exercise. Indeed, the groups reported similar levels of physical activity. Similarly, except for animal products, there were no differences in the consumed macronutrients reported by the two groups.

The differences between diet groups were minimal, possibly because the SBT+LOV group included individuals who were not following the vegetarian diet. When SBT+LOV individuals were analyzed separately, those who were 100% adherent to the vegetarian diet were more successful at both weight loss and cholesterol reduction, which suggests that vegetarian diets are efficacious for weight and cholesterol control. As in the findings of Barnard et al. (11), the subjects in the SBT+LOV groups, on average, were nearly 100% compliant to their daily fat goal (25% of calories from fat), whereas the SBT group consumed 27% of their calories from fat. Because this analysis was limited to the 6-month time-point, we cannot report the effect of the LOV diet on long-term adherence or weight loss maintenance. Similar to what has been reported by others, the SBT+LOV group had greater reductions in LDL-C (12,13,16). Rolls et al. (20) reported significant changes in weight by regularly substituting a food that is low in energy density for one that is high in energy density without restricting calories. We prescribed the same caloric and fat restrictions for both diet groups. It is not clear whether those who were adherent to the LOV diet experienced greater satiety from eating foods with reduced energy density; however, this warrants further study.

Subjects who were adherent to the LOV diet experienced significant improvements in several physical and biological outcome measures. Married participants were more adherent to the LOV diet, which might suggest that support plays a role. Most participants reported that their spouse was not willing to adopt the LOV diet but was supportive; however, some of the participants' adolescent to adult children shared the dietary changes with the parent. The African-American participants were less adherent than white participants, which might suggest that cultural differences in dietary practices and in food preferences were deterrents to maintaining the LOV diet. General approaches to enhance adherence might include the development of more practical skills in preparing vegetarian dishes, introducing a greater variety of foods, and adapting dishes to different cultural preferences. Individuals who seemed more adventurous in food preparation and eating seemed to adapt recipes and make food substitutions better. Some participants reported having difficulty eating in restaurants or being tired of having pasta and marinara sauce, which may change as more restaurants add more diverse vegetarian options to their menus. Although we provided numerous tastings to expose participants to new foods, they did not always adopt these new foods. It might have helped if we had conducted more tastings or provided more homemade rather than packaged foods. An important issue is personal preference. Individuals changed their preferences while in the study; e.g., some entered wishing to become vegetarian and changed their mind after trying it, whereas others who were randomized to the LOV diet group resisted initially but converted after experiencing positive results in their health and how they felt. This was probably the most influential factor in adherence. Thus, it would be important to use this dietary option with those who are willing to make significant changes in their diet.

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