Effects of a vegetarian diet and treatment preference on biochemical and dietary variables in overweight and obese adults: a randomized clinical trial[1–3]

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ABSTRACT

Background: A vegetarian diet may lead to numerous health benefits, including weight loss.

Objective: We examined the joint effects of personal preference of dietary treatment and a calorie-restricted, low-fat lactoovovegetarian diet (LOV-D) compared with a standard calorie-restricted, low-fat omnivorous diet (STD-D) on changes in weight, total cholesterol, ratio of LDL to HDL cholesterol (LDL:HDL cholesterol), triacylglycerols, insulin resistance, and macronutrient intake during an 18-mo study.

Design: This was a randomized clinical trial of 176 overweight and obese adults who were recruited and randomly assigned first to 1 of 2 preference conditions (yes or no). If assigned to Preference-No, they were randomly assigned to 1 of the 2 diet conditions (STD-D or LOV-D). If assigned to Preference-Yes, they were assigned to the diet they indicated as preferred at screening. The 12-mo intervention was followed by a 6-mo maintenance phase.

Results: Participants were mainly women (86.9%) and white (70.5%); 75% completed the 18-mo study. A significant interaction between preference and dietary treatment was not observed for any of the outcome variables. However, participants in the Preference-No groups significantly decreased their triacylglycerols ($P = 0.04$). The only effect observed for diet was a borderline significant decrease in LDL:HDL cholesterol for the LOV-D group ($P = 0.06$). Within the LOV-D groups, those who were 100% adherent to the LOV-D had significant and marginally significant reductions in monounsaturated fat ($P = 0.02$) and total fat ($P = 0.05$) intakes at 18 mo.

Conclusions: Our findings suggest that neither prescribing a vegetarian diet nor allowing persons to choose their preferred diet had a significant effect on outcome measures. However, all participants had a significant reduction in total energy and fat intakes and an increase in energy expenditure, which was reflected in reduced body weight. This clinical trial was registered at www.clinicaltrials.gov as NCT00330629. *Am J Clin Nutr* 2007;86:588–96.

KEY WORDS Vegetarian diet, treatment preference, randomized clinical trial, lipids, macronutrients

INTRODUCTION

The prevalence of overweight and obesity has increased dramatically in the past decade and is becoming a global epidemic (1). Studies have shown that excess weight and its associated comorbidities can be favorably modified through lifestyle changes such as adopting a healthy diet and increasing energy expenditure (2–4). However, although marked improvements have been made in initial and long-term weight losses, researchers need to identify more effective strategies that facilitate improvements in long-term maintenance (5).

Data suggest that persons who follow a vegetarian diet are more satisfied and are more likely to follow it for a longer period than other weight-loss eating plans (6, 7). Moreover, it has long been posited that a vegetarian diet may be beneficial to general health and, in particular, cardiovascular health. Indeed, following a vegetarian diet was linked to less weight gain (8), improved lipid profile (9), and increased body leanness (10), compared with nonvegetarians. One issue that was not examined in those studies is the potential self-selection effect that may exist among persons who choose to adopt a vegetarian diet because they may be more health conscious. Therefore, it is unknown whether self-selection of a vegetarian option confounds study results.

Permitting participants in a dietary intervention study to select their type of treatment may be an important factor in long-term adherence to the diet. The literature suggests that persons who receive their preferred treatment show greater improvement in the outcome under assessment; however, in the weight-loss treatment arena, the results have been inconsistent (11–14). We are unaware of any studies that have examined treatment preference in combination with a lactoovovegetarian dietary option. This study, called the PREFER study, was therefore conducted to determine the independent and combined effects of treatment preference and a standard behavioral treatment program with a calorie- and fat-restricted lactoovovegetarian diet (LOV-D) compared with a calorie- and fat-restricted standard omnivorous

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weight-loss diet (STD-D) on weight, serum lipids, insulin resistance, and macronutrient intake in overweight and obese adults. We also examined whether these outcomes differed among those who adhered to the vegetarian diet compared with those who did not. Recently, we reported preliminary results at 6 mo for this study (15). The present report provides the 18-mo outcome data for the PREFER study.

SUBJECTS AND METHODS

The PREFER study was a single-center, randomized clinical trial designed to evaluate the effects of treatment preference and 2 dietary treatment options on weight loss. The following is a summary of the recruitment, randomization, and treatment methods of the PREFER study, which were detailed elsewhere (16). All participants provided written informed consent. The study was approved by the Institutional Review Board at the University of Pittsburgh, and all procedures were followed in accordance with the ethical standards of this board.

Study population

Between September 2002 and May 2004 a total of 200 participants in 3 cohorts spaced 6 mo apart were recruited for the PREFER study. Modes of recruitment included mass mailings from purchased lists; a database of persons seeking weight-loss treatment; and telephone announcements to staff, students, and faculty at the University of Pittsburgh and University of Pittsburgh Medical Center. Eligibility criteria for study participation were as follows: *1*) age between 18 and 55 y, *2*) body mass index (BMI; in kg/m^2) of 27–43, *3*) willingness to be randomly assigned to 1 of 2 treatment-preference conditions and 1 of 2 dietary conditions, *4*) successful completion of a 5-d food dairy, *5*) willingness and ability to provide informed consent, *6*) no current medical condition requiring physician supervision of diet or physical activity, *7*) no physical limitation restricting exercise ability, *8*) not pregnant or planning to become pregnant during the 18-mo study, *9*) no current treatment with a medication that might affect weight, *10*) alcohol intake not exceeding 4 drinks/d, *11*) no participation in a weight-loss program or use of a weight-loss medication within 6 mo before study enrollment, and *12*) reported consuming of meat, poultry, or fish in the past month. Persons eligible for study participation attended an information session, when they ranked their preference for the 2 calorie- and fat-restricted dietary options (LOV-D and STD-D); participants were disqualified from the study if they selected an equal preference for the 2 dietary options. Before randomization, baseline measures were performed on all participants at the General Clinical Research Center, and a fasting plasma glucose concentration was obtained to screen for the exclusion criterion of diabetes.

Study design and randomization

A 2-by-2 factorial experimental design was used that resulted in 4 group assignments: Preference-Yes+LOV-D, Preference-Yes+STD-D, Preference-No+LOV-D, and Preference-No+STD-D. After stratifying by sex, ethnicity, and diet preference, the 200 participants were randomly allocated by minimization procedures (17) into the 2 preference groups—Preference-Yes or Preference-No (**Figure 1**). In the second stage all Preference-Yes subjects who chose the LOV-D received this option. However, only 48 (76%) of the 63 persons in the Preference-Yes group that chose the STD-D were included to avoid this subset being excessively larger than the LOV-D group. The Preference-No group was randomized with equal allocation to the STD-D or LOV-D groups. After study enrollment 9 participants were excluded because they no longer met eligibility criteria or were related to other study participants; 176 participants were included in the analyses.

The sample size for the PREFER study of 66 participants in both diet groups and both preference groups was estimated to have 80% power to detect a 2.2-kg difference between the groups, assuming a common SD of 4.4 kg ($d = 0.50$) when testing the main effects of diet and preference with the use of 2-sided 2-sample t tests with an α level of 0.05. On the basis of a fixed-effects analysis of variance (ANOVA), we calculated that 33 participants in each of the 4 groups would provide 80% power at 0.05 significant level to detect a modest effect size for the interaction between diet and preference.

Demographics

Self-reported baseline study characteristics were collected with a standardized questionnaire. Information obtained included age, sex, marital status, education, income, and weight history.

Diet intervention

The intervention lasted 12 mo followed by a 6-mo maintenance period and was previously described (16). All treatment groups attended sessions weekly for the first 6 mo, biweekly for months 7–9, and monthly for months 10–12. The maintenance phase began 12 mo after study enrollment, and no further contact was made with participants until the final (18-mo) assessment. Group sessions were led by the same multidisciplinary team that included a dietitian, exercise physiologist, and nurse-behavioral scientist. The treatment sessions focused primarily on modifying behaviors for eating and physical activity and included food tastings and skill-building exercises (ie, cooking class and grocery shopping field trip).

Participants in all treatment conditions were instructed to reduce their maximum daily energy and fat intakes at the first group session. For those weighing <90.5 kg at baseline, a diet of 1200 kcal daily was prescribed for women and 1500 kcal for men; if baseline weight was >90.5 kg, a diet of 1500 kcal daily was prescribed for women and 1800 kcal for men. Participants were encouraged to reduce fat intake to 25% of total energy intake and to engage in at least 50 min of physical activity per week, with gradual increases to at least 150 min of activity per week by 6 wk and thereafter.

We instructed participants to self-monitor and record in their paper diaries their daily energy and fat intakes, as well as the type and amount of physical activity (in min) they performed. Completed diaries were collected and a new diary was provided at each treatment session. After review and annotation by the study interventionists, the diaries were returned to the participants at the next session. If a participant missed 1 session, the diary and session materials were mailed to the participant; if 2 consecutive sessions were missed, a letter was sent to encourage the participant's return.

The sessions were held separately for the 2 dietary treatment groups, with the primary difference between the STD-D and LOV-D groups being the elimination of meat, poultry, and fish

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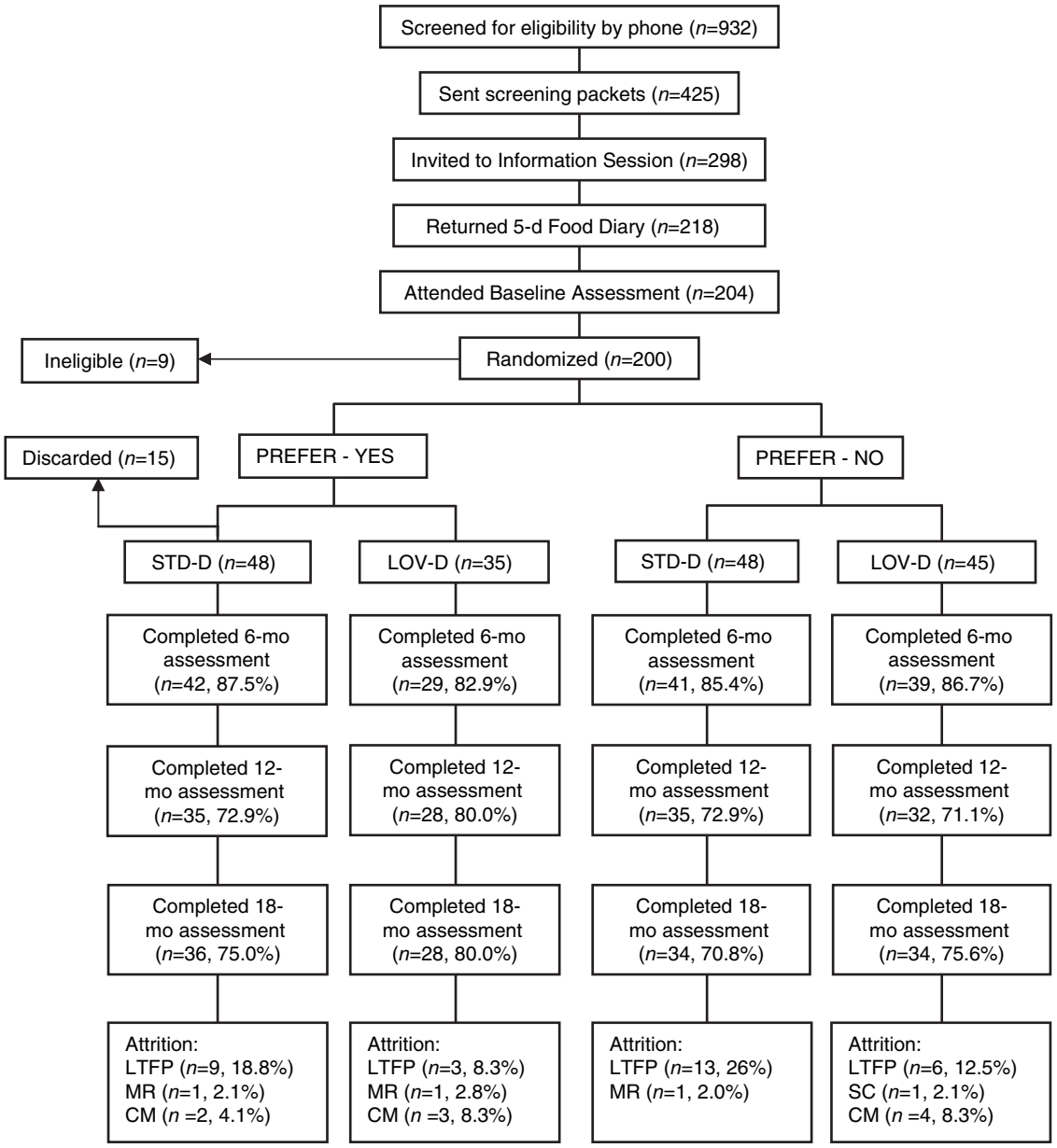

FIGURE 1. Participant flow diagram. STD-D indicates standard diet; LOV-D, lactoovovegetarian diet; LTFP, lost to follow-up; MR, medical reasons; CM, changed mind; SC, schedule conflict.

consumption for the 2 vegetarian diet groups. The LOV-D participants were instructed to begin to eliminate these foods from their diet first at breakfast, then lunch, and then dinner, and to note in their diaries any meat, poultry, or fish that they consumed. After 6 wk, participants were expected to exclude these foods completely from their diet. Both groups were taught how to select appropriate low-fat substitutes for foods high in fat. However, the focus of the LOV-D group sessions was on the elimination of meat products as a means to reduce fat intake. Participants in the LOV-D group were also instructed on how to select appropriate substitutes for meat products such as vegetable-based protein products (soy products, legumes). Treatment preference was not a focus of the intervention.

Dietary and physical activity assessments

At baseline and at each 6-mo assessment, participants completed a 3-d food record from which we assessed food intake and determined adherence to dietary goals. Participants were given verbal and written instructions on how to complete the 3-d food record and were asked to record dietary intake on 2 workdays and 1 leisure day. They were to provide product labels and recipes when the content of foods was not obvious to them. The food record data were entered in the computer and analyzed with the use of the NUTRITION DATA SYSTEM FOR RESEARCH (The Minnesota Nutrition Data System for Research, www.ncc.umn.edu; accessed 2 April 2007) software by staff at the Obesity/Nutrition Research Center at the University of Pittsburgh

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who were blinded to the treatment group and assessment period. Diets were analyzed for total energy intake, and for the percentage of total energy provided by fats (monounsaturated, polyunsaturated, and saturated), carbohydrates, and proteins.

Energy expenditure during physical activity was self-reported by the Paffenbarger Activity Questionnaire, as the total energy expenditure during daily living for the past 7 d. This questionnaire consists of 3 items that pertain to stairs climbed, blocks walked, and other leisure-time activities (18). In previous studies, the instrument showed good test-retest reliability with $r = 0.34–0.72$ (19). A metabolic equivalent value was assigned to each leisure-time activity. On the basis of the energy cost of each activity (19), we estimated combined energy expenditure (in kcal/wk) through walking, stair climbing, and all sports and leisure-time activities.

Anthropometric and biochemical measurements

All measures were obtained at baseline and repeated every 6 mo until the final 18-mo visit. Weight was measured after an overnight fast in light clothing and without shoes with the use of the Tanita bioelectrical impedance scale (Tanita Corporation of America Inc, Arlington Heights, IL). Height was measured on a wall-mounted stadiometer. BMI was calculated as weight divided by height squared.

Blood was drawn after a 12-h overnight fast and 15-min resting period and stored at −70 °C until assayed for measurements of serum glucose, insulin, total cholesterol, HDL-cholesterol, LDL-cholesterol, and triacylglycerol concentrations. Samples were measured at the Heinz Nutrition Laboratory, University of Pittsburgh, by personnel blinded to treatment group. Glucose concentration was measured with the use of the hexokinase–glucose 6-phosphate dehydrogenase enzymatic assay (Sigma Diagnostics, St Louis, MO), and insulin concentration was measured by a radioimmunoassay kit (Linco Research, St Charles, MO). Total cholesterol, HDL cholesterol, and triacylglycerols were measured enzymatically on an Abbott VP Supersystem autoanalyzer (Abbott Laboratories, Abbott Park, IL) by standardized methods according to the Centers for Disease Control and Prevention (20–23). LDL cholesterol was estimated with the use of the Friedewald equation for participants whose triacylglycerol concentrations were <400 mg/dL (24); however, when the value of triacylglycerols was >400 mg/dL, the LDL cholesterol was measured directly with the use of an automated spectrophotometric assay. The homeostasis model assessment insulin resistance index (HOMA-IR) was calculated as fasting insulin concentration (U/mL) × fasting glucose concentration (mmol/L)/22.5 (25).

Vegetarian diet adherence

The level of adherence to the LOV-D was dichotomized as 100% adherence or <100% adherence. Only participants who reported no meals containing meat, poultry, or fish on the 3-d food record at the 6-, 12-, and 18-mo assessments were included in the 100% adherence group. Participants were considered <100% adherent if they reported ≥1 meal containing meat, poultry, or fish on the 3-d food records.

Statistical analysis

Statistical analyses were performed with the use of SAS (version 9.1.3; SAS Institute Inc, Cary, NC). The intention-to-treat principle was applied to all analyses; therefore, missing endpoint data were imputed with the use of the observed value of the variable at the previous time point. Exploratory data analysis methods were used to screen for outliers, to assess missing data, and to evaluate whether underlying statistical assumptions were satisfied. Group comparative procedures (eg, ANOVA, Kruskal-Wallis test, chi-square analyses, Fisher's exact tests) were used to compare preference and diet groups on participant characteristics and response variables at baseline. Endpoint data [ie, weight, triacylglycerols, total cholesterol, ratio of LDL to HDL cholesterol (LDL:HDL cholesterol), HOMA-IR, and measures of energy and macronutrient intakes] were analyzed as percent change scores (ie, change from follow-up to baseline standardized by baseline values expressed as a percentage) with the use of mixed effects modeling specified as full-factorial with PROC MIXED. All models initially included a random effect for cohort; however, this effect was nonsignificant and was subsequently dropped from models. Baseline values for weight and total cholesterol were included in models as appropriate to control for baseline differences in preference groups for these variables. On the basis of residual analyses the underlying assumption of multivariate normality was supported. One-factor ANOVA procedures were used to compare percent change from baseline to 18 mo between adherent and nonadherent participants in the LOV-D group on biochemical (total cholesterol, LDL:HDL cholesterol, triacylglycerols, and HOMA-IR) and dietary (energy and total and different types of fats) outcome measures while controlling for identified covariates. Data on meat intake (adherence to the vegetarian diet), for those participants who missed the 6-mo assessment, were imputed from their most recent weekly diary. If participants had any meat consumption, they were categorized into the nonadherent group, whereas participants with no meat consumption were categorized into the adherent group. Wilcoxon's signed-rank test was used to test for significant change in reported physical activity over time in the total sample. We used the Sobel test to examine the potential mediating effects of physical activity on the biochemical outcomes (26).

RESULTS

Overall, 132 (75%) of the 176 participants completed the 18-mo assessment; attrition in the 4 preference-diet groups did not differ significantly ($P = 0.82$). Compared with participants who completed the final assessment, those who did not complete were younger (41.30 ± 9.01 y compared with 44.95 ± 8.52 y; $P < 0.02$) and weighed more at baseline (99.95 ± 14.60 kg compared with 93.99 ± 14.65 kg; $P = 0.02$).

Baseline characteristics

Baseline demographic and anthropometric characteristics of the PREFER study population are given in **Table 1**. The majority of participants were women (86.93%), white (70.5%), currently married or living with a partner (63.06%), and employed (93.18%). Baseline individual weights ranged from 67.62 to 136.28 kg, and the average BMI was 34.02 ± 4.09. None of the baseline variables were significantly different across the 4 groups at study enrollment; however, baseline differences were found between the Preference-Yes and Preference-No groups on baseline body weight (Yes: 97.85 ± 12.63 kg; No: 93.36 ± 16.32 kg; $P = 0.02$) and serum total cholesterol (Yes: 210.30 ± 42.46 mg/dL; No: 198.42 ± 35.91 mg/dL; $P = 0.01$).

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TABLE 1
Baseline characteristics of the PREFER study population ($n = 176$)[1]

Characteristics	Preference-Yes		Preference-No	
	STD-D ($n = 48$)	LOV-D ($n = 35$)	STD-D ($n = 48$)	LOV-D ($n = 45$)
Age (y)	43.3 ± 9.5[2]	44.37 ± 8.4	43.3 ± 8.6	45.4 ± 8.5
Formal education (y)[3]	15.1 ± 2.6	14.9 ± 2.4	15.5 ± 2.5	15.2 ± 2.7
Female [*n* (%)]	42 (87.5)	28 (80.0)	42 (87.5)	41 (91.1)
White [*n* (%)]	34 (70.8)	25 (71.4)	34 (70.8)	31 (68.9)
Married or living with partner [*n* (%)][4]	28 (59.6)	22 (64.7)	31 (64.6)	30 (66.7)
Employed [*n* (%)]	47 (97.9)	32 (91.4)	44 (91.7)	41 (91.1)

[1] STD-D, standard calorie-restricted, low-fat omnivorous diet; LOV-D, calorie-restricted, low-fat lactoovovegetarian diet. Differences across randomization groups were assessed using ANOVA or Kruskal-Wallis for continuous data and chi-square analysis and Fisher's exact test for categorical data with a significance level of $P < 0.05$. No significant differences were found.
[2] $\bar{x}$ ± SD (all such values).
[3] Missing education on 1 participant.
[4] Missing marital status on 2 participants.

Changes in anthropometric and biochemical measures

Shown in **Table 2** are the percent changes from baseline to the 18-mo assessment in body weight, total cholesterol, triacylglycerols, LDL:HDL cholesterol, and the HOMA-IR values. A significant effect for time was observed for change in body weight ($P < 0.01$) with a marginal effect for preference ($P = 0.06$); the Preference-No groups experienced a greater reduction in weight (7.9% and 8.0% compared with 3.9% and 5.3%) than did the Preference-Yes groups. For total cholesterol, a marginal effect of time was observed across all preference-diet groups ($P = 0.05$), and a significant difference was observed between preference groups in percent change in triacylglycerols over time ($P = 0.04$). Participants in the Preference-No groups decreased their triacylglycerols (STD-D by 6.73 ± 24.39%; LOV-D by 5.45 ± 32.59%). However, participants in the Preference-Yes groups increased their triacylglycerols (STD-D by 0.95 ± 36.47%; LOV-D by 8.62 ± 54.33%). When we combined preference groups and evaluated the effect of diet only on biological measures, a borderline significant ($P < 0.06$) reduction in the LDL:HDL cholesterol was found among participants in the LOV-D group compared with participants in the STD-D group at 18 mo. From baseline to 18 mo, the mean percentage change of LDL:HDL cholesterol decreased 1.53 ± 24.37% in the LOV-D groups and increased 4.12% ± 27.78% in the STD-D groups ($P = 0.16$ between groups). When the entire sample was evaluated without regard to treatment group, significant change over time was observed in HOMA-IR ($P < 0.01$). The change in total cholesterol and in the LDL:HDL cholesterol were of borderline significance ($P = 0.05$).

Changes in physical activity

With the use of the Paffenbarger questionnaire, the average amount of energy expenditure reported for 7 d at baseline across the 4 groups was as follows (median reported because of the data being skewed): Preference-Yes+STD-D, 1566.00 kcal; Preference-Yes+LOV-D, 1344.00 kcal; Preference-No+STD-D, 1432.50 kcal; and Preference-No+LOV-D, 954.00 kcal. Over time (18 mo), the self-reported energy expenditure increased to the following levels: Preference-Yes+STD-D, 2214.50 kcal; Preference-Yes+LOV-D, 1904.00 kcal; Preference-No+STD-D, 2222.50 kcal; and Preference-No+LOV-D, 2323.00 kcal with no significant differences across groups ($P = 0.52$). Physical activity had a direct effect on weight change ($P = 0.01$). We examined the effect of energy expenditure on the biochemical outcomes and found that physical activity had a total effect ($P < 0.01$) on total cholesterol values; even after controlling for weight change, physical activity had a direct effect on total cholesterol ($P = 0.02$), both observations occurred only at 0–12 mo. Similarly, physical activity had a total and direct effect on HOMA-IR only at 6 mo ($P < 0.01$). The effect of physical activity on LDL:HDL cholesterol and on triacylglycerols was mediated through weight loss.

Changes in macronutrient intake

Changes in energy and macronutrient intakes over time for the 4 treatment groups are shown in **Table 3**. A significant effect for time was noted for percent change in energy, total fat, monounsaturated fat, polyunsaturated fat, and saturated fat among the entire sample regardless of treatment group, $P < 0.05$ for all. However, no statistically significant differences in energy and macronutrient intakes were evident among the 4 treatment groups at 18 mo (ie, diet × preference × time interaction), neither was a significant diet × time nor preference × time interaction observed. Participants in the Preference-No group reported a reduced consumption of saturated fat than did participants in the Preference-Yes group ($P = 0.07$). Mixed model analysis showed the estimated mean change (SE) from baseline in saturated fat consumption as −39.0 (3.44%) and −29.58 (3.69%) for the Preference-No and Preference-Yes groups, respectively.

Adherence

Results by 2 levels of adherence to the LOV-D, 100% adherence and <100% adherence, are shown in **Table 4**. Adherence to the LOV-D did not significantly differ between the 2 preference groups ($P = 0.54$). At 6, 12, and 18 mo, respectively, 61%, 53%, and 36% of the LOV-D participants reported complete adherence to the vegetarian diet. A significant main effect for adherence was observed on total cholesterol ($P = 0.04$) and HOMA-IR ($P < 0.01$) at 6 mo (data not shown) with the adherent group having a significantly greater reduction in both measures. However, there was no longer a significant difference at 12 or 18 mo for either cholesterol or HOMA-IR. Statistically significant differences

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TABLE 2
Anthropometric and biochemical measures at all time points ($n = 176$)[1]

	Preference-Yes		Preference-No		*P*		
	STD-D ($n = 48$)	LOV-D ($n = 35$)	STD-D ($n = 48$)	LOV-D ($n = 45$)	Preference	Diet	Time
Weight (kg)							
Baseline[2]	97.9 ± 13.5[3]	97.7 ± 11.5	93.7 ± 16.6	93.0 ± 16.2			
6 mo	91.5 ± 13.6	89.9 ± 13.9	86.4 ± 17.6	85.7 ± 17.0			
12 mo	92.6 ± 13.9	90.7 ± 14.2	86.1 ± 17.5	85.1 ± 17.2	0.06	0.41	< 0.01
18 mo	94.6 ± 14.2	93.7 ± 13.4	87.6 ± 17.3	87.1 ± 16.8			
Percent change, baseline to 18 mo	−3.9 ± 6.1[4]	−5.3 ± 6.2[4]	−8.0 ± 7.8[4]	−7.9 ± 8.1[4]			
Total cholesterol (mg/dL)							
Baseline[5]	207.9 ± 44.1	213.5 ± 40.5	199.5 ± 29.8	197.2 ± 41.8			
6 mo	202.8 ± 43.4	207.5 ± 37.0	198.9 ± 37.3	187.4 ± 39.0			
12 mo	202.6 ± 43.3	209.5 ± 35.2	199.1 ± 36.3	190.3 ± 37.4	0.80	0.91	0.05
18 mo	203.8 ± 43.0	212.3 ± 34.8	203.7 ± 30.8	195.8 ± 42.4			
Percent change, baseline to 18 mo	−1.4 ± 10.4	1.0 ± 16.5	2.5 ± 10.1	−0.1 ± 12.3			
LDL:HDL cholesterol							
Baseline	2.5 ± 1.0	2.8 ± 1.1	2.3 ± 0.8	2.4 ± 0.9			
6 mo	2.6 ± 1.1	2.7 ± 0.9	2.5 ± 1.0	2.3 ± 0.8			
12 mo	2.5 ± 1.0	2.6 ± 0.8	2.3 ± 1.0	2.3 ± 0.9	0.63	0.06	0.05
18 mo	2.5 ± 1.1	2.7 ± 0.9	2.3 ± 1.0	2.3 ± 0.9			
Percent change, baseline to 18 mo	4.9 ± 33.9	−1.2 ± 26.2	3.4 ± 20.2	−1.8 ± 23.1			
Triacylglycerol (mg/dL)							
Baseline	139.2 ± 86.2	129.2 ± 63.5	132.0 ± 66.9	134.3 ± 63.7			
6 mo	116.8 ± 55.8	127.2 ± 57.9	125.1 ± 63.5	124.9 ± 56.4			
12 mo	126.8 ± 65.1	129.9 ± 57.6	119.2 ± 57.7	118.6 ± 52.0	0.04	0.34	0.37
18 mo	126.8 ± 60.8	129.2 ± 65.6	117.2 ± 58.6	119.8 ± 55.5			
Percent change, baseline to 18 mo	1.0 ± 36.5	8.6 ± 54.3	−6.7 ± 24.4	−5.5 ± 32.6			
HOMA-IR							
Baseline	4.4 ± 2.0	4.4 ± 2.0	4.4 ± 2.8	4.6 ± 2.3			
6 mo	3.7 ± 1.7	3.4 ± 1.7	3.5 ± 2.3	3.6 ± 1.8			
12 mo	3.8 ± 1.9	3.8 ± 1.5	3.6 ± 2.3	3.7 ± 2.2	0.49	0.53	< 0.01
18 mo	4.1 ± 2.1	3.7 ± 1.6	3.6 ± 2.4	4.1 ± 2.8			
Percent change, baseline to 18 mo	−1.0 ± 38.6	−11.3 ± 34.8	−10.8 ± 32.7[6]	−6.1 ± 41.6			

[1] STD-D, standard calorie-restricted, low-fat omnivorous diet; LOV-D, calorie-restricted, low-fat lactoovovegetarian diet; HOMA-IR, homeostasis model assessment insulin resistance index. Mixed effects modeling analysis was conducted. No significant 3-factor interactions were found ($P > 0.05$, all values). The only significant 2-factor interaction was preference × time for weight ($P = 0.02$).
[2] Baseline weight differed significantly by preference group, $P < 0.05$.
[3] $\bar{x}$ ± SD (all such values).
[4] Within-group comparison, $P < 0.01$.
[5] Baseline total cholesterol differed significantly by preference group, $P = 0.01$.
[6] Within-group comparison, $P < 0.05$.

were not observed between adherent and nonadherent LOV-D participants for LDL:HDL cholesterol or triacylglycerols at any of the time points. Participants who adhered to the LOV-D had significantly lower intake of energy ($P < 0.01$), total fats ($P < 0.01$), and monounsaturated fats ($P < 0.01$) at 6 mo (data not shown) than did participants who reported intake of meat, poultry, or fish. At 18 mo, significant differences remained in monounsaturated fat intake ($P = 0.02$), whereas a marginally significant difference in total fats ($P = 0.05$) was observed between the nonadherent and adherent groups.

DISCUSSION

We conducted a randomized clinical trial to determine the independent and combined effects of treatment preference and a standard behavioral treatment program with a calorie- and fat-restricted LOV-D compared with a calorie- and fat-restricted STD-D on weight loss, serum lipids, insulin resistance, and energy and macronutrient intakes in overweight and obese adults. Despite the no-contact maintenance phase between the 12- and 18-mo assessments, at 18 mo 75% of participants completed the final assessment. This retention rate was comparable to rates reported for previously conducted weight-loss studies. After an 18-mo behavioral weight-loss intervention, Jakicic et al (27) reported 78% retention, whereas others have reported 83% and 84% retention at the end of a 12-mo intervention (28, 29). Renjilian et al (14) reported a 6-mo retention rate (78%) similar to our 18-mo retention (75%). Moreover, none of those studies included a no-contact maintenance phase after the end of the active intervention as our study did.

To our knowledge, the present study is the first randomized trial to assess the effect of an LOV-D combined with participant preference of dietary treatment on weight loss, plasma lipids,

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TABLE 3
Energy and macronutrient intakes at all time points ($n = 176$)[1]

	Preference-Yes		Preference-No		*P*		
	STD-D ($n = 48$)	LOV-D ($n = 35$)	STD-D ($n = 48$)	LOV-D ($n = 45$)	Preference	Diet	Time
Total energy (kcal)							
Baseline	1941.3 ± 620.9[2]	2110.6 ± 784.5	2155.7 ± 674.8	1982.7 ± 602.1			
6 mo	1482.4 ± 614.6	1601.2 ± 626.4	1576.8 ± 560.4	1396.4 ± 316.1			
12 mo	1570.1 ± 646.0	1592.3 ± 450.2	1562.4 ± 570.0	1434.1 ± 380.0	0.08	0.99	0.03
18 mo	1581.6 ± 630.7	1668.4 ± 524.0	1567.8 ± 524.3	1471.1 ± 361.7			
Percent change, baseline to 18 mo	−15.9 ± 28.3[3]	−13.9 ± 32.4[4]	−22.9 ± 28.5[3]	−22.9 ± 18.6[3]			
Total fat (*g*)							
Baseline	75.9 ± 31.3	83.3 ± 36.0	87.3 ± 34.6	78.6 ± 31.2			
6 mo	45.9 ± 32.3	47.5 ± 31.5	50.3 ± 26.2	41.4 ± 20.9			
12 mo	52.1 ± 36.8	51.1 ± 25.0	51.0 ± 26.1	45.3 ± 21.5	0.13	0.97	< 0.01
18 mo	54.6 ± 33.8	57.6 ± 27.2	52.6 ± 23.9	46.3 ± 21.4			
Percent change, baseline to 18 mo	−23.3 ± 49.8[3]	−18.0 ± 52.8[3]	−31.5 ± 43.9[3]	−36.6 ± 27.1[3]			
Monounsaturated fat (*g*)							
Baseline	28.9 ± 12.9	31.3 ± 13.5	32.7 ± 12.6	29.1 ± 12.3			
6 mo	17.4 ± 13.1	17.5 ± 13.1	18.1 ± 9.7	14.5 ± 7.8			
12 mo	19.7 ± 14.0	18.9 ± 10.4	18.5 ± 10.1	16.2 ± 7.8	0.12	0.80	< 0.01
18 mo	20.4 ± 13.4	21.3 ± 11.2	19.8 ± 10.3	15.9 ± 7.4			
Percent change, baseline to 18 mo	−23.9 ± 53.8[3]	−20.2 ± 50.9[4]	−31.0 ± 50.0[3]	−39.9 ± 29.3[3]			
Polyunsaturated fat (*g*)							
Baseline	15.5 ± 6.5	16.8 ± 8.0	18.2 ± 9.6	15.8 ± 6.5			
6 mo	9.8 ± 6.6	10.8 ± 6.5	11.0 ± 5.6	9.9 ± 4.8			
12 mo	11.0 ± 9.1	11.4 ± 5.4	10.7 ± 5.4	10.2 ± 4.8	0.56	0.56	0.02
18 mo	11.7 ± 7.4	12.5 ± 6.5	10.7 ± 5.0	10.9 ± 5.2			
Percent change, baseline to 18 mo	−17.1 ± 58.6[4]	−7.7 ± 71.8	−23.9 ± 70.8[4]	−24.0 ± 40.7[3]			
Saturated fat (*g*)							
Baseline	25.5 ± 11.7	28.6 ± 13.7	29.6 ± 12.1	27.5 ± 13.1			
6 mo	14.9 ± 11.4	15.4 ± 10.5	17.1 ± 10.1	13.6 ± 9.1			
12 mo	17.2 ± 12.6	17.1 ± 8.3	17.3 ± 10.4	15.3 ± 9.2	0.07	0.93	< 0.01
18 mo	18.2 ± 11.7	19.5 ± 8.4	17.9 ± 9.3	15.9 ± 9.5			
Percent change, baseline to 18 mo	−23.6 ± 48.7[3]	−15.2 ± 57.7	−33.7 ± 34.8[3]	−37.5 ± 29.2[3]			

[1] STD-D, standard calorie-restricted, low-fat omnivorous diet; LOV-D, calorie-restricted, low-fat lactoovovegetarian diet. Mixed effects modeling analysis was conducted. No significant 2- or 3-factor interactions were found.
[2] $\bar{x}$ ± SD (all such values).
[3] Within-group comparison, $P < 0.01$.
[4] Within-group comparison, $P < 0.05$.

insulin resistance, and energy and macronutrient intakes in overweight and obese adults. Contrary to our expectations, the findings did not show that adopting an LOV-D results in significantly improved biochemical measures or dietary patterns than does an STD-D. The null findings are not surprising, given that most participants in the LOV-D group did not strictly adhere to the prescribed diet over time and thus may have consumed a diet similar to that of the STD-D groups as the study continued. However, all participants reduced their total energy and fat consumption and increased their physical activity as reflected in significant weight loss and reduced waist circumference (data not shown).

Barnard et al (30) examined the effects of a 10% fat, vegan diet on body weight, metabolism, and insulin sensitivity compared with the National Cholesterol Education Program diet (≤30% fat) in a 14-wk study of 64 overweight, postmenopausal women. The vegan diet group lost significantly more weight (5.8 compared with 3.8 kg) and had greater reduction in protein, fat, and cholesterol intakes than did the National Cholesterol Education Program diet group; however, no significant difference was observed between the groups in caloric intake or improvements in insulin sensitivity.

Phillips et al (10) measured dietary intake and body composition of 33 adults in the earliest stages of becoming vegetarian at baseline and 6 mo. They observed significant reductions in energy and saturated fat intakes with a significant increase in carbohydrate consumption. Significant weight change was not noted, but body composition changes that supported increased leanness were found (10). Similarly in 33 adults who self-selected a vegetarian diet, Robinson et al (9) reported significant reductions in total energy and energy from saturated fat and significant increases in carbohydrate intake. HDL cholesterol was the only significant biological change. Those studies provide additional support for the health benefits of a plant-based diet.

We have reported the 6-mo results of this study (15). Our preliminary findings indicated that adherent members of the LOV-D groups had significantly better outcomes in weight loss,

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TABLE 4
Change and percent change scores at 18 mo by adherence to calorie-restricted, low-fat lactoovovegetarian diet ($n = 80$)[1]

	100% Adherent ($n = 29$)		<100% Adherent ($n = 51$)		
	Change	Percent change	Change	Percent change	*P*
Biological outcomes					
Total cholesterol (mg/dL)	−1.9 ± 32.7[2]	0.4 ± 15.9	−1.0 ± 25.5	0.3 ± 13.2	0.97
LDL:HDL cholesterol	−0.2 ± 0.7	−0.5 ± 28.4	−0.1 ± 0.5	−2.1 ± 22.1	0.78
Triacylglycerol (mg/dL)	−23.3 ± 75.6	−6.6 ± 40.3	0.5 ± 45.4	4.8 ± 45.4	0.27
HOMA-IR	−0.9 ± 2.0	−14.8 ± 29.3[3]	−0.4 ± 2.3	−4.7 ± 42.9	0.27
Dietary outcomes					
Total energy (kcal)	−627.4 ± 648.1	−24.7 ± 22.1[4]	−398.1 ± 569.2[4]	−15.7 ± 27.3	0.13
Total fat (*g*)	−39.4 ± 35.5	−40.2 ± 32.7[4]	−23.6 ± 30.7[4]	−21.8 ± 44.2	0.05
Monounsaturated fat (*g*)	−15.5 ± 13.0	−44.9 ± 32.1[4]	−9.7 ± 12.5[4]	−23.5 ± 43.9	0.02
Polyunsaturated fat (*g*)	−6.5 ± 8.3	−26.7 ± 48.7[4]	−3.6 ± 7.1	−11.3 ± 60.5	0.25
Saturated fat (*g*)	−14.2 ± 14.0	−38.0 ± 45.5[4]	−8.4 ± 11.2[4]	−21.9 ± 44.2	0.12

[1] ANOVA and Kruskal-Wallis test were conducted.
[2] $\bar{x}$ ± SD (all such values).
[3] Within-group comparison, $P < 0.05$.
[4] Within-group comparison, $P < 0.01$.

total cholesterol, LDL cholesterol, glucose, and HOMA-IR and reduced intake of total fats than did the nonadherent members of the LOV-D group. Therefore, these data suggest the LOV-D led to substantial short-term cardiovascular health benefits. However, despite implementing measures to promote adherence, compliance to the LOV-D became a challenge over time, declining to 36% by the 18th mo. Although not significant by the standard criterion of <0.05, the 100% adherent LOV-D group compared with the <100% adherent LOV-D group consumed fewer total calories and calories from fat and experienced greater reductions in triacylglycerols and HOMA-IR. Thus, our 18-mo null results may be a reflection of insufficient statistical power because there were few 100% adherent LOV-D subjects. These findings suggest that strategies are needed to improve long-term adherence to this healthy eating plan to assess the true effects of an LOV-D intervention on dietary intake and clinical outcomes.

Further, our study results refute the notion that allowing participants to choose treatment results in favorable outcomes. Four studies examined treatment choice in relation to weight loss among adults (11, 13, 14, 31). Those studies had limitations in treatment duration, sample size, and retention, making it difficult to determine whether choice of treatment compared with assigned treatment plays a role in successful weight loss. In our study, those who did not receive their preferred treatment did better than those who received their treatment of choice. Although an explanation of this finding is not readily apparent, Preference-No participants' resolve to succeed despite their assignment may have resulted in this assignment having no influence on their behavior change over the subsequent 18 mo. Other plausible explanations might be that those who received their preferred treatment might have expected more or that they were overly confident and then realized that their treatment of choice was as difficult as other weight-loss approaches. This may be particularly relevant to those who selected the STD-D because they had the least weight change. Our findings show that providing a study participant his or her preferred choice of treatment does not necessarily lead to improved adherence or improved outcomes. It may be more important to explore the role of shared decision making (32). Studies have shown enhanced adherence when persons are permitted to participate in their care and treatment decisions, which may be more meaningful than receiving their preferred treatment (33, 34).

The primary limitation of this study was the declining compliance to the LOV-D diet over time, perhaps limiting our ability to detect differences between the dietary groups. In addition, nutritional data were collected by 3-d food records at baseline and at 6, 12, and 18 mo and may not represent dietary intake throughout the study. Further, underreporting of energy and fat intakes is common among persons with a high BMI, and our study population was selected to have high BMIs (35). However, although we recognize the limitations of assessing dietary intake in a free-living environment with the use of self-report measures (36), we considered the reporting of meat, poultry, and fish intakes by participants on the LOV-D to be reliable indicators of adherence to the LOV-D during the study. Indeed, participants' reporting of meat products in the 3-d food records was consistent with what they reported in their weekly diaries. Because of the small number of men in the study, we cannot generalize our findings to this population group. Underrepresentation of men, a common problem in weight-loss studies (29), is reflective of the smaller proportion of men who seek weight-loss treatment (37).

Nonetheless, this study has substantial strengths. Study strengths include a population-based cohort and random allocation to the intervention. In addition, despite the lack of adherence in the LOV-D group, we did not have difficulty recruiting with only 8 of 932 (<1%) of screened participants declining participation because of concern they would be assigned to an LOV-D, and we had excellent retention at 18 mo. The study is further strengthened by addressing the methodologic issue of a participant self-selection effect that may arise if more health-conscious persons opt for an LOV-D. In summary, neither an LOV-D nor treatment preference, individually or in combination, resulted in significant effects on total cholesterol, LDL:HDL cholesterol, HOMA-IR, or energy and macronutrient consumption in our study population. Results should be interpreted with consideration of the declining adherence in abstaining from meat, poultry, and fish in the LOV-D group by the 18-mo assessment. However, overall, study participants benefited from their participation with

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improvements in dietary and physical activity measures that were reflected in improved body weight.

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The author's responsibilities were as follows—LEB: study design; MTW and EM: contributed to the collection of data; SMS and OUE: analyzed the data; LEB, AGH, MAS, and MTW: drafted the manuscript. None of the authors had any conflicts of interest.

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