International Journal of Obesity (2008) 32, 166–176
 0307-0565/08 $30.00
www.nature.com/ijo

ORIGINAL ARTICLE

A randomized clinical trial of a standard versus vegetarian diet for weight loss: the impact of treatment preference

LE Burke[1], M Warziski[2], MA Styn[2], E Music[2], AG Hudson[3] and SM Sereika[4]

[1]*Department of Health and Community Systems and the Graduate School of Public Health, Department of Epidemiology, University of Pittsburgh School of Nursing, Pittsburgh, PA, USA;* [2]*Department of Health and Community Systems, University of Pittsburgh School of Nursing, Pittsburgh, PA, USA;* [3]*Department of Epidemiology, University of Pittsburgh Graduate School of Public Health, Pittsburgh, PA, USA and* [4]*Department of Health and Community Systems and the Graduate School of Public Health, Department of Biostatistics and Department of Epidemiology, University of Pittsburgh School of Nursing, Pittsburgh, PA, USA*

Background: With obesity rampant, methods to achieve sustained weight loss remain elusive.
Objective: To compare the long-term weight-loss efficacy of 2 cal and fat-restricted diets, standard (omnivorous) versus lacto–ovo–vegetarian, and to determine the effect of a chosen diet versus an assigned diet.
Design, subjects: A randomized clinical trial was conducted with 176 adults who were sedentary and overweight (mean body mass index, 34.0 kg/m^2). Participants were first randomly assigned to either receive their preferred diet or be assigned to a diet group and second, were given their diet of preference or randomly assigned to a standard weight-loss diet or a lacto–ovo–vegetarian diet. Participants underwent a university-based weight-control program consisting of daily dietary and exercise goals plus 12 months of behavioral counseling followed by a 6-month maintenance phase.
Measurements: Percentage change in body weight, body mass index, waist circumference, low- and high-density lipoprotein, glucose, insulin and macronutrient intake.
Results: The program was completed by 132 (75%) of the participants. At 18 months, mean percentage weight loss was greater ($P = 0.01$) in the two groups that were assigned a diet (standard, 8.0% (s.d., 7.8%); vegetarian, 7.9% (s.d., 8.1%)) than in those provided the diet of their choice (standard, 3.9% (s.d., 6.1%); vegetarian, 5.3% (s.d., 6.2%)). No difference was observed in weight loss between the two types of diet. Over the 18-month program, all groups showed significant weight loss.
Conclusions: Participants assigned to their dietary preference did not have enhanced treatment outcomes. However, all groups lost weight with losses ranging from 4 to 8% at 18 months.
International Journal of Obesity (2008) **32,** 166–176; doi:10.1038/sj.ijo.0803706; published online 14 August 2007

Keywords: treatment preference; lacto–ovo–vegetarian; behavioral weight-loss treatment; randomized clinical trial

Introduction

According to the most recent report by Ogden *et al.*,[1] the prevalence of overweight and obesity has not declined. Concurrent to the increasing prevalence in overweight and obesity, marked improvements have occurred in behavioral weight-loss interventions.[2] Behavioral counseling for life-style change and weight control combined with increased physical activity and reduced calorie and fat intake have proven effective for short-term weight loss.[3,4] However, researchers continue to seek methods to maintain improved dietary patterns and a healthy weight for the long term.

Adoption of a vegetarian diet has resulted in improved health outcomes. Research has shown that such diets can be followed for sustained periods[5–7] and can produce lasting weight loss.[8,9] Others' work as well as our own have shown that individuals who chose a vegetarian diet for weight loss report staying on that particular eating plan longer than some of the well-known fad diets.[6,7] In a recent observational study, women who followed a semivegetarian, lactovegetarian or vegan diet had a lower risk of overweight and obesity than omnivorous women.[10] Earlier work, by our group found that a vegetarian meal plan combined with a

Correspondence: Dr LE Burke, University of Pittsburgh School of Nursing and the Graduate School of Public Health, 3500 Victoria St, 415 Victoria Building, Pittsburgh, PA 15261, USA.
E-mail: lbu100@pitt.edu
Received 14 February 2007; revised 7 May 2007; accepted 24 June 2007; published online 14 August 2007

behavioral weight-counseling intervention led to weight loss and that those who followed the plan had not regained weight at 18 months.[11] Literature suggests that changing from a diet containing meat and fish to a vegetarian diet may result in reduced calorie and saturated-fat intake, an increase in energy from carbohydrates, resulting in a leaner body mass[12] and less weight regain.[13] While these findings are promising, they may have been partially attributable to a self-selection effect among those who adhered to the diet. Moreover, to our knowledge, only one study of vegetarian diets has targeted weight loss and that study used the more restrictive 10% fat and vegan diet.[14,15] No randomized-controlled trials have examined the role of the less restrictive lacto–ovo–vegetarian diet (LOV-D) in weight loss.

Participant preference is another factor in the success of many treatments but has rarely been examined in weight-loss efficacy.[16–19] Conceptual models such as behavioral choice theory[20] postulate that those who are matched to treatment based on their personal choices will demonstrate better outcomes than those assigned to a treatment that does not match their personal preference. The few studies that have examined the effect of providing participants their preferred weight-loss treatment have produced inconsistent findings.[16–18] Moreover, the longest study was only 6 months in duration, thus not permitting an evaluation of the long-term effects of receiving one's preference. Our preliminary study[7] did not take preference into account in the random assignment to diet, and we are unaware of any randomized clinical trials that have examined treatment preference using diets that include a vegetarian option.

We designed the present study to test two hypotheses: (1) choice of either a standard calorie- and fat-restricted diet (STD-D) or a calorie- and fat-restricted LOV-D would result in greater weight loss compared to having one of these diets randomly assigned; and (2) an LOV-D would result in greater weight loss than a STD-D.

We chose to test both of these hypotheses together to address the potential effect of selection bias in the successful adoption and long-term adherence to a LOV-D. We also evaluated the effect of the treatment assignment on waist circumference, low-density lipoprotein cholesterol (LDL-C) and high-density lipoprotein cholesterol (HDL-C), glucose, insulin and selected macronutrients and adherence to the treatment protocol.

Materials and methods

Design overview

The recruitment, randomization, treatment methods and the baseline characteristics of the study cohort have been detailed elsewhere and are summarized here.[21] Termed the PREFER study, it was a single center, randomized clinical trial designed to evaluate the effects of treatment preference and two different diets (STD-D versus LOV-D) on weight loss.

Setting and participants

We recruited 200 participants in three cohorts, which were staggered from September 2002 to May 2004, via mass mailings from purchased lists; a database of individuals seeking weight-loss treatment; and telephone announcements to staff and faculty at the University of Pittsburgh and University of Pittsburgh Medical Center. Eligibility criteria were (1) age 18–55 years, (2) body mass index (BMI) of 27 through 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-day food dairy; and (5) willingness and ability to provide informed consent. Exclusion criteria were (1) a current medical condition requiring physician supervision of diet or physical activity (for example, diabetes, post-acute myocardial infarction), (2) physical limitation restricting exercise ability, (3) pregnancy or intention to become pregnant during the 18-month study, (4) current treatment with a medication that might affect weight, (5) alcohol intake >4 drinks/day, (6) participation in a weight-loss program, or use of a weight-loss medication within the past 6 months, and (7) abstention from eating meat, poultry or fish in the past month. Eligible individuals attended an information session, where they completed a one-page form on which they ranked their preference for each of the two dietary options on a three-point Likert scale; a 'mild' preference or no preference for one diet over the other, disqualified them from the study. Baseline measures were conducted before randomization at the General Clinical Research Center (GCRC).

A power analysis based on weight loss at 18 months was conducted *a priori*. On the basis of a fixed-effects analysis of variance (ANOVA) this analysis indicated that 33 participants in each of the four groups would provide 80% power to detect a modest effect size for the interaction between diet and preference at a significance level of 0.05. To test the main effects of diet and preference using two-sided two-sample *t*-tests with a significance level of 0.05, 66 participants in both diet groups and both preference groups would provide 80% power to detect a 2.2 kg difference between the groups assuming a common s.d. of 4.4 kg ($d=0.50$).

Randomization and interventions

After stratifying for gender, ethnicity and diet preference, 200 participants were randomly assigned to one of four groups (Preference-Yes + standard diet (STD-D), Preference-Yes + LOV-D, Preference-No + STD-D, and Preference-No + LOV-D) through a two-stage randomization process, using minimization procedures.[22] In stage 1, participants were randomized to one of the two preference groups—Preference-Yes or Preference-No—with a randomization ratio of 3:2 (Figure 1). We over sampled the Preference-Yes group because we expected that a smaller proportion of our population would select the LOV-D. The 3:2 ratio was chosen, because in our pilot study approximately two-thirds of the participants indicated a preference for the standard

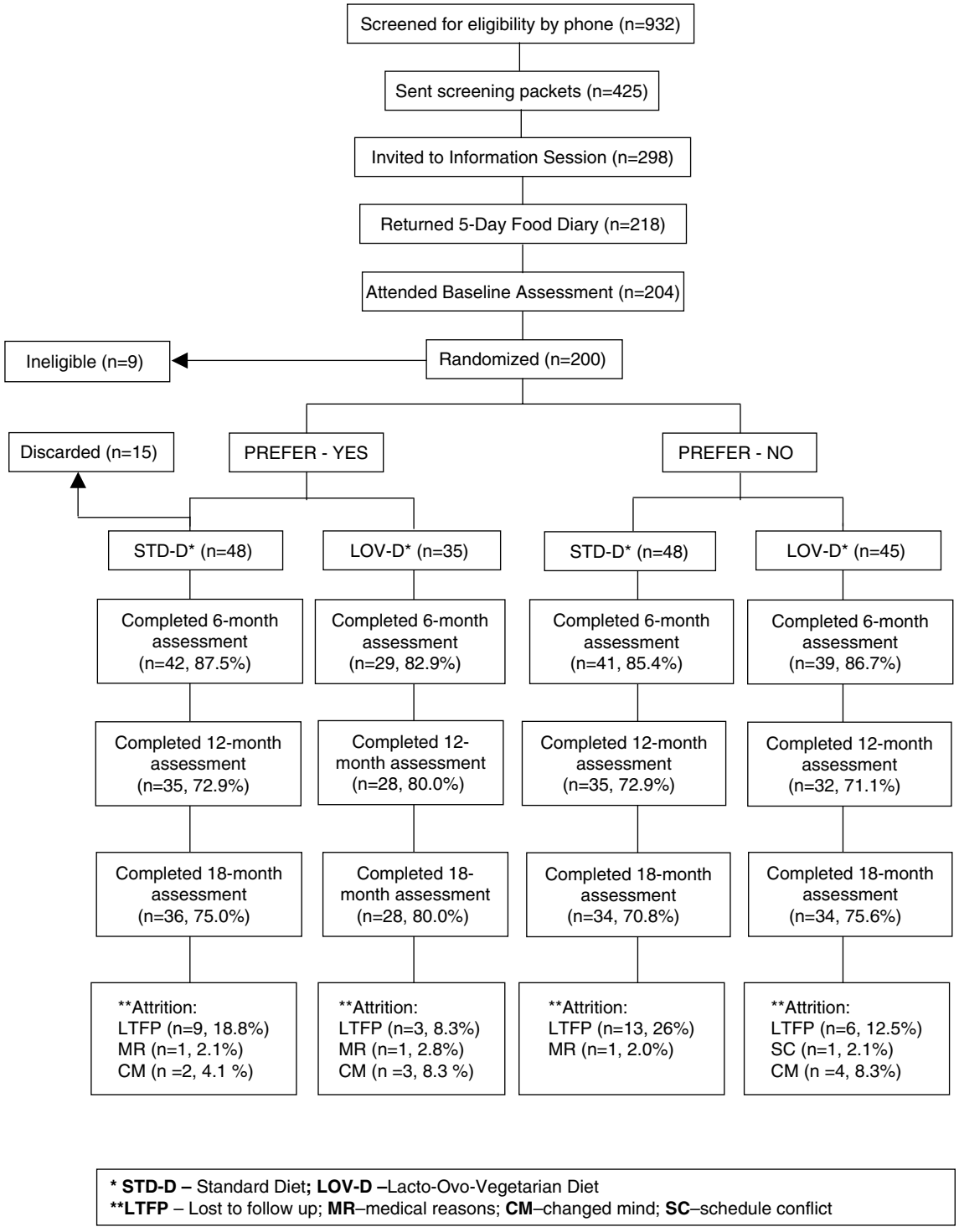

Figure 1 Participant flow diagram.

diet over the vegetarian option. In the second stage of the randomization process, all Preference-Yes participants who chose the LOV-D received this option. Only 48 of the 63 individuals in the Preference-Yes group who chose the STD-D were included to avoid this subset being excessively larger than the LOV-D group (Figure 1). The Preference-No group

was randomized with equal allocation to the STD-D or LOV-D. Nine participants were excluded after study enrollment because they no longer met eligibility criteria; thus, 176 participants are included in the present analyses.

Common components of the intervention. All participants attended weekly group sessions for the first 6 months, biweekly for months 7–9, and monthly for months 10–12. These sessions were based on standard behavioral therapy (SBT) for weight loss, a well-established approach that incorporates instruction and counseling in changing behaviors, modifying dietary intake to decrease the number of calories and amount of fat eaten, and increasing physical activity.[3,4]. Other characteristics of SBT include treatment delivered in the form of planned lessons to a group of 10–20 participants for approximately 12 months, weekly sessions initially with subsequent less frequent meetings, establishment of dietary and activity goals, self-monitoring with written feedback provided by the interventionists, provision of nutritional information, and application of several behavioral change strategies that have been proven to be effective, for example, modifying one's environment, problem-solving, modifying 'all or nothing' thinking and preventing relapse.[23] The sessions were led by a dietitian, exercise physiologist, or nurse-behavioral scientist and focused on behavioral strategies for modifying one's lifestyle, for example, controlling portion sizes, being assertive in social situations where there may be pressure to abandon healthy eating behaviors.

At the first session, participants were instructed to reduce their maximum daily calorie as follows: those weighing <90.5 kg at baseline, 1200 kcal for women and 1500 kcal for men; if baseline weight exceeded 90.5 kg, 1500 kcal for women, and 1800 kcal for men. These guidelines are based on the standard weight-loss treatment goal of 1–2 lbs per week.[4] All participants were to reduce fat intake to 25% of total kilocalorie intake and to engage in physical activity, for example, walking, for at least 50 min per week initially, gradually increasing to at least 150 min per week by week 6. We instructed them to monitor and record their daily physical activity and calorie and fat content of foods eaten in the provided weekly diary. At each session, a new diary was provided; completed diaries were collected and returned at the next session after interventionists reviewed and annotated the diaries. Diary and session materials were sent to individuals who missed a session. If participants missed two consecutive sessions, a letter was sent encouraging their return. After 12 months, the maintenance phase began, and no further contact was made with participants until the final (18-month) assessment. Additional details on the intervention are reported elsewhere.[21]

Dietary interventions. The only difference between the two diets was the elimination of meat, poultry and fish consumption by the sixth week for the two vegetarian-diet groups. Participants were instructed to eliminate these food groups at breakfast, then lunch, and then dinner and to record in their diaries when they ate meals containing these foods. Numerous opportunities were provided at the group sessions to taste vegetarian foods while the standard-diet group tasted low-fat foods. A nutritionist who was vegetarian led four LOV-D group sessions and was able to advise participants on how to adopt the more restrictive eating plan, as well as include children and other family members in the new dietary plan. The LOV-D group members also recorded the number of meals they ate that included any meat, fish or poultry in their weekly diaries. For an incentive, LOV-D participants received the magazine *Vegetarian Times* while the STD-D participants received *Cooking Light*. A cooking class and shopping tour focused on vegetarian dishes and foods for the LOV-D group and low-fat dishes and foods for the STD-D group. Otherwise, the content and behavioral strategies taught in the group sessions were the same for both diet groups.

Outcomes and follow-up

Body weight and waist circumference were obtained before randomization (baseline) and every 6 months for the next 18 months. The primary dependent measure was change in body weight from baseline to 18 months, calculated as percentage change to control for the baseline weight differences between the preference groups. Trained staff measured body weight, height and waist circumference at the GCRC using standardized procedures, forms and equipment. Weight was measured on the Tanita Digital Scale with the participant in light clothing and no shoes. Height was measured at baseline and 18 months on a wall-mounted stadiometer. Height and weight measurements were used to calculate BMI (kg/m^2). Waist circumference was measured two times using a Gullick II measuring tape. If the two values were within 2 cm of each other, an average value was computed as the outcome measure. If agreement within 2 cm was absent, the measurement was taken until agreement was met. Blood was drawn after a 12-h, overnight fast and 15-min rest period and stored at $-70^{\circ}C$ until assayed at the Heinz Nutrition Laboratory, University of Pittsburgh, by personnel blinded to treatment group assignment. Total cholesterol, HDL-C, LDL-C and triglycerides were measured enzymatically on an Abbot VP Supersystem autoanalyzer by standardized methods according to the Centers for Disease Control and Prevention. LDL-C was estimated using the Friedewald equation.[24] Plasma glucose was quantitatively determined by an enzymatic determination rad at 340/380 nm with couple enzyme reactions catalyzed by hexokinase and glucose-6-phosphate dehydrogenase. Insulin was measured using a radioactive immunoassay procedure developed by Linco Research Inc. Dietary data were collected in the form of 3-day food records which included two work days and one leisure day. The diaries were reviewed by trained research staff for completeness and clarity. The data were entered in the computer using the Nutrition Data System-Research (NDS-R) software

program by staff at the Obesity/Nutrition Research Center who were blinded to treatment group and time (The Minnesota Nutrition Data System for Research, www.ncc.umn.edu, accessed 20 April 2007).

Statistical analyses

Data were analyzed using SAS (version 9.1.3, SAS Institute Inc., Cary, NC, USA). Exploratory data analysis methods were used to screen for outliers, assess missing data and evaluate whether underlying statistical assumptions were satisfied. No outliers were identified through data screening. Data were mainly missing due to participant attrition (25%, $n=44$), which occurred at varying points in time and to a lesser extent a single intermittent missed visit. These data were assumed to be missing at random. Appropriate group comparative procedures (for example, ANOVA, Kruskal–Wallis test, χ^2 analyses and Fisher's exact test) were used to compare Preference (yes/no) groups, diet groups, and their combinations on participant characteristics and response variables at baseline. The primary end point of interest when testing the stated hypotheses was body weight; secondary endpoints included BMI, waist circumference, LDL-C, HDL-C, glucose, insulin and macronutrient intake. Percent change scores (that is, change from baseline to follow-up standardized by percentage change from baseline) were used as the dependent variable in analysis for each outcome. Since these data were longitudinally assessed, repeated measures analyses using mixed effects modeling was employed as it allows for data that are missing at random, the inclusion of fixed- and time-dependent covariates, and the modeling of the covariance matrix. Mixed models were estimated for each outcome using the restricted maximum likelihood method. While fitting these models the best-fitting covariance pattern for the repeated measures was determined using information criteria (that is, AIC and BIC). Weight and BMI were modeled by a heterogeneous Toeplitz covariance structure, while glucose, insulin, LDL-C and HDL-C were modeled by a compound symmetric covariance structure. The effects included in the mixed model included fixed effects for diet, preference, time and their interactions and a random effect for participant and cohort. Because baseline values differed for weight and cholesterol between preference groups, these values were initially included in the models as covariates. F-tests using the Kenward–Roger method for degrees of freedom were used for hypothesis testing. The level of significance for two-sided hypothesis testing was set at 0.05. On the basis of residual analyses, the underlying assumption of multivariate normality was supported and no outliers in solution were found.

Sensitivity analyses were undertaken to check the robustness of the findings due to the identified covariates, the possible random cohort effects, and the method of handling missing data. Similar findings for fixed effects (parameter estimates and test statistics) were obtained regardless of whether or not covariates were included in the repeated measures model. Random effects for cohort were not found to be statistically significant in the estimated models. Similar results were again obtained for parameter estimates and test statistics using alternate methods to handle missing data (for example, direct maximum likelihood estimation via mixed modeling, last-observation-carried forward approach, list-wise deletion). Given the findings for these sensitivity analyses, the results based on mixed effect models, which included no additional terms for cohort or covariates, are reported. Missing data were handled directly through maximum likelihood estimation using all available data. We also conducted an analysis of the completers ($n=112$) and found the same results as those derived from the mixed effects modeling.

Statement of ethics

We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during this research. The University of Pittsburgh Institutional Review Board approved the study protocol, and all participants provided written informed consent before enrollment. The study was registered with the National Institutes of Health Clinical Trials Registry, NCT study no. 00330629.

Results

As detailed in Table 1, demographic characteristics did not differ when we compared groups; however, as shown in Table 2, baseline differences were found between Preference-Yes and Preference-No participants on mean weight, Yes, 98.14 (s.d., 12.7) kg; No, 93.64 (s.d., 16.4) kg, $P=0.01$. Overall, 132 (75%) of the 176 participants completed the 18-month assessment; attrition did not differ among the groups ($\chi^2=0.92$, $P=0.82$; Figure 1). Compared to participants who completed the final assessment, those who did not complete were younger (41.3 (s.d., 9.0) years versus 44.9 (s.d., 8.5) years, $P<0.02$) and weighed more at baseline (220.5 (s.d., 32.2) kg versus 207.3 (s.d., 32.3) kg, $P=0.02$). There was no difference among the groups in adherence to the study protocol ($P>0.05$). Overall, mean attendance at group sessions was 71.3% (s.d., 27.6%) during the first 6 months (weekly sessions) and decreased to 51.8% (s.d., 37.8%) during the next 6 months (biweekly and monthly sessions).

Change in body weight, BMI and waist circumference

Table 2 shows the weights for all four groups at each assessment. Figure 2 illustrates patterns of weight change over each measurement point. A preference by time interaction ($P=0.02$) and a time effect ($P<0.001$) were found for the change in weight from baseline to 18 months. At 6 months, participants in the Preference-Yes + LOV-D group had a −9.9% (CI, −11.9 to −7.6%) weight change; those in

Table 1 Baseline characteristics of participants ($N=176$)

Characteristic	*Preference-Yes*		*Preference-No*	
	STD-D (n = *48*)	*LOV-D* (n = *35*)	*STD-D* (n = *48*)	*LOV-D* (n = *45*)
Age, years, mean (s.d.)	43.2 (9.4)	44.3 (8.4)	43.2 (8.4)	43.2 (8.6)
	No (%)[a]	No (%)[a]	No (%)[a]	No (%)[a]
Gender				
Male	6 (13)	7 (20)	6 (13)	4 (9)
Female	42 (88)	28 (80)	42 (88)	41 (91)
Race/ethnicity				
White	34 (71)	25 (71)	34 (71)	31 (69)
Non-white	14 (29)	10 (29)	14 (29)	14 (31)
Marital status[b]				
Never married	10 (21)	6 (18)	10 (21)	8 (18)
Currently married/living with partner	28 (60)	22 (65)	31 (65)	30 (67)
Formerly married	9 (19)	6 (18)	7 (15)	7 (16)
Employment status				
Currently employed	47 (98)	32 (91)	44 (92)	41 (91)
Not employed	1 (2)	3 (9)	4 (8)	4(9)
Education[c]				
High school diploma/GED or less	12 (25)	5 (15)	12 (25)	12 (27)
Vocational/technical degree	8 (17)	7 (21)	2 (4)	6 (13)
2-year college degree	7 (15)	7 (21)	7 (15)	4 (9)
4-year college degree	14 (29)	11 (32)	16 (33)	11 (24)
Post-graduate degree	7 (15)	4 (12)	11 (23)	12 (27)

Abbreviations: GED, general equivalency diploma; LOV-D, lacto–ovo–vegetarian diet; STD-D, standard diet. [a]Percentages may not add up to 100% because of rounding. [b]Missing marital status on two participants. [c]Missing education on one participant.

the Preference-Yes + STD-D group had a −7.4% (CI, −9.2 to −5.5%) weight change. Participants in the Preference-No + LOV-D group had a −9.3% (CI, −11.1 to −7.3%) weight change; those in the Preference-No + STD-D group had a −9.4% (CI, −11.0 to −7.3%) weight change. For all groups, these were significant changes from their baseline weights ($P<0.001$). Between months 6 and 18, there was a significant difference in weight regain between preference groups; participants who chose their diet regained 4.5% (CI, −5.8 to −3.2%) while those with assigned diets regained 2.1% (CI, −3.4 to −0.8%) ($P<0.001$). All four groups regained weight during the maintenance phase (months 13–18). Over time, the different diets produced no difference in percentage weight change ($P=0.30$), nor was there a preference × diet interaction ($P=0.34$). For BMI, there was no preference × diet interaction ($P=0.43$), but the preference × time interaction was significant in predicting BMI change ($P=0.02$); a marginal effect for preference alone was observed ($P=0.06$). The mixed model analysis revealed that the preference × time interaction was also marginal in predicting percent change in waist circumference over time ($P=0.07$).

Change in LDL-C, HDL-C, glucose and insulin

At 6 months, participants on the LOV-D had greater changes in LDL-C than those on the STD-D, with respective changes of −2.9% (CI, −7.7 to 1.7%) and 2.8% (CI, −1.4 to 7.0%) ($P=0.07$); however, no significant effect of diet on LDL-C was observed at 18 months ($P=0.53$). Although we found a significant effect for time on insulin and HDL-C with a 9.3% (CI, −14.8 to −3.8%) reduction in insulin and 3.5% (CI, 0.91–6.1%) increase in HDL, $P<0.001$, there were no significant main effects or interactions on glucose or LDL-C over time.

Changes in energy and selected macronutrient intake

Changes observed in kilocalorie consumption over the course of the 18-month study and changes in carbohydrates, fat, animal and vegetable protein and fiber are reported in Table 3. A mixed model analysis revealed a significant main effect for time for percent change in total energy ($P<0.001$), fat ($P<0.0001$), animal protein ($P<0.0001$), vegetable protein ($P=0.02$), and fiber ($P=0.05$). We observed no significant interactions between diet, time or preference in differences in kilocalorie and macronutrient intake among the four groups at 18 months. There was a main effect for diet on intake of animal protein ($P<0.0001$) and vegetable protein $P=0.02$) with the LOV-D groups having a greater decrease in animal protein and a larger increase in vegetable protein.

Table 2 Changes from baseline in body weight and related measures

	Preference-Yes		*Preference-No*		P-*values*		
	STD-D (n = *48*)	*LOV-D* (n = *35*)	*STD-D* (n = *48*)	*LOV-D* (n = *45*)	*Preference × time*	*Diet × time*	*Time*
Weight, mean (s.d.) (kg)							
Baseline	97.2 (12.9)	96.7 (12.1)	92.4 (16.1)	91.8 (15.4)			
6 months	89.9 (12.4)	86.5 (12.5)	83.6 (16.5)	83.4 (15.6)			
12 months	89.6 (12.9)	88.8 (14.6)	82.7 (15.2)	82.1 (15.8)	0.02	0.29	<0.0001
18 months	92.5 (13.7)	92.1 (14.1)	85.1 (16.5)	83.1 (14.7)			
Mean (s.d.) % change, baseline to 18 months	−3.9 (6.1)**	−5.3 (6.2)**	−8.0 (7.8)**	−7.9 (8.1)**			
BMI, mean (s.d.) (kg/m^2)							
Baseline	34.5 (3.9)	34.1 (3.5)	32.9 (4.1)	33.7 (4.3)			
6 months	31.9 (4.1)	30.5 (3.8)	29.8 (4.9)	30.6 (4.7)			
12 months	31.9 (4.3)	31.3 (4.3)	29.5 (4.7)	30.1 (4.8)	0.02	0.16	<0.0001
18 months	33.0 (4.5)	32.6 (4.7)	30.1 (4.6)	30.6 (4.6)			
Mean (s.d.) % change, baseline to 18 months	−3.9 (5.9)**	−4.5 (7.4)**	−7.8 (7.9)**	−7.9 (8.2)**			
Waist circumference, mean (s.d.) (cm)							
Baseline	107.2 (13.6)	106.6 (12.5)	101.8 (12.6)	104.4 (13.2)			
6 months	100.5 (11.0)	97.5 (10.1)	94.2 (12.9)	96.9 (13.6)			
12 months	99.1 (11.4)	98.1 (11.3)	94.7 (14.9)	95.6 (13.9)	0.06	0.86	0.08
18 months	101.2 (12.2)	99.7 (10.0)	94.6 (13.0)	94.6 (12.1)			
Mean (s.d.) % change, baseline to 18 months	−5.2 (8.7)**	−6.0 (7.8)**	−6.0 (9.3)**	−7.9 (8.6)**			
LDL, mean (s.d.) (mmol/l)							
Baseline	3.3 (1.0)	3.5 (1. 0)	3.0 (0.7)	3.1 (0.9)			
6 months	3.3 (1.0)	3.3 (0.9)	3.1 (0.9)	2.9 (0.8)			
12 months	3.3 (0.9)	3.3 (0.8)	2.9 (0.8)	2.9 (0.8)	0.33	0.54	0.29
18 months	3.3 (1.0)	3.4 (0.9)	3.2 (0.8)	3.1 (1.0)			
Mean (s.d.) % change, baseline to 18 months	−0.8 (18.3)	1.0 (25.8)	5.1 (15.3)	−0.5 (19.5)			
HDL, mean (s.d.) (mmol/l)							
Baseline	1.4 (0.3)	1.3 (0.3)	1.4 (0.3)	1.4 (0.3)			
6 months	1.3 (0.2)	1.2 (0.3)	1.4 (0.3)	1.3 (0.3)			
12 months	1.3 (0.3)	1.3 (0.2)	1.5 (0.3)	1.4 (0.3)	0.19	0.92	0.0001
18 months	1.3 (0.2)	1.3 (0.3)	1.5 (0.3)	1.4 (0.3)			
Mean (s.d.) % change, baseline to 18 months	0.4 (12.8)	3.6 (15.0)	4.2 (14.7)	4.5 (17.9)			
Glucose, mean (s.d.) (mmol/l)							
Baseline	5.4 (0.5)	5.4 (0.5)	5.2 (0.5)	5.3 (0.5)			
6 months	5.3 (0.5)	5.2 (0.6)	5.2 (0.4)	5.3 (0.5)			
12 months	5.3 (0.5)	5.3 (0.6)	5.2 (0.4)	5.3 (0.4)	0.17	0.45	0.96
18 months	5.5 (0.7)	5.3 (0.5)	5.0 (0.5)	5.3 (0.5)			
Mean (s.d.) % change, baseline to 18 months	1.1 (12.2)	−1.4 (9.0)	−4.0 (10.5)*	0.6 (11.7)			
Insulin, mean (s.d.) (pmol/l)							
Baseline	127.1 (52.8)	132.7 (56.3)	117.4 (56.3)	133.3 (61.1)			
6 months	104.9 (40.9)	96.5 (42.4)	89.6 (35.4)	100.0 (45.1)			
12 months	106.3 (50.7)	113.9 (43.1)	91.7 (41.0)	104.9 (61.8)	0.61	0.32	0.006
18 months	116.0 (56.3)	105.6 (42.4)	94.5 (43.8)	116.7 (71.5)			
Mean (s.d.) % change, baseline to 18 months	−5.2 (32.3)	−17.8 (26.9)**	−12.6 (32.4)*	−9.5 (36.7)			

Abbreviations: LOV-D, lacto–ovo–vegetarian diet; STD-D, standard diet. *P*-values for percent change from baseline to 18 months are indicated as follows: *$P<0.05$; **$P<0.01$.

Adherence to dietary goals

A secondary hypothesis was that individuals who were in the LOV-D group would be more adherent to the treatment protocol than those in the STD-D group. Although no difference in adherence to attendance, exercise or self-monitoring was noted between the groups, there was a significant main effect for diet in adherence to the fat-gram goal ($P=0.01$) and a marginal effect for adherence to the calorie goal ($P=0.06$) with the LOV-D group participants having higher adherence than those in the STD-D groups (data not shown). However, within the LOV-D group, not all participants were adherent to the LOV dietary guidelines, which required eliminating the consumption of meat, fish and poultry.

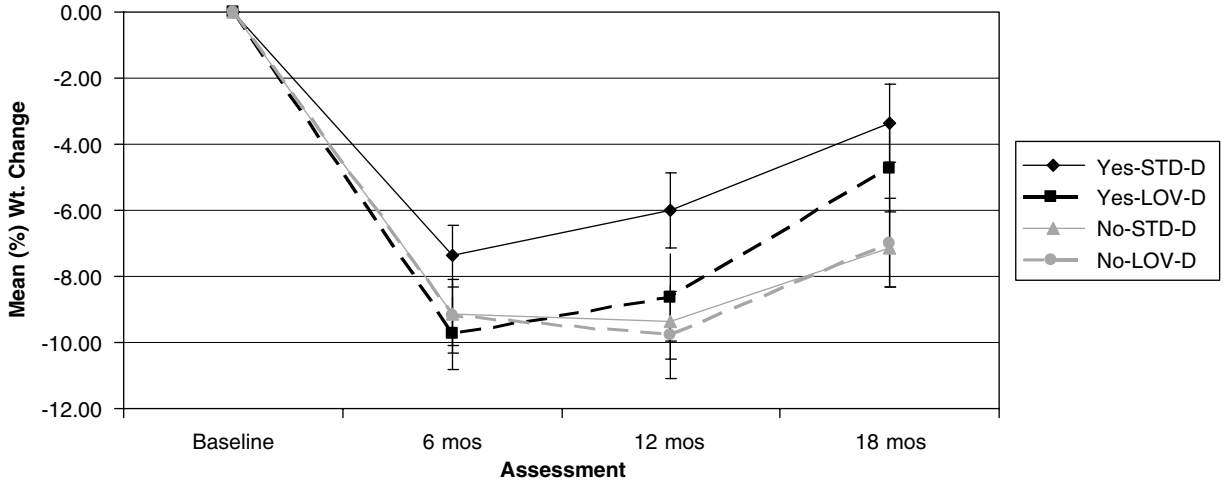

Figure 2 Percentage weight change in the four groups at each assessment. LOV-D, lacto–ovo–vegetarian diet; STD-D, standard diet.

Discussion

This is the first randomized controlled trial that tested the combination of diet (STD-D and LOV-D) and random assignment to one's preferred diet (yes/no) on weight loss and selected physical and biological outcome measures at 18 months. A strength of our study is the excellent retention. Seventy-five percent of participants completed this trial despite having no contact with the study personnel during the 12- to 18-month maintenance phase; similar retention rates have been reported for previously conducted weight loss trials. Jakicic *et al*.[25] reported 78% retention after an 18-month behavioral intervention for weight loss, and Renjilian *et al*.[18] reported a 78% retention rate after 6 months, similar to our 18-month retention (75%). Worth noting, these studies did not include a no-contact maintenance period after the active intervention, as our study did.

We tested the hypotheses that following a reduced calorie and fat LOV-D would result in greater weight loss than following a standard, reduced calorie and fat diet (STD-D) and that the capacity to select either of these diets would result in greater weight loss compared to having one of these diets randomly assigned; however, our results refute that a LOV-D or being assigned to one's preferred diet would be more likely to produce greater weight loss. On the contrary, participants who were not assigned to their preferred diet had a significantly greater weight loss than those who were allowed to choose their dietary treatment. However, it is worth noting that those in the LOV-D groups had a significantly greater reduction in animal protein and greater increases in vegetable protein and in dietary fiber, all beneficial changes.

Four studies have examined treatment choice in relation to weight loss among adults.[16,26,27,18] All of these studies had limitations in the duration of the treatment and one study in retention, making it difficult to compare findings. A study with a similar design to the one reported in this paper was conducted concurrent to our trial. Renjilian *et al*.[18] examined the effects of matching participants to treatments based on preferences for either individual or group therapy in the treatment of obesity. They randomly assigned 75 obese adults to either their preferred or nonpreferred option and found no significant effect of treatment preference or the interaction of treatment preference by type of therapy. Group therapy produced significantly greater weight loss, even among participants who preferred individual treatment. This study, which was 6 months in duration and did not conduct a post-treatment follow-up, found that the treatment itself was more important than the individual's preference, which is not a total contradiction of our findings.

Our findings demonstrated that those who did not receive their preferred treatment did better than those who received their treatment of choice. An explanation for this finding is not readily apparent; however, it might be explained by the Preference—No participants' determination to succeed despite their assignment, or simply that they forgot what their original preference was and therefore it did not influence how they carried out the behavior change over the subsequent 18 months. Another possible explanation might be that the individuals who received their preferred treatment option might have expected more than what they received, or that they were overly confident in how they would do considering that they received their preferred treatment group and then realized that it was as difficult as other weight-loss approaches. This may be particularly relevant to those who selected the standard-diet group since they had the least weight change. Our study results, taken with the findings of others who have studied choice, have demonstrated that providing a study participant his or her choice of treatment does not necessarily lead to improved adherence or improved outcomes. On the basis of general adherence literature, it may be more important to explore

Table 3 Means for energy and macronutrient intake at all time points ($N = 176$)

	Preference-Yes		*Preference-No*		P-*values*		
	STD-D (n = *48*)	*LOV-D* (n = *35*)	*STD-D* (n = *48*)	*LOV-D* (n = *45*)	*Pref*	*Diet*	*Time*
Total energy, mean (s.d.) (kcal)							
Baseline	1941.30 (620.89)	2110.57 (784.45)	2155.71 (674.77)	1982.65 (602.07)	0.09	0.81	<0.001
6 months	1328.10 (341.54)	1423.89 (373.06)	1496.06 (495.06)	1357.36 (311.08)			
12 months	1503.82 (466.04)	1573.20 (426.43)	1534.50 (509.21)	1366.49 (369.07)			
18 months	1504.21 (403.23)	1645.78 (525.04)	1599.94 (499.18)	1398.20 (353.50)			
Mean (s.d.) % change, baseline to 18 months	−16.34 (30.17)**	−12.97 (36.68)	−22.02 (32.14)**	−26.38 (17.22)**			
Total fat, mean (s.d.) (g)							
Baseline	75.94 (31.29)	83.27 (36.01)	87.33 (34.57)	78.55 (31.19)	0.15	0.71	<0.0001
6 months	36.88 (16.94)	35.99 (12.63)	44.97 (23.01)	37.21 (16.73)			
12 months	49.49 (28.34)	48.97 (23.12)	47.49 (22.75)	39.66 (17.25)			
18 months	51.17 (22.64)	56.82 (28.14)	51.56 (21.55)	41.31 (18.17)			
Mean (s.d.) % change, baseline to 18 months	−20.88 (53.76)*	−15.81 (62.54)	−31.51 (50.20)**	−42.86 (23.94)**			
Carbohydrates, mean (s.d.) (g)							
Baseline	241.07 (84.63)	266.21 (103.18)	254.69 (88.30)	246.93 (88.25)	0.53	0.50	0.84
6 months	190.58 (46.57)	223.68 (65.20)	207.40 (76.02)	213.89 (52.03)			
12 months	197.53 (60.51)	233.90 (66.63)	210.58 (77.42)	204.11 (49.29)			
18 months	198.74 (50.51)	228.00 (68.72)	217.81 (85.93)	207.69 (55.73)			
Mean (s.d.) % change, baseline to 18 months	−10.36 (31.74)	−6.08 (33.14)	−10.70 (35.56)	−9.37 (26.45)*			
Animal protein, mean (s.d.) (g)							
Baseline	50.76 (18.27)	50.69 (26.63)	60.08 (23.88)	50.62 (17.67)	0.01	<0.0001	<0.0001
6 months	39.58 (16.55)	23.18 (10.83)	43.27 (17.36)	22.65 (18.35)			
12 months	46.66 (17.55)	26.06 (12.66)	46.32 (18.98)	26.39 (15.27)			
18 months	47.04 (16.32)	36.03 (18.76)	45.84 (14.67)	29.92 (17.86)			
Mean (s.d.) % change, baseline to 18 months	−0.97 (38.11)	−11.52 (51.82)	−18.15 (44.85)*	−38.83 (32.85)**			
Vegetable protein, mean (s.d.) (g)							
Baseline	22.86 (8.64)	27.84 (12.06)	24.42 (7.99)	24.51 (9.15)	0.28	0.02	0.02
6 months	21.23 (6.65)	34.79 (19.72)	22.58 (7.46)	27.25 (7.61)			
12 months	21.59 (7.88)	33.04 (11.27)	22.53 (9.09)	26.64 (9.11)			
18 months	20.49 (6.82)	27.00 (8.83)	23.99 (10.93)	25.08 (8.66)			
Mean (s.d.) % change, baseline to 18 months	−1.63 (44.39)	8.55 (43.81	5.27 (51.95)	9.80 (56.14)			
Fiber mean (s.d.) (g)							
Baseline	15.56 (6.55)	16.06 (7.32)	15.85 (6.33)	15.76 (5.97)	0.37	0.06	0.05
6 months	15.98 (5.46)	23.05 (14.61)	16.24 (7.25)	19.87 (6.65)			
12 months	15.95 (6.34)	23.95 (12.69)	18.11 (9.75)	20.39 (6.87)			
18 months	15.49 (4.97)	20.63 (7.82)	17.33 (8.79)	18.15 (6.71)			
Mean (s.d.) % change, baseline to 18 months	13.53 (53.90)	21.77 (48.80)*	15.23 (64.56)	14.75 (40.43)*			

Abbreviations: LOV-D, lacto–ovo–vegetarian diet; STD-D, standard diet. *P*-values for within-group percent change from baseline to 18 months are indicated as follows: *$P<0.05$; **$P<0.01$.

the role of shared decision-making.[28] Studies have demonstrated enhanced adherence when individuals are permitted to participate in their care and the treatment decisions, which may be more meaningful than receiving their preferred treatment.[29,30]

Some have implicated a selection bias in the successful outcomes of studies testing vegetarian diets.[19] Our experience in this study does not support this notion. Only 8 of the 932 candidates we screened declined participation because of concern that they would be assigned to a vegetarian diet and no one withdrew from the study because they were not assigned to the diet of their choice. Thus, preference had no effect on the external or internal validity of the study. The literature suggests that individuals who follow a vegetarian eating plan report greater satisfaction and are more likely to maintain this eating pattern.[5,31,6] Indeed, we found that the LOV-D group was more adherent to the prescribed calorie- and fat-gram goals than the STD-D group and were very successful in achieving a clinically significant weight loss. However, being adherent to the meatless diet became a challenge over time, resulting in the LOV-D group participants eating a diet that may have been similar to the STD-D group. This may explain the lack of statistically significant differences between the two diet groups.

A limitation of this study, as well as other weight-loss trials,[32] is the small representation of male participants. This limitation may be the result of this being a study testing a vegetarian diet, or as previously reported data suggest, it may

be due to the fact that a lower percentage of men than women are trying to lose weight.[33,34] Unfortunately, a recent study found an increased prevalence of obesity among males;[1] therefore, we need to develop strategies to better recruit men into weight-loss studies. Given that the males in our study were highly adherent to the vegetarian diet, further research is warranted regarding the effects of a vegetarian diet on weight loss among men.

In summary, our study found that the opportunity to choose a treatment did not result in improved weight loss and that random assignment to the nonpreferred diet resulted in better weight loss than did receiving the diet of choice. Thus, matching individuals to their choice did not enhance treatment outcome for the short or long term. However, all groups lost weight with the losses ranging from 4 to 8%, losses that are clinically significant. Moreover, there were significant improvements in most groups over time in BMI, waist circumference, HDL-C, and insulin, changes that have implications for the prevention of comorbidities associated with obesity. These data suggest that study participation in general was more important than treatment preference or dietary treatment in weight loss and maintenance.

Acknowledgements

This study was supported by National Institutes of Health grants NIH, NIDDK, no. RO1-DK58631. The conduct of the study was also supported by the Data Management Core of the Center for Research in Chronic Disorders NIH-NINR no. P30-NR03924, the Obesity and Nutrition Research Center NIH-NIDDK no. DK-046204, the Heinz Nutrition Laboratory and the General Clinical Research Center, NIH-NCRR-GCRC no. 5MO1-RR00056 at the University of Pittsburgh. We thank the study participants who graciously shared their time and information with us.

References

1 Ogden C, Carroll M, Curtin L, McDowell M, Tabak C, Flegal K. Prevalence of overweight and obesity in the United States, 1999–2004. *JAMA* 2006; **295/13**: 1549–1555.
2 Wing RR. Behavioral interventions for obesity: Recognizing our progress and future challenges. *Obes Res* 2003; **11** (Supp): 3S–5S.
3 Wadden TA, Butryn ML, Byrne KJ. Efficacy of lifestyle modification for long-term weight control. *Obes Res* 2004; **12** (Suppl): 151S–162S.
4 Wing RR. Behavioral approaches to the treatment of obesity. In: Bray GA, Bourchard C, James WPT (eds). *Handbook of Obesity: Clinical Applications*. Marcel Dekker: NY, USA, 2004; 147–167.
5 Janelle KC, Barr SI. Nutrient intakes and eating behavior scores of vegetarian and nonvegetarian women. *J Am Diet Assoc* 1995; **95/2**: 180–189.
6 White RF, Seymour J, Frank E. Vegetarianism among US women physicians. *J Am Diet Assoc* 1999; **99/5**: 595–598.
7 Smith C, Burke LE, Wing R. Vegetarian and weight loss diets among young adults. *Obes Res* 2000; **8/2**: 123–129.
8 Ornish D. Avoiding revascularization with lifestyle changes: The Multicenter Lifestyle Demonstration Project. *Am J Cardio* 1998; **82**: 72T–76T.
9 Ornish D, Scherwitz LW, Billings JH, Gould L, Merritt TA, Sparler S *et al*. Intensive lifestyle changes for reversal of coronary heart disease. *JAMA* 1998; **280**: 2001–2007.
10 Newby PK, Tucker KL, Wolk A. Risk of overweight and obesity among semivegitarian, lactovegitarian, and vegan women. *Am J Clin Nutr* 2005; **81**: 1267–1274.
11 Burke LE, Smith CF, Wing RR. Efficacy of a vegetarian diet for weight loss. *Obes Res* 1999; **7** (Suppl 1): 18S.
12 Phillips F, Hackett A, Stratton G, Billington D. Effect of changing to a self-selected vegetarian diet on antropometric measurements in UK adults. *J Hum Nutr Diet* 2004; **17**: 249–255.
13 Rosell M, Appleby P, Spencer E, Key T. Weight gain over 5 years in 21 966 meat-eating, fish-eating, vegetarian, and vegan men and woman in EPIC-Oxford. *Int J Obes Relat Metab Disord* 2006; 1–8.
14 Barnard ND, Scialli AR, Turner-McGrievy G, Lanou AJ. Acceptability of a low-fat vegan diet compares favorably to a step II Diet in a randomized controlled trial. *J Cardiopulm Rehabil* 2004; **24**: 229–235.
15 Barnard N, Scialli A, Turner-McGrievy G, Lanou A, Glass J. The effect of low-fat, plant-based dietary intervention on body weight, metabolism, and insulin sensitivity. *Am J Med* 2005; **118**: 991–997.
16 Murray DC. Preferred versus nonpreferred treatment, and self-control training versus determination raising as treatments of obesity: a pilot study. *Psychol Rep* 1976; **38**: 191–198.
17 Mendonca PJ, Brehm SS. Effects of choice on behavioral treatment of overweight children. *J Soc Clin Psychol* 1983; **1/4**: 343–358.
18 Renjilian DA, Perri MG, Nezu AM, McKelvey WF, Shermer RL, Anton SD. Individual versus group therapy for obesity: Effects of matching participants to their treatment preferences. *J Consult Clin Psychol* 2001; **69/4**: 717–721.
19 King M, Nazareth I, Lampe F, Bower P, Chandler M, Morou M *et al*. Impact of participant and physician intervention preferences on randomized trials: a systematic review. *JAMA* 2005; **293/9**: 1089–1099.
20 Epstein LH. Role of behavior theory in behavioral medicine. *J Consult Clin Psychol* 1992; **60/4**: 493–498.
21 Burke LE, Choo J, Music E, Warziski M, Styn MA, Kim Y *et al*. PREFER study: a randomized clinical trial testing treatment preference and two dietary options in behavioral weight management—rationale, design and baseline characteristics. *Contemp Clin Trials* 2006; **27/1**: 34–48.
22 Pocock SJ, Simon RM. Sequential treatment assignment with balancing for prognostic factors in the controlled clinical trials. *Biometrics* 1975; **31**: 103–115.
23 Wing RR. Behavioral approaches to the treatment of obesity. In: Bray GA, Bourchard C, James WPT (eds). *Handbook of Obesity*. Marcel Dekker: NY, USA, 1998 pp 855–877.
24 Friedewald WT, Levy RI, Fredickson DA. Estimation of the concentration of low-density cholesterol in plasma without the use of the preparative ultracentrifuge. *Clin Chem* 1972; **18**: 499–502.
25 Jakicic J, Winters C, Lang W, Wing R. Effects of intermittent exercise and use of home exercise equipment on adherence, weight loss, and fitness in overweight women: a randomized trial. *JAMA* 1999; **282/16**: 1554–1560.
26 Daby R. Expressed preference for, and assignment to one of two weight loss programs: effects on weight loss and weight loss maintenance. *Psychology* 1988. Tennessee, Vanderbilt 113.
27 Fuller TC. The role of patient preferences for treatment type in the modification of weight loss behavior. *Unpublished Dissertation* 1988; Michigan State University.
28 Osterberg L, Blaschke TF. Adherence to medication. *N Engl J Med* 2005; **353/5**: 487–497.

29 Golin CE, DiMatteo MR, Gelberg L. The role of patient participation in the doctor visit: implications for adherence to diabetes care. *Diabetes Care* 1996; **19/10**: 1153–1164.
30 Feldman R, Bacher M, Campbell N, Drover A, Chockalingam A. Adherence to pharmacologic management of hypertension. *Can J Public Health* 1998; **89/5**: I16–I18.
31 Smith CF, Burke LE, Wing RR. Young adults remain on vegetarian diets longer than on weight loss diets. *Ann Behav Med* 1999; **21** (Supp): 90.
32 Tate DF, Jackvony EH, Wing RR. Effects of internet behavioral counseling on weight loss in adults at risk for type 2 diabetes: a randomized trial. *JAMA* 2003; **289/14**: 1833–1836.
33 Bish CL, Blanck HM, Serdula MK, Marcus M, Kohl III HW, Khan LK. Diet and physical activity behaviors among Americans trying to lose weight: 2000 Behavioral risk factor surveillance system. *Obes Res* 2005; **13/3**: 596–607.
34 Weiss EC, Galuska DA, Khan LK, Serdula MK. Weight-control practices among US adults, 2001–2002. *Am J Prev Med* 2006; **31/1**: 18–24.