



## PAPER

# A randomized controlled trial of a moderate-fat, low-energy diet compared with a low fat, low-energy diet for weight loss in overweight adults

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**CONTEXT:** Long-term success in weight loss with dietary treatment has been elusive.

**OBJECTIVE:** To evaluate a diet moderate in fat based on the Mediterranean diet compared to a standard low-fat diet for weight loss when both were controlled for energy.

**DESIGN:** A randomized, prospective 18 month trial in a free-living population.

**PATIENTS:** A total of 101 overweight men and women (26.5–46 kg/m<sup>2</sup>).

**INTERVENTION:** (1) Moderate-fat diet (35% of energy); (2) low-fat diet (20% of energy).

**MAIN OUTCOME MEASUREMENTS:** Change in body weight.

**RESULTS:** After 18 months, 31/50 subjects in the moderate-fat group, and 30/51 in the low fat group were available for measurements. In the moderate-fat group, there were mean decreases in body weight of 4.1 kg, body mass index of 1.6 kg/m<sup>2</sup>, and waist circumference of 6.9 cm, compared to increases in the low-fat group of 2.9 kg, 1.4 kg/m<sup>2</sup> and 2.6 cm, respectively;  $P \leq 0.001$  between the groups. The difference in weight change between the groups was 7.0 kg. (95% CI 5.3, 8.7). Only 20% (10/51) of those in the low-fat group were actively participating in the weight loss program after 18 months compared to 54% (27/50) in the moderate-fat group, ( $P < 0.002$ ). The moderate-fat diet group was continued for an additional year. The mean weight loss after 30 months compared to baseline was 3.5 kg ( $n = 19$ ,  $P = 0.03$ ).

**CONCLUSIONS:** A moderate-fat, Mediterranean-style diet, controlled in energy, offers an alternative to a low-fat diet with superior long-term participation and adherence, with consequent improvements in weight loss.

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**Keywords:** diets; weight reduction; unsaturated fat; low fat

## Introduction

Obesity is a chronic widespread disease of increasing prevalence, which has become a leading public health and clinical concern. It is now estimated that over 50 million people, or more than 23% of the adult US population, are obese.<sup>1</sup> Overweight and obesity are associated with major chronic illnesses, including hypertension, coronary artery disease, diabetes, arthritis, certain forms of cancer, and all-cause mortality.

The increasing prevalence of obesity comes at a time of more sedentary behavior and an increase in overall energy consumption. Current dietary guidelines for weight loss promotion recommend a reduction in fat intake so that 30% of energy intake comes from fat.<sup>2</sup> The rationale includes the higher energy density of fat compared to carbohydrate and protein, metabolic efficiency of converting dietary fat into adipose storage, and the low incidence of obesity in Asian countries in which dietary content of fat was traditionally low. Despite advice to the US population to reduce fat intake, incidence of obesity has actually increased.<sup>1,3</sup> Therefore, a re-evaluation of whether low-fat diets should be the preferred approach for weight reduction is needed.

There are no conclusive findings from controlled studies on the appropriate amount of fat in the diet to promote

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long-term weight reduction and maintenance, and long-term data are very limited. One published trial compared a low-fat diet with a higher-fat diet, both energy-restricted for weight loss, but only for 6 months.<sup>4</sup> The low fat diet caused slightly more weight loss early in the program, but after 2 y both groups gained all the weight back despite ongoing teaching.

A possible explanation for the limited success of some low-fat diets is that they are less appetizing, which makes long-term compliance difficult. Since it is known that the proportions of fat and carbohydrate in a fully-controlled energy-restricted diet do not affect weight loss,<sup>5,6</sup> we hypothesized that weight loss in free-living overweight subjects would be affected mainly by the energy level of the diet they self-selected, that is, the degree of adherence. We further hypothesized that, using these techniques, a moderate-fat diet based on the diets of southern Europe and the Mediterranean would be effective for weight loss in overweight subjects, and would promote long-term adherence because of the variety and taste of the foods. Unsaturated fats are more beneficial than saturated fats for cardiovascular disease,<sup>7</sup> and were therefore the main dietary

fats in our study. Therefore, we conducted a randomized trial to compare the efficacy for long-term weight loss of a moderate fat diet with 35% of energy from fat to a low-fat diet with 20% of energy from fat. Several components of weight loss programs have been associated with success, such as nutrition counseling, goal setting, behavior modification techniques, exercise, continued follow-up visits and long-term maintenance strategies. These behavioral techniques were used at the same intensity in both dietary interventions.

## Methods

### Study design

Overweight men and women were recruited for an 18-month randomized trial. Inclusion criteria included age 18–70 y, body-mass index (BMI) 26.5–46 kg/m<sup>2</sup>, nonsmokers, free of chronic disease, and willingness to attend weekly classes for the duration of the study.

We advertised the study in letters mailed to primary care physicians at Brigham and Women’s Hospital (BWH) and in posted announcements. One-hundred and seventy persons responded and were screened for eligibility (Figure 1). The

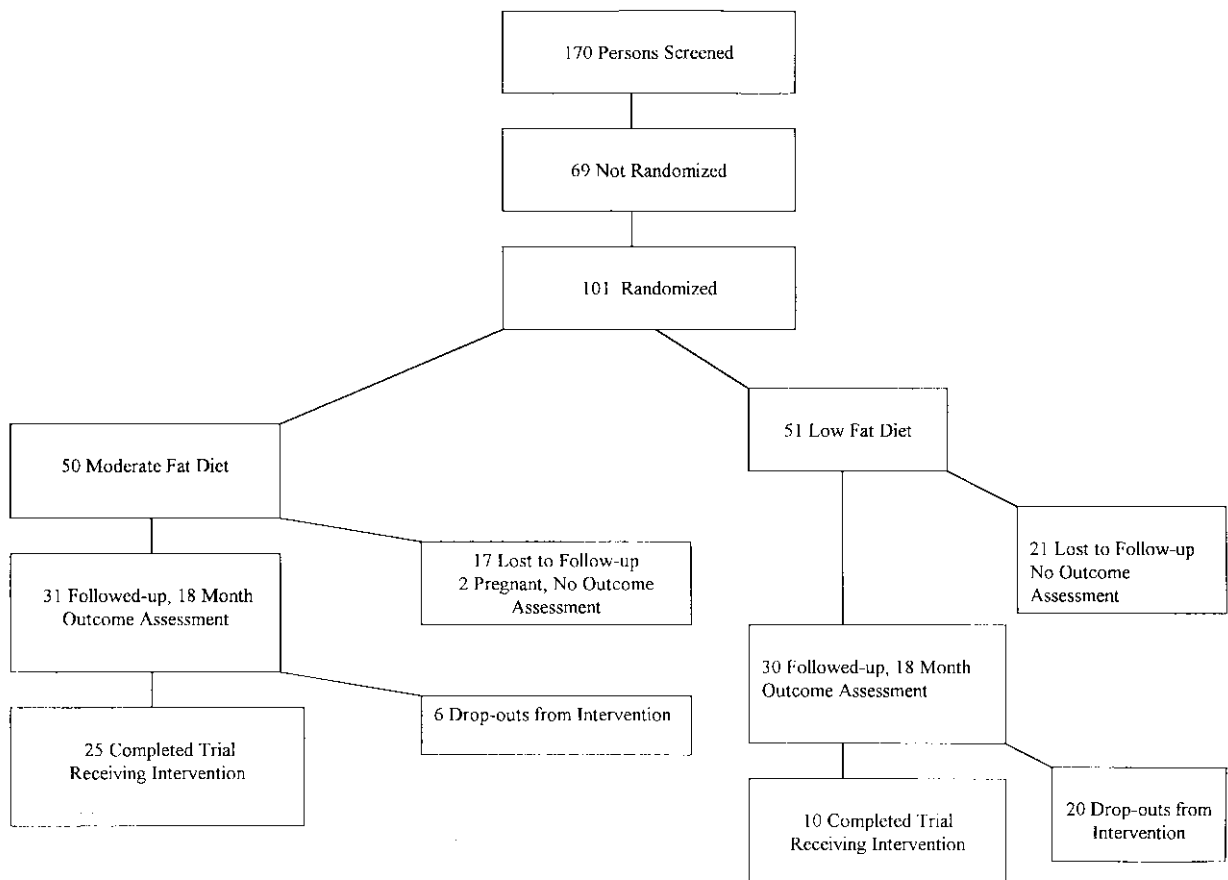


Figure 1 Trial design.

original recruitment goal was 80 subjects. After 2 months of recruitment and before any outcome data were collected, this was increased to 100. One-hundred and one subjects were eligible and were randomized. Recruitment was completed in 3 months. The study protocol was approved by the Brigham and Women's Hospital Human Subjects Committee and all randomized subjects gave their written informed consent.

Fifty subjects were randomized to an energy-controlled diet containing 35% of energy as fat, and fifty-one to an energy-controlled diet containing 20% of energy as fat. The subjects were told that the aim of the study was to compare two dietary approaches for weight loss. The study's data coordinator, who was not involved in the dietary treatment, ascertained eligibility and willingness to participate, and randomized each subject using a schedule generated by a random number table. The study coordinator assigned each subject to a diet group. Two dietitians were responsible for the diet intervention program; one was assigned to the moderate fat diet group, the other assigned to the low fat. The nutrient goals of the diets are shown in Table 1. The women were instructed to limit their energy intake to 1200kcal per day and the men to 1500kcal per day. These calorie levels were selected based on previous studies resulting in successful weight loss in obese individuals.<sup>4</sup> A meal plan using the American Dietetic Association exchange system was developed for each subject. Sample menus were provided. Subjects were then enrolled into a group education class which met weekly for 1 h. Similar teaching modules were used in each group to address behavioral modification skills and physical activity. The dietitians measured body weight of the participants who were in their diet groups weekly. Food records of daily intake were collected weekly. The dietitians analyzed each subject's food record, offering specific suggestions and recommendations to enhance compliance. The records were returned to the subjects at the following group class. Both dietitians had the same number of years and experience in treating obesity and conducting group intervention classes. They developed the teaching

modules together and taught the same weekly behavioral modules to their respective treatment groups. These procedures ensured that the intensity of the dietary programs was the same in the low-fat and in the moderate-fat groups. The intervention trial was 18 months in duration.

Participation was defined as attending group or individual counseling sessions. The group sessions were established based on the most convenient days and times for the majority of subjects. At the beginning of the trial, five different group session times were established for the moderate-fat group and five different group session times for the low-fat group. If a participant was not able to attend their usual group session, they were encouraged to attend another group session that week consistent with their group assignment. If the participant was unable to attend one of the group sessions, an individual session, by telephone or in person, was scheduled with the appropriate dietitian. The non-participants (dropouts) notified the research staff of their intention to withdraw from the study or simply stopped attending study visits. The dropouts were contacted at the end of the study for outcome measurements.

Measurements were obtained at baseline and after 6, 12 and 18 months of the dietary program. Body weight, body fat, waist and hip circumference, physical activity and nutrient intake were measured. Body weight was determined using a standard weight scale. Body fat was measured using a near-infrared light interactance device, the Futrex-5000. This technology emits near-infrared light at frequencies of 938 and 948 nm; body fat absorbs the light and lean body mass reflects the light. This method was compared to underwater weighing and assessed for reliability and validity.<sup>8</sup> Waist and hip circumferences were measured using a standard tape measure.

Analysis of nutrient intake was completed using a validated, 156 food semiquantitative food frequency questionnaire.<sup>9,10</sup> Habitual physical activity levels were ascertained by a 7 day recall questionnaire.<sup>11</sup>

**Statistical analysis**

The sample of 100 was determined to provide at least 80% power to detect a difference in weight loss of 2.3 kg (5 pounds) between the groups, allowing for a dropout rate of 33%. The primary outcome variable was change in body weight from baseline to 18 months in all randomized subjects for whom body weight measurements could be obtained, regardless of participation or adherence. A secondary analysis was change in body weight at 6, 12 and 18 months for subjects who were participating in the dietary program at each of these points in the study. A subsidiary analysis of change in body weight ('last value carried forward' or 'intention to treat'), included all randomized participants and used the last body weight measurement for the final weight. Baseline body weight was used for those who did not have any body weight measurements after randomization. Other outcome variables included changes in body

**Table 1** Nutrient goals for the intervention diets

	Moderate-fat diet	Low-fat diet
Energy (kcal) <sup>a</sup>	1200–1500	1200–1500
Fat (percentage of energy)	35	20
Saturated fatty acids (percentage of energy)	5	5
Monounsaturated fatty acids (percentage of energy)	15–20	7–8
Polysaturated fatty acids (percentage of energy)	10	7–8
Protein (percentage of energy)	15–20	15–20
Carbohydrate (percentage of energy)	45–50	60–65
Cholesterol (mg)	< 200	< 200
Dietary fiber (g)	25	25

<sup>a</sup>To convert values for total energy from kilocalories (kcal) to kilojoules (kJ), multiply by 4.184.

fat content, body mass index (BMI, defined as the weight in kilograms divided by the square of the height in meters), and waist and hip circumferences. The changes in outcome variables was compared between the diet groups by unpaired *t*-test, and within each group by paired *t*-test.<sup>12</sup> *P*-values less than 0.05, two-sided, were considered statistically significant. Results are presented as mean ± standard deviation.

## Results

Baseline characteristics for all randomized subjects were similar in the low-fat and moderate fat groups. Those who participated for the full 18 months had mean baseline BMI, body fat and waist circumference that were similar to the total cohort (Table 2). Baseline characteristics for those who participated for the full 18 months were similar in the low-fat and moderate-fat groups.

A lower participation began to occur after the first 6 months in the low-fat compared to the moderate-fat group, 45 vs 64% respectively (*P* = 0.057). At the completion of 1 y, only 27% were still participating in the low-fat diet group compared to 58% in the moderate-fat diet group (*P* < 0.002), and at completion of the 18-month trial, participation was 20 vs 54% (*P* < 0.002). Thus, participation rate stabilized after 6 months in the moderate fat diet group but progressively decreased in the low-fat group (Figure 2).

The most common reason cited in both groups for dropping out of the study was a conflict with work schedule. The best meeting times for each of the intervention groups based on the participants' schedules were ascertained and the group meeting times were then established. Interestingly, no subject in either group overtly complained about the diet, nor cited it as the reason for dropping out. Two women in the moderate-fat group became pregnant during the study.

They did, however, continue to follow the moderate-fat diet, without limiting their energy, and actively participated in the group sessions. We did not include the body weight of these two subjects in the analysis. Outcome assessment was performed on 26/66 (41%) of the dropouts. The rest of the dropouts were unavailable despite several phone calls and letters inviting them to the clinic, offering to make home visits, and giving monetary incentives.

At the completion of the study, 31 subjects in the moderate-fat group and 30 in the low-fat group were available for measurements, and were the subjects that constituted the primary analysis of the study. The moderate-fat group lost an average of 4.1 kg, whereas the low-fat group gained an average of 2.9 kg; the mean difference between the groups was 7.0 kg, 95% confidence interval −5.3 to −8.7 kg, *P* < 0.001 (Table 3). Reductions in percentage body fat, body mass index and waist circumference were all greater in the moderate fat group. The moderate fat group was continued for an additional year. The mean weight loss after 30 months compared to baseline was 3.5 kg (*n* = 19, *P* = 0.03).

Secondary analysis that included only those subjects who were participating in the program showed that weight reduction at 6 months was similar and significant in both groups, 4.9 kg in the moderate fat group (*n* = 31, *P* = 0.001), and 5.1 kg in the low fat group (*n* = 23, *P* = 0.0001; Table 3). Weight reduction was maintained at 12 months for both groups, moderate fat group −4.8 kg (*n* = 27, *P* = 0.0001), low-fat group −5.0 kg (*n* = 13, *P* < 0.03). At the completion of the 18 month trial, those actively participating in the moderate fat diet group had lost an average of 4.8 kg (*n* = 25, *P* < 0.001), while those active in the low-fat group began to regain some of the lost weight and had an average weight loss of 2.9 kg, not significantly different from baseline (*n* = 10, *P* = 0.32;

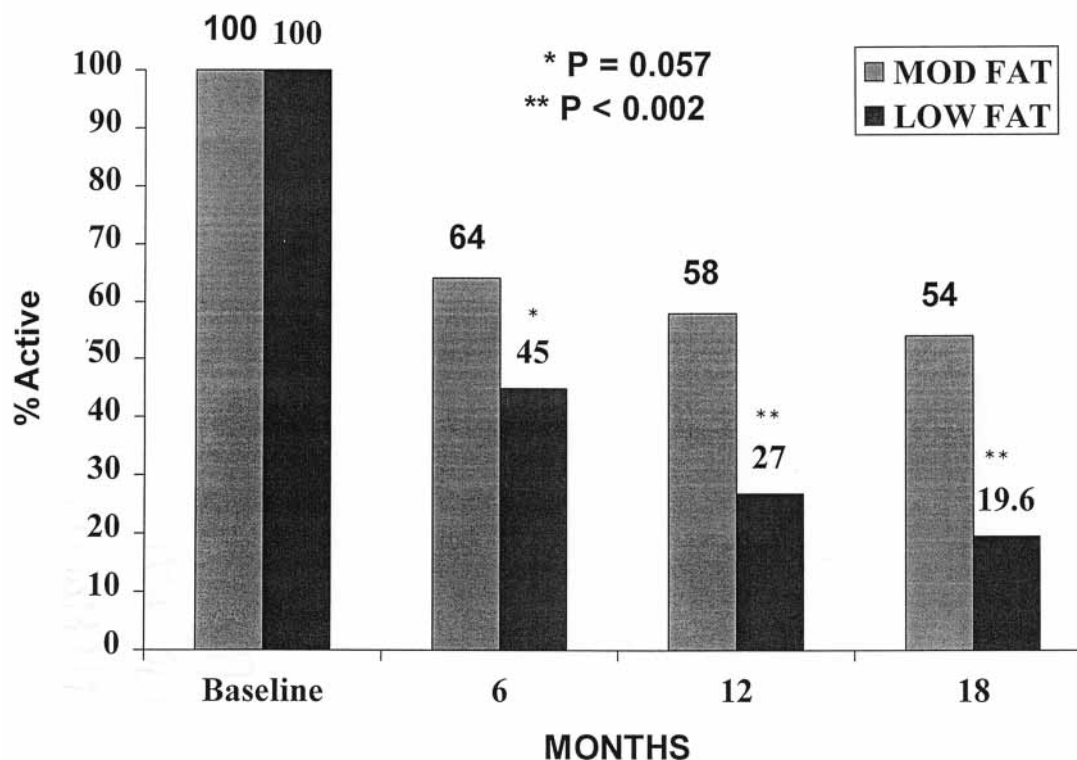
**Table 2** Baseline characteristics for all randomized subjects and for those who participated for the entire 18 month study<sup>a</sup>

Variable	Moderate-fat diet		Low-fat diet	
	All Randomized (n = 50)	Participated 18 months <sup>b</sup> (n = 25)	All Randomized (n = 51)	Participated 18 months (n = 10)
Age (y)	44 ± 10	50 ± 9	44 ± 10	53 ± 8
Sex, n (%)				
Female	44 (88%)	22 (88%)	47 (92%)	10 (100%)
Male	6 (12%)	3 (12%)	4 (8%)	0 (0%)
Ethnicity, n (%)				
White	41 (82%)	22 (88%)	40 (78%)	10 (100%)
Black	7 (14%)	3 (12%)	10 (20%)	0 (0%)
Hispanic	2 (4%)	0 (0%)	1 (2%)	0 (0%)
Weight (kg)	93 ± 32	89 ± 27	89 ± 30	88 ± 24
Ideal body weight (%)	154 ± 21	149 ± 19	150 ± 16	151 ± 15
Body mass index (kg/m <sup>2</sup> )	34 ± 5	33 ± 5	33 ± 3	33 ± 3
Body fat (%)	39 ± 6	38 ± 6	37 ± 5	39 ± 3
Waist-to-hip ratio	0.85 ± 0.07	0.86 ± 0.06	0.84 ± 0.07	0.84 ± 0.03
Waist circumference (cm)	104 ± 12	103 ± 12	101 ± 11	103 ± 9

<sup>a</sup>Values are means ± s.d.

<sup>b</sup>Subjects who remained in the dietary program for the full 18 month trial (excluding data of two active pregnant women in the moderate-fat diet).

## Participation Rates



**Figure 2** Participation rates for study subjects. Moderate-fat diet ( $n=50$  at baseline) (includes the two pregnant women); low-fat diet ( $n=51$  at baseline). \* $P=0.057$ ; \*\* $P<0.002$  between groups.

Table 3),  $P=NS$  for weight loss between the groups. The dropouts, from both groups together, had a mean weight increase of 4.2 kg ( $P<0.005$ ) from baseline, compared to a decrease of 4.3 kg ( $P<0.002$ ) in those from both groups who remained active in the program ( $P<0.001$  between the dropouts and active subjects).

'Last value carried forward', or intention to treat analysis, which included all randomized participants, showed the moderate fat group lost 2.5 kg ( $n=50$ ,  $P<0.005$ ) compared to baseline, whereas the low-fat group gained 1.1 kg ( $n=51$ ,  $P=0.26$ ;  $P=0.005$  between the groups).

Reported nutrient intake at baseline was similar in the two diet groups (Table 4). At six months, both groups reported a small decrease in energy intake. The first 6 month period is when the majority of weight loss occurred for both groups. Reported physical activity was similar in the two groups at baseline, and did not change during the trial in either group.

The reported total fat intake increased in the moderate fat diet group from 28 to 35% at 18 months (Table 4). In the low-fat diet group, total fat was similar at baseline and 18 months (31 vs 30%). Initially, total fat intake decreased in the low-fat group to 28% at 6 months and 27% at 12 months. At 18 months intake of monounsaturated fatty acids increased in the moderate fat group and decreased in the

low fat group ( $P=0.03$  between groups). The moderate-fat diet group significantly increased their fiber intake by 5.5 g per day compared to a decrease of 3.5 g per day in the low fat diet group ( $P=0.03$  between groups).

At 18 months vegetable intake increased in the moderate-fat diet 1.2 servings per day, compared to a decrease of 1 serving per day in the low-fat diet group ( $P=0.002$  between groups; Table 5). The foods that supported a higher monounsaturated fatty acid intake were peanut butter, peanuts, tree nuts (almonds, cashews, hazelnuts, macadamias, pecans, pistachios and walnuts), and olive oil. Peanut butter increased by 0.7 serving per day while both peanuts and tree nuts were increased by 0.5 serving per day. The vegetables, peanuts and tree nuts contributed to the significant increase in fiber in the moderate-fat diet group.

### Discussion

Obesity is becoming more prevalent in the US despite efforts to inform the public about the risks, and about the nutritional steps needed for its prevention. As Bray pointed out, it takes 15–20y before the known increase in prevalence of obesity translates into increased incidence of diabetes and

**Table 3** Change in body weight and related measurements<sup>a</sup>

Variable	Time in study								P-value between groups
	Active participants <sup>b</sup>						Available for measurement <sup>c</sup>		
	6 months		12 months		18 months		18 months		
	Moderate fat (n = 31)	Low fat (n = 23)	Moderate fat <sup>d</sup> (n = 27)	Low fat (n = 13)	Moderate fat <sup>d</sup> (n = 24)	Low fat (n = 10)	Moderate fat <sup>d</sup> (n = 31)	Low fat (n = 30)	
Weight (kg)	-4.9 ± 4.3***	-5.1 ± 4.6***	-4.8 ± 5.2***	-5.0 ± 7.3*	-4.8 ± 5.6***	-2.9 ± 8.6	-4.1 ± 6.5**	+2.9 ± 7.7	< 0.001
Ideal body weight (%)	-8.0 ± 7.0***	-9.0 ± 8.0***	-8.0 ± 9.0***	-8.0 ± 13*	-8.0 ± 1.0***	-5.0 ± 1.6	-6 ± 11**	+5 ± 13	0.001
BMI (kg/m <sup>2</sup> )	-2.0 ± 1.8***	-1.9 ± 1.9***	-2.0 ± 2.1***	-1.8 ± 2.9*	-1.9 ± 2.3***	-0.1 ± 4.9	-1.6 ± 2.5**	+1.4 ± 3.3*	< 0.001
Body fat (%)	-3.0 ± 5.0**	-2.0 ± 5.0***	-5.0 ± 5.0***	-2.0 ± 6.0	-3.0 ± 5.0**	-3.0 ± 4.0	NA	NA	—
Body fat content (kg)	-4.0 ± 5.1***	-3.8 ± 5.0***	-5.9 ± 5.8***	-3.5 ± 6.4	-4.2 ± 5.1***	-3.0 ± 6.3	NA	NA	—
Waist circumference (cm)	-6.0 ± 6.8***	-5.1 ± 5.4***	-7.3 ± 6.3***	-1.6 ± 9.2	-9.0 ± 7.5***	-4.8 ± 11.3	-6.9 ± 9.1***	+2.6 ± 10.5	< 0.001
Waist-to-hip ratio	-0.02 ± 0.05	-0.01 ± 0.04	0 ± 0.05	-0.03 ± 0.08	-0.02 ± 0.05*	0 ± 0.06	NA	NA	—

<sup>a</sup>Values are means ± s.d.<sup>b</sup>Active participants refers to subjects who were participating in the dietary program at the indicated time.<sup>c</sup>Available for measurement refers to all randomized subjects who were available for measurement of body weight whether or not they were participating in the dietary program.<sup>d</sup>Excludes data of two pregnant/lactating participants. Significance of changes from baseline within a group: \*\*\**P* < 0.001; \*\**P* < 0.01; \**P* < 0.05.

NA, data not available.

cardiovascular disease, and thus the increase in obesity represents a 'time bomb' for increasing morbidity, disability and health care costs.<sup>3</sup> The standard approach for weight loss is a low-fat high-carbohydrate diet, with energy level below maintenance. However, long-term adherence has been difficult to achieve with this or any other known weight loss approach.

The present study was designed to test two approaches to weight loss, a low-fat diet and a moderate-fat diet, predominantly with unsaturated fatty acids, both having the same goals for energy restriction. The results at 6 months showed similar amounts of weight loss in the two groups, about 5 kg, which represented approximately 5% of body weight. However, the moderate fat group maintained their lower average weight through the 18 month study period, whereas the low-fat group regained the body weight and ended the study with a net increase compared to baseline. More weight loss was maintained because those in the moderate-fat group were more likely to adhere to the diet and less likely to drop out of treatment.

As has been reported in other studies, many obese individuals under-report their food intake.<sup>13,14</sup> Johnson *et al* reported that women under-reported their energy intake by -2206 kJ/day ± 1841 (527 kcal ± 440), while men under-reported their energy intake by -1301 kJ/day ± 1908 (311 kcal ± 456).<sup>13</sup> In our study, it is most likely that both intervention groups underestimated their baseline kilocalories by similar amounts of approximately 500 kcal/day. This would translate into a baseline kilocalorie intake of 2386 for the moderate-fat group and 2502 for the low-fat group. The reported intake at 6 months of 1861 kcal in the moderate fat group and 1633 kcal in the low-fat group was more closely aligned with 7 day food records which were recorded by the

participants and analyzed weekly. The actual measured weights at 6 months showing a weight loss of 4.9 kg in the moderate-fat group and 5.1 kg in the low-fat group could be more closely predicted by a decrease of 500 kcal/day. The inability to meet the initial prescribed weight loss goals illustrates the difficulty that free-living overweight persons have in meeting prescribed nutrient goals for weight loss.

The strengths of the present study are its randomized design, relatively long 18-month intervention period, the same goal for energy restriction and similar intensity of intervention for the two weight-loss groups. Most previous studies of a low-fat diet were 6 months or less in duration, did not have a specific goal for energy restriction, or compared the low-fat diet to a group that received no treatment. Weaknesses of the present study include its relatively small sample size, 50–51 per group, and the lack of success in obtaining follow-up measurements of all the dropouts to achieve a complete intention-to-treat analysis. This inability to obtain endpoint measurements in 40% of randomized subjects from either the low-fat or moderate-fat group, and indeed the high dropout rate itself, are unprecedented in our 20y of experience with clinical trials in nutrition. Other weight loss studies<sup>4,15</sup> also have had higher dropout rates than in other types of dietary studies. We believe that it is most likely that the dropouts who refused end-of-study measurements, all having failed previously in weight loss programs, were not interested in being so documented in another attempt. The significant weight gain from baseline of 4.2 kg in the 26 dropouts who permitted end-of-study measurements supports this view.

The early results of our study are consistent with previous studies, showing weight loss is maximal at 3–6 months.<sup>4,16,17</sup> After such relatively short treatment periods,

**Table 4** Reported nutrient intake among subjects who were active at the designated time period<sup>a</sup>

	Baseline			6 months			12 months			18 months		
	Moderate fat (n = 42)	Low fat (n = 35)	P <sup>c</sup>	Moderate fat (n = 32)	Low fat (n = 22)	P <sup>c</sup>	Moderate fat <sup>b</sup> (n = 26)	Low fat (n = 9)	P <sup>c</sup>	Moderate fat <sup>b</sup> (n = 24)	Low fat (n = 9)	P <sup>c</sup>
Energy (kcal)	1886 ± 657	2002 ± 697	0.16	1861 ± 545	1633 ± 538	0.13	1783 ± 450	1671 ± 741	0.68	1877 ± 454	1697 ± 526	0.08
Total fat (percentage energy)	28% ± 5.6	31% ± 9.3	0.10	33% ± 5.8	28% ± 7.3	0.01	34.6% ± 6.2	27.3% ± 8.7	0.04	35% ± 6.8	30% ± 11.9	0.03
Saturated fatty acid (percentage energy)	8.9% ± 2.0	9.4% ± 2.8	0.30	8.0% ± 1.6	8.3% ± 2.4	0.61	8.5% ± 1.5	8.8% ± 1.4	0.76	9.0% ± 1.8	8.0% ± 2.5	0.11
Monounsaturated fatty acid (percentage energy)	11.2% ± 3.2	12.7% ± 5.4	0.15	15.1% ± 3.7	11.3% ± 4.2	0.001	16.0% ± 4.4	10.5% ± 3.8	0.002	16.0% ± 5.3	12.0% ± 7.7	0.03
Polyunsaturated fatty acid (percentage energy)	5.8% ± 1.7	6.6% ± 2.8	0.15	7.6% ± 1.6	5.7% ± 1.5	0.003	7.5% ± 1.4	5.4% ± 1.9	0.01	8.0% ± 1.4	7.0% ± 2.5	0.06
Carbohydrate (percentage energy)	53.6% ± 7.8	51.9% ± 9.9	0.42	50.0% ± 7.0	55.0% ± 7.7	0.02	47.7% ± 7.5	49.9% ± 10.3	0.56	47.0% ± 9.0	50.0% ± 9.5	0.35
Protein (percentage energy)	17.8% ± 3.6	17.0% ± 3.5	0.32	18.8% ± 3.6	17.7% ± 3.4	0.30	19.0% ± 4.0	20.8% ± 2.6	0.13	19.0% ± 3.6	19.0% ± 2.9	0.06
Dietary fiber (g)	19.6 ± 6.8	22.4 ± 8.9	0.14	24.1 ± 7.6	20.5 ± 6.9	0.08	23.2 ± 7.9	19.0 ± 9.2	0.24	25.0 ± 7.8	19.0 ± 6.1	0.03
(g/1000 kcal)	10.8 ± 3.1	11.5 ± 3.5	0.33	13.3 ± 3.6	12.9 ± 13.1	0.69	13.1 ± 3.3	12.0 ± 3.8	0.42	13.0 ± 4.0	12.0 ± 4.0	0.11
Cholesterol (mg)	222 ± 90	235 ± 93	0.53	189 ± 67	190 ± 89	0.97	181 ± 65	254 ± 133	0.15	194 ± 59	212 ± 94	0.97
(mg/1000 kcal)	121 ± 35	121 ± 36	0.97	103 ± 32	118 ± 47	0.20	103 ± 36	157 ± 46	0.008	105 ± 31	124 ± 37	0.06

<sup>a</sup>Values are means ± s.d.

<sup>b</sup>Excludes data on two pregnant/lactating participants.

<sup>c</sup>P-values for difference between moderate-fat and low-fat groups.

several studies found that subjects lost similar amounts of weight on a low-fat diet or an energy-restricted higher-fat diet.<sup>4,18,19</sup> Among weight loss studies of 1 y or more duration, two compared a low-fat diet to a higher-fat, lower-energy diet,<sup>4,20</sup> while one evaluated a 30% fat energy restricted diet with orlistat compared to placebo.<sup>21</sup> Jeffery *et al* studied a 6 month intervention trial and continued their comparison of the low-fat and higher-fat, low-energy approaches for a total duration of 18 months.<sup>4</sup> The subjects were counseled once per month. In contrast to the success of either approach at 6 months, the long-term results were disappointing. By 18 months, mean body weight in both groups had returned to baseline (+ 1.8 kg for the 35% fat and + 0.4 kg for the low-fat group).

Toubro and Astrup compared an *ad libitum* low-fat (20–25% of energy) diet with a higher fat (unspecified fat content) energy restricted diet to prevent regain of weight loss.<sup>20</sup> Initial weight loss of 14 kg was induced over 2–4 months by high protein intake with ephedrine 60 mg and caffeine 600 mg daily. After a 1 y weight maintenance program of one to three counseling sessions per month, the low-fat group regained 0.3 kg compared to 4.1 kg in the higher-fat energy restricted group, a non-significant difference ( $P=0.08$ ). After an additional year of follow-up which was unsupervised with no counseling, overall weight regain was 5.4 and 11.3 kg in the low-fat and higher-fat groups, respectively ( $P=0.03$ ).

Sjostrom *et al* conducted a large-scale, multicenter trial of orlistat compared with placebo in 743 overweight subjects who all received an energy restricted, 30% fat diet.<sup>21</sup> The placebo group lost 6.1 kg after 1 y on the 30% fat diet. The subjects were subsequently prescribed a eucaloric diet for an additional year of follow-up. Weight regain was 1.5 kg.

As in the present study, similar weight loss was produced after 6 months with either approach, although in contrast to the present study, in Jeffrey's study subjects in both low-fat and energy-restricted groups regained all the weight that was lost after 18 months. In the present trial, maintenance of weight loss in the moderate-fat diet group may have been due to weekly rather than monthly group counseling sessions, or to the Mediterranean-style dietary approach rather than generic guidelines to reduce energy intake in the previous study.<sup>4</sup>

The lack of success of the low-fat diet would not have been predicted by experiments on fuel metabolism and food intake. Carbohydrate is used preferentially for oxidation after a meal compared to fat, which is stored,<sup>22,23</sup> and carbohydrate stimulates satiety more than fat.<sup>23–25</sup> Carbohydrate oxidation and satiety may be linked by metabolic signaling.<sup>26</sup> Controlled studies of food intake of up to 14 days found that spontaneous intake of calories by the subjects increased as the fat content of the diet made available to them increased.<sup>23,25,27–30</sup> A separate mechanism for over-eating may be that caloric intake is related to the energy density of meals,<sup>31</sup> which in turn is determined mainly by their fat content. Finally, it is often considered that the

**Table 5** Changes in food intake among subjects who completed the dietary program<sup>a</sup>

Portions per day	6 months			12 months			18 months		
	Moderate fat (n = 31)	Low fat (n = 29)	P <sup>c</sup>	Moderate fat <sup>b</sup> (n = 25)	Low fat (n = 9)	P <sup>c</sup>	Moderate fat <sup>b</sup> (n = 24)	Low fat (n = 9)	P <sup>c</sup>
Fruit (one piece or 1/2 cup)	0.1 ± 1.2	-0.1 ± 0.9	0.92	0.2 ± 0.8	0.2 ± 0.4	0.25	0.2 ± 1.5	0.1 ± 0.8	0.82
Vegetables (4 oz)	0.9 ± 1.9	-0.1 ± 1.5	<0.001	1.0 ± 2.7	-1.2 ± 1.8	0.008	1.2 ± 1.8	-0.9 ± 1.5	0.002
Meat, fish, poultry (5 oz)	-0.6 ± 0.8	0.04 ± 0.6	0.03	-0.01 ± 0.7	0.09 ± 1.2	0.87	-1.1 ± 0.7	-0.4 ± 0.6	0.41
Cereals, breads, starches (one cup or one slice)	-0.4 ± 1.9	-1.4 ± 2.1	0.06	-0.7 ± 1.3	-2.0 ± 3.0	0.14	-0.7 ± 1.7	-1.6 ± 2.6	0.36
Beverages (8 oz)	-0.02 ± 2.4	0.5 ± 2.1	0.71	-0.5 ± 1.4	1.5 ± 1.4	0.01	0.4 ± 2.3	1.3 ± 3.4	0.45
Sweets, baked goods (one slice)	0.2 ± 3.3	-1.4 ± 2.9	0.10	0.4 ± 2.9	-1.5 ± 2.4	0.08	0.6 ± 3.4	-1.3 ± 2.6	0.09
Dairy (8 oz)	-0.8 ± 1.4	-0.7 ± 1.0	0.09	-0.6 ± 1.2	-1.2 ± 1.1	0.14	-0.6 ± 1.0	-0.2 ± 0.6	0.18
Peanut butter (1 tbsp)	0.4 ± 0.8	-0.02 ± 0.1	0.001	0.6 ± 0.7	-0.01 ± 0.2	<0.0001	0.7 ± 0.8	0.1 ± 0.3	0.002
Peanuts (1 oz)	0.4 ± 0.4	-0.01 ± 0.3	<0.0001	0.5 ± 0.5	0 ± 0.04	<0.0001	0.5 ± 0.4	0.1 ± 0.3	0.006
Tree nuts (1 oz)	0.5 ± 0.4	-0.04 ± 0.1	<0.0001	0.4 ± 0.4	-0.01 ± 0.03	<0.0001	0.4 ± 0.3	0.1 ± 0.3	0.01
Olive oil (1 tbsp)	0.2 ± 0.3	-0.2 ± 0.9	0.42	0.3 ± 0.4	0.2 ± 0.3	0.75	0.5 ± 1.2	0.1 ± 0.4	0.16

<sup>a</sup>Values are means ± s.d.

<sup>b</sup>Excludes data on two pregnant/lactating participants.

<sup>c</sup>P-values for differences between moderate- and low-fat groups.

superior sensory properties of meals that have fat<sup>32</sup> may lead to overeating.

These findings on fuel oxidation, satiety and overeating were shown under carefully controlled experimental conditions that lasted several days or weeks. Their translation to what happens during years of dietary behavior is complex, and often depends on the types of foods that are available, the willingness to prepare one's food according to specifications and to select the recommended foods for restaurant or 'take-out' meals, and the social environment that a person lives in. For example, the low-fat diet that the subjects ate may not have been less energy dense than the moderate fat diet, which was higher in vegetables and fiber. The dominating influence on food intake may not be metabolic differences between fat and carbohydrate fuels, but environmental and behavioral factors. In this regard, the present study might have produced different results if it was conducted in a different culture.

Motivation and adherence are very hard to sustain in weight loss programs or studies. Subjects in the moderate-fat group reported that the diet was more tasty than low-fat regimens that they had tried, and this may have been the cause of their increased group participation compared to the low-fat group. Fat enhances the flavor of certain foods, and may have contributed to the increase in vegetable intake in the moderate-fat diet group. For example, many subjects reported not liking fat-free and low-fat dressings, and they were encouraged to use olive oil or other non-reduced-fat salad dressings. We also recommended sautéing or stir-frying vegetables with a small amount of oil instead of using a no-fat spray or steaming the vegetables. These preparation and cooking techniques are similar to Mediterranean diets, which were used as a model to develop the moderate fat diet. In Greece, it is the custom to cook vegetables in olive oil to enhance their flavor.<sup>33</sup> The increase

in vegetables, peanuts and tree nuts improved the fiber intake, which may have increased satiety, contributing to control of caloric intake. Our subjects reported that they did not feel like they were 'dieting' because many of the foods and products they used daily were not traditional 'diet foods' (ie peanut butter, nut butters, mixed nuts). The focus was controlling portion to assist in reducing overall calories. They viewed the moderate-fat diet as a unique and more enjoyable approach.

Our results support the use of a diet moderate in fat for weight loss in obese persons, as an alternative to a standard low-fat diet to produce and maintain long-term weight loss because of the increased palatability of the foods. However, these findings need further study in larger and more diverse populations. The use of this diet to prevent the development of obesity also merits consideration and investigation.

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#### References

- 1 Kuczmarski RJ, Carroll MO, Flegal KM, Troiano RP. Varying body mass index cutoff points to describe overweight prevalence among US adults: NHANES III (1988–1994). *Obes Res* 1997; 5: 542–548.
- 2 National Institutes of Health/National Heart, Lung, and Blood Institute/Obesity Education Initiative Expert Panel. Identification, evaluation, and treatment of overweight and obesity in adults. *Obesity Res* 1998; 6(Suppl 2): S1S–209S.
- 3 Bray GA. Obesity: a time bomb to be defused. (Comment.) *Lancet* 1998; 352: 160–161.
- 4 Jeffery RW, Hellerstedt WL, French SA, Baxter JE. A randomized trial of counseling for fat restriction versus calories restriction in the treatment of obesity. *Int J Obes Relat Metab Disord* 1995; 19: 132–137.



- 5 Kinsell LW, Schlierf G. Alimentary and nonalimentary hyperglyceridemia. *Ann NY Acad Sci* 1965; **131**: 603–613.
- 6 Bray GA. *The obese patient. Major problems in internal medicine*, Vol 9. W.B. Saunders: Philadelphia, PA; 1976.
- 7 Sacks FM. Dietary prevention trials. In: Hennekens CH, Buring JE, Manson JE, Ridker PM (eds). *Clinical trials in cardiovascular disease: a companion to Braunwald's Heart Disease*. WB Saunders: Philadelphia, PA; 1999. pp 423–431.
- 8 Davis PO, Dotson CO, Manny P. NIR evaluation for body composition analysis. *Med Sci Sports Exercise* 1988; **20**.
- 9 Rimm EB, Giovannucci EL, Stampfer MJ, Colditz GA, Litin LB, Willett WC. Reproducibility and validity of an expanded self-administered semi-quantitative food frequency questionnaire among male health professionals. *Am J Epidemiol* 1992; **135**: 1114–1126.
- 10 Feskanich D, Rimm EB, Giovannucci et al. Reproducibility and validity of food intake measurements from semiquantitative food frequency questionnaire. *J Am Diet Assoc* 1993; **93**: 790–796.
- 11 Blair SN, Haskell WL, Ho P et al. Assessment of habitual physical activity by a seven-day recall in a community survey and controlled experiments. *Am J Epidemiol* 1985; **122**: 794–804.
- 12 SAS Institute Inc. *SAS/STAT User's Guide*, version 6, 4th edn. SAS Institute: Chicago, IL; 1989.
- 13 Johnson RK, Goran MI, Poehlman ET. Correlates of over- and underreporting of energy intake in healthy older men and women. *Am J Clin Nutr* 1994; **59**: 1286–1290.
- 14 Lichtman SW, Pisarska K, Berman EK et al. Discrepancy between self-reported and actual caloric intake and exercise in obese subjects. *New Engl J Med* 1992; **327**: 1893–1989.
- 15 Schlundt DG, Hill JO, Popie-Cordle J et al. Randomized evaluation of a low fat ad libitum carbohydrate diet for weight reduction. *Int J Obes Relat Metab Disord* 1993; **17**: 623–629.
- 16 Kasim SE, Martino S, Kim P et al. Dietary and anthropometric determinants of plasma lipoproteins during a long-term low-fat diet in healthy women. *Am J Clin Nutr* 1993; **57**: 146–153.
- 17 Shepard L, Kristal AR, Kushi LH. Weight loss in women participating in a randomized trial of low fat diets. *Am J Clin Nutr* 1991; **54**: 821–828.
- 18 Powell JJ, Tucker T, Fisher AG, Wilcox K. The effects of different percentages of dietary fat intake, exercise, and calorie restriction on body composition and body weight in obese females. *Am J Health Prom* 1994; **8**: 443–448.
- 19 Shah M, McGovern P, French S, Baxter J. Comparison of a low-fat, ad libitum complex-carbohydrate diet with a low-energy diet in moderately obese women. *Am J Clin Nutr* 1994; **59**: 980–984.
- 20 Toubro S, Astrup A. Randomized comparison of diets for maintaining obese subjects weight after major weight loss ad lib, low fat, high carbohydrate diet vs fixed energy intake. *Br Med J* 1997; **314**: 29–34.
- 21 Sjostrom L, Rissanen A, Andersen T et al. Randomized placebo-controlled trial of orlistat for weight loss and prevention of weight regain in obese patients. *Lancet* 1998; **352**: 167–172.
- 22 Jebb SA, Prentice AM, Goldberg GR, Murgatroyd PR, Black AE, Coward WA. Changes in macronutrient balance during over- and underfeeding assessed by 12-d continuous whole body calorimetry. *Am J Clin Nutr* 1996; **64**: 259–266.
- 23 Flatt JP. The difference in the storage capacities for carbohydrate and for fat, and its implications in the regulation of body weight. *Ann NY Acad Sci* 1987; **499**: 104–123.
- 24 Prentice AM. Manipulation of dietary fat and energy density and subsequent effects on substrate flux and food intake. *Am J Clin Nutr* 1998; **67**(3 Suppl): 535S–541S.
- 25 Stubbs RJ, Prentice AM, James WP. Carbohydrates and energy balance. *Ann NY Acad Sci* 1997; **819**: 44–69.
- 26 Rolls BJ, Kim-Harris S, Fischman MW, Foltin RW, Moran TH, Stoner SA. Satiety after preloads with different amounts of fat and carbohydrate: implications for obesity. *Am J Clin Nutr* 1994; **60**: 476–487.
- 27 Friedman MI. Fuel partitioning and food intake. *Am J Clin Nutr* 1998; **67**: 513S–518S.
- 28 Blundell JE, Macdiarmid JI. Passive overconsumption. Fat intake and short-term energy balance. *Ann NY Acad Sci* 1997; **827**: 392–407.
- 29 Stubbs RJ, Ritz P, Coward WA, Prentice AM. Covert manipulation of the ratio of dietary fat to carbohydrate and energy density: effect on food intake and energy balance in free-living men eating *ad libitum*. *Am J Clin Nutr* 1995; **62**: 330–337.
- 30 Kendall A, Levitzky DA, Strupp BJ, Lissner L. Weight loss on a low-fat diet: consequences of the imprecision of the control of food intakes in humans. *Am J Clin Nutr* 1991; **53**: 1124–1129.
- 31 Bell EA, Castellanos VH, Pelkman CL, Thorwart ML, Rolls BJ. Energy density of foods affects energy intake in normal-weight women. *Am J Clin Nutr* 1998; **67**: 412–420.
- 32 Drewnowski A, Kurth C, Holden-Wiltse J, Saari J. Food preferences in human obesity: carbohydrates versus fats. *Appetite* 1992; **18**: 207–221.
- 33 Trichopoulos A, Lagiou P, Trichopoulos D. Traditional Greek diet and coronary heart disease. *J Cardiovasc Risk* 1994; **1**: 9–15.