



CLINICAL RESEARCH STUDY

AJM Theme **AJM Theme Issue: OBESITY AND DIABETES**

The effects of a low-fat, plant-based dietary intervention on body weight, metabolism, and insulin sensitivity

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ABSTRACT

PURPOSE: This study investigated the effect of a low-fat, plant-based diet on body weight, metabolism, and insulin sensitivity, while controlling for exercise in free-living individuals.

SUBJECTS AND METHODS: In an outpatient setting, 64 overweight, postmenopausal women were randomly assigned to a low-fat, vegan diet or a control diet based on National Cholesterol Education Program guidelines, without energy intake limits, and were asked to maintain exercise unchanged. Dietary intake, body weight and composition, resting metabolic rate, thermic effect of food, and insulin sensitivity were measured at baseline and 14 weeks.

RESULTS: Mean \pm standard deviation intervention-group body weight decreased 5.8 ± 3.2 kg, compared with 3.8 ± 2.8 kg in the control group ($P = .012$). In a regression model of predictors of weight change, including diet group and changes in energy intake, thermic effect of food, resting metabolic rate, and reported energy expenditure, significant effects were found for diet group ($P < .05$), thermic effect of food ($P < .05$), and resting metabolic rate ($P < .001$). An index of insulin sensitivity increased from 4.6 ± 2.9 to 5.7 ± 3.9 ($P = .017$) in the intervention group, but the difference between groups was not significant ($P = .17$).

CONCLUSION: Adoption of a low-fat, vegan diet was associated with significant weight loss in overweight postmenopausal women, despite the absence of prescribed limits on portion size or energy intake.

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Obesity is increasingly prevalent, aggravating the risk of cardiovascular disease, diabetes, and other conditions. Prior studies have suggested that low-fat, plant-based diets reduce body weight, improve cardiovascular risk

factors and glycemic control, and, in combination with other lifestyle interventions, reverse atherosclerosis.¹⁻⁵ However, few studies have examined the effect of such diets on body weight or insulin sensitivity in overweight individuals while controlling for the confounding effects of exercise.

We therefore conducted a randomized, controlled trial to quantify the short-term effect of a low-fat, vegan diet on body weight, body composition, metabolism, and insulin

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sensitivity in overweight, postmenopausal women, using for comparison a more moderate low-fat diet.

Methods

The study methods have been reported.^{6,7} Briefly, 64 overweight or obese (body mass index [BMI] = 26-44 kg/m²) postmenopausal women were recruited through newspaper advertisements in the Washington, DC, area. Premenopausal women were excluded because of possible hormonal effects on metabolic measures.⁸ Additional exclusionary criteria included unstable medical status, history of eating disorder or substance abuse, severe mental illness, previously diagnosed diabetes, physical conditions affecting body weight (eg, Cushing's disease), recent use of estrogens, medications affecting appetite or body weight, or tobacco use.

Volunteers were randomly assigned to a low-fat vegan (intervention) diet or a diet following National Cholesterol Education Program⁹ guidelines (control) for 14 weeks. The intervention diet (10% of energy from fat, 15% protein, 75% carbohydrate) consisted of vegetables, fruits, grains, and legumes. Animal products, added oils, avocados, olives, nuts, nut butters, and seeds were proscribed. Vitamin B-12 supplementation using any standard-potency daily multivitamin was recommended for participants continuing the diet after the study's conclusion. The control diet followed the former National Cholesterol Education Program Step II guidelines (total fat \leq 30%, saturated fat \leq 7%, protein approximately 15%, carbohydrate $>$ 55% of energy; cholesterol $<$ 200 mg/day), which are similar to the current Therapeutic Lifestyle Changes diet.¹⁰

No meals were provided. Participants prepared their meals or ate at restaurants. There was no attempt to limit energy intake or to maintain isocaloric intake between the 2 groups. Participants were asked not to alter their exercise habits during the intervention period.

Participants and family members or friends were invited to 2 nutrition lectures to familiarize them with the assigned diets and study procedures. Thereafter, participants attended weekly 1-hour meetings of their assigned groups, which included nutrition and cooking instruction and group discussions conducted by a physician and a registered dietitian. Sessions for the 2 groups were identical in duration and content, except with regard to dietary details, and group leaders were instructed to make no comment favoring either diet over the other or indicating their own dietary habits.

The following measures were assessed at baseline and 14 weeks. All physical and metabolic measurements were made by clinicians blind to group assignment.

Dietary intake was recorded on 2 weekdays and 1 weekend day, using a food scale, after participants had completed a full practice record. The 3-day dietary record, prepared using a food scale, has good test-retest reliability and provides a more accurate estimate of macronutrient intake than

food-frequency questionnaires.^{11,12} Records were analyzed using Nutritionist V, Version 2.0, for Windows 98 (First DataBank Inc., Hearst Corporation, San Bruno, Calif). On 3 occasions, a registered dietitian conducted 24-hour food recalls, followed by individual meetings to discuss any deviations from the prescribed diet. Recalls were not used for statistical comparisons.

Physical activity was assessed with the Bouchard 3-Day Physical Activity Record.¹³ This measure was selected to assess the degree to which participants acceded to the requirement that they not alter their exercise habits during the study, rather than to precisely estimate energy expenditure. A study of 61 subjects showed the Bouchard 3-Day Physical Activity Record to yield highly reproducible results, as shown by an intraclass correlation of 0.96 for mean energy expenditure over 3 days, and favorable correlations with measures of physical working capacity.¹³

Body weight was determined before breakfast while participants wore undergarments, using a digital scale accurate to 0.1 kg. Body composition was measured by air-displacement plethysmography (BODPOD, Life Measurement Instruments; Concord, Calif), a highly reliable method.¹⁴ Body fat percentage was calculated from body density by the Siri equation.¹⁵ Waist circumference was measured with a tape measure placed 2.5 cm above the umbilicus. Hip circumference was measured at the maximal protrusion of the buttocks.¹⁶ Both were rounded to the nearest 5 mm.

Participants reported to the laboratory within 60 minutes of waking, after a 12-hour fast. After 30 minutes of quiet supine rest in a dimly lit room, pulse rate, respiratory rate, blood pressure, and body temperature were measured. Resting metabolic rate was then measured for 30 minutes by indirect calorimetry using a ventilated hood (Sensormedics Vmax System; Yorba Linda, Calif). Readings for the first 2 minutes and the final minute were disregarded; a mean was calculated for the remaining values. The coefficient of measurement variation using this system in the consulting laboratory is \pm 4%. Ambient temperature was maintained at 24°C, and precautions were taken to minimize disturbances that could affect metabolic rate. Heart rate and blood pressure were monitored at 30-minute intervals.

Immediately thereafter, participants were given a 720-kcal liquid meal (34% of energy from fat, 16% protein, 50% carbohydrate; Boost Plus, Mead Johnson, Evansville, Ind) to be ingested within 10 minutes. Metabolic rate was then measured as stated above for 10 minutes at 20, 50, 80, 110, 140, and 170 minutes postingestion. During each 10-minute period, results for the first 2 minutes and the final minute were disregarded, and a mean was calculated for the remaining values. Thermic effect of food for the 170-minute test period was calculated as the area between resting metabolic rate and the curve created by these time points.¹⁷

An oral glucose tolerance test was performed for 3 hours after an overnight fast.¹⁸ Serum glucose concentration was measured using an Abbott Spectrum Analyzer (Abbott Park, Ill) with a glucose oxidase method.¹⁹ Serum insulin levels

were measured by immunoassay (IMx Insulin Assay, Abbott). Missing values were estimated as follows: for intermediate values, a mean of the preceding and following value was calculated; for final values, the preceding value was used. An index of insulin sensitivity was calculated using the equation where FG = fasting glucose, FI = fasting insulin, MG = mean glucose, and MI = mean insulin.

Insulin Sensitivity Index

$$= 10\,000/\sqrt{[(FG \times FI) \times (MG \times MI)]}$$

This index of insulin sensitivity is highly correlated ($r = 0.73$, $P < .0001$) with the rate of whole-body glucose disposal during the euglycemic insulin clamp.¹⁸

The study was approved by the Georgetown University Institutional Review Board and conducted in accordance with its ethical standards. All participants gave informed consent before enrollment.

Between-subjects t tests were calculated for each measure to establish that there were no significant baseline differences between groups and to determine whether the changes associated with the intervention diet were greater than those associated with the control diet. Regression analyses assessed whether the effect of diet group on body weight was significant while controlling for baseline weight, and whether the effect of diet group on weight change was significant while controlling for changes in energy intake, resting metabolic rate, thermic effect of food, and self-reported energy expenditure.

In addition, for each diet group, paired comparison t tests were calculated to test whether the change from baseline to 14 weeks was significantly different from zero. An alpha of 0.05 was used for all statistical tests, with no adjustment for multiple comparisons.

Results

Of the 64 volunteers meeting the participation criteria, 59 completed the study (Table 1). One intervention group participant did not begin the diet, and 2 participants dropped out during the trial. (One could not attend meetings, and the other did not want to continue the diet.) Two control group participants dropped out, both for unspecified reasons. None of the differences between the groups or between completers and noncompleters in baseline body weight or any demographic, anthropometric, or metabolic measure reached statistical significance.

Despite the absence of any prescribed food intake limit, reported energy intake decreased by 366 ± 612 kcal ($P = .003$) in the intervention group and by 337 ± 388 kcal ($P = .001$) in the control group; the difference between groups was not significant (Table 2). The reductions in protein, fat, and cholesterol intake and the increase in fiber intake in the intervention group were

Table 1 Baseline demographic characteristics

	Intervention group (n = 29)	Control group (n = 30)
Mean age (y)	57.4	55.6
Age range (y)	47-71	44-73
White, non-Hispanic	22 (76%)	17 (57%)
Black, non-Hispanic	7 (24%)	12 (40%)
White, Hispanic	0 (0%)	1 (3%)
Single	8 (28%)	5 (17%)
Married	13 (44%)	18 (60%)
Separated, divorced, widowed	8 (28%)	7 (23%)
High school graduate	1 (3%)	2 (7%)
Partial college	5 (17%)	9 (30%)
College graduate	14 (49%)	10 (33%)
Advanced degree	9 (31%)	9 (30%)
No current employment	12 (41%)	8 (27%)
Service occupation	4 (14%)	6 (20%)
Technical, sales, administrative	4 (14%)	6 (20%)
Professional specialty	3 (10%)	4 (13%)
Executive, managerial	6 (21%)	6 (20%)

significantly greater than those in the control group. Reported carbohydrate intake increased in the intervention group ($P = .028$). The changes in reported physical activity did not reach statistical significance within or between groups.

Mean body weight decreased by 5.8 ± 3.2 kg in the intervention group, significantly more than the 3.8 ± 2.8 kg weight change in the control group (Table 3). Adjustment for baseline weight did not alter this finding. Resting metabolic rate decreased significantly for both groups. This finding did not change when lean body mass was controlled for in a regression analysis in the 2 groups of participants. Reductions in BMI and waist circumference were also significantly greater in the intervention group, compared with the control group.

Mean values for fasting glucose, mean glucose during oral glucose tolerance testing, and fasting insulin decreased significantly in the intervention group, whereas oral glucose tolerance and insulin sensitivity significantly improved (Table 3). However, the between-group differences for these measures and for thermic effect of food did not reach statistical significance (Table 3).

In a regression model that included changes in energy intake, resting metabolic rate, thermic effect of food, and self-reported energy expenditure as predictors of weight change, the effect of diet group remained significant (Table 4). Changes in resting metabolic rate and thermic effect of food were also significant.

Discussion

Adoption of an ad libitum low-fat, vegan diet in postmenopausal women was associated with a mean weight loss of

Table 2 Diet and activity characteristics (per day)*

Variable	Intervention group (n = 29)		Control group (n = 30)		P value†
	Baseline	14 wk	Baseline	14 wk	
Energy (kcal)	1774 ± 571	1408 ± 427	1762 ± 423	1424 ± 359	.84
Protein (g)	71 ± 22	42 ± 11	75 ± 19	65 ± 18	.006
Carbohydrates (g)	232 ± 68	274 ± 84	231 ± 56	221 ± 69	.014
Total sugar (g)	81 ± 37	88 ± 38	90 ± 36	87 ± 42	.37
Total fat (g)	62 ± 35	18 ± 12	58 ± 22	31 ± 13	.024
Saturated fat (g)	21 ± 15	3 ± 3	19 ± 9	9 ± 5	.024
Polyunsaturated fat (g)	11 ± 7	5 ± 3	11 ± 5	7 ± 5	.12
Cholesterol (mg)	230 ± 121	17 ± 33	231 ± 117	117 ± 74	.002
Calcium (mg)	680 ± 306	425 ± 148	841 ± 749	634 ± 372	.71
Sodium (mg)	2378 ± 821	2097 ± 928	2714 ± 1076	2141 ± 1035	.29
Total fiber (g)	21 ± 7	30 ± 10	19 ± 8	21 ± 8	.002
Caffeine (mg)	225 ± 169	173 ± 127	163 ± 138	168 ± 170	.069
Energy expenditure (kcal)¶	3840 ± 735	3704 ± 854	3666 ± 713	3674 ± 718	.42

*Mean ± standard deviation.

†P values for comparisons of between group (intervention vs control) changes (baseline to 14 wk).

‡P < .05, §P < .01, and ¶P < .001 for within group changes, ¶Self-report using the Bouchard 3-Day Physical Activity Record.

Change

Effect size

Change

14 wk

Baseline

Change

14 wk

Baseline

Change

14 wk

5.8 kg in 14 weeks, or 0.4 kg per week, which was significantly greater than that associated with the control diet. This magnitude of weight loss is similar to that observed with reduced-energy (eg, 1200 kcal/day) diets,²⁰ but occurred with no prescribed portion sizes, limits on energy intake, or exercise requirement.

The increased fiber intake and reduced fat intake of the vegan diet would be expected to reduce energy density, although energy density was not directly measured because of the methodologic challenges of doing so in non-institutionalized individuals preparing their own meals. A recent review showed that the addition of 14 g of dietary fiber daily is associated with a 10% decrease in energy intake.²¹ Over the short run, at least, individuals consuming reduced-energy-density diets do not increase portion sizes sufficiently to compensate for the energy deficit.^{22,23}

However, an energy intake reduction does not explain the observed weight loss, because the control group reduced its reported energy intake similarly, albeit with very different macronutrient profiles. The intervention group reduced reported fat intake significantly more than did the control group and increased reported carbohydrate intake, whereas the control group reported a slight reduction in carbohydrate intake.

In the regression model, changes in resting metabolic rate were associated with weight loss, probably because a loss of body mass typically leads to reduced energy expenditure. An increase in thermic effect of food may have contributed to the energy deficit. In the regression model, the change in thermic effect of food was a significant predictor of weight change. This variable is influenced by insulin sensitivity,²⁴ which typically increases in the context of low-fat, high-carbohydrate, or vegetarian diets, weight loss, or reduced iron stores,²⁵⁻³¹ and did so in the intervention group. The thermic effect of the meals consumed from day to day depends on their macronutrient (especially carbohydrate) content³² and would likely be higher than that observed with a single test meal in a limited 3-hour period.³³

A United States Department of Agriculture survey of 10 014 adults found that vegetarians and individuals on high-carbohydrate, low-fat diets had the lowest BMIs of the groups studied,¹ a finding confirmed in other studies.^{2,34} Vegan diets, supplemented with vitamin B-12, can be nutritionally adequate for long-term use.³⁵ Nonetheless, counseling regarding nutrient adequacy is important for any prescribed diet.

The current study has the advantage of applicability outside the research setting. Participants prepared their own meals or ate at restaurants. However, the study did not address diet sustainability over the longer term. Dietary reporting was limited to 3 days at each data point and may not represent dietary intake throughout the intervention. Underreporting of food intake is a common finding, especially in individuals with higher BMIs.³⁶

Table 3 Body composition and metabolism*

	Intervention group (n = 29)				Control group (n = 30)				P value†
	Baseline		Change		Baseline		Change		
	14 wk	14 wk	14 wk	14 wk	14 wk	14 wk	14 wk	14 wk	
Weight (kg)	89.3 ± 13.4	83.5 ± 13.5	-5.8 ± 3.2	86.1 ± 12.1	82.3 ± 12.3	-3.8 ± 2.8	-2.0 (-3.6--0.4)	.012	
BMI (kg/m ²)	33.6 ± 5.2	31.5 ± 5.3	-2.2 ± 1.2	32.6 ± 3.3	31.2 ± 3.5	-1.4 ± 1.0	-0.8 (-1.3--0.2)	.012	
Body fat (%)	48.1 ± 5.1	45.2 ± 5.5	-2.9 ± 2.4	46.7 ± 3.5	44.4 ± 4.2	-2.3 ± 2.1	-0.6 (-1.8-0.6)	.32	
Lean mass (kg)	45.9 ± 5.3	45.2 ± 5.2§	-0.7 ± 1.9§	45.7 ± 5.9	45.5 ± 5.6	-0.2 ± 1.7	-0.5 (-1.4-0.5)	.33	
Waist (cm)	99.3 ± 10.7	94.5 ± 11.2	-4.6 ± 3.6	96.5 ± 9.1	94.0 ± 9.1	-2.5 ± 3.3	-2.1 (-3.9--0.3)	.023	
Waist (in)	39.1 ± 4.2	37.2 ± 4.4	-1.8 ± 1.4	38.0 ± 3.6	37.0 ± 3.6	-1.0 ± 1.3	-0.8 (-1.5--0.1)	.023	
Hip (cm)	119.6 ± 9.1	113.5 ± 9.7	-6.2 ± 4.3	115.8 ± 8.4	111.0 ± 8.9	-4.8 ± 3.3	-1.51 (-3.5-0.5)	.13	
Hip (in)	47.1 ± 3.6	44.7 ± 3.8	-2.5 ± 1.7	45.6 ± 3.3	43.7 ± 3.5	-1.9 ± 1.3	-0.6 (-1.4--0.2)	.13	
Waist-hip ratio	0.83 ± 0.04	0.83 ± 0.05	0.0 ± 0.0	0.83 ± 0.05	0.85 ± 0.06	0.0 ± 0.0	0.0 (0.0-0.0)	.17	
Resting metabolic rate (kcal/d)	1441 ± 204	1289 ± 197	-151.5 ± 156	1392 ± 169	1291 ± 141	-101 ± 101	-50.3 (-118.8-18.2)	.15	
Thermic effect of food (kcal/170 min)	29.9 ± 11.6#	34.6 ± 11.9	4.7 ± 12.0	34.3 ± 10.4	34.6 ± 8.5	+0.3 ± 9.4	4.4 (-1.3-10.0)	.18	
Fasting glucose (mg/dL)	96.8 ± 17.3	90.2 ± 13.6	-6.5 ± 11.7	101.0 ± 34.1	99.2 ± 30.5	-1.8 ± 9.5	-4.7 (-10.2-0.9)	.10	
Mean glucose (mg/dL)	147.2 ± 50.7	136.5 ± 54.1	-10.7 ± 25.9†	146.0 ± 78.6	142.4 ± 72.4	-3.6 ± 23.1	-7.1 (-19.9-5.7)	.27	
Fasting insulin (μU/mL)	11.1 ± 6.7	9.2 ± 5.8	-1.9 ± 4.4†	13.9 ± 13.4	12.5 ± 11.9	-1.5 ± 17.0	-0.5 (-7.0-6.1)	.89	
Fasting insulin (μU/mL)**	11 (3-36)	8 (3-33)	-2 (-9±10)†	8.5 (1-74)	10 (4-68)	-1 (-60±62)	N/A	.27	
Mean insulin (μU/mL)	71.4 ± 48.9	65.1 ± 40.4	-6.3 ± 21.8	79.3 ± 56.5	67.2 ± 54.9	-12.1 ± 42.5	5.8 (-12.0-23.5)	.52	
Insulin sensitivity	4.6 ± 2.9	5.7 ± 3.9	+1.1 ± 2.4†	4.3 ± 2.8	4.6 ± 2.5	+0.3 ± 2.4	0.8 (-0.4-2.1)	.19	

BMI = body mass index, N/A = not applicable.
 *Mean ± standard deviation, except as noted.
 †P values for comparisons of between-group (intervention vs control) changes (baseline to 14 wk). ‡P < .05, §P < .01, ||P < .001, and ¶P < .0001 for within-group changes.
 #n = 28.
 **Median (range).

Table 4 Regression analysis of factors associated with weight loss

Variable	Weight loss (95% CI)
Change in energy intake*	-0.011 (-0.156, 0.134)
Change in resting metabolism*	1.510 (0.922, 2.098)§
Change in thermic effect of food*	0.084 (0.015, 0.153)‡
Change in energy expenditure*†	-0.024 (-0.130, 0.082)
Diet group (intervention vs control)	1.667 (0.332, 3.002)‡

CI = confidence interval.

*Values reflect weight loss (kg) per 100 calorie change in the predictors.

†Energy expenditure is self-reported using the Bouchard 3-Day Physical Activity Record.

‡ $P < .05$, § $P < .001$.

In conclusion, in a controlled trial, the consumption of a low-fat, vegan diet was associated with significant weight reduction, along with improvements in measures of glucose tolerance and insulin sensitivity. The effect of a vegan diet on the thermic effect of food merits further exploration. Longer-term trials will define the sustainability of the intervention diet and resultant clinical improvements.

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