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A low-fat vegan diet elicits greater macronutrient changes, but is comparable in adherence and acceptability, compared with a more conventional diabetes diet among individuals with type 2 diabetes

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Abstract

Background—Although therapeutic diets are critical to diabetes management, their acceptability to patients is largely unstudied.

Objective—To quantify adherence and acceptability for two types of diets for diabetes.

Design—Controlled trial conducted 2004 – 2006.

Subjects/setting—Individuals with type 2 diabetes (n = 99) at a community-based research facility.

Intervention—Participants were randomly assigned to a diet following 2003 American Diabetes Association (ADA) guidelines or a low-fat, vegan diet for 74 weeks.

Main outcome measures—Attrition, adherence, dietary behavior, diet acceptability, and cravings.

Statistical analyses—For nutrient intake and questionnaire scores, t-tests determined between-group differences. For diet-acceptability measures, the related samples Wilcoxon rank test assessed within-group changes; the independent samples Mann-Whitney U test compared the diet groups. Chi-square for independent samples compared the groups for changes in reported symptoms.

Results—All participants completed the initial 22 weeks; 90% (45/50) of ADA-group and 86% (42/49) of vegan-group participants completed 74 weeks. Fat and cholesterol intake fell more and carbohydrate and fiber intake increased more in the vegan group. At 22 weeks, group-specific diet adherence criteria were met by 44% (22/50) of ADA-group and 67% (33/49) of vegan-group participants (P=0.019); the ADA group reported a greater increase in dietary restraint; this difference was not significant at 74 weeks. Both groups reported reduced hunger and reduced disinhibition. Questionnaire responses rated both diets as satisfactory, with no significant differences between

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groups, except for ease of preparation, for which the 22-week ratings marginally favored the ADA group. Cravings for fatty foods diminished more in the vegan group at 22 weeks, with no significant difference at 74 weeks.

Conclusions—Despite its greater influence on macronutrient intake, a low-fat, vegan diet has an acceptability similar to that of a more conventional diabetes diet. Acceptability appears to be no barrier to its use in medical nutrition therapy.

Keywords

acceptability; adherence; diabetes

Introduction

The most urgent clinical question regarding therapeutic diets is not whether they work, but whether they are sustainable. Medical nutrition therapy is integral to diabetes management (1). However, some researchers and clinicians have raised concerns about affected individuals' ability to understand and adhere to prescribed diets (2,3).

A recent randomized, controlled trial in individuals with type 2 diabetes tested a diet regimen relying on qualitative, rather than quantitative changes (4). Based on prior studies suggesting that low-fat, plant-based diets reduce the risk of diabetes and may facilitate its management (5), the study design used a low-fat vegan diet and did not require carbohydrate counting, exchange lists, or portion limits (4). A control group followed 2003 American Diabetes Association (ADA) guidelines. Among medication-stable participants, A1c fell 1.23 points over 22 weeks in the vegan group, compared to 0.38 points in the ADA group ($P = 0.01$); body weight fell 6.5 kg in the vegan group and 3.1 kg in the ADA group ($P < 0.001$); and LDL-cholesterol fell 21.2% in the vegan group and 10.7% in the ADA group ($P = 0.02$).

Dietary adherence depends on the acceptability of prescribed diets. Therefore, in the course of this trial, the acceptability of the low-fat vegan diet and the control diet was quantified over both the short (22 weeks) and long (74 weeks) term. The results of that assessment, using global measures, including attrition and adherence rates and reported changes in dietary intake, as well as specific measures of dietary behavior, diet acceptability, diet-related benefits and symptoms, and food cravings, are reported herein. The present investigation tests the hypothesis that a low-fat vegan diet has an acceptability comparable to or better than that of a more conventional diabetes diet.

METHODS

Participants

The overall study methods have been previously described (4). Briefly, individuals with type 2 diabetes, defined by a fasting plasma glucose concentration ≥126 mg/dl on 2 occasions or a prior physician's diagnosis of type 2 diabetes with the use of hypoglycemic medications for at least 6 months, were recruited through newspaper advertisements in the Washington, D.C., area in 2 cohorts (October – December 2004 and October– December 2005), to complete the 74-week study from January 2004 through June 2005, and January 2005 through June 2006, respectively. Exclusionary criteria included hemoglobin A1c (A1c) values <6.5% or >10.5%, use of insulin for >5 years, tobacco use within the preceding 6 months, consumption of more than 2 alcoholic beverages per day, current drug abuse, pregnancy, unstable medical status, and current use of a low-fat, vegetarian diet (use of other therapeutic diets at baseline did not preclude participation). Definition of race/ethnicity was required by the National Institutes of Health to ascertain balance in group assignments and assess the degree to which the participant

sample reflected the community from which it was drawn. Participants were asked to describe themselves as white; black; American Indian, Eskimo, Aleut; or Asian, Pacific Islander; and describe their ethnicity as either Hispanic or non-Hispanic.

Random Assignment and Intervention

After medical history and physical examination, A1c was assayed using affinity chromatography on an Abbott IMx analyzer (Abbott Diagnostics, Abbott Park, IL) (6). Volunteers were then ranked in order of A1c concentrations. Using a computer-generated random-number table, they were randomly assigned in sequential pairs to a diet following 2003 ADA guidelines (7) or a low-fat, vegan diet.

For ADA-group participants, dietary energy, carbohydrate, and monounsaturated fat intake were individualized, based on each participant's need to reduce body weight and plasma lipid concentrations, following 2003 ADA guidelines (7). The diet derived 15–20% of energy from protein and <7% of energy from saturated fats. Carbohydrate and monounsaturated fats together provided 60–70% of energy intake. Dietary cholesterol was limited to 200 mg/day. ADA-group participants with a body mass index >25 kg/m^2 were prescribed daily energy intake deficits of 500–1000 kcal.

The vegan diet (approximately 10% of energy from fat, 15% protein, 75% carbohydrate) consisted of vegetables, fruits, grains, and legumes. Participants were asked to (1) avoid animal products, (2) avoid fatty foods, such as added oils, fried products, avocadoes, nuts, and seeds, and (3) favor low-glycemic-index foods, such as beans and green vegetables. Portion sizes, energy intake, and carbohydrate intake were not limited.

To meet the vitamin B_{12} needs of the vegan group while maintaining the same intervention in the ADA group, all participants were provided a vitamin B_{12} supplement (100 mcg) to be taken every other day. No other supplements were provided. For both groups, alcoholic beverages were limited to 1 per day for women, and 2 per day for men.

No meals were provided. Participants prepared their meals or ate at restaurants. Participants were asked not to alter their exercise habits during the initial 22 weeks of the study.

Each participant met with a registered dietitian experienced in the use of the assigned diet for 1 hour to establish a diet plan consistent with the diet guidelines. Thereafter, participants attended weekly 1-hour meetings of their assigned groups for nutrition and cooking instruction conducted by a physician and a registered dietitian and/or a cooking instructor for 22 weeks, followed by optional biweekly sessions for an additional 52 weeks. Sessions for the 2 groups were similar 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.

Dietary and Clinical Measures

Body weight was determined at week 0, before breakfast while participants wore hospital gowns, using a digital scale (FS-0900, Befour, Inc., Saukville, WI) accurate to 0.1 kg. Height was measured at week 0 while participants stood barefoot with their backs to a wall-mounted tape measure with heels against the wall, and was recorded to the nearest 0.5 cm. A 3-day dietary record was completed by each participant at weeks 0, 11, 22, and 74 on 2 weekdays and 1 weekend day, using a food scale, after participants had completed a practice record for 3 days. Diet records were reviewed by a registered dietitian at time of collection to determine completeness and obtain additional details. When participants were unable to provide necessary details for specific foods, data-entry rules developed by the Nutrition Coordinating Center, University of Minnesota, were used, with additional rules established by a registered

dietitian certified by the Nutrition Coordinating Center in accordance with its prescribed procedures (8).

In addition, at weeks 4, 8, 13, 20, 33, 45, and 60, a registered dietitian made unannounced telephone calls to each participant to administer a 24-hour diet recall, using a multi-pass approach (Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN, software version 5.0, Food and Nutrient Database 35, released May 2004) (9) and reported instances of poor dietary adherence to the dietitians responsible for the initial dietary instruction for additional dietary counseling as needed. Using the Nutrition Data System for Research software version 5.0 (9), a registered dietitian certified by the Nutrition Coordinating Center analyzed all 3-day dietary records and diet recalls.

For statistical purposes (not for participant education), dietary adherence for the vegan group was defined as the absence of meat, poultry, fish, dairy, or egg intake reported on 24-hour recalls or incidentally at any point and, on 3-day dietary records at 22 and 74 weeks, saturated fat ≤5% and total fat ≤25% of energy, and average daily cholesterol intake ≤50 mg. Adherence for the ADA group was defined as average daily energy intake on the 22-week and 74-week 3-day dietary records being no more than 200 kcal in excess of the intake prescribed by the registered dietitian, and saturated fat 10% of energy. Individuals who attended fewer than 10 of the first 22 weekly sessions were also considered nonadherent on either diet.

At weeks 0, 22, and 74, participants completed the Eating Inventory, the Food Acceptability Questionnaire, and the Food-Craving Inventory. The Eating Inventory provides quantitative measures of three aspects of eating behavior (10): The dietary restraint measure is an index of the extent to which participants feel constrained by their assigned diets. The disinhibition factor indicates overeating in response to stress or other cues. The hunger factor assesses the subjective experience of hunger as part of one's typical daily life.

The Food Acceptability Questionnaire (11) asks participants to answer the following questions related to the foods they have been eating during the preceding two weeks, using seven-point response scales:

1. How well do you like these foods?
2. How well do you like the taste of these foods?
3. How appealing or unappealing do you find the appearance of these foods?
4. How boring are these foods?
5. How easy or difficult has it been for you to prepare these foods?
6. How easy or difficult has it been for you to purchase these foods?
7. How easy or difficult has it been for you to maintain your current diet at restaurants?
8. How much effort does it take for you to stay on this diet?
9. How satisfied or dissatisfied do you feel after eating a meal on this diet?
10. Overall, how satisfied or dissatisfied are you with this diet?

Test-retest reliability of a previous version of the questionnaire was assessed in a sample of 18 respondents completing the questionnaire on two occasions approximately one week apart. The test-retest correlations (either Pearson r, or gamma, an index of concordance) ranged from 0.70 to 1.00 (11).

The Food Acceptability Questionnaire also asks respondents to indicate whether they have frequently experienced any of the following the perceived benefits or adverse effects during

the preceding two weeks: increased or decreased energy, weight loss or gain, better or worse sleep than usual, dizziness, better digestion, gassiness, or changes in hair texture or growth.

The Food-Craving Inventory is a 28-item questionnaire that presents a reliable and valid measure of general and specific food cravings (12).

After data entry, all data were reviewed for accuracy by a second data manager. Data forms and samples were identified with participant numbers only. The Institutional Review Board of the George Washington University approved the protocol, and all participants gave written informed consent before enrollment.

Statistical Analyses

Between-subjects t-tests were calculated for demographic and nutrient measures to establish whether there were significant differences between the groups at baseline. For nutrient intake and Eating Inventory and Craving Questionnaire scores, paired comparison t-tests were calculated within each diet group to assess whether the mean changes from baseline to 22 and 74 weeks were significantly different from zero. Between-subject t-tests were calculated to determine differences between the diets at 22 and 74 weeks.

For the Food Acceptability Questionnaire items, the related samples Wilcoxon rank test assessed within-group changes over time and the independent samples Mann-Whitney U test to compare the diet groups, both at baseline and at 22 and 74 weeks. For perceived benefits and adverse effects listed in the Food Acceptability Questionnaire, the chi-square test for independent samples compared the two diet groups in frequency of changes in reported symptoms from baseline to final time points and paired-comparison t-tests to assess within-group changes over time. An alpha of 0.05 was used for all determinations of significance.

RESULTS

Participants

Of 1,049 individuals initially screened by telephone, 99 met study criteria and were randomly assigned to the ADA (n = 50) or vegan (n = 49) diet groups. The reasons for exclusion were: A1c values outside the required range (n = 201), failure to meet other participation criteria (n = 279), inability to attend scheduled meetings (n = 187), failure to keep interview appointment (n = 153), reluctance to change diet (n = 72), and other or unspecified (n = 58). The sample was predominantly white or black, female, married, and well-educated **(**Table 1). There were no significant differences between the groups for any demographic variable except for occupation. More vegan-group participants were retired; fewer were employed.

All participants completed 22-week assessments. Seven (14%) vegan and 5 (10%) ADA-group participants failed to complete 74-week laboratory assessments. There were no significant differences between these individuals and study completers. Within the ADA group, 8 participants failed to complete 22-week dietary records, as did 3 vegan-group participants, and 5 ADA-group and 2 vegan-group participants failed to complete 22-week questionnaires. Seven ADA participants and 9 vegan participants failed to complete 74-week dietary records, and 8 ADA and 12 vegan participants failed to complete 74-week questionnaires.

Nutrient Changes and Dietary Adherence

Reported diet changes from baseline to 74 weeks were similar to those from baseline to 22 weeks (Table 2). Of individuals who provided data at both 22 weeks and 74 weeks, mean reported energy intake fell in both diet groups, despite the fact that no energy intake limit was prescribed for the vegan group. Reported fat, saturated fat, and cholesterol intake fell in both

groups, but did so significantly more in the vegan group. Carbohydrate and fiber intake increased in the vegan group, with smaller changes in these variables in the ADA group.

At 22 weeks, all dietary adherence criteria were met by 44% (22/50) of ADA-group and 67% (33/49) of vegan-group participants; this between-group difference was significant ($X^2(1,n=99) = 5.47$, P = 0.019). Of the 28 ADA-group violators at 22 weeks, 17 exceeded the saturated fat criterion (10% of energy), 2 exceeded individualized energy intake limits, and 10 attended fewer than 10 meetings (some participants violated more than one criterion). Of the 16 vegan-group violators at 22 weeks, 7 exceeded criteria for total (25% of energy) or saturated (5% of energy) fat; 11 reported at least one episode of consuming meat, poultry, fish, dairy products or eggs; and 3 attended fewer than 10 group meetings. At 74 weeks, dietary adherence criteria were met by 48% (24/50) in the ADA group and 51% (25/49) in the vegan group; the between-group difference was no longer significant ($X^2(1,n=99) = .10$, p = 0.75).

Within the vegan group, retired individuals were not more likely than working individuals to be adherent. At 22 weeks, 73% (11/15) of retirees and 65% (22/34) of nonretirees were adherent ($X^2(1,n=49) = 0.353$, P= 0.55.) At 74 weeks, 60% (9/15) of retirees and 47% (16/34) of nonretirees were adherent ($X^2(1,n=49)= 0.697$, P = 0.40). In the ADA group, retired individuals were more likely to be adherent at 22 weeks: 100% (4/4) of retirees and 39% (18/46) of nonretirees were adherent ($X^2(1,n=50) = 5.53$, P = 0.02). This was not true at 74 weeks: 75% (3/4) of retirees and 46% (21/46) of nonretirees were adherent (X^2 (1,n=50) = 1.27, P = 0.26).

Dietary Restraint, Disinhibition, and Hunger

The groups did not significantly differ in their baseline distributions of scores for dietary restraint, disinhibition, or hunger as reported on the Eating Inventory **(**Table 3). At 22 weeks, dietary restraint had increased in both groups, but did so to a greater degree in the ADA group, suggesting that ADA-group participants felt more perturbed or constrained by their assigned diet, compared with the vegan group (P = 0.003). Disinhibition and hunger scores fell in both groups, suggesting that participants were less likely to overeat in response to stress or other cues and had less hunger at 22 weeks, compared with baseline, with no between-group differences. Findings at 74 weeks were similar to those at 22 weeks, except that the between-group difference in dietary restraint was no longer significant (Table 3).

Food Acceptability

Differences in food acceptability between the two diet groups were generally small and nonsignificant **(**Table 4). For the question, “How well do you like these foods?” the median 22-week response in both groups was 5 (“a fair amount”) with no response lower than 4 (“moderately”) in either group. The overall satisfaction with the diets was similar as well, with a 22-week median response of 6 (“moderately satisfied”) for the vegan group and 5 (“More satisfied than dissatisfied”) for the ADA group. The one question yielding a significant difference between groups was, “How easy or difficult has it been for you to prepare these foods?”, for which the change-score distribution was more favorable for the ADA diet, although the median rating on this item (5, “fairly easy”) did not change for either group. At 74 weeks, there were no significant between-group differences.

Many participants in both groups reported increased energy, weight loss, better digestion, and better sleep, particularly over the initial 22 weeks, and there were more reports of gassiness in the vegan group, although not significantly more than in the ADA group **(**Table 5.)

Cravings

There were no food groups for which craving scores increased in either diet group **(**Table 6). On the contrary, craving scores diminished slightly in every category for both groups at 22

weeks, with a similar pattern at 74 weeks. Between groups differences were not significant, except for the initial reduction in fat cravings, which was greater for the vegan group (P = 0.05).

There were no treatment-related serious adverse effects.

DISCUSSION

In this group of self-selected research volunteers, those assigned to a low-fat vegan diet reported major changes in nutrient intake that largely persisted for 74 weeks. Reductions in reported fat, saturated fat, and cholesterol intake and increases in carbohydrate and fiber intake were greater in the vegan group, compared with the ADA group. These changes are similar to those reported in earlier studies using low-fat vegan diets (13). Neither diet was associated with increases in reported hunger, tendency to overeat, or cravings. Compared with the ADA diet, the vegan diet required slightly more initial effort, but was less likely to be described as constraining. These findings suggest that both a vegan diet and a diet following 2003 ADA guidelines meet a reasonable level of acceptability, at least among motivated individuals, although the vegan diet appears to elicit much more pronounced long-term nutritional changes.

Dietary changes are essential for management of body weight, glycemia, blood lipids, and blood pressure, yet the acceptability of therapeutic diets has been largely neglected in clinical research. In the current study, dietary acceptability was assessed using a variety of indices, including attrition, adherence, and nutritional changes, as well as instruments quantifying eating behavior, diet acceptability, and cravings.

To the extent that attrition serves as a crude indicator of diet acceptability, it is noteworthy that there was no attrition during the initial 22 weeks. In previous diet studies for diabetes, attrition has varied widely. Attrition was low in older individuals (6% in a 10-week study [2] and 8% in a 6-month study [14]), and higher in a California Health Maintenance Organization study (15% at 5 months) (15), a Costa Rican study (19% at 12 weeks) (16), two Minneapolis studies (18% [17] and 46% [18], both at 6 months), and an Urban Atlanta study (approximately 50% at 6 months) (19).

Dietary adherence criteria were met by a somewhat higher percentage in the vegan group (67%, 33/49) at 22 weeks, compared with the ADA group (44%, 22/50). These criteria, however, were not identical for the two groups. Notably, the vegan group had no energy intake limit, but had a stricter criterion for saturated fat (5% vs. 10% of energy). These criteria were used solely for statistical purposes and were more permissive than the guidelines used in presenting the diets to the participants. It is of concern that saturated fat intake in the ADA group exceeded 10% of energy for 34% (17/50) of participants at 22 weeks. This may have been the result of a focus on carbohydrate, at the expense of attention to fat intake, on the part of many ADA–group participants. At 74 weeks, group-specific dietary adherence criteria were met by similar numbers within each group—48% (24/50) in the ADA group and 51% (25/49) in the vegan group (p = 0.75). It is possible that the change from weekly meetings to biweekly optional meetings may have adversely influenced adherence; prior studies have shown that continued nutrition education increases adherence (2).

The increase in dietary restraint among ADA-group participants at 22 weeks suggests that the ADA diet may have been experienced as somewhat more demanding than the vegan diet. Although the difference was statistically significant, it was moderate in magnitude at 22 weeks and no longer significant at 74 weeks. In a 14-week trial of a diet based on National Cholesterol Education Program guidelines, which are similar in certain respects (reductions in saturated fat and cholesterol) to the ADA guidelines, in postmenopausal overweight women, disinhibition and hunger scores fell (improved), although reported dietary restraint increased,

suggesting that participants felt somewhat perturbed by the diet change, but were less likely to overeat in response to food cues and were less hungry (20).

The ADA guidelines require vigilance regarding portion sizes to limit fat and carbohydrate intake and set energy-intake limits for overweight individuals. In contrast, the vegan diet requires participants to forgo certain familiar foods and, in some cases, to learn new tastes and new cooking methods. However, it does not limit portion sizes, energy intake, or carbohydrate intake, or require counting or estimating quantities of foods or food constituents.

Despite a wide range of responses to the Food Acceptability Questionnaire items, there was no suggestion of a lack of acceptability of either diet. This is not surprising for the ADA diet, which is drawn from familiar foods. The vegan diet required marginally more initial effort, but this difference was no longer apparent at 74 weeks.

Neither group reported increased cravings for any foods, and the vegan group reported a small but significant reduction in craving for fatty foods at 22 weeks, compared with the ADA group. This finding contradicts the notion that individuals adopting vegan diets have continued cravings for excluded foods. On the contrary, the desire for fatty foods appeared to diminish.

Overall, these results accord with prior studies of the acceptability of vegetarian or vegan diets. In a study of a program of lifestyle changes for reversing coronary atherosclerosis, there were no identifiable differences in the acceptability of a low-fat, vegetarian diet, compared to the diets followed by control participants referred to their physicians for cardiac care (21). At five-year follow-up, most patients continued to maintain reductions in plasma cholesterol concentration and body weight, suggesting that dietary modifications had been largely maintained (22).

In a trial using a low-fat, vegan diet for dysmenorrhea, participants reported after five weeks that the vegan diet required somewhat more effort, compared to an unrestricted diet, but was otherwise no different in any measure of acceptability or enjoyment (23). Among overweight, postmenopausal women randomly assigned to either a low-fat, vegan diet or a diet following the guidelines of the National Cholesterol Education Program, there were no between-group differences on any measure of acceptability. (24). Similarly, in a study of 250 young women who had tried both energy-restricted weight-loss diets and vegetarian diets, the median duration on an energy-restricted diet was 4 months, while the median duration on a vegetarian diet was 24 months (25).

Vegetarian and vegan diets have demonstrated efficacy in the management of cardiovascular disease (22), weight problems (26), and diabetes (4). That they are also perceived as practical and acceptable to many patients, at least in the research setting, is clinically important.

The findings of the present study and previous investigations show that vegetarian and low-fat vegan diets should not be described as extreme, difficult, or unacceptable, at least among research volunteers. They are highly effective in adducing major nutrient intake changes and achieve levels of adherence and acceptability comparable to those of other therapeutic diets. Nonetheless, while vegan diets have the advantages of being lower in fat, saturated fat, and cholesterol, and higher in fiber and complex carbohydrate, compared with omnivorous diets, planning is important with regard to sources of vitamins B12 and D, calcium, and iodine. (27)

The study's strengths include a demographically varied population, a sample size that was adequate to show between-group differences in nutrient intake, the use of multiple independent quantitative measures of adherence and acceptability, and an appropriate follow-up period. The present study also has limitations. All participants had diabetes and were self-selected

research volunteers. Many were well-educated. Hospital and community dietetic practices include many such individuals, but also include patients with less education and motivation. The randomization procedure produced groups that were dissimilar for occupational status. Fewer ADA participants were retirees; retirees were more likely than workers to be adherent at 22 weeks (although this difference was no longer present at 74 weeks). All participants also had access to group support throughout the study. Dietary intake was based on self-report, which is vulnerable to distortion based on participants' tendency to provide socially desirable responses and to underreporting, especially in individuals with higher BMIs (28).

CONCLUSIONS

Among individuals with type 2 diabetes in a research study, a low-fat vegan diet led to greater reductions in fat, saturated fat, and cholesterol intake and greater increases in fiber and complex carbohydrate intake, compared with a diet following 2003 ADA guidelines, but was not viewed as less acceptable. Acceptability to patients should not be viewed as a barrier to its clinical use. The vegan diet requires marginally more initial effort, but was experienced as less constraining initially, and both diets were deemed generally acceptable by most participants.

While not all individuals adhere to prescribed diets for diabetes, our findings indicate that many do. In a context in which group support can be provided for motivated persons, pessimism regarding their ability to adhere to therapeutic diets is not justified.

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Table 1

Demographic characteristics of participants at baseline

		Vegan Group (n = 49)	ADA[a] Group (n = 50)	P-value[b]
Mean age, range (years)		56.7, 35–82	54.6, 27–80	0.29
Body mass index (kg/m^2)		33.9 ± 7.8	35.9 ± 7.0	0.18
Sex				0.26
	Male	22 (45%)	17 (34%)	
	Female	27 (55%)	33 (66%)	
Race, ethnicity				0.71[c]
	Black, non-Hispanic	22 (45%)	22 (44%)	
	White, non-Hispanic	21 (47%)	22 (44%)	
	White, Hispanic	4 (8%)	2 (4%)	
	Asian, non-Hispanic	2 (4%)	4 (8%)	
Marital status				0.08
	Not married	20 (41%)	26 (52%)	
	Married	29 (59%)	24 (48%)	
Education				0.69
	High school, partial or graduate	6 (12%)	3 (6%)	
	College, partial or graduate	26 (53%)	25 (50%)	
	Graduate degree	17 (35%)	22 (44%)	
Occupation				0.04
	Service occupation	3 (6%)	7 (14%)	
	Technical, sales, administrative	16 (33%)	18 (36%)	
	Professional or managerial	15 (31%)	21 (42%)	
	Retired	15 (31%)	4 (8%)	
Years since diabetes diagnosis (mean, standard deviation)		8.6 (6.8)	8.5 (6.1)	0.96

[a] ADA=American Diabetes Association

[b] P-values refer to t-tests for continuous variables and Chi Square for categorical variables.

[c] P-value calculated for race distribution; for ethnicity (Hispanic versus non-Hispanic), P = 0.39

Table 2

Macronutrient intake at weeks 0, 22, and 74 for participants with data at all time points.[a]

Vegan (n = 38)					ADA[b] (n = 39)					
Week 0	Week 22	Change Wk 0–22	Week 74	Change Wk 0–74	Week 0	Week 22	Change Wk 0–22	Week 74	Change Wk 0–74	P-value[c]
1801.0±75.0	1413.3±65.4	−387.8±54.4****	1374.5±84.3	−426.5±85.4****	1832.8±96.6	1383.3±59.8	−449.6±83.3****	1404.6±67.2	−428.2±83.9****	0.99
36.3±1.4	17.9±1.0	−18.4±1.8****	21.8±1.5	−14.5±1.9****	34.7±1.3	33.2±1.2	−1.4±1.5	33.5±1.4	−1.1±1.8	<0.0001
11.8±0.6	3.5±0.3	−8.3±0.6****	5.0±0.5	−6.8±0.7****	10.8±0.5	9.4±0.4	−1.4±0.6*	9.8±0.5	−1.0±0.6	<0.0001
7.4±0.4	6.2±0.4	−1.2±0.5*	6.9±0.4	−0.5±0.6	7.2±0.3	7.6±0.3	+0.4±0.4	7.7±0.5	+0.5±0.6	0.21
154.7±16.4	15.7±5.4	−139.0****±17.7	31.8±8.3	−122.9±17.6****	167.3±11.4	137.9±10.2	−29.3±12.3*	164.1±13.7	−3.2±13.2	<0.0001
47.7±1.8	71.7±1.2	+24.0±2.1****	67.0±1.8	+19.3±2.5****	46.6±1.5	47.8±1.6	+1.2±1.6	47.3±1.7	+0.7±2.0	<0.0001
17.0±0.6	14.0±0.3	−3.0±0.6****	14.6±0.5	−2.4±0.7**	19.1±0.6	20.9±0.6	+1.8±0.7*	20.7±0.7	+1.6±0.9	0.0007
11.1±0.7	25.6±1.1	+14.6±1.1****	22.1±1.2	+11.1±1.1****	11.3±0.7	13.9±0.9	+2.7±1.1	13.8±0.8	+2.5±0.9‡	<0.0001

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Table 3

Restraint, disinhibition, and hunger, as reported using the Eating Inventory, indicating changes from baseline to 22 weeks and from baseline to 74 weeks.[a]

	Vegan (n = 47 at 22 weeks, 37 at 74 weeks)			ADA[b] (n = 44 at 22 weeks, 42 at 74 weeks)				
	Week 0	Final	Change	Week 0	Final	Change	Effect size	P-value[c]
Dietary restraint								
0–22 weeks	9.5 ± 0.5	12.0 ± 0.5	+2.5 ± 0.6****	9.0 ± 0.7	14.0 ± 0.6	+5.0 ± 0.6****	−2.5 ± −4.1 to −0.9	0.003
0–74 weeks	9.2 ± 0.5	11.1 ± 0.6	+1.9 ± 0.7**	9.4 ± 0.7	12.5 ± 0.7	+3.2 ± 0.6****	−1.3 ± −3.1 to 0.5	0.15
Disinhibition								
0–22 weeks	6.9 ± 0.6	5.6 ± 0.5	−1.3 ± 0.4**	8.4 ± 0.5	6.3 ± 0.6	−2.1 ± 0.4****	0.8 ± −0.4 to 2.0	0.17
0–74 weeks	6.3 ± 0.7	5.6 ± 0.6	−0.7 ± 0.4	8.2 ± 0.6	6.5 ± 0.6	−1.7 ± 0.5**	+1.0 ± −0.3 to 2.3	0.14
Hunger								
0–22 weeks	4.3 ± 0.4	3.4 ± 0.3	−0.9 ± 0.4*	4.9 ± 0.5	4.1 ± 0.5	−0.8 ± 0.4*	−0.1 ± −1.1 to 1.0	0.92
0–74 weeks	3.9 ± 0.5	3.3 ± 0.5	−0.6 ± 0.6	5.1 ± 0.5	4.6 ± 0.5	−0.5 ± 0.3	−0.1 ± −1.4 to 1.1	0.83

[a] Mean values ± standard error of the mean.

[b] ADA=American Diabetes Association

[c] P-values for comparisons of between-group (vegan vs ADA) changes (baseline to final values)

* P < 0.05,

** P < 0.01,

*** P < 0.001, and

**** P < 0.0001 for within-group changes

Table 4

Food acceptability as rated on the Food Acceptability Questionnaire, indicating changes from baseline to 22 weeks and from baseline to 74 weeks.[a]

	Vegan Group (n = 47 at 22 weeks, 36 at 74 weeks)			ADA[b] Group (n = 44 at 22 weeks, 41 at 74 weeks)			
Variable	**Baseline**	**Final**	**Change**	**Baseline**	**Final**	**Change**	**P Value[c]**
1. How well do you like these foods? (1= not at all, 7 = extremely)							
0–22 weeks	5 (5–6)	5 (5–6)	0 (−1 to +1)	5 (4–6)	6 (5–6)	0 (0 to +1))	0.22
0–74 weeks	5 (5–6)	5 (5–6)	0 (0 to +1)	5 (4–6)	5 (4–6)	0 (0 to +1)	0.95
2. How well do you like the taste of these foods? (1= not at all, 7 = extremely)							
0–22 weeks	5 (5–6)	5 (5–6)	0 (−1 to +1)	5 (4.5 –6)	6 (5–6)	0 (0 to +1)	0.16
0–74 weeks	5 (4.5–6)	5.5 (5–6)	0 (0 to +1)	5 (4–6)	5 (5–6)	0 (−1 to +1)	0.62
3. How appealing or unappealing do you find the appearance of these foods? (1= extremely unappealing, 7 = extremely appealing)							
0–22 weeks	5 (5–6)	6 (5–6)	0 (−1 to +1)	5 (4–6)	5 (4.5–6)	0 (−1 to +1)	0.87
0–74 weeks	5 (4.5–6)	5 (5–6)	0 (−1 to 0)	5 (4–6)	5 (4–6)	0 (−1 to +1)	0.52
4. How boring are these foods? (1= not at all, 7 = extremely)							
0–22 weeks	2 (1–3)	3 (2–3)	0 (−1 to +1)	3 (1.5–4)	3 (2–4)	0 (−1 to +1)	0.71
0–74 weeks	2 (1–3.5)	3 (2–4)	0 (−1 to +2)	3 (2–4)	3 (1–4)	0 (−1 to +1)	0.54
5. How easy or difficult has it been for you to prepare these foods? (1= extremely difficult, 7 = extremely easy)							
0–22 weeks	5 (4–6)	5 (4–5)	0 (−2 to 0)	5 (4–5.5)	5 (4–6)	0 (−1 to +1)	0.02
0–74 weeks	5 (4–6)	5 (4–6)	0 (−1 to +1)	5 (4–5)	5 (4–6)	0 (0 to +1)	0.14
6. How easy or difficult has it been for you to purchase these foods? (1= extremely difficult, 7 = extremely easy)							
0–22 weeks	5 (4–7)	5 (4–6)	0 (−2 to +1)	5 (4–6)	5 (4–6)	0 (−1 to +1)	0.63
0–74 weeks	5 (4–6)	5 (4–6)	0 (−1 to +1)	5 (4–6)	5 (5–6)	0 (−1 to 0)	0.38
7. How easy or difficult has it been for you to maintain your current diet at restaurants? (1= extremely difficult, 7 = extremely easy)							
0–22 weeks	3.5 (2–5)	3 (2–5)	0 (−2 to +1)	3.5 (3–4)	3.5 (3–5)	0 (0 to +1)	0.23
0–74 weeks	4 (2–5)	3 (2–5)	0 (−1 to +1)	4 (3–4)	3 (2–5)	0 (−1 to +1)	0.59
8. How much effort does it take for you to stay on this diet? (1= more effort than is possible, 7 = no effort at all)							
0–22 weeks	4 (4–5)	4 (3–5)	0 (−1 to +1)	4 (3–5)	4 (3–5)	0 (−1 to +1)	0.52
0–74 weeks	4 (3–5)	3 (2–5)	−1 (−2 to 0)	4 (3–4)	4 (3–4)	0 (−1 to +1)	0.14
9. How satisfied or dissatisfied do you feel after eating a meal on this diet? (1 = extremely dissatisfied, 7 = extremely satisfied)							
0–22 weeks	5 (4–6)	5 (5–6)	0 (0 to +1)	5 (4–5)	5 (4–6)	0 (0 to +1)	0.40
0–74 weeks	5 (4–6)	5 (4–6)	0 (−1 to +2)	5 (4–5)	5 (4–6)	0 (0 to +1)	0.49

	Vegan Group (n = 47 at 22 weeks, 36 at 74 weeks)			ADA[b] Group (n = 44 at 22 weeks, 41 at 74 weeks)			
Variable	**Baseline**	**Final**	**Change**	**Baseline**	**Final**	**Change**	**P Value[c]**
10. Overall, how satisfied or dissatisfied are you with this diet? (1 = extremely dissatisfied, 7 = extremely satisfied)							
0–22 weeks	4.5 (4–6)	6 (5–7)	+1 (0 to +2)	4 (4–5)	5 (4.5–6)	+1 (0 to +2)	0.67
0–74 weeks	4 (3–5)	6 (5–6)	1 (0 to +3)	4 (4–5)	5 (4–6)	0 (0 to +2)	0.13

[a] Medians. Interquartile ranges are shown in parenthesis.

[b] ADA=American Diabetes Association

[c] P-values for between-group (vegan vs ADA) differences in changes from baseline to final values.

Table 5

Symptoms and benefits as reported on the Food Acceptability Questionnaire, indicating changes from baseline to 22 weeks and from baseline to 74 weeks.

Symptom	Vegan (n = 47 at 22 weeks, 36 at 74 weeks)			ADA[a] (n = 44 at 22 weeks, 41 at 74 weeks)			P-value[b] week 22	P-value[b] week 74
	Week 0	Week 22	Week 74	Week 0	Week 22	Week 74		
Increased energy	9% (4/47)	43% (20/47)****	25% (9/36)***	18% (8/44)	39% (17/44)*	22% (9/41)	0.4137	0.0920
Decreased energy	28% (13/47)	17% (8/47)	22% (8/36)	25% (11/44)	25% (11/44)	24% (10/41)	0.5817	0.4580
Weight loss	19% (9/47)	60% (28/47)****	22% (8/36)	16% (7/44)	41% (18/44)**	20% (8/41)	0.3234	0.5847
Weight gain	21% (10/47)	21% (10/47)	14% (5/36)	18% (8/44)	23% (10/44)	24% (10/41)	0.8825	0.1845
Dizziness	2% (1/47)	0% (0/47)	0% (0/36)	5% (2/44)	7% (3/44)	5% (2/41)	0.1484	0.3547
Better digestion	11% (5/47)	30% (14/47)*	19% (7/36)	7% (3/44)	18% (8/44)	24% (10/41)*	0.6685	0.7062
Gassiness	28% (13/47)	45% (21/47)*	31% (11/36)	18% (8/44)	18% (8/44)	29% (12/41)	0.2633	0.8447
Improved hair texture	6% (3/47)	11% (5/47)	0% (0/36)	2% (1/44)	2% (1/44)	2% (1/41)	0.3590	0.6391
Excess hair growth	0% (0/47)	2% (1/47)	3% (1/36)	0% (0/44)	2% (1/44)	2% (1/41)	0.9624	0.9257
Hair thinning or loss	6% (3/47)	6% (3/47)	8% (3/36)	9% (4/44)	2% (1/44)	2% (1/41)	0.2341	0.7691
better sleep than usual	11% (5/47)	28% (13/47)*	19% (7/36)	9% (4/44)	27% (12/44)**	17% (7/41)	0.8599	0.8895
Worse sleep than usual	11% (5/47)	6% (3/47)	14% (5/36)	14% (6/44)	7% (3/44)	7% (3/41)	0.9010	0.2997

[a] ADA=American Diabetes Association

[b] P-values represent significance of differences between diet groups in frequency of changes in reported symptoms from baseline to final time points, using Chi square.

* P < 0.05,

** P < 0.01,

*** P < 0.001, and

**** P < 0.0001 for within-group changes

Table 6

Cravings, as reported using the Food-Craving Inventory, indicating changes from baseline to 22 weeks and from baseline to 74 weeks.[a]

	Vegan (n = 47 at 22 weeks, 37 at 74 weeks)			ADA[b] (n = 44 at 22 weeks, 42 at 74 weeks)				
	Week 0	Final	Change	Week 0	Final	Change	Effect size	P-value[c]
0 to 22 Weeks								
Fat	2.1 ± 0.1	1.7 ± 0.1	−0.3 ± 0.1***	2.0 ± 0.1	2.0 ± 0.1[d]	−0.1 ± 0.1	−0.2 ± −0.5 to 0.0	0.05
Sweets	2.2 ± 0.1	1.8 ± 0.1	−0.4 ± 0.1***	2.3 ± 0.1	2.1 ± 0.1	−0.2 ± 0.1	−0.2 ± −0.5 to 0.1	0.17
Carbohydrate	2.3 ± 0.1	2.0 ± 0.1	−0.2 ± 0.1**	2.3 ± 0.1	2.2 ± 0.1	−0.1 ± 0.1	−0.1 ± −0.4 to 0.1	0.28
Fast Food	2.2 ± 0.1	2.0 ± 0.1	−0.2 ± 0.1	2.4 ± 0.1	2.1 ± 0.1	−0.3 ± 0.1***	+0.1 ± −0.1 to 0.4	0.30
Total	2.2 ± 0.1	1.9 ± 0.1	−0.3 ± 0.1***	2.2 ± 0.1	2.1 ± 0.1	−0.1 ± 0.1	−0.1 ± −0.4 to 0.1	0.17
0 to 74 Weeks								
Fat	2.0 ± 0.1	1.8 ± 0.1	−0.2 ± 0.1*	2.0 ± 0.1	2.0 ± 0.1	0.0 ± 0.1	−0.2 ± −0.4 to 0.1	0.14
Sweets	2.2 ± 0.1	1.9 ± 0.1	−0.3 ± 0.1**	2.3 ± 0.1	2.1 ± 0.1	−0.2 ± 0.1	−0.1 ± −0.4 to 0.1	0.30
Carbohydrate	2.2 ± 0.1	2.1 ± 0.1	−0.1 ± 0.1	2.3 ± 0.1	2.1 ± 0.1	−0.1 ± 0.1	0 ± −0.3 to 0.2	0.85
Fast Food	2.2 ± 0.1	2.0 ± 0.1	−0.2 ± 0.1	2.3 ± 0.1	2.2 ± 0.1	−0.1 ± 0.1	0 ± −0.3 to 0.2	0.74
Total	2.1± 0.1	1.9 ± 0.1	−0.2 ± 0.1	2.2 ± 0.1§	2.1± 0.1	−0.1 ± 0.1	−0.1± −0.3 to 0.1	0.26

[a] Mean values ± standard error of the mean.

[b] ADA=American Diabetes Association

[c] P-values for comparisons of between-group (vegan vs ADA) changes (baseline to final values)

[d] The difference between initial and final scores for fat intake in the ADA group does not correspond to the change score, due to rounding.

* P < 0.05,

** P < 0.01,

*** P < 0.001, and

**** P < 0.0001 for within-group changes