RESEARCH
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Turning the Waiting Room into a Classroom: Weekly Classes Using a Vegan or a Portion-Controlled Eating Plan Improve Diabetes Control in a Randomized Translational Study

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ABSTRACT

Background In research settings, plant-based (vegan) eating plans improve diabetes management, typically reducing weight, glycemia, and low-density lipoprotein (LDL) cholesterol concentrations to a greater extent than has been shown with portion-controlled eating plans.

Objective The study aimed to test whether similar benefits could be found using weekly nutrition classes in a typical endocrinology practice, hypothesizing that a vegan eating plan would improve glycemic control, weight, lipid concentrations, blood pressure, and renal function and would do so more effectively than a portion-controlled eating plan.

Design In a 20-week trial, participants were randomly assigned to a low-fat vegan or portion-controlled eating plan.

Participants/setting Individuals with type 2 diabetes treated in a single endocrinology practice in Washington, DC, participated (45 starters, 40 completers).

Intervention Participants attended weekly after-hours classes in the office waiting room. The vegan plan excluded animal products and added oils and favored low-glycemic index foods. The portion-controlled plan included energy intake limits for weight loss (typically a deficit of 500 calories/day) and provided guidance on portion sizes.

Main outcome measures Body weight, hemoglobin A1c (HbA1c), plasma lipids, urinary albumin, and blood pressure were measured.

Statistical analyses performed For normally distributed data, *t* tests were used; for skewed outcomes, rank-based approaches were implemented (Wilcoxon signed-rank test for within-group changes, Wilcoxon two-sample test for between-group comparisons, and exact Hodges-Lehmann estimation to estimate effect sizes).

Results Although participants were in generally good metabolic control at baseline, body weight, HbA1c, and LDL cholesterol improved significantly within each group, with no significant differences between the two eating plans (weight: −6.3 kg vegan, −4.4 kg portion-controlled, between-group P=0.10; HbA1c, −0.40 percentage point in both groups, P=0.68; LDL cholesterol −11.9 mg/dL vegan, −12.7 mg/dL portion-controlled, P=0.89). Mean urinary albumin was normal at baseline and did not meaningfully change. Blood pressure changes were not significant.

Conclusions Weekly classes, integrated into a clinical practice and using either a low-fat vegan or portion-controlled eating plan, led to clinical improvements in individuals with type 2 diabetes.
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IN RESEARCH STUDIES, DIETARY INTERVENTIONS HAVE been shown to substantially improve diabetes management.[1,2] However, translating research findings into meaningful interventions in clinical settings is challenging. Office practices may not have dietetic professionals on staff and may lack physical space for classes. The benefits of changes in eating patterns can be easily confounded by medication changes. Nonetheless, improvements in diabetes management are valuable, particularly when they are in the form of nutrition therapy, which, unlike pharmacologic interventions, has few if any negative side effects or major implementation costs. Some evidence shows that low-fat vegan eating plans may be particularly effective for weight, glycemic, and lipid control, even in the absence of specific limits on energy or carbohydrates.[3]

This clinical trial ascertained the effects of a simple, on-site program of nutrition instruction for individuals with type 2 diabetes, using weekly classes in the office waiting room of a private endocrinology practice in Washington, DC. It used, in randomized fashion, low-fat vegan and portion-controlled eating plans, testing the hypotheses that a vegan intervention would (1) improve glycemic control, body weight, plasma lipid concentrations, blood pressure, and indices of renal function in a within-group analysis during a 20-week intervention, and (2) do so more effectively than an intervention using a portion-controlled eating plan.

RESEARCH SNAPSHOT

Research Question: Can the benefits of dietary interventions for people with type 2 diabetes found in the research setting translate into similar benefits in a typical diabetes clinic, and, if so, does a vegan eating plan lead to greater improvements than a portion-controlled eating plan?

Key Findings: A 20-week randomized clinical trial testing the benefits of vegan and portion-controlled eating plans, provided through weekly classes, showed that both plans significantly improved body weight (−6.3 kg vegan, −4.4 kg portion-controlled), glycemic control (HbA1c −0.40 percentage point in both groups), and lipid concentrations (LDL cholesterol −11.9 mg/dL vegan, −12.7 mg/dL portion-controlled), with no significant differences between the two eating plans.

METHODS

The study was a 20-week nutrition intervention using a weekly on-site class structure in an established endocrinology practice. There was no untreated group. The protocol was approved by Ethical & Independent Review Services, Independence, MO, a private institutional review board. All participants gave written informed consent. The study was registered on ClinicalTrials.gov, identifier NCT01222429.

RECRUITMENT

Individuals being treated for type 2 diabetes in a Washington, DC, private endocrinology practice were notified by mail or waiting-room fliers about the study. Volunteers were screened by telephone, and those appearing to meet participation criteria were interviewed in person and invited to complete a practice 3-day dietary record.

Inclusion criteria were (1) a diagnosis of type 2 diabetes mellitus, as defined by a fasting plasma glucose concentration $\geq$126 mg/dL on two occasions or a prior physician's diagnosis of type 2 diabetes with the use of hypoglycemic medications for at least 6 months; (2) hemoglobin A1c (HbA1c) between 6.5% and 10.5%; (3) age at least 18 years; (4) ability and willingness to be assigned to either a low-fat, vegan, or portion-controlled eating plan and participate in all components of the study; and (5) diabetes medications unchanged for 1 month before volunteering for the study.

Exclusion criteria were (1) body mass index >45 (calculated as kg/m^2); (2) alcohol consumption of more than two drinks per day or the equivalent, episodic increased drinking (eg, more than two drinks per day on weekends), or a history of alcohol abuse or dependency followed by any current use; (3) use of recreational drugs in the past 6 months; (4) pregnancy; (5) signs or symptoms of acute uncontrolled diabetes, including but not limited to polyuria, polydipsia, blurred vision, or uncontrolled weight loss; (6) unstable medical status; (7) already following a low-fat, vegetarian eating pattern; and (8) lack of English fluency.

The study was completed in two replications beginning in 2011 and 2014, respectively, to maximize recruitment. In each replication, HbA1c concentrations were obtained, and participants were then ranked in order of HbA1c levels. Using a computer-generated random-number table, they were randomly assigned in sequential pairs to vegan and portion-controlled groups. Because assignment was done simultaneously, allocation concealment was unnecessary.

Each participant in both groups met with a registered dietitian nutritionist (RDN) to develop an individualized eating plan. These meetings followed a set agenda, which was identical for all participants within each group. Thereafter, participants in both groups were asked to follow their assigned eating plans and attend weekly 1-hour meetings held after hours in the office waiting room for instruction and support.

Before each meeting, all participants were weighed privately and were made aware of their body weights. The waiting room chairs were set in a circle that could accommodate approximately 15 participants. The timing and curricula for the two groups were identical, except for the eating plan guidelines. All sessions were conducted by an RDN, nurse, physician, cooking instructor, or research staff and included information on diabetes, nutrition, meal planning, shopping, food preparation techniques, recipes, and discussion of everyday dietary challenges, such as dining out and healthful snacking.

The vegan group was asked to follow a low-fat, low-glycemic index, vegan eating plan. According to the Academy of Nutrition and Dietetics, vegan eating patterns meet all nutritional requirements when appropriately planned and accompanied by supplemental vitamin B-12.[4] The eating plan consisted of whole grains, vegetables, legumes, and fruits. Animal products and added oils were excluded; no restrictions were placed on energy or carbohydrate intake. In choosing carbohydrate-containing foods, participants were encouraged to select those retaining their natural fiber and having a glycemic index <70, using tables standardized to a value of 100 for glucose. No meals were provided.

The eating plan was expected to derive approximately 10% of energy from fat, 10% to 15% of energy from protein, and the remainder from carbohydrates, and to provide approximately 30 to 40 g fiber per day.

The portion-controlled group participants received eating plans following accepted principles for individualized medical nutrition therapy, including energy limits when needed for weight loss (typically a deficit of 500 calories/day) and guidance on portion sizes, distributing carbohydrates throughout the day, reducing saturated fats, favoring high-fiber foods, and limiting sodium.

Participants in both groups were provided with a commercially available vitamin B-12 (100 μg) supplement and asked to take it every other day. For both groups, alcoholic beverages were limited to one per day for women and two per day for men.

The study did not seek to separate the effects of nutritional changes from those of group support; nor did it aim to construct isocaloric interventions, which is not feasible in free-living participants preparing their own meals, nor desirable given that the portion-controlled eating plan used energy restriction as a key weight-loss strategy and the vegan plan permitted unlimited energy intake.

At weeks 3 and 15, an RDN made unannounced telephone calls to each participant to administer a 24-hour food recall, using a multi-pass approach (Nutrition Coordinating Center, University of Minnesota). These recalls were not subjected to statistical analysis but allowed the investigators to check for poor adherence.

All participants were asked not to alter their exercise patterns and not to change their use of medications or nutritional supplements, except as recommended by their personal physicians. All participants were under the care of a single endocrinologist, who did not participate in the study intervention or assessment and who was asked to avoid changing medications during the study to the extent possible, except in cases of medical necessity (eg, hypoglycemia or hypotension). Many participants also had primary care physicians who were notified of their patients' participation and were also asked not to change medication regimens except as clinically required.

NUTRITIONAL AND CLINICAL MEASURES

At baseline, height was measured without shoes and with the participant's back to a wall-mounted measuring tape, and heels against the wall, and recorded to the nearest 0.5 cm.

Because dopamine activity plays a role in appetitive behavior and because certain D2 dopamine receptor Taq 1A genotypes (A1A1, A1A2) have been associated with obesity,[5] these genotypes were ascertained on all participants by using the polymerase chain reaction (PCR) method[6] to assess whether the genotypes were similarly distributed between the two intervention groups.

At baseline and 20 weeks, participants were asked to report changes in their health and medication use, and the following determinations were made. For physiological and laboratory measures, the determinations were made by technicians blind to group assignment after subjects had completed a 12-hour fast.

Dietary intake was assessed with a 3-day food record. Participants were given instructions on estimating portion sizes using food models, along with a sample record. Dietary intake data were collected and analyzed by using Nutrition Data System for Research (NDSR) software versions 2010[7] and 2014[8] by an RDN certified by the Nutrition Coordinating Center, University of Minnesota.

Body weight was measured in light, indoor clothing, without shoes, to the nearest 0.1 kg, using a digital scale (model FS0900, Befour, Inc).

Blood pressure was measured using a digital blood pressure monitor and a cuff of a size appropriate to the participant's arm, at the level of the heart, after participants had rested in a seated position for 5 minutes without talking or reading. Three measurements were taken at 1-minute intervals. The first was disregarded, and the mean of the remaining two measurements was calculated.

HbA1c, plasma glucose, plasma cholesterol and triglyceride concentrations, and urinary albumin concentrations were measured, using standard methods, at Quest Diagnostics, Secaucus, NJ.

Medication changes for each participant were assessed based on self-report, buttressed by chart reviews in cases involving any question of the accuracy of self-report, and were classified as a net increase, net decrease, mixed changes (changes in opposing directions for two or more medications), or no change.

PHYSICAL ACTIVITY

The International Physical Activity Questionnaire (IPAQ) short form assessed recent physical activity patterns. The method is highly reliable; an assessment of test–retest repeatability produced a correlation of 0.8.[9]

STATISTICAL PROCEDURES

A power analysis was done to determine sample sizes, based on HbA1c changes observed in prior studies. An alpha of .05 was used to test for group differences. The sample size needed to demonstrate a significant difference with power of 0.80 for effect size of 0.64 was estimated at 32 per group. Expecting up to 20% attrition, we aimed to recruit 40 participants in each group, for a total of 80.

Descriptive statistics for demographic and clinical variables were calculated for each group. Categorical baseline factors were compared between treatment groups by using the χ^2 test or Fisher's exact test in the case of small cell counts. Distributions of changes in clinical outcomes from baseline to 20 weeks were assessed for approximate normality. For outcomes whose change distributions were sufficiently close to normality, one-sample and two-sample t tests were used to assess the significance of within-group changes and to compare magnitudes of between-group changes, respectively. For outcomes with excessively skewed change distributions (HbA1c, fasting plasma glucose, urinary albumin, and IPAQ), rank-based approaches were implemented, including the Wilcoxon signed-rank test to assess the significance of within-group changes, and the Wilcoxon two-sample test to compare changes between the groups; exact Hodges-Lehmann estimation was used to provide an estimate of effect size for these outcomes. A two-sided alpha of .05 was used for all statistical tests. Reported P values are not adjusted for multiple comparisons.

RESULTS

Seventy-six patients inquired about the study. Of these, 27 were excluded for the following reasons: HbA1c outside the acceptable range (n=7), unable to attend weekly meetings (n=3), no longer a patient in the practice (n=2), unwilling to alter food habits (n=1), failed to attend in-person interview (n=5), withdrew before acceptance (n=6), and lost to follow-up during the evaluation process (n=3). An additional four volunteers failed to attend the baseline assessment. As a result, 45 volunteers (29 in 2011 and 16 in 2014) were accepted into the study and randomly assigned to the vegan group (n=21) or the portion-controlled group (n=24). Demographic data are described in Table 1. No significant differences were found between groups. The A1 allele was

Table 1. Baseline demographic and genetic characteristics of 45 participants in a study of dietary interventions for type 2 diabetes[a]

	Vegan group	Portion-controlled group	*P* value
n	21	24	
Mean age, range (y)	61 (41-79)	61 (30-75)	0.87
Sex, n (%)			0.28
Male	8 (38)	13 (54)	
Female	13 (62)	11 (46)	
Race and ethnicity, n (%)			0.096
White, non-Hispanic	13 (62)	7 (29)	
Black, non-Hispanic	6 (29)	14 (58)	
White, Hispanic	1 (5)	1 (4)	
Black, Hispanic	0 (0)	1 (4)	
Asian, non-Hispanic	1 (5)	1 (4)	
Education, n (%)			
High school graduate	1 (5)	2 (8)	0.72
Partial college	5 (24)	7 (29)	
College graduate	6 (29)	4 (17)	
Master's degree	7 (33)	6 (25)	
Doctoral degree	2 (10)	5 (21)	
Dopamine receptor genotypes, n (%)			0.76
DRD2 A1A1	3 (14)	2 (8)	
DRD2 A1A2	6 (29)	9 (38)	
DRD2 A2A2	12 (57)	13 (54)	

[a]Percentages for some series may not total 100% because of rounding.

found in 44% of participants, without a significant difference in distribution between the two groups.

Two vegan group participants and three portion-controlled group participants failed to complete 20 weeks of study (one moved, one withdrew, and three were lost to follow-up). Therefore, 19 vegan group and 21 portion-controlled group participants completed the study. Food records were completed at baseline and 20 weeks by 19 participants in each group.

Food Intake and Physical Activity

Both groups made substantial changes in eating patterns (Table 2). According to the food records, both groups reduced their energy intake. The vegan group increased its carbohydrate intake (+54 g/d), and the portion-controlled group reduced its intake of carbohydrate (−14 g/d, between-group P=0.0024). However, as percentages of energy, carbohydrate intake rose in both groups (vegan, 49% to 71% of energy; portion-controlled, 43% to 50% of energy, P=0.0013). The percentage of energy from fat decreased in both groups (vegan, 33% to 18%; portion-controlled, 39% to 30%, P=0.0476). The reductions in saturated fat and cholesterol were greater in the vegan group (P=0.0341 and P=0.0012, respectively). The percentage of energy from protein decreased in the vegan group (18% to 14%) but increased in the portion-controlled group (19% to 21%; P=0.0004). Iron intake increased slightly in the vegan group and decreased slightly in the portion-controlled group; the between-group difference did not reach statistical significance.

Although participants were asked not to alter their physical activity levels, both groups increased their reported physical activity (Table 3). This was especially true for the portion-controlled group. However, variability was large, and the difference between groups for the change in activity was not statistically significant.

Clinical Changes

Body weight fell by 6.3 kg in the vegan group and 4.4 kg in the portion-controlled group (P=0.10, Table 3). Body mass index decreased by 2.3 points and 1.5 points in the vegan and portion-controlled groups, respectively (P= 0.075).

In the vegan group, medications for glycemic control were reduced in four participants and mixed (medication changes in opposite directions) in two, and medication use could not be accurately assessed in two more. In the portion-controlled group, medications were increased in three participants, decreased in six, and mixed in four. This left 11 and eight study completers with unchanged medication regimens for glycemic control in the vegan and portion-controlled groups, respectively. HbA1c values were highly skewed; median HbA1c values fell 0.40 percentage points in both groups (P=0.68). Median fasting glucose values decreased by 16.0 mg/dL in the vegan group and 12.5 mg/dL in the portion-controlled group (P=0.71).

Total and low-density lipoprotein (LDL) cholesterol concentrations were low at baseline in both groups, reflecting the use of lipid-lowering medications by most participants at baseline. Several participants also altered their lipid-lowering medications during the study, despite the request that they not do so, leaving 14 vegan group and 16 portion-controlled group study completers who did not report changes in these medications. The laboratory failed to report an LDL cholesterol value for one vegan group participant. LDL cholesterol values fell significantly in both groups, with no significant difference between groups (vegan, −11.9; portion-controlled, −12.7; P=0.89). Triglyceride concentrations increased (but not significantly) in the vegan group and decreased significantly in the portion-controlled group; the difference between groups did not reach statistical significance (P=0.06).

Tests of renal function were, on average, in the normal range at baseline and showed no consequential changes during the study. Other changes in clinical variables are reported in Table 3.

DISCUSSION

In this study of patients with well-controlled type 2 diabetes, a simple intervention of group instruction and support for changes in eating patterns led to significant additional improvements in key clinical measures. Both eating plans led to

Table 2. Nutrient intake[a] of individuals completing a randomized trial of dietary interventions for type 2 diabetes

	Vegan Group (n=19)			Portion-Controlled Group (n=19)[b]			
	Baseline	Final	Change	Baseline	Final	Change	*P* value[c]
Energy (kcal)	1,695±129	1,491±129	−204±95*	1,638±131	1,332±85	−306±100**	0.4612
Carbohydrate (g)	212±20	265±24	54±16**	180±19	166±14	−14±13	0.0024
Carbohydrate (% energy)	49±2	71±2	22±3***	43±2	50±2	7±3*	0.0013
Fat (g)	64±5	31±3	−32±5***	72±6	46±4	−26±6***	0.3886
Fat (% energy)	33±2	18±2	−15±2***	39±2	30±2	−9±2***	0.0476
Saturated fat (g)	20±2	6±1	−14±2***	21±2	14±1	−7±2**	0.0341
Saturated fat (% energy)	10±1	4±1	−7±1***	12±1	9±1	−3±1**	0.0038
Protein (g)	70±5	51±5	−19±4***	76±5	69±5	−6±5	0.0804
Protein (% energy)	18±1	14±1	−4±1**	19±1	21±1	2±1*	0.0004
Cholesterol (mg)	174±17	5±2	−169±16***	241±29	209±34	−33±34	0.0012
Calcium (mg)	750±91	540±58	−210±79*	713±110	620±50	−93±87	0.3249
Iron (mg)	18±2	19±3	2±2	13±1	12±1	−1±1	0.3321
Sodium (mg)	3,154±267	2,685±263	−469±324	3,159±305	2,417±184	−742±278*	0.5265

[a]Mean±standard error.

[b]Of the 19 vegan group and 21 portion-controlled group participants who completed the study, 2 portion-controlled group participants failed to provide adequate dietary records, leaving 19 in each group.

[c]*P* values for comparisons of between-group (vegan vs portion-controlled) changes (baseline to 20 weeks).

*$P<0.05$.

**$P\leq0.01$.

***$P<0.001$ for within-group changes.

improvements in body weight, HbA1c, and LDL cholesterol concentrations that were significant within each group, with no significant differences in effectiveness between the two regimens in this small trial. Mean HbA1c values were below 7.0% in both groups at baseline and fell an additional 0.4 percentage point in each group. Mean LDL cholesterol values were well below 100 mg/dL at baseline, and the dietary interventions improved control further. The modest increase in triglycerides observed in the vegan group accords with previous studies that have observed that, compared with individuals following omnivorous diets, those following vegetarian or vegan diets have slightly lower triglyceride concentrations in observational studies but slightly higher triglyceride concentrations in clinical trials,[10] typically to a degree that is not significant statistically or clinically.[11]

Previous studies have shown that group-based diabetes self-management education reduces body weight, glycemia, blood pressure, and medication requirements.[12] In a 4-year trial, a group education program proved more effective in preventing deterioration of metabolic control in individuals with type 2 diabetes, compared with individual consultations.[13] An advantage of dietary interventions, compared with pharmacologic treatments, is that they typically improve several endpoints concurrently. This has been particularly demonstrated with vegan regimens, which improve body weight as well as or better than calorie-restricted regimens when prescribed without explicit limits on energy intake,[4] presumably because of their low energy density. Because they contain no animal fat or cholesterol and are typically rich in dietary fiber, vegan diets improve lipid control.[10] In the current study, both groups already had good lipid control at baseline, limiting the study's ability to make between-group comparisons of lipid-lowering effects. Low-fat vegan eating patterns also improve glycemic control[14] and blood pressure,[15] reverse coronary atherosclerosis,[16] and greatly reduce the risk of cardiovascular events.[11] Nonetheless, both programs tested in this intervention study yielded significant clinical benefits.

Although both vegan and portion-controlled eating plans have been shown to be effective at improving glycemic control and cardiovascular risk,[17] they affect blood glucose via somewhat different presumed mechanisms. Both cause weight loss, which should help glycemic control, but by reducing carbohydrate intake, the portion-controlled plan reduces blood sugar directly, without necessarily addressing insulin resistance.[2] The low-fat vegan plan greatly reduces fat intake while increasing carbohydrate intake, apparently reducing intramyocellular and hepatocellular lipid, which is at the root of insulin resistance.[3]

The strikingly high (44%) prevalence of the DRD2 Taq1 A1 allele is similar to that reported in a previous study of individuals with type 2 diabetes and is clinically important because of the presumed link between this allele and alcoholism, drug abuse, compulsive gambling, and obesity, suggesting that the allele is associated with dopamine-seeking behavior.[4] A structured program of weekly classes and weekly weigh-ins may be especially supportive in these individuals. However, small sample numbers prevented a comparison between those with and without the A1 allele.

Because this study included volunteers who were not confined to a metabolic ward or otherwise restricted and took place in their doctor's waiting room, these findings can

Table 3. Clinical measures[a] in individuals with type 2 diabetes participating in a randomized clinical trial of two dietary interventions

	Vegan Group			Portion-Controlled Group			Effect Size (vegan vs portion-controlled)	*P* value[b]
Laboratory measures	Baseline	Final	Change	Baseline	Final	Change		
Weight (kg), completers, 19 vegan, 21 portion-controlled	97.8±4.1	91.5±3.8	−6.3±1.0***	95.9±4.0	91.5±3.8	−4.4±0.6***	−2.0 (−4.3 to 0.4)	0.10
BMI[c], completers, 19 vegan, 21 portion-controlled	34.9±1.5	32.6±1.3	−2.3±0.4***	33.0±1.3	31.5±1.2	−1.5±0.2***	−0.8 (−1.7 to 0.1)	0.075
Hemoglobin A1c (%) median, completers, no medication changes (11 vegan, 8 portion-controlled)	6.7	6.2	−0.4*	6.8	6.2	−0.4**	0.1 (−0.2 to 0.6)	0.68
Fasting plasma glucose, mg/dL[d], median, completers, no medication changes (11 vegan, 8 portion-controlled)	125.0	109.0	−16.0	126.0	101.0	−12.5	7.5 (−14 to 44)	0.71
Total cholesterol, mg/dL[e], mean, completers, no medication changes (14 vegan, 16 portion-controlled)	157.4±7.6	146.4±7.8	−10.9±6.5	155.6±6.0	136.7±7.1	−18.9±3.8***	8.0 (−7.0 to 23.0)	0.28
LDL[f] cholesterol, mg/dL[e], mean, completers, no medication changes (13 vegan, 16 portion-controlled)	75.6±8.1	63.7±7.7	−11.9±3.9**	74.8±4.9	62.1±4.6	−12.7±3.6**	0.8 (−10.1 to 11.6)	0.89
HDL[g] cholesterol, mg/dL[e], mean, completers, no medication changes (14 vegan, 16 portion-controlled)	54.6±4.6	51.2±4.8	−3.4±1.6*	57.7±3.8	56.6±3.9	−1.1±1.5	−2.4 (−6.8 to 2.1)	0.29
Triglycerides, mg/dL[h], mean, completers, no medication changes (14 vegan, 16 portion-controlled)	155.9±25.9	176.7±31.1	20.8±21.4	115.6±10.8	90.7±8.7	−24.9±7.1**	45.7 (−2.1 to 93.6)	0.06
Urinary albumin/24h, median mg/dL, mean, completers, no medication changes (11 vegan, 8 portion-controlled)	0.7	0.8	0.2*	0.6	0.6	−0.05	0.75 (0.1 to 9.8)	0.027
Blood pressure, systolic (mm Hg) mean, completers, no medication changes (9 vegan, 13 portion-controlled)	133.4±2.3	131.8±4.1	−1.6±2.9	126.8±4.8	119.7±4.0	−7.1±3.9	5.5 (−5.6 to 16.5)	0.31
Blood pressure, diastolic (mm Hg) mean, completers, no medication changes (9 vegan, 13 portion-controlled)	79.7±3.8	78.6±3.5	−1.2±3.4	76.6±2.0	71.9±2.2	−4.7±2.5	3.5 (−5.1 to 12.1)	0.40
IPAQ[i] (MET[j]/24h) median (15 vegan, 16 portion-controlled)	810	1,092	0	1,579	3,186	1,370*	−1,097 (−1,999.5 to 113)	0.089

[a]Mean±standard error, except as noted.
[b]*P* values for comparisons of between-group (vegan vs portion-controlled) changes (baseline to 20 weeks). For factors that show a median, the *P* value was calculated via Wilcoxon test, and effect size calculated using a Hodges-Lehmann estimate for location shift along with an exact 95% CI for this shift.
[c]BMI=body mass index (calculated as kg/m^2).
[d]To convert mg/dL glucose to mmol/L, multiply mg/dL by 0.0555. To convert mmol/L glucose to mg/dL, multiply mmol/L by 18.0. Glucose of 125 mg/dL=6.94 mmol/L.
[e]To convert mg/dL cholesterol to mmol/L, multiply mg/dL by 0.0259. To convert mmol/L cholesterol to mg/dL, multiply mmol/L by 38.6. Cholesterol of 157.4 mg/dL=4.08 mmol/L.
[f]LDL=low-density lipoprotein.
[g]HDL=high-density lipoprotein.
[h]To convert mg/dL triglycerides to mmol/L, multiply mg/dL by 0.0113. To convert mmol/L triglycerides to mg/dL, multiply mmol/L by 88.6. Triglycerides of 155.9 mg/dL=1.76 mmol/L.
[i]IPAQ=International Physical Activity Questionnaire.
[j]MET=metabolic equivalents.
*$P<0.05$.
**$P\leq0.01$.
***$P<0.001$ for within-group changes.

reasonably translate into other clinical settings. The demographic characteristics of this study population—mostly older than 60 years of age and predominantly black or white—are similar to those of many other clinics, although the educational level of our participants may have been higher than for some settings.

However, this study also has important limitations. Recruitment fell short of the numbers called for by the power analysis, because of having exhausted the patient population of the practice. Glycemia and plasma lipids were already well controlled at baseline, limiting the potential for further reductions. Nonetheless, both eating plans, presented through weekly class series, did indeed yield significant improvements.

The degree of support (weekly classes and weekly weigh-ins) was greater than that typically provided in the clinical setting. This is not a limitation to the generalizability of our findings; rather, the simple structured and continuing support provides an important model for clinical practices to consider.

Changes in medication use complicated the interpretation of study findings. In a prior study by the current investigators, most diabetic individuals treated with insulin or insulin secretagogues required medication reductions after starting vegan eating plans to avoid recurrent hypoglycemia.[18] The confounding effect of medication changes can be reduced by excluding patients on insulin and insulin secretagogues and by shortening the length of clinical trials; however, these steps also would reduce the generalizability of the findings.

An additional limitation to studies in free-living participants is the degree of uncertainty as to the extent to which participants have adhered to their prescribed nutrition or medication regimens. Food records and telephone monitoring were used in an effort to minimize this problem; in addition, the observed changes in body weight, glycemic control, and plasma lipids provided some reassurance that participants did indeed make substantial nutrient changes.

Although participants were asked not to alter their physical activity, the study took place in the late winter and spring, a time when physical activity would naturally increase. Participants in both groups increased their reported physical activity, particularly in the portion-controlled group, which may have influenced HbA1c or other variables. In addition, most participants lost weight, which may have influenced their aptitude for physical activity.

Despite these limitations, this study has demonstrated that a simple program of instruction and support leads to significant improvements in diabetes management. It was not adequately powered to differentiate the effects of the two active regimens. In future studies, testing the effects of a program of this type in a larger participant group with less well-controlled diabetes, lipid values, or blood pressure would be helpful. More research is also needed on the application of nutritional interventions to the prevention of diabetes complications.

In conclusion, a simple program of weekly classes for instruction and support, integrated into a clinical practice and using either a low-fat vegan or portion-controlled eating plan, led to clinical improvements. Because of the widespread and serious nature of diabetes—a leading contributor to cardiovascular disease, blindness, amputations, and renal impairment—improvements in its management are of great value.

References

1. Emadian A, Andrews RC, England CY, Wallace V, Thompson JL. The effect of macronutrients on glycaemic control: A systematic review of dietary randomised controlled trials in overweight and obese adults with type 2 diabetes in which there was no difference in weight loss between treatment groups. *Br J Nutr*. 2015;114(10):1656-1666.
2. American Diabetes Association. Standards of medical care in diabetes—2017: Lifestyle management. *Diabetes Care*. 2017;40(suppl 1):S33-S43.
3. Barnard ND, Katcher HI, Jenkins DJA, Cohen J, Turner-McGrievy G. Vegetarian and vegan diets in type 2 diabetes management. *Nutr Rev*. 2009;67(5):255-263.
4. Melina V, Craig W, Levin S. Position of the Academy of Nutrition and Dietetics: Vegetarian diets. *J Acad Nutr Diet*. 2016;116(12):1970-1980.
5. Barnard ND, Noble EP, Ritchie T, et al. D2 Dopamine receptor Taq1A polymorphism, body weight, and dietary intake in type 2 diabetes. *Nutrition*. 2009;25(1):58-65.
6. Grandy DK, Zhang Y, Civelli O. PCR detection of the TaqA RFLP at the DRD2 locus. *Hum Mol Genet*. 1993;2(12):2197.
7. *NDSR* [computer software]. Version 2010. Minneapolis, MN: Nutrition Coordinating Center; 2010.
8. *NDSR* [computer software]. Version 2014. Minneapolis, MN: Nutrition Coordinating Center; 2014.
9. Craig CL, Marshall AL, Sjostrom M, et al. International physical activity questionnaire: 12-country reliability and validity. *Med Sci Sports Exerc*. 2003;35(8):1381-1395.
10. Yokoyama Y, Levin SM, Barnard ND. Association between plant-based diets and plasma lipids: A systematic review and meta-analysis. *Nutr Rev*. 2017;75(9):683-698.
11. Wang F, Zheng J, Yang B, Jiang J, Fu Y, Li D. Effects of vegetarian diets on blood lipids: A systematic review and meta-analysis of randomized controlled trials. *J Am Heart Assoc*. 2015;4(10):e002408.
12. Deakin T, McShane CE, Cade JE, Williams RD. Group based training for self-management strategies in people with type 2 diabetes mellitus. *Cochrane Database Syst Rev*. 2005;2:CD003417.
13. Trento M, Passera P, Bajardi M, et al. Lifestyle intervention by group care prevents deterioration of type II diabetes: A 4-year randomized controlled clinical trial. *Diabetologia*. 2002;45(9):1231-1239.
14. Yokoyama Y, Barnard ND, Levin SM, Watanabe M. Vegetarian diets and glycemic control in diabetes: A systematic review and meta-analysis. *Cardiovasc Diagn Ther*. 2014;4(5):373-382.
15. Yokoyama Y, Nishimura K, Barnard ND, et al. Vegetarian diets and blood pressure: A meta-analysis. *JAMA Intern Med*. 2014;174(4):577-587.
16. Ornish D, Scherwitz LW, Billings JH, et al. Intensive lifestyle changes for reversal of coronary heart disease. *JAMA*. 1998;280(23):2001-2007.
17. Franz MJ, MacLeod J, Evert A, et al. Academy of Nutrition and Dietetics Nutrition Practice Guideline for type 1 and type 2 diabetes in adults: Systematic review of evidence for medical nutrition therapy effectiveness and recommendations for integration into the nutrition care process. *J Acad Nutr Diet*. 2017;117(10):1659-1679.
18. Barnard ND, Cohen J, Jenkins DJ, et al. A low-fat, vegan diet improves glycemic control and cardiovascular risk factors in a randomized clinical trial in individuals with type 2 diabetes. *Diabetes Care*. 2006;29(8):1777-1783.

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STATEMENT OF POTENTIAL CONFLICT OF INTEREST

N. D. Barnard writes books and articles and gives lectures related to nutrition and health, and has received royalties and honoraria from these sources. N. D. Barnard, S. M. Levin, and R. Flores are affiliated with the Physicians Committee for Responsible Medicine, which promotes the use of low-fat, plant-based diets and discourages the use of animal-derived, fatty, and sugary foods. L. Gloede practices medical nutrition therapy in her private practice, Nutrition Coaching, LLC, and at several worksite wellness centers.

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