



# 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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## ARTICLE INFORMATION

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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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**I**N RESEARCH STUDIES, DIETARY INTERVENTIONS HAVE been shown to substantially improve diabetes management.<sup>1,2</sup> 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.<sup>3</sup>

## RESEARCH

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.

## 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](https://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  $\text{kg}/\text{m}^2$ ); (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

## 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.

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.<sup>4</sup> 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  $\mu\text{g}$ ) 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.

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