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Effect of Allowing Choice of Diet on Weight Loss

A Randomized Trial

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Background: Choosing a diet rather than being prescribed one could improve weight loss.

Objective: To examine whether offering choice of diet improves weight loss.

Design: Double-randomized preference trial of choice between 2 diets (choice) versus random assignment to a diet (comparator) over 48 weeks. (ClinicalTrials.gov: NCT01152359)

Setting: Outpatient clinic at a Veterans Affairs medical center.

Patients: Outpatients with a body mass index of at least 30 kg/m^2.

Intervention: Choice participants received information about their food preferences and 2 diet options (low-carbohydrate diet [LCD] or low-fat diet [LFD]) before choosing and were allowed to switch diets at 12 weeks. Comparator participants were randomly assigned to 1 diet for 48 weeks. Both groups received group and telephone counseling for 48 weeks.

Measurements: The primary outcome was weight at 48 weeks.

Results: Of 105 choice participants, 61 (58%) chose the LCD and 44 (42%) chose the LFD; 5 (3 on the LCD and 2 on the LFD) switched diets at 12 weeks, and 87 (83%) completed measurements at 48 weeks. Of 102 comparator participants, 53 (52%) were randomly assigned to the LCD and 49 (48%) were assigned to the LFD; 88 (86%) completed measurements. At 48 weeks, estimated mean weight loss was 5.7 kg (95% CI, 4.3 to 7.0 kg) in the choice group and 6.7 kg (CI, 5.4 to 8.0 kg) in the comparator group (mean difference, −1.1 kg [CI, −2.9 to 0.8 kg]; $P = 0.26$). Secondary outcomes of dietary adherence, physical activity, and weight-related quality of life were similar between groups at 48 weeks.

Limitations: Only 2 diet options were provided. Results from this sample of older veterans might not be generalizable to other populations.

Conclusion: Contrary to expectations, the opportunity to choose a diet did not improve weight loss.

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Various dietary approaches have been shown to be effective for weight management, alleviation of risk factors, and disease prevention (1–9). Regardless of the approach, greater adherence to dietary recommendations has been the best predictor of weight loss (10). Therefore, new strategies that maximize dietary adherence are needed to help patients experience the maximum health benefits.

Allowing persons to choose among evidence-based dietary strategies intuitively holds promise for improving dietary adherence because it is patient-centered, offering the opportunity to select a diet on the basis of food preferences or other factors that patients may value. If allowing choice among diets improves weight outcomes, as has been suggested (11–13), various dietary approaches could be made available to those seeking weight loss and strategies could be developed to facilitate choice. In this double-randomized preference trial, we evaluated whether participants who were allowed the opportunity to choose between 2 diets would lose more weight than those randomly assigned to a diet.

Methods

Setting and Participants

Details of the study protocol have been reported elsewhere (14). Participants were recruited from clinics of the Durham Veterans Affairs Medical Center (VAMC) in Durham, North Carolina, between May 2011 and June 2012. Participants were eligible if they had a body mass index (BMI) of at least 30 kg/m^2, a regular VAMC provider, access to a telephone, and reliable transportation. Participants were ineligible for the following reasons: aged 75 years or older, serum creatinine level greater than 132.6 μmol/L (>1.5 mg/dL) (men) or greater than 114.9 μmol/L (>1.3 mg/dL) (women), liver disease, type 1 diabetes, hemoglobin A_{1c} level of 12% or greater, daily insulin use, unstable heart disease, organ transplant, blood pressure of 160/100 mm Hg or greater, fasting triglyceride level of 6.8 mmol/L (600 mg/dL) or greater, low-density lipoprotein cholesterol level of 4.9 mmol/L (190 mg/dL) or greater, pregnancy, breastfeeding, lack of birth control if premenopausal, dementia, severe psychiatric illness, recent substance abuse, recent weight-loss attempt, or presence of a pacemaker or defibrillator. Outpatients who met entry criteria for age, BMI, and VAMC provider and lived within a 50-mile radius were mailed a letter inviting them to call if they were interested in participating. Patients could also self-refer via advertisements posted in clinics or could be referred by health care personnel. Research assistants assessed eligibility using the electronic medical record; a telephone screen; and an

See also:

Summary for Patients I-22

EDITORS' NOTES

Context

Permitting a choice in the diet to follow has been proposed as a means to improve weight-loss efforts.

Contribution

This randomized trial found that patients who were allowed to choose their diets did not lose more weight than those whose diets were assigned to them.

Caution

Only 2 diet choices were offered.

Implication

The ability to choose a diet might not improve weight-loss results.

in-person screen, at which written, informed consent was obtained. Potential participants who expressed a strong aversion to one of the diets were informed that they might be randomly assigned to that diet and should enroll only if that would be acceptable. The Institutional Review Board of the Durham VAMC approved the study.

Randomization

We randomly assigned eligible participants in parallel fashion and a 1:1 ratio to the choice or comparator group by using a computerized random-number generator in blocks of fewer than 10, stratified by sex, BMI (<40 or ≥40 kg/m^2), and diagnosis of type 2 diabetes. Comparator participants underwent a second 1:1 randomization to either the low-carbohydrate diet (LCD) or the low-fat diet (LFD). Only the study statisticians were aware of the randomization sequence. The project coordinator entered final eligibility data into the database, which automatically generated the group assignment for eligible participants. Participants were not made aware of their assignment and were thus not considered randomly assigned until their first group visit.

Interventions

Choice Group Procedures

At the first group visit, choice group participants received summary results from the Geiselman Food Preference Questionnaire (FPQ), which was administered at the screening visit and indicated which of the 2 diet options their preferences aligned with (15). The FPQ uses a Likert scale of 1 (dislike extremely) to 9 (like extremely) to assess preferences for 72 foods that are common sources of macronutrients in the typical U.S. diet. Participants scoring higher in the Low Carbohydrate/High Protein summary category of the FPQ were advised that their food preferences aligned best with the LCD, whereas those scoring higher in the Low Fat/High Simple Sugar or Low Fat/High Complex Carbohydrate categories were advised that their preferences aligned best with the LFD. Participants then received verbal and printed information about the 2 diets, including foods emphasized and deemphasized, sample menus, and evidence for safety and efficacy. Participants were asked not to discuss their decision with other study participants but were allowed to consult with nonparticipants. Participants were advised that they could use all of this information to inform their choice of diet. The following week, the study dietitian called participants to elicit their diet choice, with diet counseling starting at the subsequent group visit. At this stage of enrollment, participants in each of 4 cohorts (approximately 50 per cohort) were placed into 4 small groups of approximately 12 participants each (choice-LCD, choice-LFD, comparator-LCD, and comparator-LFD). At week 12, choice participants had the option of switching to the other diet, in which case they received personal counseling for the new diet and subsequently joined the corresponding choice diet group.

Comparator Group Procedures

At the first group visit, comparator group participants learned of their diet assignment and received an overview of the study design and procedures but were advised not to begin the diet until the subsequent study visit to parallel the timeline of the choice group. Comparator participants then received counseling specific to their randomly assigned diet for the duration of the study.

Procedures Common to All Participants

Group sessions occurred every 2 weeks for 24 weeks, then every 4 weeks for 24 weeks, with a telephone call from the dietitian between these monthly sessions. In both groups, sessions consisted of measurements followed by group counseling by a single study dietitian. Counseling consisted of dietary and physical activity topics as well as behavioral elements (such as mindful eating and planning for high-risk situations). A pocket guide to counting calories, fat, and carbohydrates was provided (16). Participants were advised to strive for 30 minutes of moderate-intensity aerobic physical activity 5 days per week (17). A study physician was available as needed for antihypertensive or antiglycemic medication adjustments that followed an algorithm (Appendix Figures 1 to 4, available at www.annals.org).

The telephone counseling focused on individual goal setting and problem solving and incorporated principles of motivational interviewing (18). Using a script, the dietitian helped the patient identify and rank possible goals and then develop and refine action plans (19). The dietitian recorded the goals and action plans electronically so that progress could be assessed during subsequent calls.

Dietary Interventions

Participants received a book and printed handouts specific to the diet they were following (20, 21). For the LCD, carbohydrate intake was initially restricted to ap-

proximately 20 g/d, but calories were not restricted (7, 22). Participants were instructed on how to increase carbohydrate intake gradually as they neared their weight-loss goal or if cravings threatened adherence. For the LFD, intake of total fat was restricted to less than 30% of the daily energy intake, intake of saturated fat was restricted to less than 10% of the daily energy intake, intake of cholesterol was restricted to less than 300 mg/d (21, 23), and energy intake was restricted by subtracting 500 kcal from the daily maintenance energy requirement (24).

Outcome Measures

Body weight, the primary outcome, was measured at each of the 19 visits at the same time of day on a standardized digital scale with participants in light clothing and shoes removed. Secondary outcomes were measured every 12 weeks for a total of 5 measurements. Waist circumference was measured with a nonelastic tape measure placed on the skin horizontally at the iliac crest (23).

Dietary adherence was assessed using the Block Brief 2000 Food Frequency Questionnaire (FFQ), which assesses more than 70 food items (25). A summary measure of dietary adherence was calculated because the LCD and LFD have different dietary goals. The measure was calculated beginning at 12 weeks because dietary adherence did not apply at baseline. The calculation was the percentage of deviation from the goal macronutrient intake, with lower values considered to be greater adherence. For the LFD, the goal was no more than 30% of daily calories from fat. For the LCD, the goal was no more than 10% of daily calories from carbohydrates, based on our previous study showing that this was the mean percentage intake at 2 weeks (22).

Weight-related quality of life was assessed with the Impact of Weight on Quality of Life-Lite questionnaire (IWQOL-Lite) (26, 27), which has a total score and 5 subscales (physical function, self-esteem, sex life, public distress, and work); higher scores indicate higher quality of life. Physical activity was assessed with the long version of the International Physical Activity Questionnaire (IPAQ) (28). We developed a knowledge assessment for each diet consisting of 47 items and scored as the percentage of total items answered correctly.

Measurements were performed by trained, blinded research personnel or hospital laboratory personnel, except for diet-specific knowledge questionnaires, which were administered by unblinded personnel.

Statistical Analysis

The primary and secondary analyses were conducted on an intention-to-treat basis, with participants analyzed in the group to which they were randomly assigned, regardless of intervention adherence (29). Descriptive statistics of dietary energy and nutrient intake measured by the Block FFQ were calculated to assess diet composition. For continuous longitudinal outcomes, linear mixed-effects models (PROC MIXED) were used to test hypotheses of treatment differences over time (30). The final models included the fixed-effects linear, quadratic, cubic, or quartic time and associated time-by-group interaction terms to account for the fact that weight loss is not a smooth process over time. The randomization stratification variables (sex, BMI of <40 or ≥40 kg/m^2, and diabetes status) were also included in the final models as fixed effects. A random effect was fit to account for clustering by counseling group, and covariance terms were fit for the repeated measures over time. For the IPAQ, change from baseline was used as the outcome due to normality assumptions. Longitudinal models used all available data, including data from participants who had missing observations or were lost to attrition. The estimation procedure implicitly accommodated missingness related to a prior outcome or to other baseline covariates in the model (that is, data missing at random [MAR]). To assess the robustness of the primary model to the missing observations, we multiply imputed missing longitudinal weight measurements by using a Markov-chain Monte Carlo algorithm incorporating additional variables beyond those in the linear mixed-effects models to strengthen the MAR assumption. In a sensitivity analysis, we included interaction terms for diet type and diet type by week to examine the effect of inclusion of these terms on treatment effects. We also fit models to explore weight loss for the subgroups of patients who attended fewer than 15 or 15 or more (approximately 80%) of the 19 group sessions. Statistical analyses were performed using SAS, version 9.2 (SAS Institute), and R (R Foundation for Statistical Computing) (**Appendix**, available at www.annals.org).

On the basis of previous data, a 2-sided type I error rate of 0.05, and 80% power, we estimated that 216 patients (108 in each group) were needed to detect a 4.4-kg mean difference in weight between the choice and comparator groups at 48 weeks, an amount (approximately 4%) that is considered clinically significant (13). We used an intraclass correlation coefficient and the correlation between repeated weight measurements (ρ) to adjust the variance of a 2-sample difference-in-means test (the difference in weight at 48 weeks between the choice and comparator groups) to account for clustering and the longitudinal design, respectively (31, 32). Sample size calculations assumed a within-patient correlation of weight of 0.90 and a 25% final dropout rate and accounted for clustering by counseling group by using an intraclass correlation coefficient of 0.005.

Role of the Funding Source

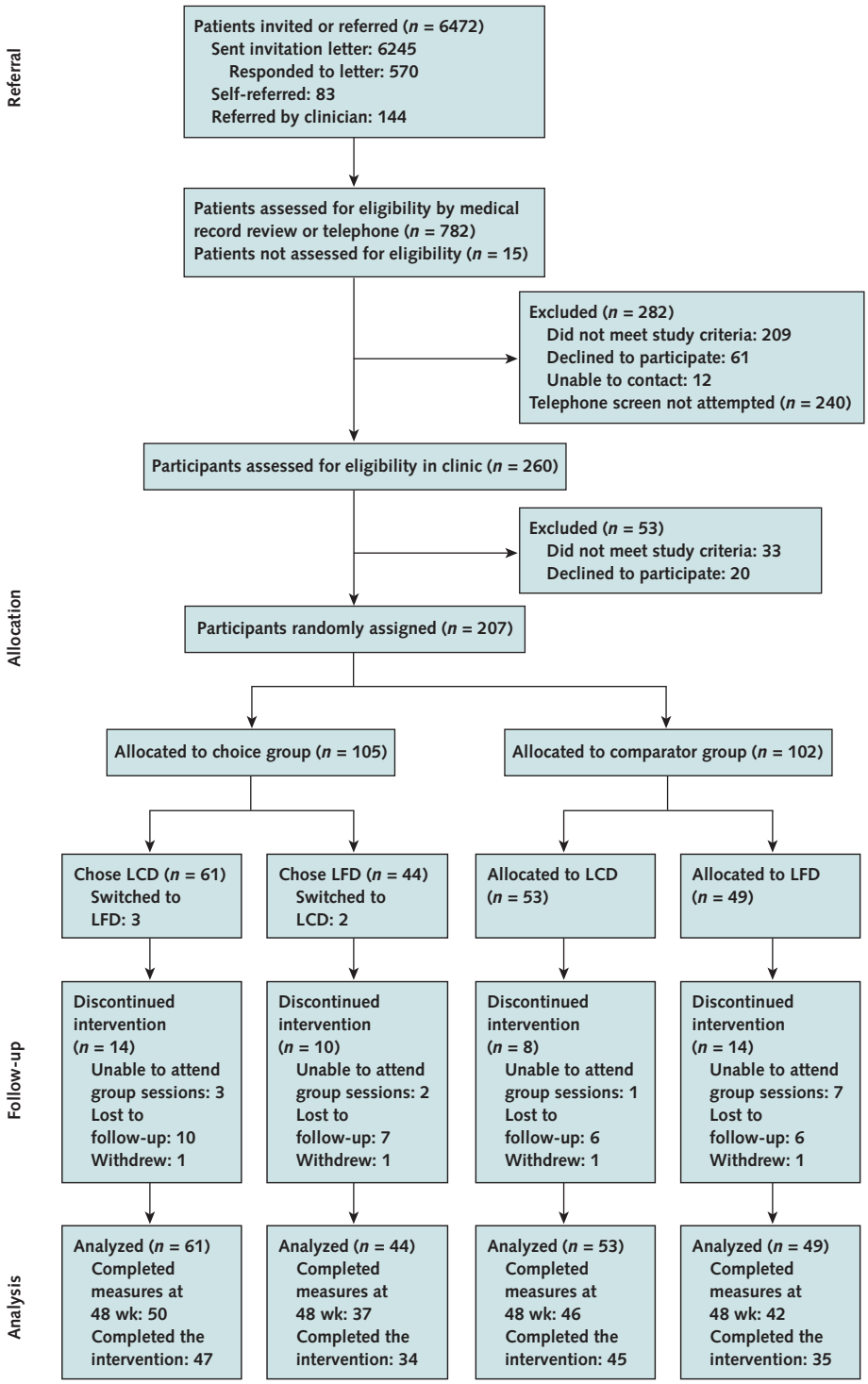
The funding source had no role in the design, conduct, or analysis of the study or the decision to submit the manuscript for publication.

RESULTS

Participants, Retention, and Attendance

We received 570 inquiries from 6245 letters sent to potentially eligible patients and separately received 83 self-referrals and 144 referrals from clinicians (**Figure 1**). A total of 207 participants was eligible; pro-

Figure 1. Study flow diagram.



LCD = low-carbohydrate diet; LFD = low-fat diet.

vided written, informed consent; and attended the first group session. One hundred five were randomly assigned to the choice group, and 102 were assigned to the comparator group. Among these, 87 (83%) choice participants and 88 (86%) comparator participants completed weight measurements at 48 weeks. At baseline, the mean age of participants was 55 years and the mean BMI was 36 kg/m^2. Fifty-one percent were African American, 27% were women, and 23% had type 2 diabetes (Table 1).

In the choice group, 61 (58%) participants chose the LCD and 44 (42%) chose the LFD; in the comparator group, 53 (52%) participants were randomly assigned to the LCD and 49 (48%) were assigned to the LFD. Among choice group participants, 71% (54 [89%] of those choosing the LCD and 21 [48%] of those choosing the LFD) chose the diet aligning with their food preferences according to the FPQ (33). At 12 weeks, 3 choice-LCD participants and 2 choice-LFD participants switched diets. The mean numbers of group sessions attended (of 19) and calls completed (of 6) were 13.5 and 2.5, respectively, for choice participants and 14.8 and 3.0, respectively, for comparator participants. The proportion of participants who attended at least 15 of the 19 group sessions was 55.2% in the choice group and 67.6% in the comparator group.

Weight Outcomes

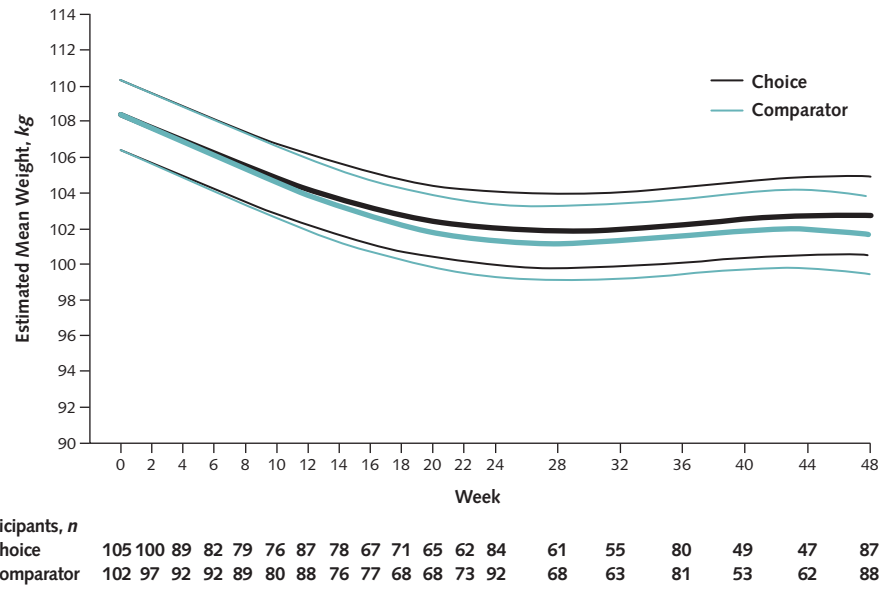
At 48 weeks, estimated mean weight loss was 5.7 kg (95% CI, 4.3 to 7.0 kg) in the choice group and 6.7 kg (CI, 5.4 to 8.0 kg) in the comparator group, for a mean difference of −1.1 kg (CI, −2.9 to 0.8 kg; P = 0.26) (Figure 2). The mean weight-loss estimates translate to a percentage change in weight from baseline of 5.6% for the choice group and 6.2% for the comparator group. There was no estimable random effect of group clustering for weight. We found similar weight-loss results when we used the multiply imputed data sets (mean difference, −1.3 kg [CI, −3.1 to 0.6 kg]; P = 0.17)

Table 1. Baseline Participant Characteristics

Variable	All (n = 207)	Choice Group			Comparator Group		
		All (n = 105)	Completers (n = 87)	Noncompleters (n = 18)*	All (n = 102)	Completers (n = 88)	Noncompleters (n = 14)*
Demographic characteristics							
Mean age (SD), *y*	55 (11)	54 (11)	55 (10)	49 (13)	55 (10)	57 (10)	47 (6)
Women, *n (%)*	55 (27)	28 (27)	25 (29)	3 (17)	27 (26)	25 (28)	2 (14)
Race, *n (%)*							
African American	106 (51)	45 (43)	39 (45)	6 (33)	61 (60)	49 (56)	12 (86)
White	93 (45)	54 (51)	45 (52)	9 (50)	39 (38)	37 (42)	2 (14)
College degree, *n (%)*	73 (35)	34 (32)	31 (36)	3 (17)	39 (38)	34 (39)	5 (36)
Clinical measures							
Mean body weight (SD), *kg*	108 (20)	109 (21)	109 (22)	108 (16)	108 (19)	107 (19)	112 (22)
Mean BMI (SD), *kg/m²*	36 (6)	36 (6)	36 (7)	35 (4)	36 (5)	36 (5)	37 (5)
BMI ≥40 kg/m², *n (%)*	37 (18)	20 (19)	17 (20)	3 (17)	17 (17)	14 (16)	3 (21)
Mean waist circumference (SD), *cm*†	46 (5)	46 (6)	46 (6)	46 (5)	46 (5)	46 (5)	45 (7)
Mean systolic blood pressure (SD), *mm Hg*‡	131 (14)	131 (14)	131 (14)	135 (12)	131 (14)	132 (15)	127 (10)
Mean diastolic blood pressure (SD), *mm Hg*‡	85 (9)	86 (9)	85 (9)	89 (10)	84 (8)	85 (8)	84 (8)
Diet preference according to Geiselman FPQ, *n (%)*§							
Low-carbohydrate	155 (76)	77 (73)	62 (71)	15 (83)	78 (80)	66 (79)	12 (86)
Low-fat	48 (24)	28 (27)	25 (29)	3 (17)	20 (20)	18 (21)	2 (14)
Mean IWQOL-Lite score (SD)							
Total‖	72 (19)	72 (20)	72 (21)	67 (13)	72 (19)	71 (19)	73 (17)
Physical function‖	63 (24)	63 (24)	64 (24)	60 (25)	63 (24)	63 (24)	59 (25)
Self-esteem‖	65 (28)	65 (29)	68 (30)	54 (22)	66 (27)	65 (28)	68 (23)
Sex life¶	76 (28)	76 (29)	77 (28)	68 (30)	77 (28)	75 (30)	88 (15)
Public distress‖	87 (19)	87 (20)	86 (22)	91 (11)	88 (17)	87 (17)	94 (13)
Work‖	82 (21)	82 (20)	83 (21)	78 (12)	81 (22)	81 (22)	83 (21)
Risk factors							
Smoker, *n (%)*‖	19 (9)	8 (8)	7 (8)	1 (6)	11 (11)	8 (9)	3 (21)
Median physical activity (IQR), *min/wk***							
Walking	180 (30–600)	180 (30–630)	180 (25–630)	300 (40–600)	180 (40–600)	178 (45–500)	240 (0–1050)
Moderate activity	360 (90–720)	290 (15–720)	240 (0–540)	720 (360–1080)	480 (120–840)	390 (120–740)	660 (480–1200)
Diabetes, *n (%)*	47 (23)	23 (22)	21 (24)	2 (11)	24 (24)	22 (25)	2 (14)

BMI = body mass index; FPQ = Food Preference Questionnaire; IQR = interquartile range; IWQOL-Lite = Impact of Weight on Quality of Life-Lite questionnaire.
* Final measurements (at 48 wk) not obtained.
† Missing for 2 participants from each group.
‡ Missing for 1 participant from each group.
§ Missing for 4 participants from the comparator group.
‖ Missing for 1 participant from the comparator group.
¶ Missing for 2 participants from the choice group and 3 participants from the comparator group.
** Assessed with the International Physical Activity Questionnaire. Missing for 3 participants from each group.

Figure 2. Mean weight trajectories and 95% CIs over 48 wk.



Estimated from linear mixed models.

as well as in the sensitivity analysis that adjusted for diet type (mean difference, −1.1 kg [CI, −3.0 to 0.7 kg]; P = 0.23) (**Appendix Figure 5**, available at www.annals.org). In the exploratory subgroup analysis, the estimated mean weight loss at 48 weeks for participants who attended at least 15 group counseling visits was 7.6 kg in the choice group and 8.2 kg in the comparator group; for those who attended fewer than 15 visits, weight loss was 2.7 kg in the choice group and 2.8 kg in the comparator group. Body mass index and waist circumference results mirrored the weight-loss results (**Table 2**).

Dietary Adherence, Physical Activity, and Quality-of-Life Outcomes

Macronutrient composition diverged as expected on the basis of assigned diets in both groups (**Appendix Table**, available at www.annals.org). Dietary adherence was similar between groups (P = 0.66) (**Table 2**). Across time points, LCD participants correctly answered a mean of 81% to 88% of items on the LCD knowledge questionnaire, and LFD participants correctly answered a mean of 63% to 79% of items on the LFD knowledge questionnaire. We found no differences between groups in change in IPAQ scores or IWQOL-Lite total or subscale scores from baseline (**Table 2**).

DISCUSSION

It is believed that psychological factors, such as motivation, engagement, and compliance, may be optimized with a preferred rather than randomized treatment, leading to better outcomes in participants receiving the preferred treatment when they cannot be blinded to treatment, as is the case in dietary counseling studies (34). The double-randomized preference design of our study allowed us to determine that preference did not meaningfully affect weight loss. Moreover, the range of estimated weight differences between groups in the 95% CIs does not contain a clinically meaningful difference in favor of the choice group.

A previous study used a similar design to examine the effects of offering a choice of diets. In the PREFER (Paving the Road to Everlasting Food and Exercise Routine) study, 176 participants with at least a moderate preference for either an LFD or a lacto-ovo-vegetarian (LOV) diet were randomly assigned to a choice or no-choice group (35). Participants in the choice group lost less weight (−3.9% and −5.3% for chosen LFD and LOV diet, respectively) than those assigned a diet (−8.0% and −7.9% for assigned LFD and LOV diet, respectively) (P = 0.02 for interaction of study group by time). To aid choice, PREFER participants received a printed summary of the primary components of each diet before indicating their preference. In contrast, our procedures mimicked an informed decision-making process by presenting individualized feedback about food preferences assessed by the FPQ followed by verbal and written information about the diets. Our study design also offered participants the opportunity to switch diets at 12 weeks. Another distinction regards the diet options: In the PREFER study, the LOV diet was chosen substantially less often than the LFD, whereas in our study, the LCD was chosen more often than the LFD. Because of these design features, our results might be more generalizable to a clinic setting where commonly desired diet options are offered to patients without a strong preference by using a facilitated decision-making approach. Another difference between the studies was that our sample comprised pri-

Table 2. Estimated Mean Differences of Outcomes for Choice and Comparator Groups, by Time Point*

Measurement	Choice Group	Comparator Group	Mean Difference (Choice − Comparator) (95% CI)	*P* Value
Body weight, *kg*				
Baseline	108.4	108.4	–	
12 wk	104.2	103.9	0.3 (−0.6 to 1.2)	
24 wk	102.0	101.3	0.7 (−0.6 to 2.0)	
36 wk	102.2	101.6	0.6 (−1.0 to 2.3)	
48 wk†	102.7	101.7	1.1 (−0.8 to 2.9)	0.26
Waist circumference, *cm*				
Baseline	45.9	45.9	–	
12 wk	44.0	43.7	0.3 (−0.2 to 0.8)	
24 wk	43.2	43.1	0.2 (−0.4 to 0.8)	
36 wk	43.2	43.1	0.1 (−0.6 to 0.8)	
48 wk‡	43.5	43.1	0.4 (−0.3 to 1.2)	0.28
Diet adherence, *% deviation from goal*				
12 wk	7.2	8.6	−1.3 (−4.9 to 2.2)	
24 wk	7.1	8.4	−1.3 (−4.8 to 2.3)	
36 wk	8.4	8.7	−0.3 (−3.9 to 3.3)	
48 wk§	9.4	10.3	−0.9 (−4.9 to 3.1)	0.66
IWQOL-Lite score				
Total				
Baseline	71.5	71.5	–	
12 wk	77.5	78.3	−0.8 (−3.3 to 1.7)	
24 wk	79.3	81.6	−2.3 (−5.1 to 0.4)	
36 wk	79.8	82.7	−2.9 (−6.0 to 0.2)	
48 wk‖	81.9	82.7	−0.8 (−4.1 to 2.6)	0.65
Physical function				
Baseline	62.7	62.7	–	
12 wk	69.9	70.7	−0.7 (−4.0 to 2.5)	
24 wk	71.4	75.3	−4.0 (−7.4 to −0.5)	
36 wk	71.6	77.1	−5.6 (−9.6 to −1.5)	
48 wk	75.1	76.6	−1.5 (−5.7 to 2.7)	0.49
Self-esteem				
Baseline	65.5	65.5	–	
12 wk	72.3	74.8	−2.5 (−6.6 to 1.6)	
24 wk	76.5	78.4	−1.9 (−6.5 to 2.7)	
36 wk	79.0	79.4	−0.4 (−5.3 to 4.5)	
48 wk	80.3	80.5	−0.2 (−5.2 to 4.9)	0.95
Sex life				
Baseline	76.3	76.3	–	
12 wk	83.5	81.8	1.7 (−3.5 to 6.8)	
24 wk	84.0	84.1	−0.2 (−5.5 to 5.2)	
36 wk	82.9	84.7	−1.8 (−7.1 to 3.5)	
48 wk¶	85.3	85.0	0.3 (−5.9 to 6.4)	0.93
Public distress				
Baseline	87.3	87.3	–	
12 wk	89.4	90.6	−1.2 (−4.3 to 1.9)	
24 wk	91.0	91.6	−0.5 (−3.7 to 2.6)	
36 wk	91.6	91.4	0.2 (−3.1 to 3.5)	
48 wk	90.5	91.3	−0.7 (−4.1 to 2.6)	0.67
Work				
Baseline	81.9	81.9	–	
12 wk	86.2	87.1	−0.9 (−4.0 to 2.2)	
24 wk	87.4	88.9	−1.5 (−5.0 to 2.0)	
36 wk	87.7	89.3	−1.5 (−5.5 to 2.5)	
48 wk**	89.6	90.3	−0.7 (−4.9 to 3.5)	0.73
Change from baseline in walking, *min/wk*††				
12 wk	6.0	4.4	1.6 (−37.3 to 40.6)	
24 wk	6.0	2.7	3.2 (−74.6 to 81.1)	
36 wk	5.9	1.1	4.9 (−112.0 to 121.7)	
48 wk‡‡	5.9	−0.6	6.5 (−149.3 to 162.2)	0.93

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Table 2–Continued

Measurement	Choice Group	Comparator Group	Mean Difference (Choice − Comparator) (95% CI)	*P* Value
Change from baseline in moderate physical activity, *min/wk*††				
12 wk	21.8	59.4	−37.6 (−101.7 to 26.6)	
24 wk	26.3	67.5	−41.1 (−142.3 to 60.0)	
36 wk	18.5	29.2	−10.7 (−140.0 to 118.5)	
48 wk‡‡	−1.5	−55.1	53.6 (−124.7 to 231.9)	0.55

IWQOL-Lite = Impact of Weight on Quality of Life-Lite questionnaire.
* Values are means estimated by linear mixed-effects models. Model estimated means for each measurement were constrained to be equal between the choice and comparator groups at baseline. Mean differences may not compute from displayed data due to rounding.
† Missing for 18 participants from the choice group and 14 participants from the comparator group.
‡ Missing for 19 participants from the choice group and 14 participants from the comparator group.
§ Missing for 26 participants from the choice group and 21 participants from the comparator group.
‖ Missing for 26 participants from the choice group and 18 participants from the comparator group.
¶ Missing for 28 participants from the choice group and 22 participants from the comparator group.
** Missing for 27 participants from the choice group and 18 participants from the comparator group.
†† Assessed with the International Physical Activity Questionnaire.
‡‡ Missing for 28 participants from the choice group and 19 participants from the comparator group.

marily men and was more racially mixed, an important distinction because men and minority groups are underrepresented in weight-loss trials (36, 37).

Another study examined the relationship between diet preference and outcomes in a standard randomized trial comparing the LCD and the LFD (38). In that study, participants did not have the opportunity to choose their diet; rather, their preference was assessed on a Likert-type scale before and after random assignment to one of the diets. In analyses, participants who received their baseline preference actually lost statistically significantly less weight (−7.7 kg) than those who did not receive their baseline preference (−9.7 kg) (P = 0.04 for comparison) or those who did not express a preference (−11.2 kg) (P < 0.001 for comparison).

These results converge to suggest that providing a choice of diets to patients does not enhance and may even hinder weight loss. One reason may be that persons are more likely to overeat when following a diet that emphasizes foods they find palatable. Palatability is a major determinant of food intake and total caloric intake (39–41). Another reason may be a "personal trainer" effect, in which persons may be more adherent to a fitness program if directed on what exercises to do rather than choosing on their own.

An unexpected finding was that few of the choice group participants elected to switch diets at 12 weeks. We purposely chose this time point so that participants would have had ample time to learn and experience the initial diet choice before having the opportunity to switch but also would not yet have reached the period at 4 to 6 months when weight loss typically plateaus, which might have led some participants to switch even though the diet was a good fit.

An interesting result was that the FPQ categorized a higher percentage of participants as having food preferences aligning with the LCD compared with the LFD. This may have at least partially resulted from participant demographic characteristics, given that our sample comprised predominantly men and research has shown that men are more likely to prefer foods that are high in fat (39, 42). Nevertheless, the ultimate diet choice breakdown was more balanced, with 58% choosing the LCD and 42% choosing the LFD, and sensitivity analyses adjusting for diet type mirrored the primary results.

Having predominantly men in the sample might limit the generalizability of our results, as could the age of the sample. Having more than 2 diet options might have had broader appeal for participants but would have been logistically difficult, so we chose the 2 diets that we believed had the strongest evidence base and greatest appeal in our patient population yet were diverse in macronutrient content. Advising participants not to enroll if they had a strong aversion to one of the diets may have weakened the potential beneficial effect of choice on adherence but occurred rarely (n = 2) and was done to minimize differential attrition between the groups. An additional difficulty we faced was analyzing dietary adherence when each group included 2 diets with different macronutrient goals. We used the Block Brief FFQ, which is known to underestimate energy and macronutrient intake, and calculated the percentage of deviation from the macronutrient goal, which did not perfectly reflect the carbohydrate goal in the LCD or the energy goal in the LFD. Any inaccuracy, however, should have existed similarly in both study groups.

Offering choice among diet options did not improve weight loss, dietary adherence, or weight-related quality of life in participants who did not have a strong diet preference at baseline. Given that diverse diets have been shown to be effective for weight loss, future research might examine matching patients to their optimal diet on the basis of other characteristics (such as metabolic profile or genetics) instead of their preferences.

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cal Research Center, Louisiana State University, Baton Rouge, Louisiana.

Note: Drs. Coffman and Smith conducted the data analysis. Drs. Yancy and Coffman, who are affiliated with the Durham VAMC and Duke University Medical Center, had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Disclaimer: This article is the result of work done with resources and the use of facilities at the Durham VAMC. The views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs, the U.S. government, Duke University, Pennington Biomedical Research Center, Louisiana State University, or Virginia Commonwealth University.

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Reproducible Research Statement: *Study protocol and statistical code:* The authors are willing to share the study's protocol and statistical code to approved persons through written agreements with the authors (e-mail, yancy006@mc.duke.edu) and as approved by the Durham VAMC Institutional Review Board. *Data set:* Not available.

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Statistical expertise: C.J. Coffman, V.A. Smith.
Obtaining of funding: W.S. Yancy, C.J. Coffman, P.J. Geiselman, C.I. Voils.
Administrative, technical, or logistic support: W.S. Yancy, C.J. Coffman, E.Z. Oddone.
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Appendix: Technical Appendix

Model Selection and Fitting Process

The process for selecting the best model for each outcome involved 2 steps. First, we determined the "best" covariance structure by fitting "hybrid" models with a random effect for group and different covariance structures, including compound symmetry, autoregressive (1), Toeplitz, exponential, power, and unstructured, for the serial correlation between time points and a set of random coefficient models that included a random effect for group and random intercept and linear slope for participants, as well as a random effect for group and random intercept, random linear slope, and random quadratic slope. These models were fit using restricted likelihood estimation, and Akaike information criteria (AIC) for model selection (43) were assessed to determine the best-fit model.

Second, we used the covariance structure identified in step 1 for each outcome to determine the best mean structure. In this step, we fit separate models using linear time, quadratic time, cubic time, and quartic time for the fixed effects for each outcome. These models were fit using maximum likelihood estimation, and AIC model selection criteria were assessed to determine the best-fit model.

Following this process for each outcome, we ran the "best-fit" model including stratification variables and estimated group differences at 48 weeks from these models. All of the final models were fit using restricted likelihood estimation. The final model for weight was determined by this process and accounted for the covariance in weight within individual over time by using a spatial correlation structure [SP(EXP)(week)]. This model was used for all subsequent sensitivity analyses.

Multiple Imputation Procedure

We conducted a sensitivity analysis using a multiple imputation approach that included additional variables beyond those in our random-effects models to strengthen the MAR assumption. As a first step, we used *t* tests and chi-square tests as appropriate to assess the association of each potential variable with missingness at week 48, and any variable with an association *P* value of 0.1 or less was included in the imputation model. Variables assessed included age, race, smoking status, waist size at baseline, education level, systolic and diastolic blood pressures at baseline, diet preference at baseline, a scale of how successful the participant believed they would be at losing weight, whether the participant had attempted weight loss previously, the number of persons living in the participant's household, socioeconomic status, employment status, number of minutes spent walking per week, number of minutes of moderate exercise per week, which diet the participant was following (LCD vs. LFD), and 6 quality-of-life scores (physical function, self-esteem, sex life, public distress, work, and total). Of these, the following were associated with missing status at week 48 and were therefore included in the imputation model: number of persons living in the household, employment status, age, number of minutes of moderate exercise per week, and public distress quality-of-life score. The imputation model also included randomization group, stratification variables (sex, type 2 diabetes status, and BMI category), and all collected weight measurements at the 19 possible time points. Missing weight measurements at any of the 19 time points were imputed using a Markov-chain Monte Carlo algorithm with 10 imputations. The imputation provided results similar to those of the primary analysis. Models run on the imputed data sets estimated weight loss to be 1.3 kg less (CI, −3.1 to 0.6 kg; $P = 0.17$) in the choice group than the comparator group.

Web-Only Reference

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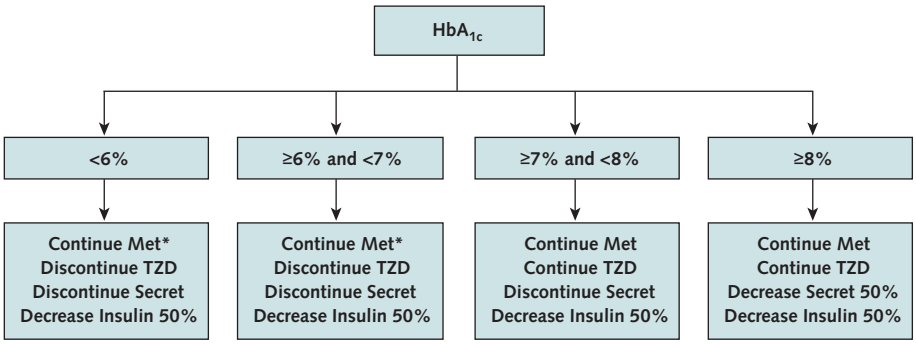
Appendix Figure 1. Initial diabetes medication adjustment.

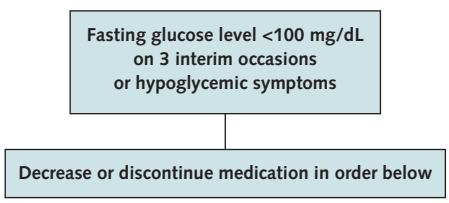


*If monotherapy, then metformin will be decreased 50% for HbA_{1c} <7%.
Alpha-glucosidase inhibitors will be stopped for the duration of the study.
Incretin/amylin agonists will not be adjusted initially.

Rationale
1) If glycemic control is only fair, then continue insulin sensitizers
2) Discontinue secretagogues that increase the risk of hypoglycemia
3) Reduce insulin because of reduced dietary carbohydrate and/or energy intake
4) If fair/poor control and on no medication, start without medication and assess at 2 weeks

HbA_{1c} = hemoglobin A_{1c}; Met = metformin; Secret = secretagogues; TZD = thiazolidinediones.

Appendix Figure 2. Medication adjustment for follow-up hypoglycemia in patients taking medication in addition to metformin.



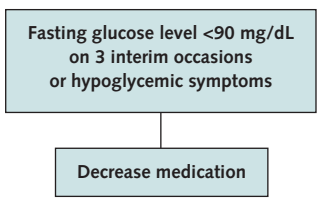
Hypoglycemia defined as >1 "unassisted" episodes, or 1 "assisted" episode (requiring emergency medical care) in the previous 2 weeks.

Decrease medications as follows:
Oral agents: 50% reduction in dose
Insulin: 50% reduction in total daily dose

Order of discontinuation of medication:
First removed: insulin or secretagogues based on patient preference
Then: thiazolidinediones
Then: metformin and GLP-1/amylin agonists

GLP-1 = glucagon-like peptide-1.

Appendix Figure 3. Medication adjustment for follow-up hypoglycemia in patients taking metformin only.

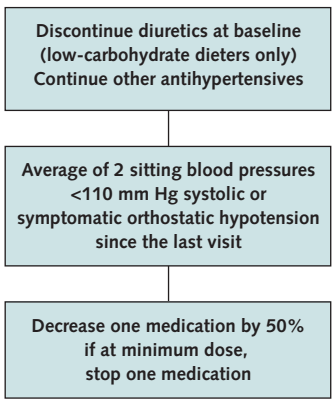


Hypoglycemia defined as >1 "unassisted" episodes, or 1 "assisted" episode (requiring emergency medical care) in the previous 2 weeks.

Decrease metformin with the following stepwise changes:
a) 1000 mg am/1000 mg pm
b) 1000 mg am/500 mg pm
c) 500 mg bid
d) 500 mg qd
e) discontinue

am = morning; bid = twice daily; pm = evening; qd = every day.

Appendix Figure 4. Medication adjustment for hypertensive patients taking medication.

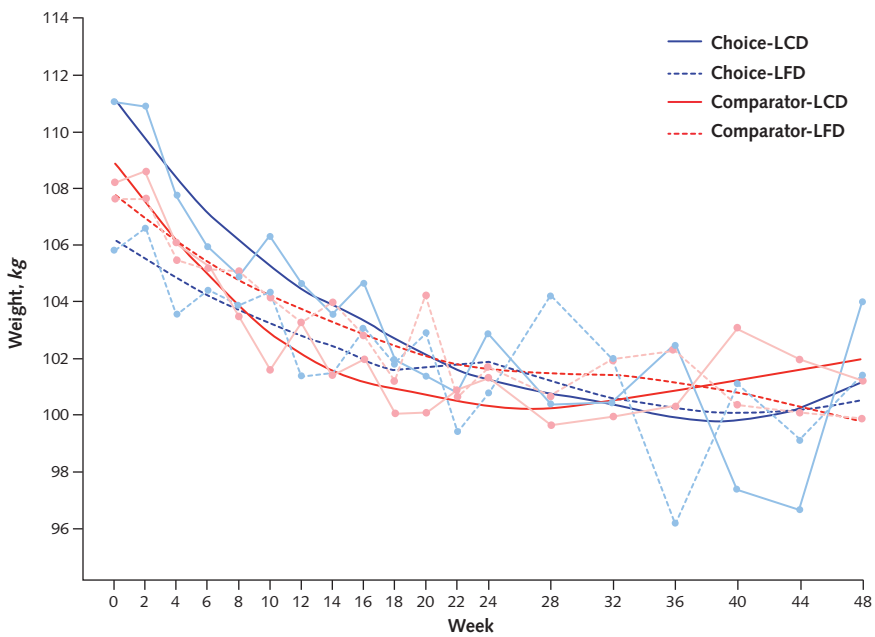


Orthostatic hypotension is defined as dizziness or lightheadedness when changing from sitting to standing position.

If a low-carbohydrate diet participant is receiving high-dose diuretic at baseline for edema, this may be halved rather than discontinued.

After 1 month, low-dose diuretics may be restarted (or doses can be returned to baseline if blood pressure is elevated).

Appendix Figure 5. Smoothed spline trajectories of weight over 48 wk, by diet type and group (*dark blue* and *red lines*), and observed mean trajectories of weight over 48 wk, by diet type and group (*light blue* and *pink lines*).



Participants, *n*																			
Choice	105	100	89	82	79	76	87	78	67	71	65	62	84	61	55	80	49	47	87
Comparator	102	97	92	92	89	80	88	76	77	68	68	73	92	68	63	81	53	62	88

LCD = low-carbohydrate diet; LFD = low-fat diet.

Appendix Table. Dietary Intake and Diet Knowledge, by Study Group and Time Point*

Variable	Choice Group		Comparator Group	
	Low-Carbohydrate Diet (*n* = 61)†	Low-Fat Diet (*n* = 44)‡	Low-Carbohydrate Diet (*n* = 53)	Low-Fat Diet (*n* = 49)
Energy, *kcal/d*				
Baseline	2010 (1156)	1631 (736)	1584 (642)	2210 (1695)
12 wk	1083 (508)	957 (431)	1168 (493)	1307 (741)
24 wk	1085 (611)	985 (419)	970 (434)	1158 (591)
36 wk	1158 (602)	968 (353)	998 (391)	1169 (550)
48 wk	1212 (614)	937 (303)	1042 (431)	1259 (751)
Carbohydrates, *g/d*				
Baseline	203 (110)	182 (84)	172 (77)	236 (202)
12 wk	45 (38)	110 (51)	56 (40)	151 (86)
24 wk	54 (58)	117 (55)	47 (36)	135 (69)
36 wk	66 (57)	118 (60)	49 (32)	134 (66)
48 wk	79 (67)	117 (44)	60 (41)	145 (90)
Carbohydrates, *% daily kcal*				
Baseline	41.6 (7.4)	45.4 (8.6)	43.8 (8.3)	41.6 (6.5)
12 wk	16.8 (9.3)	47.3 (10.3)	19.6 (11.9)	46.3 (7.6)
24 wk	19.0 (10.7)	48.1 (12.0)	19.8 (11.8)	46.9 (7.4)
36 wk	22.4 (12.6)	47.5 (12.0)	20.4 (10.6)	46.1 (7.5)
48 wk	24.8 (13.8)	51.3 (12.2)	23.5 (13.2)	46.3 (8.3)
Total fat, *g/d*				
Baseline	97 (66)	72 (37)	72 (32)	103 (77)
12 wk	73 (35)	38 (20)	75 (32)	54 (34)
24 wk	70 (36)	39 (21)	63 (28)	48 (26)
36 wk	71 (36)	37 (13)	64 (28)	48 (24)
48 wk	74 (40)	35 (16)	65 (31)	53 (34)
Total fat, *% daily kcal*				
Baseline	42.2 (5.0)	38.7 (7.5)	40.8 (7.4)	42.5 (5.4)
12 wk	60.5 (9.0)	35.2 (8.8)	57.8 (10.6)	37.2 (6.4)
24 wk	58.3 (11.4)	35.0 (8.8)	58.3 (9.9)	36.8 (6.6)
36 wk	55.4 (11.8)	34.9 (9.1)	57.4 (8.4)	36.8 (5.5)
48 wk	55.4 (11.2)	32.6 (8.5)	55.8 (11.5)	37.6 (6.1)
Saturated fat, *g/d*				
Baseline	32 (22)	24 (12)	24 (11)	34 (26)
12 wk	25 (13)	12 (6)	25 (13)	17 (10)
24 wk	23 (12)	13 (7)	21 (10)	15 (8)
36 wk	24 (13)	12 (4)	22 (10)	15 (9)
48 wk	25 (14)	12 (5)	21 (10)	17 (12)
Saturated fat, *% daily kcal*				
Baseline	14.0 (2.4)	13.0 (3.0)	13.3 (2.5)	14.1 (2.0)
12 wk	20.4 (4.2)	11.3 (3.2)	19.2 (4.6)	11.4 (2.0)
24 wk	19.8 (5.6)	11.5 (3.1)	19.1 (4.4)	11.5 (2.2)
36 wk	18.5 (4.9)	11.3 (3.6)	19.3 (4.0)	11.7 (2.9)
48 wk	18.3 (4.6)	11.2 (3.4)	18.3 (4.0)	12.0 (2.5)
Protein, *g/d*				
Baseline	81 (48)	66 (30)	63 (26)	88 (60)
12 wk	62 (33)	43 (22)	67 (34)	61 (34)
24 wk	59 (34)	46 (23)	53 (27)	51 (27)
36 wk	62 (36)	44 (15)	55 (25)	54 (28)
48 wk	61 (34)	43 (20)	53 (27)	55 (31)
Protein, *% daily kcal*				
Baseline	16.4 (2.6)	16.5 (3.5)	16.0 (3.2)	16.4 (2.8)
12 wk	22.9 (4.9)	18.0 (3.3)	22.4 (5.4)	18.6 (2.9)
24 wk	22.1 (4.6)	18.9 (5.6)	21.8 (5.1)	18.0 (3.6)
36 wk	21.2 (5.0)	18.8 (4.1)	21.7 (4.4)	18.4 (3.6)
48 wk	20.2 (5.1)	18.0 (4.3)	20.5 (5.5)	17.6 (3.2)

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Appendix Table–Continued

Variable	Choice Group		Comparator Group	
	Low-Carbohydrate Diet (*n* = 61)†	Low-Fat Diet (*n* = 44)‡	Low-Carbohydrate Diet (*n* = 53)	Low-Fat Diet (*n* = 49)
Low-carbohydrate diet knowledge, *% correct responses*				
12 wk	84 (9)	–	85 (10)	–
24 wk	85 (11)	–	85 (16)	–
36 wk	84 (12)	–	88 (10)	–
48 wk	82 (17)	–	81 (18)	–
Low-fat diet knowledge, *% correct responses*				
12 wk	–	63 (21)	–	73 (18)
24 wk	–	77 (12)	–	75 (11)
36 wk	–	79 (7)	–	78 (12)
48 wk	–	77 (11)	–	78 (10)

* Values are means (SDs).
† After 12 wk, *n* = 60.
‡ After 12 wk, *n* = 45.