Dietary compliance and cardiovascular risk reduction with a prepared meal plan compared with a self-selected diet[1–3]

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See corresponding editorial on page 421.

ABSTRACT Noncompliance with therapeutic diets remains a major obstacle to achieving improvements in cardiovascular disease (CVD) morbidity and mortality. This study compared dietary compliance and CVD risk factor response to two dietary interventions designed to treat hypertension, dyslipidemia, and diabetes mellitus. In a multicenter trial, 560 adults were randomly assigned to either a self-selected, mixed-food plan (n = 277), or a nutrient-fortified prepared meal plan (n = 283); each was designed to provide 15–20% of energy from fat, 55–60% from carbohydrate, and 15–20% from protein. Nutrient intake was estimated from 3-d food records collected biweekly throughout the 10-wk intervention. Compliance was determined by evaluating the participants' ability to meet specific criteria for energy intake [± 420 kJ (100 kcal) from the midpoint of the prescribed energy range], fat intake (< 20%, < 25%, or < 30% of energy from total fat), and the National Cholesterol Education Program/American Heart Association Step 1 and 2 diet recommendations. Compliance with energy, fat, and Step 1 and 2 criteria was better in participants who followed the prepared meal plan than in those who followed the self-selected diet ($P < 0.0001$). Compliant participants in both groups achieved greater reductions in body weight, systolic and diastolic blood pressure, and total and low-density-lipoprotein cholesterol than noncompliant participants ($P < 0.05$). In general, better endpoint responses were observed with lower fat intakes regardless of group assignment. The prepared meal plan is a simple and effective strategy for meeting the many nutrient recommendations for CVD risk reduction and improving dietary compliance and CVD endpoints. *Am J Clin Nutr* 1997;66:373–85.

KEY WORDS Dietary compliance, cardiovascular disease risk factors, dietary fat, cholesterol, saturated fat, hypertension, dyslipidemia, non-insulin-dependent diabetes mellitus, National Cholesterol Education Program, American Heart Association Step 1 and 2 diets, self-selected diet, prepared diet

INTRODUCTION

Diet is the cornerstone of therapy for the treatment of hypertension, dyslipidemia, and diabetes mellitus (1–7). Numerous studies have shown that specific dietary modifications (**Table 1**; 8) can effectively lower elevated blood cholesterol concentrations, decrease high blood pressure, and improve insulin sensitivity in persons with non-insulin-dependent diabetes mellitus (NIDDM) (6, 7). Studies conducted in controlled research settings have shown that clinical endpoint responses to dietary therapy are significant and consistent (9–12); in some persons, diet therapy alone can normalize endpoint measures. However, intervention studies in free-living individuals generally report lower responsiveness and greater variability in endpoint responses with diet therapy (13–16).

Compliance is widely recognized as essential to eliciting maximal responses to diet therapy. Even in patients who initially achieve a desirable clinical response to a therapeutic diet, there is invariably some recidivism over time (17), often resulting in patients becoming discouraged with what they perceive to be ineffective therapy, and ultimately discontinuing prescribed diets. This is particularly problematic for individuals for whom multiple dietary modifications are recommended, such as simultaneous reductions in energy, fat, and sodium intakes.

It has been shown that intensive interventions and close follow-up and monitoring are effective in increasing dietary compliance (18–21). In addition, it is clear that providing food to patients facilitates compliance (22). Although both of these

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TABLE 1
Dietary recommendations of national health organizations for prevention and treatment of chronic diseases[1]

Recommendation	Organization
≤ 30% of energy from total fat	AHA (1), NCEP (2,3), ADA (4), NRC (7)
8–10% of energy from saturated fat	AHA, NCEP (Step 1), ADA, NRC
< 7% of energy from saturated fat	NCEP (Step 2)
≤ 15% of energy from monounsaturated fat	AHA, NCEP, ADA
≤ 10% of energy from polyunsaturated fat	AHA, NCEP, ADA
< 300 mg cholesterol	AHA, NCEP (Step 1)
< 200 mg cholesterol	NCEP (Step 2)
55–60% of energy from carbohydrate	AHA, NCEP, ADA
< 2400 mg Na	AHA, NCEP, ADA, JNC (5)
20–30 g dietary fiber	AHA, NCEP, ADA
RDA for vitamins and minerals	AHA, NCEP, JNC, NRC, DHHS (6)

[1] AHA, American Heart Association; NCEP, National Cholesterol Education Program; ADA, American Diabetes Association; NRC, National Research Council of the National Academy of Sciences; JNC, Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure; DHHS, US Department of Health and Human Services; RDA, recommended dietary allowances (8).

approaches can be effective in free-living individuals, it is important for health professionals recommending nutritional therapy to determine which approach (or combination of both) achieves maximal compliance, or alternatively, what degree of compliance can be achieved with either strategy. Resolution of this question will be important in prescribing effective nutrition programs for reducing the risk of chronic disease.

Using data acquired in the multicenter, randomized Cardiovascular Risk Reduction Dietary Intervention Study (23), we evaluated dietary compliance with two food plans. One was designed to meet the numerous macro- and micronutrient dietary recommendations of major national health organizations (Table 1; 1–8) for the prevention and treatment of hypertension, dyslipidemia, and NIDDM, and the second was developed to be equivalent in total fat, carbohydrate, and protein content. The two interventions were *1*) a prepackaged, nutrient-fortified prepared meal plan that was provided to the participants, and 2) an exchange-based self-selected diet for which participants chose and prepared their own meals based on a prescribed number of food servings using the American Dietetic Association (ADA) exchange lists. In addition, we evaluated and compared the responses to diet in compliant and noncompliant individuals to determine the influence of different dietary compliance criteria on clinical outcomes and thereby validate the efficacy and rationale for dietary therapy for individuals at increased risk of cardiovascular disease (CVD).

SUBJECTS AND METHODS

The study was conducted at 10 clinical centers. The study protocol was approved by the institutional review board at each of the centers, and written informed consent was obtained from each participant before entry into the study.

Participants

Adult men and women with essential hypertension, dyslipidemia, NIDDM, or any combination of these were recruited through outpatient clinics and advertisements (23). Inclusion criteria included the following preliminary criteria: *1*) aged 25–70 y, *2*) body mass index (BMI; kg/m^2) ≤ 42, and *3*) one or more of the following additional criteria:

1) Hypertension: taking no antihypertensive medication, and average sitting systolic blood pressure (SBP) of 140–180 mm Hg, sitting diastolic blood pressure (DBP) of 90–105 mm Hg, or both; or stabilized through use of antihypertensive medications for ≥ 1 mo before the study and average sitting SBP of 135–180 mm Hg or DBP of 85–100 mm Hg.

2) Dyslipidemia: taking no lipid-lowering medication, and total cholesterol concentration of 5.69–7.76 mmol/L (220–300 mg/dL), triacylglycerol concentration of 2.25–11.29 mmol/L (200–1000 mg/dL), or both, or stabilized through use of lipid-lowering medications for ≥ 1 mo before study, and a cholesterol concentration of 5.17–6.72 mmol/L (200–260 mg/dL), triacylglycerol concentration of 2.25–11.29 mmol/L (200–1000 mg/dL), or both.

3) NIDDM: taking no hypoglycemic agents, fasting blood glucose concentration > 7.8 mmol/L (140 mg/dL), and glycated hemoglobin (Hb A_{1c}) concentration ≤ 200% of the median for the assay (≤ 15.4%); or stabilized through use of oral hypoglycemic agents for ≥ 1 mo before study with Hb A_{1c} concentrations 100–175% of the median for the assay (7.7–13.4%).

4) A combination of disorders: meet the criteria for more than one of the above categories.

Exclusion criteria included life-threatening diseases, insulin treatment, being a woman who was pregnant or not practicing birth control, substance or alcohol abuse, and refusal to discontinue vitamin-mineral supplements.

Study design

Baseline period

A 4-wk baseline period (week −4 through 0) preceded the 10-wk treatment period. Participants were advised to maintain their usual diets and were seen weekly for blood pressure and weight measurements. They were instructed on the completion of 3-d food records and two of these were collected during this period. In addition, a physical examination was conducted and fasting blood was collected for measurement of a chemistry profile, plasma insulin and Hb A_{1c} concentrations, and lipid and lipoprotein determinations. Current smoking status, physical activity, and alcohol use were assessed by questionnaire.

Participants were instructed to maintain their current physical activity levels throughout the intervention.

Nutrition prescriptions

At week −2, before random assignment, a nutrition prescription was calculated for each patient by the study nutritionist using the Harris-Benedict equation (24) and an activity factor to estimate the individual's energy needs for weight maintenance or loss. Nutrition prescription calculations were cross-checked by the coordinating center for accuracy. Prescriptions targeted a 840-kJ (200 kcal) range, the lowest being 5040–5876 kJ/d (1200–1399 kcal). Weight loss was limited to 1 kg/wk and to a total of 11 kg for the intervention. Participants not desiring weight loss were prescribed an isoenergetic diet.

Randomization

At week −2, participants were randomly assigned by the coordinating center to either the prepared meal plan or the self-selected diet group, stratified by four diagnostic categories and clinic site. A total of 560 participants were randomly assigned: 153 with hypertension, 162 with dyslipidemia, 148 with NIDDM, and 97 with a combination of these.

Treatment period

Participants consumed either the prepared meal plan or self-selected meals (described below) for 10 wk. They were seen every 2 wk for measurements of blood pressure and weight and collection of a 3-d food record. Fasting blood was collected at weeks 0 and 10 for the measurements described above, at week 4 for glucose and lipoproteins, and again at week 8 for lipoproteins.

Dietary intervention

The total fat, carbohydrate, and protein composition of both nutrition plans was 15–20% of energy from fat, 55–60% from carbohydrate, and 15–20% from protein. The prepared meal plan met nutrient recommendations for sodium, total and saturated fat, cholesterol, fiber, and carbohydrates (Table 1), and was fortified with vitamins and minerals to meet ≥ 100% of the recommended dietary allowance (RDA) for adults (8) for virtually all nutrients, with the exception of vitamin D. For persons desiring weight loss, an energy intake that would achieve a 0.5–1.0-kg loss/wk was prescribed. For all other participants, an energy level was prescribed to maintain their weight.

At week 0, all participants were counseled regarding their assigned therapeutic diet and were provided with educational materials to help them adhere to their program for the 10-wk intervention. In addition to the food-record instructions that participants received in the baseline period, all participants were given at week 0 a supplemental manual containing instructions on food-record collection and their individual nutrition prescriptions. Participants in the self-selected food group also received ADA/American Diabetic Association food exchange lists (25), sample menus, and sample recipes.

The prepared meals were produced by the Campbell Soup Company (Camden, NJ), and included 6 breakfast, 8 lunch, 10 dinner, and 6 snack selections. Meals were ordered by participants at clinic visits and the foods were delivered to their homes. Participants were instructed to consume one serving each day of the breakfast, lunch, and dinner entrees, and to include one serving daily of fruit, vegetables, and low-fat dairy products. Prepackaged snacks or additional entrees were used to adjust the energy of the diet prescription. One optional selection daily was also allowed from a bonus list that included one alcoholic beverage or the energy equivalent in fruit, vegetables, or low-fat dairy products.

Participants in the self-selected diet group were prescribed a specific number of servings from each of the ADA exchange lists that were congruent with providing 15–20% of energy from fat, 55–60% from carbohydrate, and 15–20% from protein. As an example, the 5040–5876-kJ range included the following number of servings from the exchange lists: seven bread/starch, four vegetable, two fruit, two nonfat milk, and three lean meat. Because of the low total fat goal, which allowed consumption of only nonfat dairy products and a limited number of lean meat exchanges, the self-selected diet closely approximated or met the saturated fat and cholesterol goals of the National Cholesterol Education Program and American Heart Association (NCEP/AHA) Step 2 diet. Participants in the self-selected food group were also allowed to select one serving daily from the bonus list. Because of the very low-fat nature of both plans, no further instruction related to achieving specific dietary goals for cholesterol and saturated fat was provided to participants in the self-selected diet group. A monetary allowance was provided weekly for food purchases. All participants received travel compensation at the end of the study.

Dietary methodology

Food records were analyzed for nutrient composition at the coordinating center by using a licensed copy of the University of Minnesota Nutrition Coordinating Center Nutrition Data System (NDS version 2.8, 1995; University of Minnesota, Minneapolis) and the product content of the prepackaged meals provided by the manufacturer. Participants provided two 3-d food records during the baseline period and five during the intervention period, each comprising two nonconsecutive weekdays and one weekend day. Food records were reviewed for detail and completeness by study nutritionists at weeks −2 and −1 during the baseline period and at each clinic visit during the intervention period. Estimated nutrient intakes from all food records collected during the intervention were averaged for determination of dietary compliance.

Nutritionist training

To ensure that participants received uniform dietary instruction from study nutritionists at all centers, a training meeting was held before the beginning of the trial. All nutritionists received NDS-based instruction on the appropriate completion of 3-d food records, determination of diet prescriptions, and implementation of the dietary protocol. The accuracy of all diet prescriptions was cross-checked by the coordinating center. Nutritionists were also trained to instruct participants to collect detailed and accurate food records, and how to instruct participants to adhere to their prescribed diet.

Patient counseling

During the baseline period, participants were provided materials with detailed instructions on how to collect accurate 3-d

food records. At the week 0 visit, participants were told their random assignment (prepared meal plan or self-selected food diet) and given educational materials and verbal instructions for following their prescribed diet plans. Dietary counseling (explanation and advice regarding implementation of the assigned intervention) was provided by the study nutritionists to all participants at weeks 0 and 2. No further diet-specific counseling was provided to participants after the week 2 visit.

Assessment of dietary compliance

Because food records can appropriately be used to monitor group compliance in dietary intervention studies (26), dietary compliance was assessed from 3-d food records by evaluating the ability of participants to meet specific dietary criteria for intakes of energy, percentage of energy from total fat, and the NCEP/AHA Step 1 and 2 dietary recommendations. Baseline nutrient intakes were estimated by averaging nutrient intake from two 3-d food records, collected at weeks −2 and −1; treatment compliance was determined by averaging nutrient intake from each of five 3-d food records collected at weeks 2, 4, 6, 8, and 10.

Energy compliance was determined by calculating the difference between reported energy intake and the midpoint of the prescribed energy range. The energy prescription was in 840-kJ increments (200 kcal), and participants with intakes less than or within 420 kJ (100 kcal) of the midpoint of the prescribed range were considered compliant. Because the fat composition of both prescribed dietary plans averaged 17%, this was used as an index of compliance, albeit somewhat arbitrarily, on the basis of the prescribed diet (≈20%), what we anticipated the self-selected diet could actually achieve based on reports from the Women's Health Trial (≈25%; 27), and what is currently recommended for prevention and treatment of CVD (< 30%; 3). Because both prescribed plans were very low in total fat, the proportion of participants who were able to meet the NCEP/AHA Step 1 and Step 2 dietary guidelines, which include criteria for intake of total fat, saturated fat, and cholesterol, was also determined. The recommended total fat intake is < 30% of energy to meet Step 1 and Step 2 guidelines. Step 1 recommendations specify a daily dietary intake of < 300 mg cholesterol and 8–10% of energy from saturated fat; Step 2 recommendations specify < 200 mg cholesterol and < 7% of energy from saturated fat.

Outcome measurements

A manual of operations was developed for the study detailing routine and standardized methods for all measurements obtained in this trial. Joint training programs were held for all study personnel at the 10 sites to provide uniform instructions for blood pressure measurement, collection of blood samples, and sample handling. For assessment of each of the biochemical measures, a central Centers for Disease Control and Prevention–certified laboratory was used, and all data from the laboratories was provided to the coordinating center. Each study site and laboratory was monitored periodically by coordinating center personnel during the study for compliance with all protocol procedures.

Blood pressure was determined in accordance with the recommendations of the AHA (28). Plasma lipoproteins were determined at the Northwest Lipid Research Laboratories, University of Washington. Total cholesterol was measured by the colorimetric enzymatic endpoint method (Abbott Spectrum Analyzer; Abbott Laboratories, Abbott Park IL). High-density-lipoprotein (HDL) cholesterol was analyzed by the heparin-manganese method (29). Low-density-lipoprotein (LDL) cholesterol was calculated by using the Friedewald algorithm (30). Insulin was measured by using a solid-phase radioimmunoassay (RIA, Coat-A-Count; Diagnostic Products, Los Angeles) at the Hormone and Mineral Laboratory, Oregon Health Sciences University, Seattle. Glucose concentration and blood chemistry values were measured by SmithKline Beecham Clinical Laboratories, Seattle.

Statistical analysis

The study was designed to detect differences between treatment groups of 3 mm Hg in blood pressure, 0.25 mmol/L (10 mg/dL) in plasma cholesterol, 0.23 mmol/L (20 mg/dL) in triacylglycerols, 0.56 mmol/L (10 mg/dL) in plasma glucose, and a 1% difference in Hb A_{1c}. With a power ≥ 80% and a two-sided α of 0.05, these differences were detectable with a sample of 80 in each group based on variation as defined in a preliminary study.

All data except weight were averaged over the baseline period when multiple measures were available. Weight at week 0 was considered baseline weight. For blood pressure and lipoproteins, measurements at weeks 8 and 10 were averaged for computation of the compliance effect. On the basis of an intention-to-treat analysis, the last available measurement in the treatment period was used for participants who did not complete the study. Nine participants in the prepared meal group and three in the self-selected diet group left the study after random assignment but before beginning treatment and were not included in the analysis. A repeated-measures analysis of variance model was used to analyze differences between baseline and treatment periods.

Changes in nutrient intake from baseline to treatment were analyzed by using analysis of variance with repeated measures. When treatment differences in baseline nutrient intake existed ($P < 0.01$), analysis of covariance of the change scores with baseline as the covariate was used to control for baseline intake. Change scores for nutrients that were different between treatments at baseline were adjusted to the overall average at baseline. For analysis of change in endpoint responses, a repeated-measures analysis of variance was used to determine whether at the end of the treatment period, endpoint responses had changed significantly from baseline.

For analysis of the proportion of participants meeting dietary compliance criteria, and the compliance-endpoint responses, chi-square tests were used to detect independence of categorical factors. The effect of dietary compliance on endpoints was determined across treatment groups by two-way analysis of variance with compliance and treatment as the main effects, and compliance by treatment as the interaction. Univariate analysis of variance was used for comparing mean differences in continuous outcomes. All values are presented as means ± SDs. All observed P values are reported as two-sided with the level of significance set at $P < 0.05$.

RESULTS

The demographic characteristics of the study population are shown in **Table 2**. The 560 participants included 314 women and 246 men; average age was 54 y (range: 26–70 y). The cohort was 85% white, 10% African American, 2% Hispanic, 2% Asian or Pacific Islander, and 1% Native American. There were no significant differences in the distribution of age, sex, ethnicity, BMI, current smoking status, habitual alcohol use, level of education, or physical activity between treatment or diagnostic groups, with the exception of the dyslipidemia group in which there were more African American and Hispanic participants in the self-selected diet group ($P = 0.01$). A week 10 visit was completed by 92% of the prepared meal group and 97% of the self-selected diet group ($P = 0.04$).

Changes in average daily nutrient intakes from baseline to the end of treatment stratified by sex and treatment group, are shown in **Table 3**. Within each treatment group, participants reported significantly decreased energy intake and significantly changed intake of all nutrients over the study period ($P < 0.05$) with the exception of protein for women in the prepared meal group ($P = 0.48$). When comparing nutrient changes between diets, there were greater reductions in reported intakes of total fat; percentage energy from total, saturated, and monounsaturated fat; cholesterol; and sodium in participants following the prepared meal plan than in those following the self-selected diet ($P < 0.001$). There were greater increases in reported intakes of percentage energy from carbohydrate, and as expected because of fortification, in calcium, fiber, potassium, magnesium, and folate intakes in participants consuming the prepared meal plan compared with those consuming the self-selected diet ($P < 0.001$).

The percentage of participants meeting criteria for energy, fat, and compliance with Step 1 and 2 diets are shown in **Figure 1**. Across all definitions of compliance, participants following the prepared meal plan were significantly more compliant with their diet prescriptions than were participants in the self-selected diet group ($P < 0.0001$). Energy compliance (below or within the prescribed energy range) was achieved by 83% of prepared meal plan participants compared with 72% of the self-selected diet participants. As expected, percentage compliance increased in both groups as the definitions for fat compliance became more liberal. At the level of < 20% of energy from fat, 78% of prepared meal plan participants compared with 23% of self-selected diet participants achieved compliance; at the level of < 25% of energy from fat, 93% of the prepared meal plan participants compared with 56% of the self-selected diet participants achieved compliance; and at the level of < 30% of energy from fat, 95% of prepared meal participants compared with 78% of self-selected diet participants achieved compliance.

In addition, participants following the prepared meal plan were better able to meet the NCEP/AHA Step 1 and 2 recommendations than was the self-selected diet group. In the prepared meal plan group, 97% of participants met Step 1 recommendations compared with 73% of the self-selected diet group. Step 2 recommendations were achieved by 81% of the prepared meal group and 41% of the self-selected diet group. Because of the high proportion of participants following the prepared meal plan that reported low fat intakes, the number of participants comprising the noncompliant groups in the higher fat compliance categories was very small: < 25% fat—3% noncompliance ($n = 9$); < 30% fat—1% noncompliance ($n = 3$); and Step 1—3% noncompliance ($n = 7$).

Changes in study endpoints from baseline to the end of treatment stratified by sex and treatment group are shown in **Table 4**. Within treatment groups, significant reductions were observed for SBP and DBP ($P < 0.0001$), plasma cholesterol ($P < 0.0001$), triacylglycerols for the self-selected diet group ($P < 0.01$) and for men in the prepared meal plan group ($P < 0.05$), LDL cholesterol ($P < 0.001$), HDL cholesterol for the prepared meal plan group ($P < 0.01$) and for women in the self-selected diet group ($P < 0.001$), very-low-density-lipoprotein (VLDL) cholesterol for the self-selected diet ($P < 0.01$) and for men following the prepared meal plan ($P < 0.05$), insulin ($P < 0.5$), Hb A_{1c} ($P < 0.0001$), glucose ($P < 0.001$), and body weight ($P < 0.0001$). Between treatment groups, significantly greater reductions in SBP and DBP ($P < 0.05$, men) and body weight ($P < 0.05$) were observed in participants following the prepared meal plan compared with the self-selected diet.

The effects of dietary compliance on study endpoints are shown in **Figures 2–4**. These figures represent the change in

TABLE 2
Demographic characteristics of study participants

	Prepared meal plan ($n = 283$)		Self-selected diet ($n = 277$)	
	Men ($n = 114$)	Women ($n = 169$)	Men ($n = 132$)	Women ($n = 145$)
Age (y)	55 ± 10[1]	54 ± 10	53 ± 9	54 ± 9
Race (%)				
White	84	85	86	83
African American	13	9	8	11
Other	3	6	6	6
BMI (kg/m^2)	31 ± 4	31 ± 5	31 ± 4	31 ± 5
Current smokers (%)	16	9	12	10
Alcohol intake (%)[2]	56	48	62	54
Education (y)	15.0 ± 3.0	14.2 ± 2.7	14.9 ± 3.0	13.8 ± 2.5

[1] $\bar{x}$ ± SD.
[2] Percentage reporting more than one serving within the past month.

TABLE 3
Changes in reported daily nutrient intakes in study participants stratified by sex and treatment group from baseline to the end of treatment[1]

	Prepared meal plan			Self-selected diet		
	Baseline (n = 169 W, 114 M)	Treatment (n = 163 W, 109 M)	Change (n = 163 W, 109 M)	Baseline (n = 145 W, 132 M)	Treatment (n = 142 W, 128 M)	Change (n = 142 W, 128 M)
Women						
Energy						
(kJ)	7442 ± 1932[2]	6031 ± 1210	−1371	7424 ± 2077	5821 ± 1356	−1625
(kcal)	1772 ± 460	1436 ± 288	−327	1768 ± 494	1386 ± 323	−387
Protein (g)	74 ± 18	72 ± 11	−1[3]	72 ± 19	67 ± 15	−6
Carbohydrate (g)	227 ± 65	217 ± 43	−10	217 ± 65	201 ± 51	−17
Total fat (g)	65 ± 25	29 ± 11	−35	69 ± 27	37 ± 15	−31
Energy from fat (%)	32 ± 7	18 ± 3	−14[3]	34 ± 6	24 ± 6	−10
Energy from protein (%)	17 ± 3	20 ± 2	3	17 ± 3	20 ± 3	3
Energy from carbohydrate (%)	52 ± 8	61 ± 4	9	49 ± 7	58 ± 6	9
Energy from SFA (%)	10.9 ± 3.0	6.2 ± 1.3	−4.7[3]	11.4 ± 2.8	7.5 ± 2.1	−3.8
Saturated fat (g)	22 ± 10	10 ± 4	−12	23 ± 10	12 ± 5	−11
Energy from PUFA (%)	6.6 ± 1.9[4]	4.6 ± 0.7	−2.0	7.2 ± 2.0[4]	5.2 ± 1.7	−2.0
PUFA (g)	13.2 ± 5.6	7.4 ± 2.5	−6	14.2 ± 6.1	8.1 ± 3.3	−6
Energy from MUFA (%)	12.2 ± 3.1	6.2 ± 1.5	−5.9[3]	13.1 ± 2.7	8.9 ± 2.6	−4.1
MUFA (g)	25 ± 10	10 ± 4	−14	26 ± 11	14.2 ± 6.1	−12
Cholesterol (mg)	219 ± 107	104 ± 47	−109[3]	226 ± 105	146 ± 61	−79
Calcium (mg)	787 ± 297	1726 ± 295	937[3]	730 ± 245	801 ± 242	69
Fiber (g)	19.2 ± 7.3	30.4 ± 5.4	11.2[3]	18.0 ± 6.0	20.9 ± 6.4	2.8
Potassium (mg)	2748 ± 754	3980 ± 662	1229[3]	2649 ± 621	2909 ± 718	241
Sodium (mg)	3110 ± 947	2274 ± 462	−790[3]	3049 ± 971	2697 ± 758	−352
Magnesium (mg)	291 ± 80	573 ± 91	282[3]	277 ± 72	290 ± 74	12.1
Folate (μg)	275 ± 105	649 ± 113	374[3]	254 ± 82	306 ± 98	49
Men						
Energy						
(kJ)	9332 ± 2612[4]	7768 ± 1631	−2002[5]	10 466 ± 3114[4]	8097 ± 1766	−1929[5]
(kcal)	2222 ± 622[4]	1849 ± 388	−477[5]	2492 ± 741[4]	1928 ± 421	−459[5]
Protein (g)	92 ± 25[4]	86 ± 15	−10[5,6]	102 ± 31[4]	92 ± 20	−6[5]
Carbohydrate (g)	267 ± 86	287 ± 60	20[3]	291 ± 94	270 ± 69	−18
Total fat (g)	87 ± 33[4]	37 ± 14	−56[5,6]	101 ± 38[4]	55 ± 19	−40[5]
Energy from fat (%)	35 ± 7	18 ± 3	−17[3]	36 ± 7	26 ± 7	−10
Energy from protein (%)	17 ± 3	19 ± 2	2[3]	17 ± 3	19 ± 3	3
Energy from carbohydrate (%)	48 ± 8	62 ± 4	14[3]	47 ± 8	56 ± 7	9
Energy from SFA (%)	11.5 ± 2.9	6.3 ± 1.1	−5.1[3]	11.9 ± 2.9	8.2 ± 2.7	−3.7
Saturated fat (g)	29 ± 12[4]	13 ± 5	−18[5,6]	34 ± 14[4]	18 ± 7	−14[5]
Energy from PUFA (%)	7.0 ± 2.0	4.5 ± 0.7	−2.5	7.3 ± 2.1	5.3 ± 1.4	−2.0
PUFA (g)	17.4 ± 8.0[4]	9.2 ± 2.8	−10[5,6]	20.5 ± 9.5[4]	11.4 ± 3.8	−8[5]
Energy from MUFA (%)	13.5 ± 3.0	6.1 ± 1.3	−7[3]	13.8 ± 2.9	9.7 ± 2.8	−4
MUFA (g)	34 ± 13[4]	13 ± 5	−23[5,6]	39 ± 15[4]	21 ± 8	−16[5]
Cholesterol (mg)	310 ± 136	114 ± 51	−193[3]	347 ± 156	219 ± 82	−127
Calcium (mg)	886 ± 323	2125 ± 399	1236[3]	951 ± 407	1054 ± 396	125
Fiber (g)	21.7 ± 7.9	35.9 ± 6.6	14.2[3]	22.6 ± 8.1	27.1 ± 8.5	4.9
Potassium (mg)	3248 ± 933	4780 ± 845	1532[3]	3413 ± 1031	3873 ± 1114	494
Sodium (mg)	3880 ± 1124[4]	2625 ± 578	−1444[5,6]	4344 ± 1536[4]	3794 ± 1140	−380[5]
Magnesium (mg)	345 ± 109	692 ± 132	347[3]	363 ± 113	391 ± 108	32
Folate (μg)	309 ± 116	749 ± 131	441[3]	335 ± 131	415 ± 150	86

[1] All nutrient changes within treatment groups were significantly different from baseline, $P < 0.001$, except for magnesium in the self-selected diet group women, $P < 0.05$, and self-selected group men, $P < 0.01$; protein in prepared meal group women, $P = 0.48$, and all men, $P < 0.01$; carbohydrate in prepared meal group women and all men, $P < 0.05$. SFA, saturated fatty acids; PUFA, polyunsaturated fatty acids; MUFA, monounsaturated fatty acids.
[2] $\bar{x}$ ± SD.
[3] Significantly different from the change in the self-selected diet, $P < 0.05$.
[4] Significant difference in nutrient intake between groups, $P < 0.01$.
[5] Adjusted changes.
[6] Significantly different from the adjusted change in the self-selected diet, $P < 0.05$.

study endpoints according to different criteria for dietary compliance. Regardless of what criteria were used to assess dietary compliance (ie, energy, total fat, and Step 1 or Step 2 diet goals), participants in each treatment group who met compliance criteria had significantly greater reductions in body weight, SBP, DBP, and total, LDL-, and HDL-cholesterol

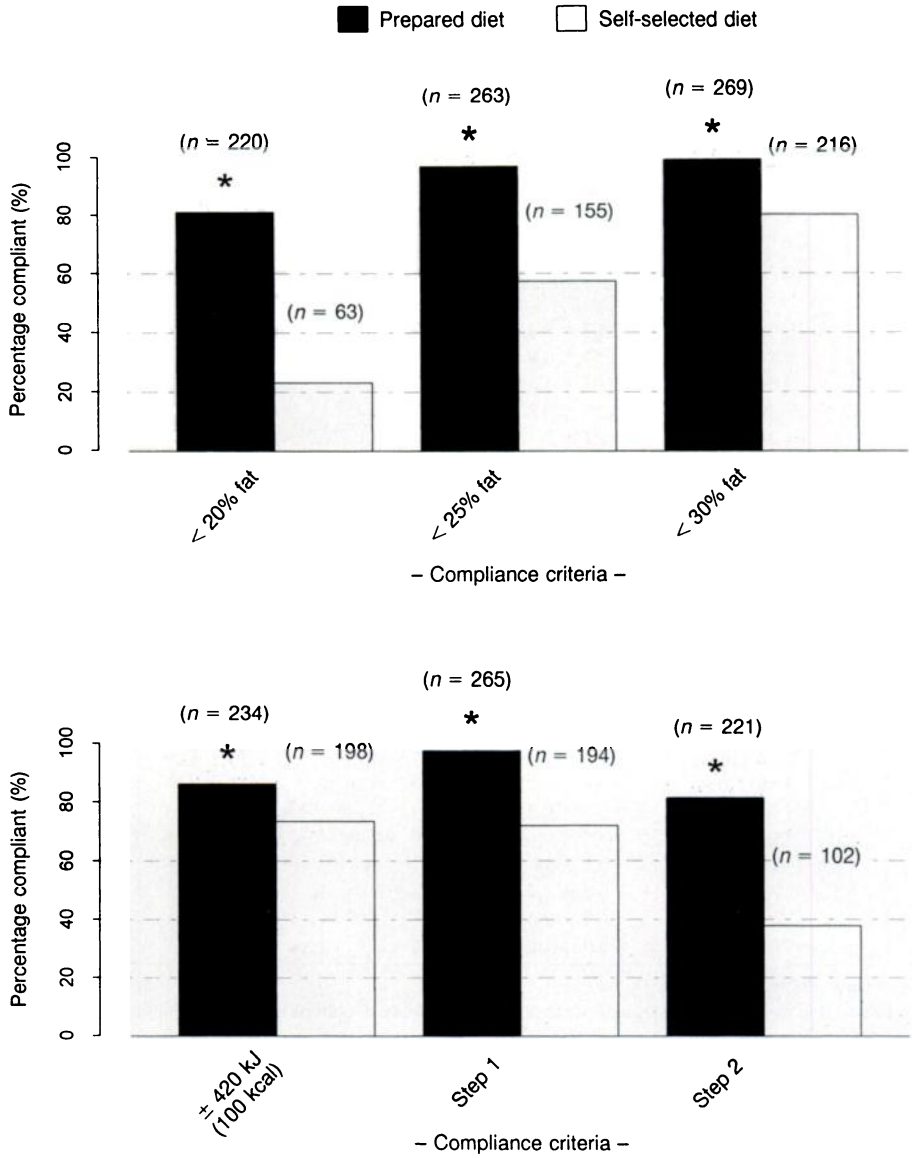

FIGURE 1. Proportion of participants meeting dietary compliance criteria with the prepared meal plan and self-selected diet. Participants meeting compliance criteria who were on the prepared meal plan reported greater compliance ($P < 0.0001$) than did participants following the self-selected diet within each compliance category. *Significantly different from the self-selected diet within compliance categories, $P < 0.0001$.

concentrations compared with noncompliant participants. No significant differences in carbohydrate metabolism were observed between compliant and noncompliant groups except for plasma glucose, which was significantly reduced, regardless of treatment group, in participants who were noncompliant with the energy intake criteria ($P < 0.01$). In general, there was no significant influence of treatment on endpoint responses after compliance was controlled for, except for body weight, for which the effect of treatment was significant ($P < 0.015$) for all compliance criteria, and for SBP and DBP among energy intake criteria only. In addition, the only endpoints for which the effect of compliance differed according to treatment group (compliance by treatment interaction) were DBP ($P < 0.0566$) and LDL cholesterol ($P < 0.008$) within the energy intake category. In general, better endpoint responses were observed with lower fat criteria, and Step 2 criteria resulted in better endpoint responses than did Step 1 criteria. Note that because of the small number of prepared meal plan participants in the noncompliant groups for the higher-fat categories (< 25% fat: $n = 9$; < 30% fat: $n = 3$; and Step 1: $n = 7$), our confidence is limited in the accuracy and stability of the endpoint responses in these subgroups.

DISCUSSION

Noncompliance with therapeutic dietary regimens for the treatment of chronic diseases remains a major obstacle to decreasing disease morbidity and mortality. Depending on the intensity of the intervention, varying degrees of compliance have been reported in studies in which dietary modifications have been used as treatment for one or more chronic conditions (13–21). The primary factors contributing to noncompliance include difficulties of participants in understanding therapeutic

TABLE 4
Changes in study endpoints stratified by sex and treatment group from baseline to end of treatment in study participants[1]

	Prepared meal plan			Self-selected diet		
	Baseline (n = 169 W, 114 M)	Treatment (n = 163 W, 109 M)	Change (n = 163 W, 109 M)	Baseline (n = 145 W, 132 M)	Treatment (n = 142 W, 128 M)	Change (n = 142 W, 128 M)
Women						
Sitting systolic blood pressure (mm Hg)	133.4 ± 15.6	127.4 ± 15.2	−6.1 ± 9.6[2]	132.0 ± 12.0	127.4 ± 13.5	−4.5 ± 9.6[2]
Sitting diastolic blood pressure (mm Hg)	83.2 ± 8.4	79.7 ± 8.3	−3.4 ± 5.4[2]	83.1 ± 7.6	80.3 ± 8.0	−2.7 ± 5.1[2]
Cholesterol (mmol/L)	5.81 ± 0.82	5.55 ± 0.84	−0.27 ± 0.59[2]	5.85 ± 0.85	5.62 ± 0.88	−0.22 ± 0.52[2]
Triacylglycerol (mmol/L)	2.09 ± 1.40	2.03 ± 1.85	−0.07 ± 1.34	2.09 ± 1.43	1.97 ± 1.36	−0.14 ± 0.61[4]
LDL (mmol/L)	3.59 ± 0.87	3.41 ± 0.80	−0.19 ± 0.45[2]	3.57 ± 0.81	3.43 ± 0.77	−0.12 ± 0.43[4]
HDL (mmol/L)	1.24 ± 0.35	1.21 ± 0.33	−0.04 ± 0.14[4]	1.31 ± 0.34	1.28 ± 0.34	−0.03 ± 0.13[4]
VLDL (mmol/L)	0.96 ± 0.64	0.93 ± 0.85	−0.03 ± 0.61	0.96 ± 0.66	0.90 ± 0.63	−0.06 ± 0.28[4]
Insulin (pmol/L)	95.6 ± 67.2	76.9 ± 47.9	−16.5 ± 49.2[2]	107.0 ± 122.0	90.2 ± 78.4	−18.7 ± 91.8[4]
Hb A_{1c} (%)	6.8 ± 1.7	6.5 ± 1.3	−0.3 ± 0.7[2]	6.9 ± 1.8	6.7 ± 1.6	−0.2 ± 0.6[2]
Plasma glucose (mmol/L)	7.1 ± 3.2	6.4 ± 2.8	−0.6 ± 1.9[2]	7.4 ± 3.5	6.8 ± 3.0	−0.6 ± 1.6[2]
Weight (kg)	83.2 ± 15.9	78.4 ± 15.1	−4.8 ± 3.0[2,5]	82.8 ± 16.4	80.1 ± 15.9	−2.8 ± 2.8[2]
Men						
Sitting systolic blood pressure (mm Hg)	133.6 ± 11.8	126.6 ± 11.2	−7.0 ± 8.5[2,6]	135.8 ± 13.6	131.1 ± 15.0	−4.8 ± 8.5[2]
Sitting diastolic blood pressure (mm Hg)	86.8 ± 7.0	81.3 ± 6.9	−5.4 ± 5.9[2,7]	88.1 ± 7.4	84.9 ± 8.3	−3.2 ± 5.1[2]
Cholesterol (mmol/L)	5.55 ± 0.77	5.15 ± 0.77	−0.39 ± 0.57[2]	5.46 ± 0.91	5.13 ± 0.92	−0.33 ± 0.61[2]
Triacylglycerol (mmol/L)	2.29 ± 1.53	2.12 ± 1.44	−0.17 ± 0.75[4]	2.20 ± 1.29	1.99 ± 1.36	−0.21 ± 0.82[4]
LDL (mmol/L)	3.48 ± 0.80	3.19 ± 0.72	−0.30 ± 0.49[2]	3.43 ± 0.87	3.22 ± 0.82	−0.21 ± 0.46[2]
HDL (mmol/L)	1.01 ± 0.25	0.98 ± 0.23	−0.03 ± 0.11[4]	1.01 ± 0.25	1.00 ± 0.22	−0.02 ± 0.10
VLDL (mmol/L)	1.05 ± 0.70	0.97 ± 0.66	−0.09 ± 0.38[4]	1.01 ± 0.59	0.91 ± 0.62	−0.09 ± 0.38[4]
Insulin (pmol/L)	119.0 ± 169.0	89.6 ± 81.1	−27.7 ± 115.0[4]	107.0 ± 83.6	90.9 ± 59.9	−16.7 ± 67.2[4]
Hb A_{1c} (%)	7.2 ± 1.7	6.7 ± 1.4	−0.4 ± 0.9[2]	7.2 ± 1.8	6.7 ± 1.5	−0.5 ± 0.9[2]
Plasma glucose (mmol/L)	7.5 ± 3.2	6.7 ± 2.4	−0.7 ± 1.9[4]	7.9 ± 3.6	7.0 ± 2.8	−0.9 ± 2.4[2]
Weight (kg)	97.2 ± 16.3	92.7 ± 16.1	−4.5 ± 3.6[2,5]	98.7 ± 14.7	95.1 ± 14.7	−3.5 ± 3.3[2]

[1] $\bar{x}$ ± SD. Hb A_{1c}, glycated hemoglobin.
[2–4] Significant changes from baseline to the end of treatment were noted for all study endpoints except for triacylglycerols and VLDL in women in the prepared meal plan group and HDL in men in the self-selected diet group: [2] $P < 0.0001$, [4] $P < 0.001$, [4] $P < 0.05$.
[5–7] Significant change from baseline for diet group: [5] $P < 0.0001$, [6] $P < 0.05$, [7] $P < 0.01$.

diets, the time commitment required for food planning and preparation, and the restrictive nature of many therapeutic plans. Furthermore, prescribed diets for CVD risk reduction typically include multiple dietary modifications that make simplifying dietary compliance a complex and arduous task.

The prepared meal plan was created to circumvent these problems and to incorporate the many risk-reducing dietary guidelines of major health organizations. In so doing, the prepared meal plan also simplified the tasks of portion control, food selection, and meal preparation, while achieving recommended nutrient intakes for CVD risk reduction. The results of this large, well-controlled multicenter trial indicate that dietary compliance was significantly better in participants who followed the prepared meal plan than in those following a self-selected therapeutic diet, and that regardless of the type of dietary intervention, compliant participants achieved significantly better improvements in study endpoints than did noncompliant participants.

As a percentage of total energy intake, the prepared meal plan provides ≈17% fat, 21% protein, and 62% carbohydrate; the self-selected diet matched the prepared meal plan for these three macronutrients. As illustrated by the average change in reported nutrient intakes, participants following the prepared meal plan reported intakes almost identical to the macronutrient composition of the plan, whereas participants consuming the self-selected diet reported higher fat intakes (25% of energy); not surprisingly, it was more difficult to self-select a dietary plan very low in fat and to maintain that low fat intake over 10 wk. Despite this difference in reported fat intake between treatment groups, it is remarkable that with limited dietary instruction, participants following the self-selected diet were able to achieve not only a significant reduction in total fat intake, but also significant reductions in intakes of saturated fat and cholesterol, ie, the majority of self-selected diet participants (73%) were able to achieve a Step 1 diet. The difficulty in achieving the goals of a Step 2 diet as well as a very-low-fat diet (eg, ≈20% of energy from fat) illustrates the advantages of a prepared meal plan in achieving marked reductions in dietary total and saturated fat intake.

It is also likely that there was a differential bias in reported nutrient intake between the two treatment groups. Underreporting can be a result of memory errors, inaccurate portion size estimates, and deliberately false reporting related to the natural tendency of participants to try to please their health care providers (31). Given that average underreporting of nutrient intake is ≈20% in individuals selecting their own foods (31),

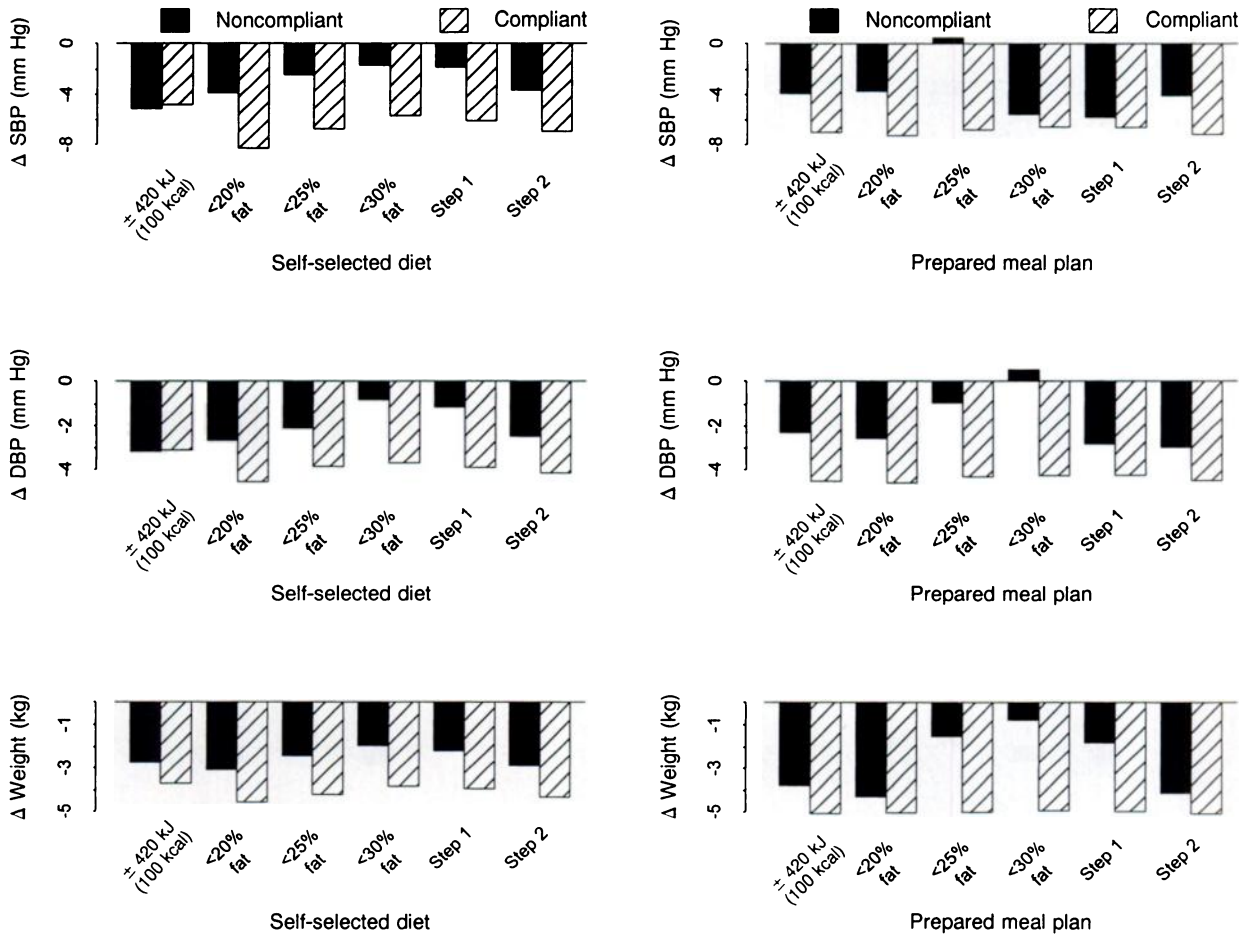

FIGURE 2. Effect of dietary compliance on changes in sitting systolic and diastolic blood pressure (SBP and DBP) and body weight in participants following the prepared meal plan and self-selected diet. Significant compliance effects were found for all compliance criteria, $P < 0.001$, except for the effect of energy compliance on SBP and DBP. The pooled effect of treatment on blood pressure was not significant except for SBP ($P < 0.05$) and DBP ($P < 0.01$) for participants compliant with energy intake criteria. The pooled effect of treatment on body weight was significant for all compliance measures, $P < 0.03$. A borderline significant ($P < 0.0566$) compliance by treatment interaction was noted for DBP within the energy compliance category. Because of the small number of prepared meal plan participants in the noncompliant groups in the higher-fat categories, our confidence is limited in the accuracy and stability of the endpoint responses in these subgroups (*see* Results). (The data set used to construct the figure is available from the authors on request.)

the self-selected diet group reported significantly greater energy restriction (22% for men, 23% for women) than did the prepared meal group (17% for men, 19% for women), yet they experienced less weight loss. Because the prepared foods were provided in predetermined quantities, participants in this group would likely have found it easier to recall the amount of food consumed and therefore were able to more accurately estimate actual intake. By contrast, participants in the self-selected diet group likely underreported nutrient intake to a greater extent than those in the prepared meal plan group, as is typical in free-living subjects who are asked to document their dietary intakes.

Three-day food records provide valid and reliable estimates of current nutrient intake (32) and are known to be a good method of monitoring dietary compliance in dietary intervention trials (26, 32). The use of food records to estimate nutrient intake in diet studies has been criticized because the act of recording itself may produce changes in eating behaviors; because the current study was specifically designed to achieve dietary changes, for our purposes that effect was not seen as a limitation. However, it is possible, and likely unavoidable, that intakes reported during the recording periods differed from intakes throughout the remainder of the intervention.

The prepared meal plan enabled participants to achieve better compliance than participants following the self-selected diet, presumably by providing a simple and convenient dietary program that met all the dietary guidelines recommended by national health organizations (Table 1; 1–8). The plan not only provides recommended macronutrient intakes (low amounts of total fat, saturated fat, and cholesterol) for prevention and treatment of CVD, but also meets the recommendations for modified micronutrient intake including sodium, calcium, potassium, magnesium, folate, and dietary fiber (1–7). As our results show, achieving Step 2 recommended intakes in a self-selected diet by using a typical nutritional counseling paradigm is somewhat more difficult. Compliance in the prepared meal plan group was likely enhanced further by elimination of the complexities associated with "healthy" meal planning and preparation, as well as by the provision and home delivery of the foods.

The present study showed that, independent of the type of dietary intervention, compliant participants had significantly

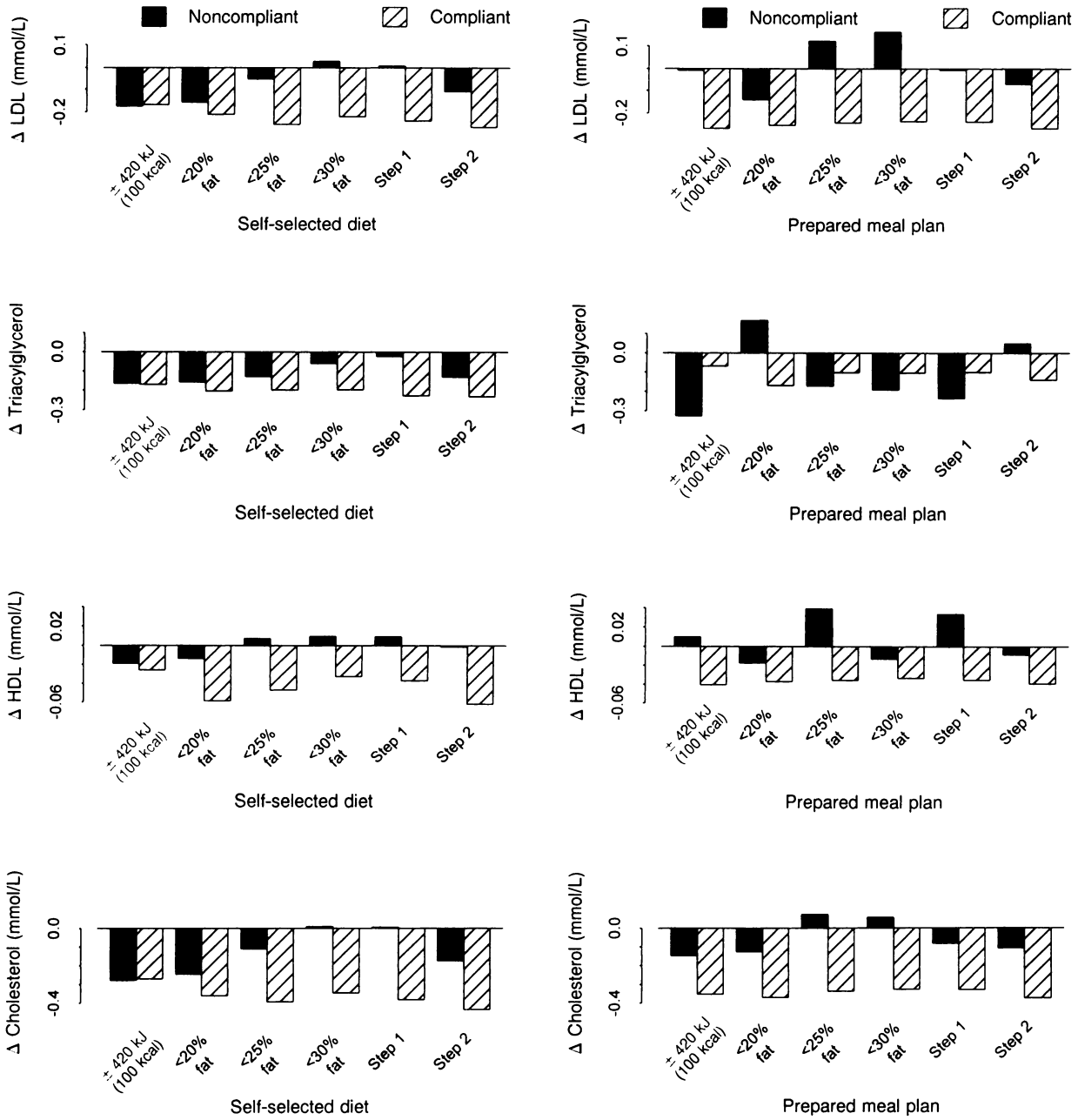

FIGURE 3. Effect of dietary compliance on plasma changes in lipoproteins in participants following the prepared meal plan and self-selected diet. A significant compliance effect on total and LDL cholesterol was found for all fat criteria ($P < 0.05$) and Step 1 and Step 2 criteria ($P < 0.001$). Energy compliance was significant for LDL and HDL cholesterol concentrations, $P < 0.05$. A significant ($P < 0.0008$) compliance by treatment interaction was noted for LDL cholesterol within the energy compliance category. There was no significant pooled effect of treatment on changes in plasma lipoproteins independent of compliance category. Because of the small number of prepared meal plan participants in the noncompliant groups in the higher-fat categories, our confidence is limited in the accuracy and stability of the endpoint responses in these subgroups (*see* Results). (The data set used to construct the figure is available from the authors on request.)

reduced blood pressures, plasma lipids, and body weights across all levels of dietary compliance criteria compared with their noncompliant counterparts. Although reductions in plasma HDL were also apparent, this is not unexpected given the significant reductions observed in both total dietary fat and total blood cholesterol. Although numerous studies have clearly shown that diet can effectively lower elevated blood cholesterol and decrease high blood pressure (33–38), low compliance typically precludes participants from achieving optimal endpoint responses. Thus, these findings emphasize the importance of dietary compliance in improving clinical outcomes and underscore the efficacy of dietary therapy in the treatment of hypertension and hypercholesterolemia.

The lack of a significant compliance effect on carbohydrate metabolism is curious but not entirely surprising given the lack

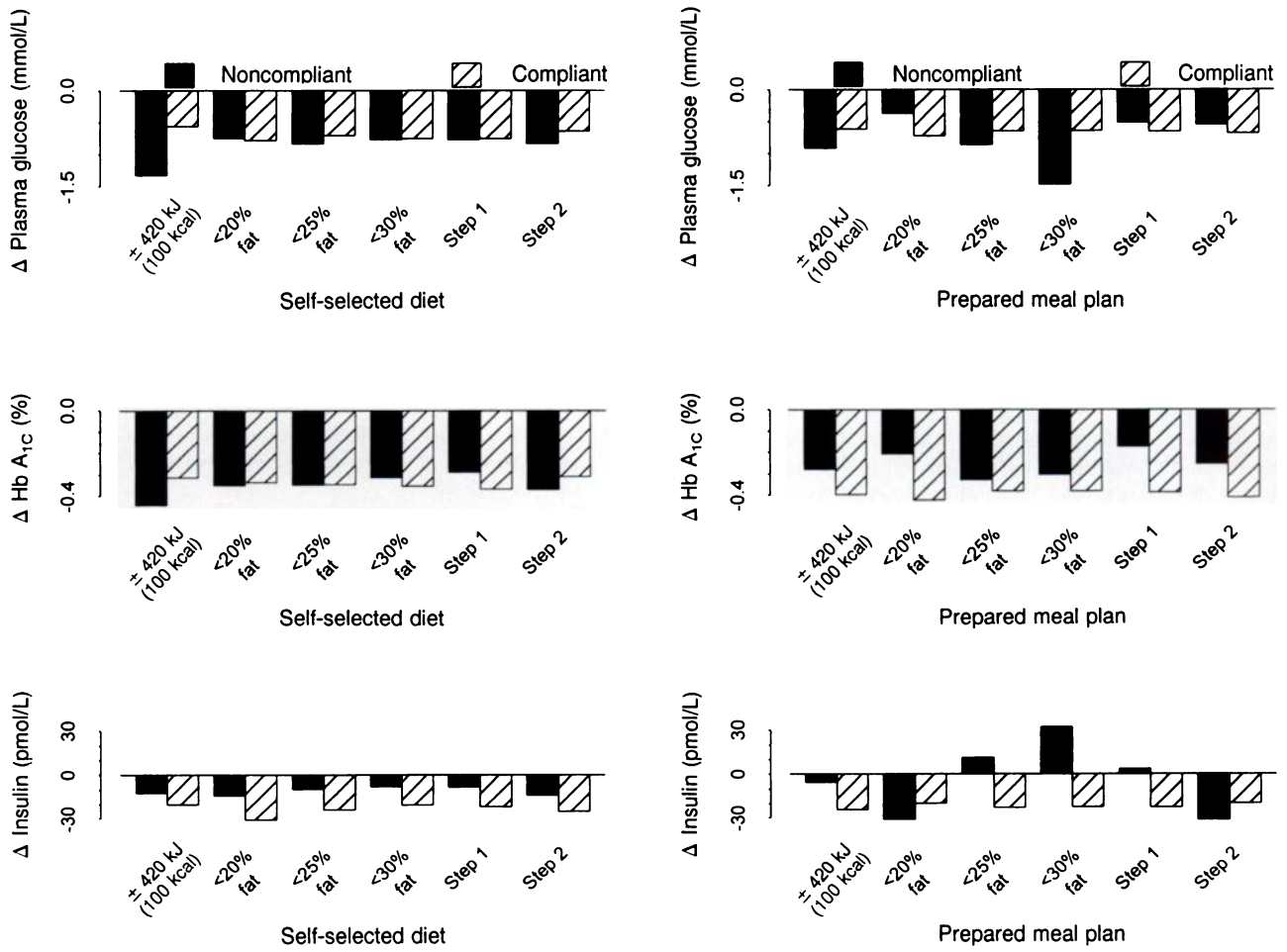

FIGURE 4. Effect of dietary compliance on changes in carbohydrate metabolism in participants following the prepared meal plan and self-selected diet. A significant compliance effect on plasma glucose was found for energy criteria only ($P < 0.05$). There was no significant pooled effect of treatment on changes in carbohydrate metabolism independent of compliance category. Because of the small number of prepared meal plan participants in the noncompliant groups in the higher-fat categories, our confidence is limited in the accuracy and stability of the endpoint responses in these subgroups (*see* Results). Hb A_{1c}, glycated hemoglobin. (The data set used to construct the figure is available on request to the authors.)

of consensus on the optimal nutrient composition of a diet for patients with NIDDM. Diets high in complex carbohydrates (≈60% of energy), high in soluble fiber, and moderate to low in saturated fat contribute to improved glycemic control (4). Whereas both the prepared meal plan and self-selected diet groups achieved significant reductions in indexes of carbohydrate metabolism over the 10-wk intervention period, with one exception in which greater reductions in plasma glucose were observed in participants noncompliant with their energy prescription, there appeared to be no significant effect of dietary compliance on these endpoints. This may be related to the fact that the compliance criteria used in the present study were defined primarily according to dietary fat composition. Diets low in total fat may not be necessary for optimal glycemic control (4).

Note that in the present study the intervention was only 10 wk in duration. The short-term success observed with the prepared meal plan may not translate into long-term dietary change, a necessary component to reduced CVD risk. However, the optimal nutrient composition of the prepared meal plan, combined with the convenience and ease in meeting therapeutic goals, are likely to promote continued compliance with a long-term therapeutic plan. Provision of food in the form of prepackaged meals has been shown to facilitate achievement of dietary goals (22). Although it is unlikely that participants will use the prepared meal plan as an exclusive food source long-term, incorporating the prepared meal plan into the lifestyles of at-risk persons would clearly help them meet long-term prescribed dietary goals.

The results of this study underscore the necessity of a high degree of compliance to achieve optimal reductions in CVD risk factors by dietary means. Both dietary interventions resulted in improvements in study endpoints, but prepared meal plan participants achieved more favorable changes in diet composition and in compliance. It is encouraging to note that a relatively high proportion of self-selected diet participants were able to achieve therapeutic dietary goals, and that regardless of the type of dietary intervention, individuals who meet dietary goals for CVD risk reduction achieve improvements in biological endpoints. However, barriers to achieving optimal compliance with therapeutic dietary regimens remain a major deterrent to the successful prevention and treatment of CVD, the leading cause of death in this country. Thus, creating programs that will optimize dietary compliance is criti-

cally important to reducing morbidity and mortality due to diet-sensitive chronic diseases. The prepared meal plan provides a simple and effective modality for meeting the plethora of dietary guidelines recommended for prevention and treatment of chronic diseases, for improving dietary compliance, and for reducing CVD risk.

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