A Randomized Trial of Improved Weight Loss With a Prepared Meal Plan in Overweight and Obese Patients

Impact on Cardiovascular Risk Reduction

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Objective: To assess the long-term effects of a pre-packaged, nutritionally complete, prepared meal plan compared with a usual-care diet (UCD) on weight loss and cardiovascular risk factors in overweight and obese persons.

Design: In this randomized multicenter study, 302 persons with hypertension and dyslipidemia (n=183) or with type 2 diabetes mellitus (n=119) were randomized to the nutrient-fortified prepared meal plan (approximately 22% energy from fat, 58% from carbohydrate, and 20% from protein) or to a macronutrient-equivalent UCD.

Main Outcome Measures: The primary outcome measure was weight change. Secondary measures were changes in blood pressure or plasma lipid, lipoprotein, glucose, or glycosylated hemoglobin levels; quality of life; nutrient intake; and dietary compliance.

Results: After 1 year, weight change in the hypertension/dyslipidemia group was −5.8±6.8 kg with the prepared meal plan vs −1.7±6.5 kg with the UCD plan (P<.001); for the type 2 diabetes mellitus group, the change was −3.0±5.4 kg with the prepared meal plan vs −1.0±3.8 kg with the UCD plan (P<.001) (data given as mean±SD). In both groups, both interventions improved blood pressure, total and low-density lipoprotein cholesterol levels, glycosylated hemoglobin level, and quality of life (P<.02); in the diabetic group, the glucose level was reduced (P<.001). Compared with those in the UCD group, participants with hypertension/dyslipidemia in the prepared meal plan group showed greater improvements in total (P<.01) and high-density lipoprotein (P<.03) cholesterol levels, systolic blood pressure (P<.03), and glucose level (P<.03); in participants with type 2 diabetes mellitus, there were greater improvements in glucose (P=.046) and glycosylated hemoglobin (P<.02) levels. The prepared meal plan group also showed greater improvements in quality of life (P<.05) and compliance (P<.001) than the UCD group.

Conclusions: Long-term dietary interventions induced significant weight loss and improved cardiovascular risk in high-risk patients. The prepared meal plan simultaneously provided the simplicity and nutrient composition necessary to maintain long-term compliance and to reduce cardiovascular risk.

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Rates of obesity and overweight in the United States are at an all-time high, affecting an estimated 97 million adults, or roughly 55% of persons aged 20 years or older. The medical risks of excess body weight are well documented, with primary risk manifest in the morbidity and mortality associated with cardiovascular disease and type 2 diabetes mellitus. For overweight individuals with or at high risk of developing these conditions, weight reduction remains the first-line treatment strategy; even modest weight loss has been shown to decrease plasma lipid levels and high blood pressure and, in diabetic patients, to improve glycemic control. However, realization of the health benefits of weight loss requires long-term compliance with therapeutic diets, and it is well established that the difficulties inherent in dietary compliance are a major cause of the failure of most weight reduction efforts.

The Cardiovascular Risk Reduction Dietary Intervention Trial was undertaken to evaluate the effects on weight loss and cardiovascular disease risk factors of a nutrient-fortified prepared meal plan compared with a self-selected usual-care diet (UCD). The meal plan comprises various foods and snacks formulated to meet the myriad of dietary guidelines of national health organizations specific for re-
PATIENTS AND METHODS

This randomized clinical trial of a prepared meal plan was conducted in 2 separate cohorts: persons with hypertension and dyslipidemia or persons with type 2 diabetes mellitus. It was conducted at 5 university-based medical centers, including Oregon Health Sciences University, Portland; Pennsylvania State University, University Park; St Luke’s Roosevelt Hospital, New York, NY; University of Alabama at Birmingham; and University of California at Davis. The protocol was approved by the institutional review board at each of the centers, and written, informed consent was obtained from each participant before enrollment into the study. This subgroup analysis of the original study is limited to overweight or obese individuals (BMI, ≥25). The primary outcome of this study is weight change, and the secondary outcomes are lipid levels, blood pressure, glycemic control, nutrient intake, and quality of life.

PARTICIPANTS

Adult men and women with hypertension/dyslipidemia or with type 2 diabetes mellitus, who had been advised by their physicians or nurses to follow special diets to manage their conditions, were recruited through outpatient clinics and advertisements. Inclusion criteria were age 25 to 70 years, a BMI of 42 or less, and one of the following diagnostic measures:

1. Hypertension/dyslipidemia. Untreated hypertension/dyslipidemia were defined as an average sitting systolic blood pressure of 140 to 180 mm Hg and/or a sitting diastolic blood pressure of 90 to 105 mm Hg and a fasting plasma cholesterol level of 5.69 to 7.76 mmol/L (220-300 mg/dL) and/or a fasting plasma triglyceride level of 2.26 to 11.29 mmol/L (200-1000 mg/dL). Treated hypertension/dyslipidemia were defined as stabilized while taking medications for 1 month or longer before the study, a diastolic blood pressure of 100 mm Hg or lower, and a fasting cholesterol level of 6.72 mmol/L or lower (≤260 mg/dL).

2. Type 2 diabetes mellitus. These persons were taking no hypoglycemic agents, had a fasting blood glucose level of greater than 7.8 mmol/L (≥140 mg/dL), and had a glycosylated hemoglobin (HbA1c) level of 200% or less of the median for the assay (≤15.9%); or were stabilized while taking oral hypoglycemic agents for 1 month or longer before the study, with an HbA1c level of 110% to 175% of the median for the assay (7.7%-13.3%).

Exclusion criteria for the full study included insulin treatment, substance abuse, and any serious health problems as noted on history or physical examination that would interfere with study participation. For the subgroup analysis, participants with a baseline BMI of 25 or less were excluded.

DESIGN

Baseline Period

A 4-week baseline period preceded the 52-week treatment period. During this period, participants were advised to maintain their usual diets and were seen in the clinic on 3 occasions for measurements of blood pressure and weight. Two fasting blood samples and one 4-day food record were collected. All participants were advised to maintain their usual physical activity levels throughout the duration of the study.

Nutrition Prescriptions

For each participant, a nutrition prescription (energy intake) was calculated during baseline using the Harris-Benedict equation and an activity factor to estimate individual energy needs. All participants were prescribed hypoenergetic nutrition prescriptions with weight loss not to exceed 0.90 kg/wk for the intervention. The prescriptions targeted an 835.8-J range, the lowest being 5040.0 to 5875.8 kJ/d. Participants received their nutrition prescriptions and instructions for their use at week 0, along with their randomization assignment.

Randomization

Individuals in each cohort were randomized separately to the prepared meal plan or the UCD, stratified by clinic site. Randomization was done by the study coordinating center at Oregon Health Sciences University after documentation that the subject met all the inclusion and exclusion criteria. The randomization scheme was computer generated, with assignments by a locked computer file at the coordinating center. Randomization was done following the participant’s second clinic visit during the baseline period, and assignments were conveyed to the respective clinic sites by telephone and facsimile.

Treatment Period

Participants were assigned to either the prepared meal plan or the UCD for 52 weeks. Weight and blood pressure were measured, and blood was drawn for measurements of lipids and glucose metabolism during study visits at weeks 0, 10, 12, 24, 26, 50, and 52. All measurements were performed by study nurses unaware of the treatment assignment to maintain blinding; only the dietician at each site was aware of the randomization group. Participants in both groups returned completed 4-day food records at weeks 12, 26, and 52. Prepared meal plan participants received diet adherence support at clinic visits or by telephone at

Continued on next page
approximately monthly intervals throughout the treatment period.

DIETARY INTERVENTIONS

The macronutrient composition of both dietary interventions targeted 22% energy from fat, 58% energy from carbohydrate, and 20% energy from protein. The prepared meal plan comprises 7 breakfast, 13 lunch, 12 dinner, and 8 snack selections. The meals are formulated to provide recommended levels of sodium, total and saturated fat, cholesterol, and fiber; and are fortified to meet at least 100% of the recommended dietary allowance for 22 essential vitamins and minerals. Prepared meal plan participants ordered their meal choices every 2 weeks by telephone, and the foods were delivered to their homes.

For the prepared meal plan, participants were instructed to consume 1 breakfast, lunch, and dinner, supplemented with 1 serving each of fruit, vegetable, and low-fat dairy products daily. They could also select 1 item per day from a “bonus list” (in quantities equivalent to approximately 420 kJ), including vegetable oils, alcoholic beverages, or the energy equivalent in fruits, vegetables, or low-fat dairy products. If needed, prepared snacks were used to meet prescribed energy needs.

The UCD group was prescribed a macronutrient-equivalent diet based on the exchange-list system of the American Dietetic and American Diabetes Associations; the number of servings from each exchange list was determined by the individual’s nutrition prescription. These participants could also select 1 serving daily from the bonus list. To balance provision of the foods to the prepared meal plan group, persons consuming the UCD received monetary compensation for food purchases. All participants received travel compensation in the clinic at weeks 0, 12, 26, and 52.

OUTCOME MEASUREMENTS

Blood pressure measurements were standardized across centers by a studywide training session. Plasma lipoprotein levels were determined at Northwest Lipid Research Laboratories, University of Washington, Seattle. Total cholesterol was measured by the colorimetric enzymatic end point method (Abbott Spectrum Analyzer; Abbott Laboratories, Abbott Park, Ill). High-density lipoprotein (HDL) cholesterol was analyzed by the heparin-manganese method. Low-density lipoprotein (LDL) cholesterol was calculated using the Friedewald algorithm. Insulin was measured by solid-phase radioimmunoassay (Coat-A-Count; Diagnostic Products, Los Angeles, Calif) at the Hormone and Mineral Laboratory, Oregon Health Sciences University. The glucose level was measured by SmithKline Beecham Clinical Laboratories, Seattle.

Food records were analyzed at the coordinating center with a licensed copy of the Nutrition Coordinating Center database of the University of Minnesota, St Paul (Nutrition Data System, version 2.8, 1995) supplemented by the product content of meals provided by Campbell Soup Company, Camden, NJ. Dietary compliance was calculated based on the percentage of energy from fat, saturated fat, and cholesterol to assess achievement of guidelines for American Heart Association Step I (<10% of energy from saturated fat, ≤30% of energy from total fat, and <300 mg/d of cholesterol) and Step II (<7% of energy from saturated fat, ≤30% of energy from total fat, and <200 mg/d of cholesterol) diets.

Quality of life was assessed using a battery of self-administered questionnaires that measured health- and nutrition-related quality of life. The health-related instruments included the Mental Health Inventory and the General Perceived Health, Daily Activities, Work Performance and Satisfaction, and Sexual Function scales. Nutrition-related measures addressed nutritional health perception, hassles, affect, social function, and satisfaction. These instruments are described in detail elsewhere.

STATISTICAL ANALYSIS

This study had 80% power, with a 2-sided α error level of 5%, to detect differences between treatment groups of approximately 2 mm Hg in systolic blood pressure, 0.10 mmol/L (4 mg/dL) in plasma cholesterol level, and 0.2% difference in HbA1c level, with at least 80 persons per group. All baseline data except weight were averaged during the baseline period when multiple measures were available; baseline weight was that recorded at the last visit before the intervention. The blood pressure and lipoprotein level were averaged at weeks 10 and 12, 24 and 26, and 50 and 52, respectively. Baseline and treatment measurement data are expressed as means ± SDs.

A repeated-measures analysis of variance model was used to analyze differences between baseline and treatment periods for each cohort; this allowed computation of the effect of diet between periods and of the differential effect of the diets. An intention-to-treat approach was used. For analysis of the proportion of participants meeting dietary compliance criteria, and the proportion of participants achieving ≥5% weight loss, χ² tests were used to detect independence of categorical factors. Additional analyses of quality-of-life data included computation of a responsiveness index for each reported score. This was calculated by dividing the change score between baseline and each week by the mean within-person SD of change between 2 measures during baseline. A score of 0.3 was a priori selected as a conservative estimate of clinical importance.

RESULTS

BASELINE PARTICIPANT CHARACTERISTICS

The baseline characteristics of the study population are shown in Table 1. There were no significant differ-
ences in the distribution of age (P ≥ .71), sex (P ≥ .71), ethnicity (P ≥ .16), or BMI (P ≥ .07) between treatment or diagnostic groups.

Participants qualifying for the study with hypertension and dyslipidemia or with type 2 diabetes mellitus were randomized to either the prepared meal plan or the usual-care diet. The study schema is shown for assessment of body weight and secondary outcomes. Participants with a body mass index (calculated as weight in kilograms divided by the square of height in meters) less than 25 were excluded from this subgroup analysis (n = 11 in the hypertension/dyslipidemia group and n = 13 in the diabetes mellitus group). Of the 183 randomized participants with hypertension/dyslipidemia and the 119 with type 2 diabetes mellitus who qualified as being overweight or obese, 56 did not complete a week 52 visit. The most frequent reason given for early withdrawal from the study was the excessive time commitment required to complete the study.

Table 1. Baseline Characteristics of Study Participants*

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Prepared Meal Plan (n = 93)</th>
<th>Usual-Care Diet (n = 90)</th>
<th>Prepared Meal Plan (n = 56)</th>
<th>Usual-Care Diet (n = 63)</th>
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<tr>
<td>Age, mean ± SD, y</td>
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<td>54.0 ± 9.9</td>
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<td>9</td>
</tr>
<tr>
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<td>6</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>BMI, mean ± SD†</td>
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<td>33.0 ± 4.4</td>
<td>34.5 ± 4.5</td>
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<td>Overweight, No. (%)‡</td>
<td>30 (32)</td>
<td>32 (36)</td>
<td>17 (30)</td>
<td>12 (19)</td>
</tr>
<tr>
<td>Obese, No. (%)§</td>
<td>63 (68)</td>
<td>58 (64)</td>
<td>39 (70)</td>
<td>51 (81)</td>
</tr>
</tbody>
</table>

*Data are given as the number of participants unless otherwise indicated.
†BMI indicates body mass index (calculated as weight in kilograms divided by the square of height in meters).
‡Defined as a BMI between 25.0 and 29.9.
§Defined as a BMI of 30 or greater.

PREPARED MEAL PLAN ADHERENCE

Adherence to the prepared meal plan was monitored by reports at clinic visits and by the patterns of ordering the prepared meals. Program adherence was defined as follows, and pertains to food ordering patterns between the week 12 and the week 52 visits: full program adherence, 21 meals per week; partial adherence, averaged to less than 21 meals per week; and off the program, did not order any prepared meals. The ordering patterns of participants with hypertension/dyslipidemia and of those with type 2 diabetes mellitus were as follows at week 26: full program, 49% and 53%; partial program, 45% and 44%; and off the program, 6% and 2%, respectively. At week 52, these respective proportions were as follows: full program, 33% and 39%; partial program, 56% and 38%; and off the program, 11% and 29%.

ADVERSE EFFECTS

Diet-related adverse effects in the prepared meal plan vs the UCD group were reported by 10% vs 1% of participants with hypertension/dyslipidemia (P < .05) and 6% vs 2% of participants with type 2 diabetes mellitus. Three symptoms accounted for these differences: flatulence, 2% vs 0% for hypertension/dyslipidemia and 3% vs 0% for diabetes; abdominal pain, 3% vs 0% for hypertension/dyslipidemia and none for type 2 diabetes mellitus; and diarrhea, 3% vs 0% for hypertension/dyslipidemia and none for type 2 diabetes mellitus. With few exceptions, symptoms were reported at only 1 visit, were self-limiting, and thus did not affect program adherence.

OUTCOME MEASURES

Hypertension/Dyslipidemia Group

Weight Loss. Participants consuming the prepared meal plan lost significantly more weight than those consuming the UCD during the 52-week study period (P < .001).

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In the prepared meal plan group, the average weight loss from baseline was 6.9 ± 4.0 kg after 12 weeks, 7.8 ± 6.3 kg after 26 weeks, and 5.8 ± 6.8 kg after 52 weeks of treatment; they maintained 74% of their week 26 weight loss by the end of the study. The UCD group lost 2.3 ± 3.6 kg after 12 weeks, 2.4 ± 5.4 kg after 26 weeks, and 1.7 ± 6.5 kg after 52 weeks of treatment; they maintained 71% of their week 26 weight loss after 26 weeks, and 5.8 ± 6.8 kg after 52 weeks of treatment. The prepared meal plan group had significantly greater reductions in weight loss and percentage of weight loss from baseline at week 52 compared with the UCD group (P < .001). Week 52 changes in weight loss were significantly different in both diet groups (P < .001).

Blood Pressure. The prepared meal plan group had significantly greater reductions in systolic blood pressure during the study period than the UCD group (P < .03); no significant (P = .21) difference between groups was observed for diastolic blood pressure (Table 2). Week 52 blood pressure changes from baseline were significantly reduced in both diet groups (P < .001).

Lipids and Lipoproteins. Changes in total (P < .01) and HDL (P < .03) cholesterol levels during 52 weeks were significantly different in the prepared meal plan group compared with the UCD group; no significant differences were observed between diets for LDL cholesterol (P = .14) or triglyceride (P = .54) levels. Week 52 changes in total, LDL, and HDL cholesterol levels from baseline were significantly different in both diet groups (P < .001).

Indexes of Glycemic Control. Participants consuming the prepared meal plan had significantly greater reductions in glucose level during the study period than those consuming the UCD (P < .03) (Table 2). No significant differences were observed between diet groups for insulin (P = .07) and HbA1c (P = .11) levels. Week 52 changes in insulin and HbA1c levels from baseline were significantly reduced in both diet groups (P < .001).

Reported Nutrient Intake. Reported intake of selected macronutrients at baseline and week 52 is shown in Table 3. Participants in the prepared meal plan group had greater increases during the study period in carbohydrate intake and greater reductions in intakes of cholesterol and percentage of energy from total fat compared with UCD participants (P < .001). Changes in reported intakes of energy and percentage of energy from protein did not differ between diet groups during the study period. Reported intakes of all nutrients changed from baseline during the study period in both diet groups (P < .01).

Dietary Compliance. Throughout the intervention period, the prepared meal plan group reported greater compliance with American Heart Association Step I and Step II dietary recommendations compared with the UCD group (P < .001). At baseline, 29% of both dietary groups reported compliance with Step I recommendations; 5% of the prepared meal plan group and 12% of the UCD group met Step II guidelines. Compliance with Step I recommendations across the weeks of study was achieved by the following proportions of the prepared meal plan group compared with the UCD group: 92% vs 44% at week 12, 75% vs 37% at week 26, and 74% vs 37% at week 52. The proportions compliant with Step II guidelines were as follows: 72% vs 19% at week 12, 56% vs 19% at week 26, and 43% vs 17% at week 52.
Quality of Life. During the intervention period, participants in the prepared meal plan group reported significantly greater improvements in quality of life compared with UCD participants on the following scales: Mental Health Inventory (P < .01), General Health Perceptions (P < .001), Daily Activities (P < .001), Work Performance (P < .001), Nutritional Hassles (P < .001), Social Function (P < .045), Nutrition and Affect (P < .001), and Satisfaction With Diet (P < .001).

Type 2 Diabetes Mellitus Group

Weight Loss. Participants consuming the prepared meal plan lost significantly more weight than participants consuming the UCD (P < .001). In the prepared meal plan group, the average weight loss from baseline was 4.7 ± 4.0 kg after 12 weeks, 5.5 ± 6.4 kg after 26 weeks, and 3.0 ± 5.4 kg after 52 weeks of treatment; these participants maintained 55% of their week 26 weight loss by the end of the study. The UCD group lost 1.3 ± 2.5 kg after 12 weeks, 1.5 ± 3.2 kg after 26 weeks, and 1.0 ± 3.8 kg after 52 weeks of treatment; this group maintained 67% of their week 26 weight loss by the end of the study. Weight loss of at least 5% was achieved by 12 (29%) of 41 prepared meal plan participants compared with 5 (10%) of 51 UCD participants (P < .03).

Blood Pressure. Changes in systolic or diastolic blood pressure were not significantly different in participants consuming the prepared meal plan compared with the UCD (Table 2). Week 52 blood pressure changes from baseline were significantly reduced in both diet groups (P < .001).

Lipids and Lipoproteins. The change in total (P < .03) and LDL (P < .01) cholesterol levels between diet groups during the 52-week trial was significantly different in the prepared meal plan compared with the UCD group; no significant differences were observed between diets in HDL cholesterol or triglyceride levels (Table 2). Despite a decrease in total cholesterol level after 12 weeks with the prepared meal plan, the cholesterol level increased during the remainder of the trial; in the UCD group, the cholesterol level did not change markedly from baseline. Week 52 changes in total, LDL, and HDL cholesterol levels from baseline were significantly different in both diet groups (P < .02).

Indexes of Glycemic Control. Participants consuming the prepared meal plan had significantly greater reductions in glucose (P = .046) and HbA1c (P < .02) levels during the study period than those consuming the UCD. No differences were observed between diet groups in insulin level (Table 2). Week 52 changes in glucose, insulin, and HbA1c levels from baseline were significantly different in both diet groups (P < .001).

Reported Nutrient Intake. Reported intake of selected macronutrients at baseline and week 52 is shown in Table 3. Participants in the prepared meal plan group had greater increases during the study period in carbohydrate intake and greater reductions in intakes of cholesterol and percentage energy from total fat compared with UCD par-
participants (P<.001). Changes in reported intakes of energy and percentage energy from protein did not differ between diet groups during the study period. Reported intakes of all nutrients changed from baseline during the study period in both diet groups (P<.01).

Dietary Compliance. At weeks 12 and 26, the prepared meal plan group was more compliant with American Heart Association Step I and Step II dietary recommendations compared with the UCD group (P<.001). At baseline, 16% of the prepared meal plan group and 11% of the UCD group were compliant with Step I recommendations; 4% of the prepared meal plan group and 5% of the UCD group met Step II guidelines. Compliance with Step I recommendations across the weeks of study was achieved by the following proportions of the prepared meal plan group compared with the UCD group: 87% vs 31% at week 12, 68% vs 33% at week 26, and 56% vs 36% at week 52. The proportions compliant with Step II guidelines were as follows: 64% vs 12% at week 12, 39% vs 11% at week 26, and 31% vs 15% at week 52.

Quality of Life. During the intervention period, participants in the prepared meal plan group reported significantly greater improvements in quality of life compared with UCD participants on the following scales: Mental Health Inventory (P<.04), Daily Activities (P<.03), Nutritional Hassles (P<.01), Nutritional Health Perceptions (P<.001), Nutrition and Affect (P<.01), and Satisfaction With Diet (P<.001).

Table 3. Changes in Reported Macronutrient Intake in Study Participants Consuming the Prepared Meal Plan and the Usual-Care Diet*

<table>
<thead>
<tr>
<th>Macronutrient Intake</th>
<th>Prepared Meal Plan</th>
<th>Usual-Care Diet</th>
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<tr>
<td></td>
<td>Baseline (n = 98)</td>
<td>Week 52 (n = 72)</td>
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<tr>
<td>Energy, kJ/d (kcal/d)</td>
<td>9011 ± 2832</td>
<td>6703 ± 1909</td>
</tr>
<tr>
<td>Energy from protein, %</td>
<td>16.3 ± 3.4</td>
<td>18.4 ± 3.0</td>
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<tr>
<td>Energy from carbohydrate, %</td>
<td>50.6 ± 8.3</td>
<td>58.4 ± 7.5</td>
</tr>
<tr>
<td>Energy from fat, %</td>
<td>32.7 ± 7.1</td>
<td>23.3 ± 6.5</td>
</tr>
<tr>
<td>Energy from saturated fat, %</td>
<td>11.0 ± 2.8</td>
<td>7.9 ± 2.6</td>
</tr>
<tr>
<td>Cholesterol, mg†</td>
<td>285 ± 148</td>
<td>150 ± 94</td>
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</table>

Participants With Type 2 Diabetes Mellitus

<table>
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<th>Macronutrient Intake</th>
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<th>Usual-Care Diet</th>
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<tr>
<td></td>
<td>Baseline (n = 56)</td>
<td>Week 52 (n = 39)</td>
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<tr>
<td>Energy, kJ/d (kcal/d)</td>
<td>8920 ± 3020</td>
<td>6415 ± 2026</td>
</tr>
<tr>
<td>Energy from protein, %</td>
<td>17.5 ± 4.0</td>
<td>19.3 ± 3.4</td>
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<tr>
<td>Energy from carbohydrate, %</td>
<td>48.5 ± 8.2</td>
<td>54.0 ± 9.1</td>
</tr>
<tr>
<td>Energy from fat, %</td>
<td>35.2 ± 7.2</td>
<td>27.6 ± 8.6</td>
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<tr>
<td>Energy from saturated fat, %</td>
<td>11.8 ± 2.9</td>
<td>9.0 ± 2.8</td>
</tr>
<tr>
<td>Cholesterol, mg†</td>
<td>306 ± 155</td>
<td>181 ± 124</td>
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</table>

*Data are given as mean ± SD. †P<.001 for the difference in the nutrient change over time between diets.

To our knowledge, this is the first year-long randomized trial in persons with established risk factors for cardiovascular disease to test the effect on weight loss of a prepared meal plan meeting all of the nutrient recommendations of national health organizations. The results demonstrate that the prepared meal plan is more effective in inducing weight loss in such subjects than a macronutrient-equivalent UCD. Accordingly, the prepared meal plan was more effective in improving multiple risk factors while simultaneously enhancing the participants’ quality of life.

After 6 months of consuming the prepared meal plan, weight reduction was 8% and 6% of baseline in participants with hypertension/dyslipidemia and in those with type 2 diabetes mellitus, respectively, compared with 2% for both diagnostic groups in participants receiving the UCD. At 1 year, weight loss had regressed to 6% and 3% of baseline in participants with hypertension/dyslipidemia and in those with type 2 diabetes mellitus, respectively, while consuming the prepared meal plan. However, among participants compliant with Step I recommendations, weight loss had improved to 7% and 5% of baseline levels, respectively.

Short-term weight reductions of 5% to 15% have been reported to significantly improve obesity-related comorbidities. The weight loss we observed among prepared meal plan participants is consistent with those prior reports and other nonpharmacological weight loss interventions. The greater weight loss in the prepared meal plan group likely reflects, in part, better dietary compliance and, thus, greater sustained reductions in energy and fat intake.

Blood pressure, plasma lipid and lipoprotein levels, and glycemic control indexes improved significantly in both intervention groups. Weight changes as small as 2% of baseline were associated with modest but significant improvements in total, LDL, and HDL cholesterol (hypertension/dyslipidemia group only); glucose (diabetic group only); insulin; and HbA1c, lev-
The prepared meal plan was associated with a more favorable risk factor profile, including systolic blood pressure (hypertension/dyslipidemia group only) and HDL cholesterol, glucose, and HbA1c (diabetic group only) levels.

The response in total and LDL cholesterol with the prepared meal plan compared with usual care may be due in part to the participants’ modestly elevated baseline lipid levels. Higher baseline lipid levels are more responsive to lipid-lowering interventions. In our study, baseline levels were only borderline high in the hypertension/dyslipidemia group and normal in the diabetic group. Similarly, baseline dietary fat intake was not excessively high, possibly attenuating greater lipid responses with the intervention. Mean fat intakes averaged 32% energy from fat in the hypertension/dyslipidemia group and 35% in the diabetic group, approaching the American Heart Association recommendation of 30%. Improvements in HDL cholesterol level were greater among the participants with hypertension/dyslipidemia consuming the prepared meal plan (P<.03) and nearly so in participants with type 2 diabetes (P<.06). This finding is consistent with other reports of weight loss–associated increases in HDL cholesterol level and is essential to improving cardiovascular risk.

Prior concerns that substantial reductions in dietary fat and reciprocal increases in carbohydrate intake would exacerbate plasma triglyceride levels and indexes of glycemic control, particularly in participants with type 2 diabetes, were not observed, likely as a result of weight loss. To the contrary, triglyceride levels initially decreased in participants with type 2 diabetes mellitus consuming the prepared meal plan, with a commensurate reported fat intake of 24% at week 26. By week 52, triglyceride levels were essentially unchanged among the dietary groups. More important, during the year, plasma glucose and HbA1c levels significantly improved in participants with type 2 diabetes consuming the prepared meal plan compared with those consuming the UCD.

The enhanced quality of life reported with the prepared meal plan may be essential to the success of this program. Improved clinical outcomes are not necessarily sufficient motivation to assure long-term patient acceptance of dietary changes. Results from numerous interventions intended to modify chronic disease risk have shown that patients must perceive themselves as better off or the intervention will not be sustained. Improved quality of life has been shown previously to be positively related to weight loss. The enhanced quality-of-life scores in the prepared meal plan group reflect not only the weight loss but also concurrent reductions in cardiovascular disease risk factors, perceived beneficial changes in dietary practices, positive effect associated with personal control of disease management, and the simplicity of achieving these multiple benefits. Thus, our observation that quality of life improved may be critical to assuring longer adherence to this dietary intervention.

Our findings support the therapeutic concept that modest and substantial weight loss through dietary means improves cardiovascular disease risk factors. In addition, we have documented the safety, efficacy, and acceptability of a prepared meal program in this year-long randomized trial. While other dietary and pharmacological approaches may offer similar benefits, documentation through a 12-month intervention period awaits critical testing.

These findings validate the hypothesis of a positive impact of long-term dietary interventions on weight loss and cardiovascular risk reduction in high-risk patients. The prepared meal plan promoted and sustained long-term weight loss and reduced cardiovascular risk. The simplicity, variety, portion control, and nutrient composition necessary to enhance and maintain long-term dietary compliance while concomitantly improving quality of life were critical to achieving these outcomes.

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