ORIGINAL INVESTIGATION

The National Cholesterol Education Program Diet vs a Diet Lower in Carbohydrates and Higher in Protein and Monounsaturated Fat

A Randomized Trial

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Background: In the United States, obesity is a major clinical and public health problem causing diabetes, dyslipidemia, and hypertension, as well as increasing cardiovascular and total mortality. Dietary restrictions of calories and saturated fat are beneficial. However, it remains unclear whether replacement of saturated fat with carbohydrates (as in the US National Cholesterol Education Program [NCEP] diet) or protein and monounsaturated fat (as in our isocaloric modified low-carbohydrate [MLC] diet, which is lower in total carbohydrates but higher in protein, monounsaturated fat, and complex carbohydrates) is optimal.

Methods: We randomized 60 participants (29 women and 31 men) to the NCEP or the MLC diet and evaluated them every 2 weeks for 12 weeks. They were aged 28 to 71 years (mean age, 44 years in the NCEP and 46 years in the MLC group). A total of 36% of participants from the NCEP group and 35% from the MLC group had a body mass index (calculated as weight in kilograms divided by the square of height in meters) greater than 27. The primary end point was weight loss, and secondary end points were blood lipid levels and waist-to-hip ratio.

Results: Weight loss was significantly greater in the MLC (13.6 lb) than in the NCEP group (7.5 lb), a difference of 6.1 lb ($P=.02$). There were no significant differences between the groups for total, low density, and high-density lipoprotein cholesterol, triglycerides, or the proportion of small, dense low-density lipoprotein particles. There were significantly favorable changes in all lipid levels within the MLC but not within the NCEP group. Waist-to-hip ratio was not significantly reduced between the groups ($P=.27$), but it significantly decreased within the MLC group ($P=.009$).

Conclusions: Compared with the NCEP diet, the MLC diet, which is lower in total carbohydrates but higher in complex carbohydrates, protein, and monounsaturated fat, caused significantly greater weight loss over 12 weeks. There were no significant differences between the groups in blood lipid levels, but favorable changes were observed within the MLC diet group.

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In the United States, obesity is a major clinical and public health problem causing diabetes, hypertension, and abnormalities in lipid metabolism[1,2] as well as higher cardiovascular[3-6] and total mortality.[4-7] Nearly 55% of the US population has a body mass index (BMI, calculated as weight in kilograms divided by the square of height in meters) of 25 to 30 (overweight) or greater than 30 (obese).[8,9] Despite many available diet programs, the prevalence of obesity continues to rise. While reduction of calories and saturated fat are generally accepted as beneficial, it is unclear whether replacement of saturated fat with either carbohydrates or protein and monounsaturated fat is optimal. The American Heart Association (AHA) has classified obesity as a major modifiable risk factor for coronary heart disease.[10] Furthermore, even modest weight loss (5%-10% of body weight) has beneficial effects on blood pressure as well as lipid[11-13] and glucose levels.[12]

For many years the US National Cholesterol Education Program (NCEP) and the AHA have advocated low-calorie and low-fat diets that are high in carbohydrates.[14,15] Adherence to such diets up to 1 year reduces high-density lipoprotein (HDL) cholesterol[16-20] and increases triglyceride levels.[20] Because elevated HDL and triglyceride levels appear to be independent risk factors for cardiovascular disease, a controversy has arisen about whether to replace saturated fat with carbohydrates.[21] In its recent revision, the AHA continues to recom-

Table 1. Composition of the Study Diet*

Component	Phase 1 (Weeks 1-2)		Phase 2 (Weeks 3-4)		Phase 3 (Weeks 5-12)	
Protein	28		30		33	
Carbohydrate	10		27		28	
Fat						
Saturated	13		8		8	
Monounsaturated	17	62	18	43	17	39
Polyunsaturated	32		17		14	
Total	**100**		**100**		**100**	

*Values are given as daily percentage of caloric intake.

mend a lower intake of calories and saturated fat but encourages the substitution of carbohydrates for unsaturated fat.[22] It remains unclear, however, whether an isocaloric diet lower in carbohydrates and higher in protein and monounsaturated fat would have a more favorable effect on weight loss than the NCEP Step II diet. To test this hypothesis, we randomized patients to the NCEP diet or an isocaloric modified low-carbohydrate (MLC) diet lower in total carbohydrates but higher in protein, monounsaturated fat, and complex carbohydrates.

METHODS

PARTICIPANTS

The institutional review board of Mount Sinai Medical Center–Miami Heart Institute reviewed and approved the trial. Subjects were recruited by media announcements. The inclusion criteria were age older than 18 years, a BMI of 27 or greater, and the willingness and stated ability to adhere to a prescribed diet for 3 months at home without alteration in levels of physical activity. The exclusion criteria were a history of thyroid disease or insulin-dependent diabetes mellitus, pregnancy, unstable medical conditions, and current use of oral or parenteral corticosteroids, testosterone, appetite suppressants, or other medications known to affect weight or appetite. The use of lipid-lowering agents was permitted if it had not been changed during the 3 months prior to participation. The 2 participants meeting this criterion agreed not to change their medication or dosage during the 12 weeks of the trial. Each eligible participant gave written informed consent.

TRIAL DESIGN

Randomization was done using a block design by sex to achieve an equal sex distribution. The 60 participants (29 women and 31 men) enrolled to the NCEP or the MLC diet were between 27 and 71 years old (mean age, 44 years in the NCEP and 46 years in the MLC group), with a BMI greater than 27 (35.5 in the NCEP and 34.9 in the MLC group). For issues of feasibility and compliance, 2 couples sharing a household were randomized to the NCEP diet and 2 to the MLC diet.

Follow-up visits for diet counseling and anthropometric measurements occurred every 2 weeks.

CLINICAL PROCEDURES

The baseline evaluation, randomization, and first session of dietary counseling were completed on the first day. Weight was measured with indoor clothing and without shoes on a single scale. Height was measured with all subjects standing erect without shoes, using the same vertical rod. Hip girth was measured at the largest horizontal circumference around the buttocks and waist girth at the narrowest circumference viewed from the front. Both were taken with a nonelastic tape measure with the subjects standing. All anthropometric measurements were obtained by an observer blinded to the treatment assignment. At 12 weeks, participants also completed validated questionnaires to evaluate their level of satisfaction with diet and counseling.[23,24]

DIETARY INTERVENTION

A single specially trained dietitian and nurse practitioner instructed participants about their assigned diet and provided them with written guidelines. All participants, regardless of their assignment, met with the dietitian or the nurse practitioner for 1 hour at the first visit and 30 minutes at subsequent visits. To assess the appropriateness of the foods consumed, 24-hour food recalls were obtained. Because the goal of the 24-hour food recalls was to provide feedback to the participants, the information was insufficient to perform any quantitative analysis.

In the NCEP diet the percentages of calories from fat (30%), carbohydrate (55%), and protein (15%) were unchanged throughout the trial. Saturated fat comprised less than 7% of the total fat intake, and monounsaturated fat between 10% and 15%. The diet was tailored to provide approximately 1300 calories for women and 1600 calories for men.

The MLC diet consisted of 2 phases of 2 weeks' duration and of a third or maintenance phase of 8 weeks. The first phase was characterized by higher intake of fat (62%), very low intake of carbohydrates (10%), and an intake of protein of 28%. In the second phase fat intake was decreased to 43% whereas carbohydrate intake was increased to 27% and protein intake to 30%. In the third phase, the percentages of calories were 39% from fat, 28% from carbohydrates, and 33% from protein. The percentages of calories from monounsaturated fats were 13% in phase 1 and 8% in phases 2 and 3. In the maintenance phase the approximate numbers of calories consumed based on the recommended guidelines were also about 1300 for women and 1600 for men (**Table 1**).

Foods recommended in the MLC diet included those high in protein (ie, lean meats), monounsaturated fats (ie, olive, canola, and sunflower oils as well as peanuts, almonds, pecans, and avocado), and fibers but with a low glycemic index. The glycemic index is a measure of the level to which a food raises blood glucose and elicits an insulin response compared with pure glucose (100%). Therefore, foods with a low glycemic index are those that produce a slow and more sustained rise in blood glucose, and thus potentially provide a greater sensation of satiety (eg, soy beans and peanuts have a glycemic index between 10% and 19%).[25] Participants assigned to the MLC diet were advised to avoid simple sugars, which have a high glycemic index, as well as refined or highly processed foods. All MLC participants were also encouraged to eat vegetables in unlimited quantities and snack on foods containing protein (eg, yogurt) and/or with a low glycemic index (eg, peanuts). Additional fiber in the form of psyllium (1 teaspoon in a half glass of water before lunch and dinner) was also recommended.

The goal of the 3 phases in the MLC diet was to gradually introduce carbohydrates into the diet, beginning with more complex carbohydrates (with a lower glycemic index) and following with foods containing less complex carbohydrates (with a higher glycemic index). Because foods with a higher glycemic index may be associated with a feeling of early hunger or "craving," it was expected that this type food would give a feedback signal that would help the participants in their future selection of food. This approach was effective in one of our earlier trials.[26]

LABORATORY PROCEDURES

At the beginning and end of the trial, blood was collected from the antecubital vein after a 12- to 14-hour fast. Plasma was separated within 2 hours and kept at 4°C until it was processed. Total cholesterol and triglyceride concentrations were measured by enzymatic procedures[27] and HDL cholesterol by dextran–sulfate-magnesium precipitation[28]; LDL cholesterol was calculated as total cholesterol minus the sum of HDL cholesterol and very-low-density lipoprotein (VLDL) cholesterol[29] and VLDL as the triglyceride concentration divided by 5. Serum was also obtained and samples stored at −70° to analyze LDL subclasses by gradient gel electrophoresis (performed by Berkeley HeartLab, Berkeley, Calif), with particular focus on particle diameter of major LDL peak and the proportion of small, dense LDL subclasses (sum of peaks IIIA, IIIB, IVA, IVB). Based on the availability of remaining stored serum, gradient gel electrophoresis could be performed for 45 randomized participants (23 in the NCEP and 22 in the MLC group).

END POINTS

The primary end point was weight loss and secondary end points were various lipid parameters as well as waist-to-hip ratio.

STATISTICAL ANALYSIS

The size of the sample was chosen to provide more than 90% power to detect a difference of 10 lb in weight loss between the NCEP and MLC groups at a 2-sided α level of significance of 5%. For the significance of differences between the groups, *t* tests for continuous variables and χ^2 tests for discrete variables were used. For triglycerides, a continuous variable not normally distributed and skewed toward higher values, logarithmic transformations were performed. For discrete variables in which the sample size was 5 or less, the Fisher exact test was used. All *P* values were 2-sided.

RESULTS

From January 1998 to January 1999, 60 subjects, 29 men and 31 women, were randomized for the trial. Their mean age was 45 years and mean BMI was 35. At the end of the trial, complete data obtained for 54 participants (25 in the NCEP and 29 in the MLC group) formed the basis for these analyses. Of the 6 participants who did not complete the study, 5 were in the NCEP and 1 in the MLC group. The mean follow-up duration for the NCEP and the MLC groups were 90 and 92 days, respectively (*P* was not significant), and the mean numbers of visits were 5.5 and 6.1 (*P* was not significant).

At baseline, there were no significant differences in age, weight, BMI, waist-to-hip ratio, and any of the lipid variables between the NCEP and MLC groups (**Table 2**). The frequencies of myocardial infarction, stroke, congestive heart failure, hypertension, and non–insulin-dependent diabetes mellitus, and use of lipid-lowering agents were low, and not significantly different between the groups.

Weight loss was significantly greater in the MLC (13.6 lb) than in the NCEP group (7.5 lb, a difference of 6.1 lb (*P*=.02) (**Table 3**). Although the waist-to-hip ratio was not significantly different between the groups, it was significantly reduced within the MLC but not in the NCEP group. Total cholesterol levels were similarly reduced by both diets, and LDL cholesterol levels were not significantly different between the 2 groups. However, LDL cholesterol levels were significantly reduced within the NCEP group (−6.4 mg/dL [−0.17 mmol/L]; *P*=.05) but not the MLC group (−3.9 mg/dL [−0.10 mmol/L]; *P*=.48). There were no significant differences between groups regarding HDL values. The NCEP group experienced a significant reduction in HDL levels (−3.8 mg/dL [−0.10 mmol/L]; *P*=.006) but the MLC group did not (−1.3 mg/dL [0.03 mmol/L]; *P*=.46). Triglyceride levels were not significantly different between the groups. They were significantly lowered within the MLC group (−42.0 mg/dL [−10.88 mmol/L]; *P*=.003) but not the NCEP group (−15.2 mg/dL [3.89 mmol/L]; *P*=.20). The ratio of total cholesterol concentration to HDL cholesterol concentration was not significantly changed by either diet.

Regarding the LDL subclasses, there were no significant differences between the MLC and NCEP groups. At baseline, particle size of the major LDL peak correlated with triglyceride (*R*=−0.65; *P*<.001) and HDL (*R*=0.51; *P*<.001) concentrations but not with total or LDL cholesterol. At 3 months, the increase in LDL particle size correlated with magnitude of triglyceride reduction (*R*=−0.47; *P*<.001). The particle size of the major LDL peak in patients adhering to the NCEP diet did not change significantly (from 262.2 to 263.4 nm; *P*=.20). In contrast, the particle size of the major LDL peak increased significantly in the MLC group (from 259.4 to 264.2 nm; *P*=.001) (Table 3). In addition, the proportion of small, dense LDL subclasses (sum of IIIA, IIIB, IVA, and IVB) decreased significantly in the MLC (by 6.1%; *P*=.02) but not in the NCEP group (by 1.4%; *P*=.29).

Table 2. Baseline Characteristics of Study Subjects*

Characteristic	Diet Group: MLC (n = 29)	Diet Group: NCEP (n = 25)	*P* Value
Age, y	46 ± 10	44 ± 10	.52
Women	14 (48)	14 (56)	.57
Weight, kg	99.1 ± 31.9	99.9 ± 21.1	.93
Body mass index†	34.9 ± 4.0	35.5 ± 6.0	.63
Waist-to-hip ratio	0.93 ± 0.1	0.90 ± 0.1	.39
Lipids, mg/dL			
Total cholesterol	212.9 ± 46.2	205.8 ± 36.5	.54
LDL cholesterol	128.3 ± 44.8	122.4 ± 26.7	.56
HDL cholesterol	50.3 ± 14.3	54.3 ± 18.6	.38
Triglycerides	181.3 ± 134.0	145.6 ± 80	.25
Peak LDL size, nm	25.9 ± 0.9	26.2 ± 1.0	.20
Dense LDL, %	36.6 ± 17.4	35.1 ± 13.7	.75
Hypertension	13 (44.8)	7 (28.0)	.20
Myocardial infarction	2 (6.9)	0	.20
Congestive heart failure	0	0	NA
Strokes	0	0	NA
Diabetes mellitus	2 (6.9)	0	.20
Current smoker	2 (6.9)	2 (8.0)	.88
Lipid-lowering drugs	2 (6.9)	0	.20

Abbreviations: HDL, high-density lipoprotein; LDL, low-density lipoprotein; MLC, modified low carbohydrate; NA, not applicable; NCEP, National Cholesterol Education Program.

SI conversion factors: To convert cholesterol to millimoles per liter, multiply by 0.0259; triglycerides to millimoles per liter, multiply by 0.0113.

*Continuous variables are expressed as mean ± SD and discrete variables as number (percentage).

†Body mass index is calculated as weight in kilograms divided by the square of height in meters.

Table 3. Randomized Comparisons Between the MLC and NCEP Step 2 Diets Within and Between Groups*

Variable	Diet Group: MLC (n = 22)	*P* Value	Diet Group: NCEP (n = 23)	*P* Value	*P* Value Between Groups
Primary outcome					
Weight, lb	−13.6 ± 4.0	<.001	−7.5 ± 4.4	.001	.02
Secondary outcomes					
Waist-to-hip ratio	−0.02 ± 3.82	.009	−0.01 ± 3.47	.20	.27
Lipids, mg/dL					
Total cholesterol	−11.9 ± 29.2	.04	−13.3 ± 17.5	.001	.83
HDL cholesterol	−1.3 ± 9.4	.46	−3.8 ± 6.3	.006	.27
LDL cholesterol	−3.9 ± 27.4	.48	−6.4 ± 15.6	.05	.68
Triglycerides	−42.0 ± 101.3	.003	−15.3 ± 46.2	.20	.12
Total/HDL cholesterol	0.13 ± 0.91	.45	−0.07 ± 0.59	.60	.36
LDL particle size peak, nm	4.8 ± 6.3	.001	1.2 ± 4.3	.20	.41
Percentage of dense LDL	−6.1 ± 12.4	.02	−1.4 ± 6.1	.29	.17

Abbreviations: HDL, high-density lipoprotein; LDL, low-density lipoprotein; MLC, modified low carbohydrate; NCEP, National Cholesterol Education Program.
SI conversion factors: To convert cholesterol to millimoles per liter, multiply by 0.0259; triglycerides to millimoles per liter, multiply by 0.0113.
*Values are given as mean ± SD unless otherwise indicated.

Table 4. Participant Satisfaction Scores Regarding Diet and Diet Counseling*

Variable	Diet Group: MLC (n = 29)	Diet Group: NCEP (n = 25)
Satisfaction		
Overall satisfaction	4.2 ± 0.9	3.6 ± 1.2
Frequency of hunger	3.8 ± 1.0	3.6 ± 1.1
Satisfaction with taste	4.2 ± 0.9	3.9 ± 1.2
Satisfaction with amount	3.9 ± 0.8	3.7 ± 1.1
Difficulty eating out	3.9 ± 1.2	3.4 ± 1.4
Interference with daily activities	4.2 ± 1.1	3.6 ± 1.3
Difficulty shopping for food	4.2 ± 1.1	4.0 ± 1.1
Difficulty planning and preparing meals	4.1 ± 0.9	3.5 ± 1.3
Diet counseling		
Dietitians' knowledge of obesity	6.4 ± 1.0	6.4 ± 1.0
Dietitians' knowledge of the diet	6.7 ± 0.7	6.4 ± 0.8
Satisfaction with dietitians' explanation	6.7 ± 0.7	6.3 ± 1.1
Satisfaction with dietitians' answers	6.8 ± 0.7	6.7 ± 0.7
Satisfaction with the quality of the written guidelines	6.2 ± 1.3	6.4 ± 0.9
Satisfaction with adaptation of diet to personal taste and habits	6.1 ± 1.2	5.6 ± 1.8
Satisfaction with participation in diet planning	6.2 ± 1.2	5.7 ± 1.6

*Scores are given as mean ± SD from a scale where 1 is the lowest and 7 the highest score. There were no significant differences between the groups.

Plasma ketone body concentrations were measured at the end of the trial and all participants were found without ketosis. In addition, there were no significant differences in glucose, insulin, and C-reactive protein levels between the NCEP and MLC groups. Satisfaction with the diet and counseling were similar in both groups (**Table 4**).

COMMENT

In this randomized trial the MLC diet low in carbohydrates and relatively high in predominantly monounsaturated fat and protein caused more weight loss than the NCEP diet, had no adverse effects, and improved lipid variables after 12 weeks.

The MLC diet was designed based on observations that rapid and significant weight loss occurred in patients adhering to popular high-fat, low-carbohydrate diets. However, the most popular of these diets emphasizes the consumption of saturated fats. Although fat content in the MLC diet was relatively high, the fats consumed were mostly monounsaturated. Diets rich in monounsaturated fatty acids lower total and LDL cholesterol while preserving HDL cholesterol levels.[30-33] The beneficial effect of diets rich in unsaturated fats on lipoprotein levels may extend to benefits on cardiovascular disease.[21] The MLC diet recommended lower total carbohydrate intake but a higher consumption of complex carbohydrates, those with a low glycemic index, given the known detrimental effect of foods with a high glycemic index on HDL[34] and triglyceride levels.[35,36]

There were no significant differences between the MLC and NCEP groups regarding waist-to-hip ratio. Within the MLC group, however, there was a significant decrease. It should be noted that this trial was designed with sufficient statistical power to assess between-group differences in weight but not in other anthropometric measures or lipid variables. Nonetheless, it is interesting to note that the preferential deposition of abdominal fat (the central or android pattern) is an independent cardiovascular risk factor.[37-39] Central obesity is often associated with hyperinsulinemia, glucose intolerance, high triglyceride and low HDL cholesterol levels, and hypertension,[40-42] which contributes to the metabolic syndrome. The metabolic syndrome is a major clinical and public health problem. It is a clinical problem because, for those who have it, the overall risk of coronary heart disease is far greater than the simple arithmetic sum of the individual risks[43-45]; it is a public health problem because, in the United States, 40% of adults older than 40 years are affected.[46]

Hypertriglyceridemia is an independent risk factor for coronary heart disease.[47-50] Overweight individuals, espe-

cially those with central obesity, often have hypertriglyceridemia, a component of the metabolic syndrome. Although there were no significant differences between the groups, the MLC diet markedly and significantly reduced triglycerides. This finding in the MLC diet group may be a consequence of the patients' greater weight loss and their consumption of foods with a low glycemic index.

There were no significant differences between the 2 groups for any lipid variables. Nonetheless, the NCEP, but not the MLC diet, significantly reduced HDL as well as LDL cholesterol levels. Diets low in saturated fats but high in carbohydrates may result in a reduction in HDL cholesterol levels. The clinical relevance of reducing HDL cholesterol levels by dieting is not clear. For example, in a small randomized trial,[51] patients who followed a low-fat diet for 5 years experienced regression of coronary atherosclerosis. These patients had a significant, long-term reduction in HDL cholesterol level without any apparent adverse consequences. However, in that trial, other intense lifestyle changes, including smoking cessation and increased levels of exercise, may have confounded the lipid results. Although the NCEP diet significantly reduced LDL cholesterol, the effect size was small, and neither diet significantly changed the total cholesterol-to-HDL ratio.

There were additional significant changes in lipid variables within the MLC but not within the NCEP diet group. Specifically, the MLC diet was associated with increased particle size of the major LDL peak and a reduction in the proportion of small, high-density LDL particles. The clinical implications of a change in LDL particle size and density without a change in overall concentration of LDL cholesterol is not clear. However, a preponderance of small, dense LDL particles is commonly associated with hypertriglyceridemia.[52] Indeed, the marked reduction in triglyceride levels in the MLC diet group was associated with an increase in the particle size of the major LDL peak. This finding was not present in the NCEP diet group, possibly because of the more modest reduction in triglyceride levels.

The rationale for the stepped approach of the MLC diet included motivation and education. In the first stage, patients promptly lose weight because of the significant reduction in calories. This motivates them to proceed to the later stages of the diet. The educational aspects of the stepped approach to diet are also important. Patients learn the effects of different foods on their weight and how to identify foods higher in monounsaturated fat and with a lower glycemic index to reduce postprandial craving.

Overall, despite the added complexity of the MLC diet, with its stepped approach, both groups of patients were similarly satisfied with their assigned diets and the dietary counseling. Of interest, 5 of the 6 participants who did not complete the trial were assigned to the NCEP diet. This may reflect a lack of early weight loss or dissatisfaction with the diet. The latter possibility is supported by long-term data from a randomized trial, which demonstrated significantly less weight loss as well as lower compliance with a low-protein, high-carbohydrate diet.[53]

In recently revised dietary guidelines the AHA recommended a diet low in saturated but high in monounsaturated fat as an option for individuals with low HDL-cholesterol, elevated triglyceride, and elevated small, dense LDL-cholesterol levels. The AHA recognized that LDL cholesterol levels might be reduced by substituting either carbohydrates or monounsaturated fat for saturated fat, and that this approach lacks the potentially detrimental effect of high-carbohydrate, lower-fat diets on HDL and triglyceride levels.[22] The data from the present trial are compatible with this recent AHA revision.

Popular low-carbohydrate, high-fat diets have been criticized for promoting ketosis, a sign of metabolic derangements. We were unable to detect ketone bodies in any of the study participants. However, the tests for ketosis were performed at the end of the trial, during the maintenance phase of the MLC diet, when calories from carbohydrates were much less restricted. Thus, we cannot exclude the possiblilty of ketosis during the early phase of the MLC diet.

The trial was intended to be isocaloric in both randomized groups. Because of limitations inherent in food diaries and calorie counts, we cannot exclude small differences in overall caloric intake between groups.

The trial duration of 12 weeks was relatively short but sufficient to observe a greater decrease in body weight in the MLC than in the NCEP diet group. It remains unclear whether this beneficial effect would be maintained over a prolonged period of years. It is also unclear whether the observed apparently beneficial but nonsignificant changes in blood lipid concentration and waist-to-hip ratio would increase, decrease, or remain the same.

Overweight and obesity have reached epidemic proportions in the United States. Approximately $68 billion per year are spent on health problems directly associated with excessive body weight. Weight reduction programs and special food regimens represent an incremental additional societal cost of $30 billion per year.[54] Traditionally, low-fat diets with a high carbohydrate content have been recommended as healthier diets to promote weight loss,[55,56] but their effect on weight is modest, and they may increase triglyceride and lower HDL cholesterol levels.

While any expected incremental benefits of different diets are small to moderate, the clinical and public health implications are very large for a condition as common and serious as obesity. Thus, randomized trials of large sample size and long duration of dietary interventions represent the most reliable design strategy to provide data on obesity and weight loss likely to have an impact on the health and health care expenditures of the US population. Further randomized trials of sufficient size and duration are necessary to confirm or refute the current findings.

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