Chapter 1. Introduction and summary of the dietary and nutritional methods and findings in the Multiple Risk Factor Intervention Trial

Jeffrey A Cutler and Jeremiah Stamler

INTRODUCTION

Nutrition science occupies a central place for understanding the etiology, pathogenesis, treatment, and prevention of atherosclerotic and hypertensive cardiovascular diseases. Accordingly, nutrition knowledge was central to the background, design, and conduct of the Multiple Risk Factor Intervention Trial (MRFIT). As a consequence, the trial generated one of the largest sets of high-quality longitudinal nutrition data ever assembled. This data set is potentially of great value, both for elucidating issues addressed directly by the MRFIT objectives and design and for exploring other nutrition questions of current interest in cardiovascular epidemiology.

This monograph is organized as follows: Chapter 2 is a brief summary of the MRFIT background, rationale, design, implementation, and main results. Of the two detailed chapters on nutritional and related methods, Chapter 3 describes the data collection instruments and intervention program. Chapter 4 examines four methods issues related to analyses of MRFIT dietary and other data, with a focus on underestimation of the strength of relations between dietary and other variables. Chapters 5–8 report findings related to the major objectives of the trial itself: baseline characteristics of the cohort, changes in food and nutrient intakes attributable to the special intervention (SI) program, relations of these changes as well as of weight change to blood lipid change, and factors involved in the degree of adherence to dietary goals. Chapter 9 addresses an issue that must always be considered in the context of dietary change: nutritional adequacy. Finally, Chapters 10–14 explore other relations: those of dietary carbohydrates, including fiber, to blood lipids; multiple dietary variables to blood pressure; dietary and other factors to body weight; and smoking status to patterns of dietary intake and weight. Am J Clin Nutr 1997;65(suppl):184S–90S.

DESIGN AND METHODS

Chapter 2: brief description of MRFIT

MRFIT was one of the coronary heart disease prevention trials recommended to the National Heart and Lung Institute in 1971 as an alternative to a national single-factor dietary trial, which was judged to be infeasible. MRFIT was a randomized, primary prevention trial conducted at 22 US clinical centers from 1973 to 1982, and was designed to test whether lowering elevated serum cholesterol concentrations, diastolic blood pressure (DBP), and cigarette smoking would reduce coronary heart disease mortality. After three screening visits for determination of eligibility, men aged 35–57 y (n = 12,866) with one or more of these risk factors were randomly assigned to the SI or usual care (UC) group and were followed for 6–8 y. UC men were given information on risk factors, referred to their usual sources of care, and reexamined annually. SI participants received group and individual counseling about a fat-modified diet, a stepped-care drug treatment program for diastolic hypertension (after an initial attempt at blood pressure control by weight reduction, if indicated), and for cigarette smokers, counseling aimed at cessation. SI men had risk factor assessments every 4 mo. Annual examinations were generally identical to those given to UC men and always included measurements of blood cholesterol. A listing of the variables measured at each visit along with the design and main results of MRFIT are included in this chapter.

Chapter 3: methods of dietary and nutritional assessment and intervention

Various dietary instruments were used in MRFIT, either to assist with the SI program or to assess trial outcomes by comparing the SI and UC groups. For the latter purpose, the 24-h recall was the main method, and was selected with the understanding that the single recall collected at baseline and at most annual visits—considered by itself—would be useful mainly for assessing groups rather than individuals. Major components of the data collection and analysis system developed for the 24-h recall included central training and certification of nutritionists, a central nutrient coding system, and a food grouping system to assist interventionists in using recall data for counseling. Nutrition-related questions asked of all participants addressed 1) (during screening) exclusion criteria potentially affecting protocol adherence, 2) diets prescribed by personal physicians during follow-up, 3) other potential social influences on dietary behavior, and 4) meal patterns, including

1 From the Prevention and Demonstration Research Branch, National Heart, Lung and Blood Institute, National Institutes of Health, Bethesda, MD, and the Department of Preventive Medicine, Northwestern University, Chicago.
2 Address reprint requests to GA Grandits, Division of Biostatistics, University of Minnesota, 2221 University Avenue, SE, Minneapolis, MN 55414.
meals eaten away from home. At some annual visits, a short food-frequency questionnaire was administered.

Several additional nutritional assessment methods were used for SI men only to assist them in attaining the dietary goals. These goals consisted chiefly of reduced intake of saturated fat and cholesterol and modest increases in intake of polyunsaturated fat; total fat intake was also decreased, primarily for control of energy intake. Short-term success at attainment of these nutritional goals was evaluated by means of 3-d food records collected before the intervention and after the initial 10-wk intensive-intervention period. The MRFIT nutrient goals, which became more rigorous at certain points in the trial, were translated into food patterns. Adherence to these food patterns was also assessed by scoring 3-d records and by subjective evaluation by nutritionists throughout the trial.

Chapter 4: methods issues in analyses of dietary data

This chapter examines four methods issues in analyses of MRFIT dietary and other data. Each of these has bearing on the interpretation of results presented in other chapters of this monograph.

The MRFIT sample selection process and its effect on relations among variables

Of the 361,662 men attending the first screening visit, 20,080 attended a second screening visit; at the end of a third screening visit attended by 14,111 men, a total of 12,866 were found to be eligible and were randomly assigned into the trial. Their selection was based on a combined three-factor coronary heart disease risk score calculated from concentrations of serum total cholesterol (TC), DBP, and cigarette use (number/d), as measured on the first screening visit. Men in the top 15% (later changed to 10%) of this combined score were eligible on the basis of distribution of this score in the Framingham Study cohort. Many men were eligible on the basis of high levels for two risk factors, even though they were low for a third. This resulted in risk factor associations for the 12,866 men that were different from those of men in general populations, including the 361,662 men who attended the first screening.

Thus, for the 12,866 men, there was an inverse association between cigarette use and TC ($r = -0.21$), ie, nonsmokers and light smokers had higher TC concentrations. But in unselected populations, these two variables are unrelated or have a low-order positive relation, eg, for the 361,662 attendees of the first screening, $r = 0.04$. Similarly, DBP and smoking were inversely related for the 12,866 randomly assigned men ($r = -0.54$), but were minimally correlated for the 361,662 men ($r = -0.03$). Also, TC and DBP were inversely correlated for both nonsmokers and smokers for the 12,866 men ($r = -0.37$ and $-0.36$, respectively) but were positively related for the 361,662 men ($r = 0.17$ and $0.14$, respectively). These consequences of the selection criteria need to be considered when assessing relations in the trial cohort of 12,866 men. Thus, a smaller decrease in TC with dietary intervention for smokers than for nonsmokers may be due at least in part to less responsiveness and to less motivation, hence less adherence, with lower mean baseline concentrations. Analyses in this monograph dealt with this problem: baseline concentrations of these and related traits were adjusted for and the sample was stratified into subgroups, eg, TC change for nonsmokers and smokers stratified by baseline TC concentration.

Difference between serum cholesterol at the first screening and plasma cholesterol at the second screening, and estimation of mean baseline TC for randomly assigned men

For the 12,866 participants, mean serum TC at the first screening was 253.8 mg/dL and mean plasma TC at the second screening (on average, 44 d later) was 240.3 mg/dL. Three reasons for this lower concentration are regression to the mean, plasma TC concentrations that were $\sim 3\%$ lower than serum concentrations, and participants who may have made dietary changes leading to lower TC. Corrected for the serum-plasma analytic differences, the mean cholesterol concentration at the second screening was 248.6 mg/dL. The residual difference of 5.2 mg/dL is attributable to the first and third of the cited reasons, mainly the first. Other data indicate little additional regression to the mean between the second screening and randomization at the third screening. Therefore, follow-up TC concentrations (year 1, 2, etc) can be compared with second screening concentrations to assess influences of postbaseline factors, including dietary intervention.

Reliability of nutrient intake estimated from 24-h dietary recall data

Nutrition data for individuals that are based on one 24-h dietary recall are of limited reliability because of substantial intrapersonal variability in day-to-day nutrient intake; hence, for example, analyses of nutrient-TC and nutrient-blood pressure relations for individuals are biased toward zero because of misclassification (nutrient values based on one recall not accurately reflecting average or usual nutrient intake)—the regression-dilution bias problem. This results in regression coefficients that are only a fraction of true coefficients, and loss of statistical power to detect true relations. Chapter 4 gives detailed data quantifying these problems for the nutrients measured in MRFIT. It also includes data on the improvements in this situation with use of nutrient data from the four or five recalls collected per man during the trial, and references statistical methods for correcting coefficients for regression-dilution bias.

Underreporting of food intake at annual follow-up visits

The SI men apparently underreported their food intake during the trial. Mean baseline energy intake for all men was 2419 kcal (10 129 kJ/d; for SI men during follow-up years 1–6, the mean was 545 kcal (2280 kJ) lower, but for UC men was 176 kcal (736 kJ) lower, a long-term difference not corroborated by the difference between these two groups in weight loss (3 lb, or 1.4 kg). Likely explanations are underreporting or underconsumption on the day before the recall. This underreporting or underconsumption may or may not be "across-the-board" in terms of foods and nutrients, eg, foods high in total fat, saturated fat, and cholesterol may be particularly underreported or underconsumed, introducing biases into the data. With nutrient data expressed in terms of energy density (eg, % of energy or mg/1000 kcal), the assumption is implicit that underreporting is "across the board," ie, nonreported foods had the same nutrient composition as did reported foods. With nutrient data expressed in absolute amounts (eg, g/d or mg/d), the assumption
is implicit that unreported foods contained none of the nutrients of concern. No methods exist to correct for these problems. Significant nutrient-blood lipid, nutrient-blood pressure, and other relations reported in this monograph were found despite these sources of bias in the data, however, and reflect the quality of the data collection and analysis methods and the advantages of multiple 24-h recalls per person and a large sample size.

RESULTS RELATED TO TRIAL GOALS

Chapter 5: food and nutrient intakes at baseline

This chapter describes food and nutrient intakes reported at baseline and relates these variables to other facets of reported dietary behavior, to the major risk factors, and to sociodemographic characteristics of MRFIT men. Intakes of total fat (38.4% of energy), saturated fatty acids (SFAs; 14.2%), and dietary cholesterol (492 mg/d) were similar to amounts seen in the first and second National Health and Nutrition Examination Surveys, also conducted in the 1970s, and were generally lower than findings from studies carried out in the 1960s, providing evidence that the public was heeding advice from sources such as the American Heart Association.

There were inverse relations between total serum cholesterol and intake of total fat, saturated and monounsaturated fatty acids, and dietary cholesterol. These paradoxical associations were largely attributable to findings in 21% of men who reported following a special diet, indicating that prescription of or adherence to such a diet increases with severity of hypercholesterolemia. Fat intake was directly related to the number of meals per week eaten away from home and to the presence and intensity of smoking (cigarettes smoked/d). These associations may reflect both situational and motivational factors affecting dietary choices. Patterns of food and nutrient intake were similar for men stratified by baseline blood pressure and antihypertensive treatment; the few significant differences were modest in degree.

Intake of total energy as well as percentage of energy from various dietary fats decreased with age, as did use of sucrose and caffeine. White men ate more dairy products of various fat content than did other ethnic groups, whereas black men had higher intakes of eggs, sugars, and sweets than did others. Asians had the highest intake of cereal foods. Those with more education ate less high-fat meat products, more fruit, and more polyunsaturated oils, but also more high-fat dairy products and less breads and cereals. They also used more alcohol than those with less education.

Chapter 6: changes in macronutrient and food group intakes during trial years 1–6

This chapter presents the changes in dietary intake reported by SI and UC men from baseline through 6 y of follow-up. Changes in nutrient intakes in SI men after 1 y of following the intensive-intervention program were as follows: reduction in total fat (from 38.4% to 34.3% of energy), SFAs (from 14.2% to 10.4% of energy), and dietary cholesterol (from 448 to 263 mg/d), and an increase in polyunsaturated fatty acids (PUFAs) (from 6.4% to 8.6% of energy). The Keys score—which is based on dietary SFAs, PUFAs, and cholesterol and is an indicator of expected change in serum cholesterol—decreased by about one-third. These changes were maintained but did not increase through the remaining 5 y of the study. They were substantially and significantly greater in SI than in UC men, in whom only small changes in similar directions were observed. However, favorable mean changes in SI participants did not attain dietary specifications (nutrient goals) at any annual examination, although percentage of energy from saturated fat approached the original basic MRFIT goal (10%) from the first year onward.

Reduction in food group intake, accounting for most of the change in SFA intake by SI participants, included reductions in high-fat meats and high- and medium-fat dairy products. However, these food groups (except for medium-fat dairy) remained major sources of SFAs, as did low- and medium-fat meats, baked goods, and desserts. Proportionately, oils high in PUFAs became a more important source of SFAs than before the intervention despite the limited emphasis in the intervention program on an increase in PUFAs. Dietary cholesterol was reduced primarily through substantial decreases in egg and high-fat meat intakes. During the follow-up period, almost one-half of dietary cholesterol was derived from low- and medium-fat meats.

Several baseline factors were associated with amount of dietary change in SI men. These associations were most consistent for the integrative variables: for nutrients, Keys score, and for foods, total intake of so-called “avoid” and “once-in-a-while” foods. Greater changes were seen in 1) men with higher baseline serum cholesterol concentrations, 2) those not consuming a special diet, 3) nonsmokers followed by lighter smokers, 4) hypertensive than in nonhypertensive men, 5) older participants, 6) white than in black men (for Keys score but not for food groups), 7) moderate drinkers than in nondrinkers or those consuming ≥ 22 drinks per week, and 8) those with no “life events” than in those reporting one or more putatively adverse life events. Most of these associations can be interpreted as factors likely to increase motivation for change or to decrease barriers or interfering influences. No consistent associations were observed with body mass index (BMI), marital status, education, or type A behavior pattern (Jenkins Activity Score).

Chapter 7: relation of changes in dietary lipid intake and weight during trial years 1–6 to changes in blood lipids

This chapter focuses on change in blood lipids during trial years 1–6 and on relations of change in dietary lipids and weight to change in blood lipids in all SI and UC men and for SI men stratified by baseline hypertensive status, use of diuretics during the trial, and baseline smoking status (see summary of Chapter 14). To estimate expected effects on blood lipids of reported change in dietary lipids, change in the Keys score was used as a single number summarizing change in reported dietary lipids: change in Keys score is the difference between Keys score at baseline (from one dietary recall) and the average Keys score during the six trial years (from four or five dietary recalls). Imprecision in change in Keys score for each man, primarily because only one recall was available at baseline, produced regression-dilution bias in analyses of relations between dietary lipids and blood lipids (see summary of Chapter 4).

For SI men, the mean decrease in serum TC from the first screening averaged 16.9 mg/dL (6.7%) during the 6 y of the
trial; for UC men the decrease was 9.7 mg/dL (3.8%) (SI – UC = 7.2 mg/dL; P < 0.001). For plasma low-density-lipoprotein cholesterol (LDL-C), decreases from the second screening were 10.6 mg/dL (6.6%) for SI men and 5.4 mg/dL (3.4%) for UC men (SI – UC = 5.2 mg/dL). The difference in the decrease in plasma TC between SI and UC men was 6.2 mg/dL. Changes in blood TC and LDL-C at years 1 and 2 were maintained for men in both groups throughout the trial. Mean weight loss was 3.0 lb (1.36 kg) for the SI group and 0.1 lb (0.05 kg) for the UC group. Mean weight fell initially in both groups with a difference between the SI and UC groups of almost 3 lb (1.4 kg) at years 2–4. Mean BMI (kg/m²) remained high throughout, ~27 for men in the SI group in years 1–4.

Changes in serum and plasma TC, within each group and for the SI compared with the UC group (net differences), were directly related to baseline concentrations. For the 84% of men with serum TC concentrations ≥220 mg/dL at the first screening, the mean decrease was 7.8% for those in the SI group (short of the 10% design goal) and 4.8% for those in the UC group (compared with an expected 0.0%).

Changes in dietary lipid intake, ie, in Keys score, for SI men were significantly related to changes in blood TC, LDL-C, and triglycerides (P < 0.001) but not to changes in high-density-lipoprotein cholesterol (HDL-C). When weight change was controlled for, changes in Keys score were still significantly related to changes in blood TC and LDL-C but not to changes in triglycerides. For the 20% of men in the highest quintile of Keys score change, the expected decrease in serum TC was 40.6 mg/dL; the observed decrease was 19.6 mg/dL. This difference reflects imprecision in 24-h recall data and under-reporting of SFA and cholesterol intakes by SI men during the trial, ie, reported adherence compared with actual adherence to dietary recommendations.

Change in Keys score and change in weight were significantly correlated and were both significantly and independently related to change in TC and LDL-C. Thus, men in the upper tertile of Keys score change (mean change: –35.8 mg/dL) and in the upper tertile of weight change (mean change: –13.6 lb, or –6.18 kg) had a decrease in serum TC of 24.2 mg/dL, whereas those with a similar Keys score change but a weight loss of only 2.8 lb (1.27 kg) had a mean decrease in TC of 17.7 mg/dL. These data indicate that loss of an additional 10.8 lb (4.91 kg) with the fat-modified diet increased the serum TC-lowering effect by almost 1.4 times (24.2/17.7 = 1.37). Correspondingly, weight loss increased favorable effects on other blood lipids. In these analyses, there was a significant inverse relation of weight change, but change in Keys score was not related to HDL-C change. In men with substantial weight loss averaging almost 14 lb (6.36 kg), plasma HDL-C rose significantly and triglycerides fell significantly in all three tertiles of Keys score. These findings underscore the importance for overweight persons of both sustained dietary lipid modification and weight loss to achieve sustained, significant favorable effects in all blood lipid values.

Effects of change in diet and weight on blood lipids were qualitatively similar for SI men who were either nonhypertensive or hypertensive at baseline, but were quantitatively less for hypertensive men for serum TC, HDL-C, and triglycerides. Throughout the trial, effects on blood lipids tended to be quantitatively more favorable for men not receiving than for those receiving diuretic treatment, but for the latter, combined diet and diuretic treatment was associated with favorable effects on blood lipids.

Nonsmokers had greater decreases than did smokers in blood TC, LDL-C, and triglycerides, reflecting greater changes in reported dietary lipids (Keys score), greater weight loss, and higher initial values. Nonsmokers had no change in HDL-C and smokers, a slight increase, probably due to smoking cessation. For both nonsmokers and smokers, changes in Keys score and in weight were related to changes in blood TC, LDL-C, and triglycerides; change in weight (but not in Keys score) was related to change in HDL-C.

Chapter 8: dietary adherence

This chapter presents findings on adherence to the MRFIT eating pattern by SI participants, on the basis of measures other than 24-h dietary recall and blood cholesterol concentrations (see summaries of Chapters 6 and 7). These additional assessments, not applied to UC men, included 1) subjective rating by a nutritionist, used during follow-up years 1 and 2, and 2) food record rating, an assessment from a 3-d food record of dietary lipid intake with a scoring system that assigned points to fat-containing foods on the basis of their lipid-raising or -lowering potential, used during years 3–6. (A typical American diet in the 1970s had a food record rating of ≥20, whereas complete adherence to the MRFIT pattern scored ≤9.) An additional tool used during the latter part of the trial was a checklist to evaluate degree of shortfall of participants’ diet from recommendations, level of motivation toward adherence, and factors in the social environment potentially influencing dietary behavior.

Taken together, subjective ratings and food record ratings indicated that ~40-65% of participants were good or excellent adherers, with declines in these percentages over time. There were consistently strong relations between these ratings and change in serum cholesterol throughout the trial. However, nutritionists were not blinded to the participants’ previous blood lipid concentrations when they gave ratings. Checklist evaluations gave similar overall findings, with about one-half to three-quarters of participants rated positively on infrequency of deviation from eating pattern, motivation, and conducive environment, and with consistent associations between these ratings and serum cholesterol change. Hence, all these instruments for adherence monitoring appear to yield valid measures. Additionally, several baseline traits predicted adherence, as assessed by these measures and by 24-h recall data. Adherence was better in older participants and tended to be best in Asian men, followed by white participants. There were no associations of adherence with educational attainment or marital status.

Adherence was related to alcohol consumption, but unlike findings from 24-h recalls for foods and nutrients, nondrinkers rather than light drinkers were rated best. Those with fewer life events adhered better, but there was no relation with Jenkins score for type A behavior. Lower frequency of eating meals away from home was associated with better adherence. BMI was inversely associated with adherence ratings, although heavier participants exhibited greater changes in serum cholesterol, perhaps reflecting their poorer baseline diets and thus more room for improvement. Adherence was also directly related to baseline measurements of both serum cholesterol and diastolic blood pressure, as well as hypertensive status. Non-
smokers had better adherence than did cigarette smokers. These relations of adherence indexes with major risk factors were similar to those reported for dietary change and major risk factors (see summary of Chapter 6).

Chapter 9: micronutrient intake and nutritional adequacy of diets

This chapter addresses the question of whether a fat-modified diet as implemented by MRFIT SI participants affects intake of vitamins and minerals, and whether adequacy of intake relative to standards is altered by this dietary intervention. Of 15 micronutrients estimated from 24-h recalls, with established recommended dietary allowances (RDAs), most means for SI men during the trial were above the RDA; a few were slightly below; lowest was zinc at 77%. On an absolute basis, intake of all 19 measured micronutrients tended to decrease during intervention, attributable largely to underreporting of intake during follow-up.

Calculated as nutrient densities (per 1000 kcal), only retinol and vitamin B-12 decreased, and mean values for both total vitamin A and vitamin B-12 remained far above both RDAs and indexes of nutritional quality (the corresponding standard based on nutrient density). Those nutrients that remained below the index of nutritional quality during follow-up, even though not reduced below baseline by this measure, were vitamin D, calcium, iron (marginally), and zinc. Analyses by food groups indicated that improvement might have been achieved for these nutrients by greater replacement of high- and medium-fat dairy products with low-fat dairy products (for vitamin D and calcium) and of high-fat meats with low-fat meats, fish, or poultry (for iron and zinc) or (because iron intake was adequate) by increasing consumption of vegetables and whole-grain products.

Further assurance of the safety of the eating pattern was provided by analyses that showed more favorable micronutrient profiles in men who adhered best to the intervention program, as measured by quintiles of serum cholesterol reduction and weight loss. Comparison of intakes of SI men during follow-up with data from other population surveys of middle-aged men during the 1970s and early 1980s indicated similar intakes of 12 micronutrients, with trends toward higher intakes of vitamins A and C, potassium, and magnesium by the MRFIT cohort.

OTHER RESULTS

Chapter 10: relation of dietary carbohydrate intake to blood lipids

This chapter explores relations of reported intake of dietary carbohydrates—total, complex (starch), refined and processed sucrose, and other simple carbohydrates—to plasma lipids at baseline and during trial years 1–6. At baseline, total carbohydrate intake (% of energy) was inversely related to plasma TC and HDL-C when age, DBP, cigarettes smoked/d, race, BMI, antihypertensive drug use, dietary lipids (SFA, PUFA, and cholesterol), and alcohol were controlled for; starch and other simple carbohydrates were unrelated to plasma lipids, and sucrose was inversely related to HDL-C.

During trial years 1–6, SI men increased their intake of starch and other simple carbohydrates as they decreased their intake of fat and of refined and processed sucrose. Total carbohydrate intake of SI men was inversely related to TC, LDL-C, and HDL-C. Thus, for men in the highest quintile (average: 55% of energy) compared with men in the lowest quintile (31% of energy), TC was lower by 6.6 mg/dL (2.9%), LDL-C by 2.7 mg/dL (1.8%), and HDL-C by 2.9 mg/dL (6.6%). Starch and sucrose intakes were also inversely related to HDL-C. In contrast, intake of other simple carbohydrates was directly related to HDL-C and inversely related to plasma TC and LDL-C: for men in the highest quintile of intake of other simple carbohydrates (average: 24% of energy) compared with men in the lowest quintile (8% of energy), plasma TC was lower by 3.7 mg/dL (1.6%), LDL-C was lower by 4.3 mg/dL (2.8%), and HDL-C was higher by 1.6 mg/dL (3.8%). Thus, in addition to dietary lipid composition and body mass, dietary carbohydrate composition can have important influences on plasma TC, LDL-C, and HDL-C. No significant relations were found, however, between change from baseline in any of the four carbohydrate variables and change in plasma lipids. Findings were generally similar for the UC group.

Chapter 11: dietary fiber and blood lipids

This chapter addresses relations between intake of fiber—total, soluble, and insoluble—and blood lipids, with use of baseline data (single measurement), an average of four to five 24-h recalls, and blood lipid determinations collected during annual follow-up examinations. Change from baseline to average follow-up values was also studied. No associations were observed in the baseline data. Consistent highly significant inverse associations were seen in analyses of follow-up measurements. Results from change data were of intermediate strength and consistency. These variations were in all likelihood due to low reliability of a single 24-h recall at baseline for determination of dietary intake and change in intake for individuals.

From follow-up data, plasma TC and LDL-C concentrations were lower by ~5 mg/dL for SI men in quintile 5 of total fiber intake (25 g/d) compared with men in quintile 1 (8 g/d), after adjustment for average BMI and intake of alcohol, saturated and polyunsaturated fatty acids, and dietary cholesterol. Results were similar for UC men. There were no adverse effects on HDL-C, nor any consistent associations with plasma triglycerides. These findings indicate that increasing dietary fiber can provide additional reduction in blood TC and LDL-C and consequent improvement in the lipid profile, over and above the beneficial effects of a fat-modified diet.

Chapter 12: relation of body mass and intakes of alcohol, nutrients, fiber, and caffeine to blood pressure

This chapter presents analyses on relations between dietary variables and blood pressure, systolic (SBP) and DBP. Method problems of these analyses are reviewed, all of which tend to result in underestimation of the true relation of dietary variables to blood pressure (eg, due to regression-dilution bias). Possible confounding variables, eg, age, race, education, serum cholesterol, smoking, and special diet status, and for specific nutrients, BMI and alcohol intake, were controlled for in all analyses of dietary factor and blood pressure relations. The relation of each dietary factor to blood pressure was analyzed 1) at baseline, 2) for trial years 1–6 for the SI group, 3) for trial
years 1–6 for the UC group, 4) for trial years 1–6 for both groups, 5) for change from baseline to years 1–6 in the SI group, and 6) for change from baseline to years 1–6 in the UC group. This set of six analyses was done for diet-SBP and diet-DBP relations for all participants, for men receiving antihypertensive drug treatment, and for men not receiving antihypertensive drug treatment. (For baseline analyses, drug treatment was defined by baseline status; for years 1–6 and for change analyses, drug treatment was defined by year-6 status.) Most regression coefficients were not corrected for regression-dilution bias. Nutrient data for trial years 1–6, based on four or five dietary recalls per man, are more reliable than baseline or change data, which are based on only one recall per man. Therefore, this summary focuses on data for trial years 1–6, for SI and UC men pooled.

Regression analyses confirmed previously shown direct independent relations of BMI, intakes of alcohol and sodium, and the ratio of sodium to potassium to blood pressure, and an inverse relation of potassium to blood pressure. These variables were related to both SBP and DBP. In addition, with control for BMI, alcohol, and multiple other variables, the following other dietary blood pressure relations were indicated (for dietary factors considered singly): dietary starch was directly related to SBP and DBP; dietary SFA, cholesterol, and Keys score were directly related to DBP; dietary magnesium, fiber, and caffeine were inversely related to SBP and DBP; and dietary protein, PUFA, the ratio of PUFA to SFA, and other simple carbohydrates were inversely related to DBP.

Chapter 13: relation of food and nutrient intakes to body mass

This chapter summarizes weight-related and BMI-related findings from other chapters and then focuses on two further sets of relations: 1) food group and nutrient intakes and weight change during follow-up years 1–6, and 2) baseline factors associated across-sectionally with BMI and longitudinally with weight change. Results were generally consistent between SI and UC groups, although relations involving dietary intake variables were stronger for the SI group.

In previous chapters of this monograph, it was shown that BMI was related to pattern of nutrient intake and to blood pressure at baseline. For SI participants, weight loss enhanced the response of blood lipids to dietary fat modification and contributed significantly to blood pressure reduction. SI non-smokers were successful at sustained weight loss (average of 6.4 lb, or 2.91 kg). SI smokers who quit during the trial experienced only a modest gain in weight that was less than that for those who quit early (2.8 lb, or 1.27 kg); however, weight gain for even early quitters in the SI group was less than that for early quitters in the UC group (5.4 lb, or 2.45 kg).

Weight change was related similarly both to dietary composition averaged over follow-up recalls and to changes from baseline. The greater the weight loss (compared with men who experienced little change or gained weight), the larger the reductions in and the lower the intake of refined and processed sucrose, total fat, saturated and monounsaturated fatty acids, dietary cholesterol, and total energy. These patterns reflect the influence of lower percentages of energy from medium-fat dairy products, eggs, visible fats high in SFAs, crackers and snacks, and refined or processed sugars and sweets (in both groups). In addition, for SI men these patterns reflect lower percentages of energy from high-fat meats, dairy products, and baked goods or desserts. Both groups also showed a direct association of amount of weight loss with increased or higher percentages of energy from total and nonsucrose simple carbohydrates and fiber, and, for SI men, with higher percentages of energy from starch. These nutrient patterns were due to higher percentages of energy from low-fat dairy products, breads and cereals, fruit, and vegetables, and, for SI men, from low-fat baked goods and desserts. Overall, substantial weight loss was associated with a diet of lower energy density. Accordingly, reported intakes of several essential micronutrients, eg, β-carotene, vitamin C, vitamin B-6, and (in the SI group) potassium, were higher for those who lost weight.

In both groups, baseline predictors of weight loss were higher DBP and higher serum cholesterol, both of which were associated with higher BMI at baseline. Conversely, cigarette smoking was related to lower baseline BMI and to less weight loss. Weight loss was less in both groups in those consuming a special diet or receiving antihypertensive medication at baseline, perhaps because at entry to MRFIT such participants had already lost as much weight as they could. Older men had higher BMIs at baseline than did younger men, and (in the SI group) lost more weight. Baseline BMI was inversely related to alcohol intake and attained years of education; it was higher in white and black than in Asian men, and in married compared with other men. BMI was also positively associated with number of life events reported (an index of stress) and with percentage of meals eaten away from home.

Chapter 14: relation of smoking status at baseline and during trial years 1–6 to intake of foods and nutrients and to weight

This chapter describes dietary composition according to presence and intensity of cigarette smoking at baseline and changes in smoking status during follow-up. Findings related to baseline smoking status are summarized from earlier chapters of this monograph and extended. Main results deal with five patterns of smoking behavior throughout the trial: 1) sustained nonsmoking, 2) early (years 1–2) sustained quitting, 3) late (years 3–6) sustained quitting, 4) recidivism, and 5) continued smoking. These are related to intake of nutrients and food groups during follow-up and to change from baseline. These smoking patterns are also related to changes in body weight and blood lipids.

Eating and drinking patterns of smokers were less favorable than for nonsmokers at baseline with respect to total energy and percentage of energy from total and saturated fat, cholesterol per 1000 kcal, and intake of high-fat meats, high-fat dairy products, eggs, and sweets. Smokers also consumed more alcohol and less fruit, vegetables, low-fat dairy products, and desserts than did nonsmokers. Food group differences translated to lower intake (per 1000 kcal) of β-carotene; vitamins C, B-6, B-12, and E; thiamin; and iron. In general, similar differences were seen between heavy and light smokers.

During the trial, SI men (and similarly, but to a lesser degree, UC men) who quit smoking showed more favorable changes in diet than did those who continued to smoke, and these changes were in many instances as great as those made by nonsmokers. For example, order of change in Keys score, from largest to smallest, in the SI group was as follows: nonsmokers, early quitters, late quitters, recidivists, and continued smokers. The
difference between all quitters and continued smokers was significant \( P < 0.001 \); that between all quitters and recidivists had a \( P \) value of 0.003. For micronutrients, significantly greater increases in SI quitters compared with continued smokers were seen for vitamins E, C, and B-6; thiamin; folic acid; and potassium. Such differences reflected greater increases in fruit intake in quitters than in those who continued to smoke.

Weight gain of 3.8 lb (1.73 kg) was seen in SI men who quit smoking (early quitters: 2.8 lb, or 1.27 kg; late quitters: 5.4 lb, or 2.45 kg) in contrast with nonsmokers, who lost an average of 6.4 lb (2.91 kg) during the trial. This gain by smokers was, however, less than that in corresponding UC quitters, who gained 6.5 lb (2.95 kg). These results show that this problem associated with smoking cessation is amenable to control with nutritional counseling. Moreover, despite weight gain, the net change in HDL-C for SI quitters was positive, nearly reaching the level for nonsmokers. With the associated decrease in LDL-C, as large proportionately as that for nonsmokers, early SI quitters had the most improvement in the ratio of LDL-C to HDL-C among all these subgroups during the trial.

These findings among MRFIT smokers indicate that unfavorable nutritional patterns place such persons at double jeopardy regarding coronary heart disease and other chronic disease risks and that many smokers can be helped so that their long-term risks are improved not only by ending their addiction to tobacco, but also by achieving healthier eating patterns.