Implementation of a 4-y, high-fiber, high-fruit-and-vegetable, low-fat dietary intervention: results of dietary changes in the Polyp Prevention Trial[1,2]

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ABSTRACT

Background: The Polyp Prevention Trial (PPT) was a multicenter randomized clinical trial designed to determine the effects of a high-fiber (4.30 g/MJ), high-fruit-and-vegetable (0.84 servings/MJ), low-fat (20% of energy from fat) diet on the recurrence of adenomatous polyps in the large bowel.

Objective: Our goal was to determine whether the PPT intervention plan could effect change in 3 dietary goals and to examine the intervention's effect on the intake of other food groups and nutrients.

Design: Participants with large-bowel adenomatous polyps diagnosed in the past 6 mo were randomly assigned to either the intervention (n = 1037) or the control (n = 1042) group and remained in the trial for 4 y. Three dietary assessment instruments were used to measure dietary change: food-frequency questionnaires (in 100% of the sample), 4-d food records (in a 20% random cohort), and 24-h dietary recalls (in a 10% random sample).

Results: Intervention participants made and sustained significant changes in all PPT goals as measured by the dietary assessment instruments; the control participants' intakes remained essentially the same throughout the trial. The absolute differences between the intervention and control groups over the 4-y period were 9.7% of energy from fat (95% CI: 9.0%, 10.3%), 1.65 g dietary fiber/MJ (95% CI: 1.53, 1.74), and 0.27 servings of fruit and vegetables/MJ (95% CI: 0.25, 0.29). Intervention participants also reported significant changes in the intake of other nutrients and food groups. The intervention group also had significantly higher serum carotenoid concentrations and lower body weights than did the control group.

Conclusion: Motivated, free-living individuals, given appropriate support, can make and sustain major dietary changes over a 4-y period. *Am J Clin Nutr* 2001;74:387–401.

KEY WORDS Dietary intervention, nutrition intervention, dietary change, dietary fiber intake, dietary fat intake, fruit and vegetable intake, clinical trial, plasma cholesterol, serum carotenoids, body weight, Polyp Prevention Trial

INTRODUCTION

Although the importance of dietary change for disease prevention is widely accepted (1, 2), the difficulty of making and sustaining long-term changes (for ≥1 y) is equally well documented (3, 4). Can free-living individuals make multicomponent changes in eating patterns and sustain them over a long period of time? If changes are made, what new foods do individuals choose to achieve these dietary goals? We focus on the National Cancer Institute's Polyp Prevention Trial (PPT) intervention results in the context of these 2 important questions.

The PPT was designed to advance our understanding of how diet affects risk of colorectal cancer. Adenomatous polyps, considered a necessary precursor of most colorectal malignancies, were used as the endpoint measure (5, 6). Most previous adenomatous polyp trials investigated the effects of specific supplements, such as fiber (7), calcium (8), and antioxidant vitamins (β-carotene and vitamins C and E) (9, 10). It may be, however, that overall food consumption patterns, more so than the consumption of any single nutrient, are associated with cancer and chronic disease prevention (11, 12).

In 1990 results from several observational studies suggested 3 main dietary factors as protective against cancer of the large bowel: low fat intake, high fiber intake, and high fruit and vegetable (FV) intake (13–19). Hence, the intervention arm of the PPT focused on these factors. The dietary goals were to consume ≤20% of energy from fat, ≥4.30 g fiber/MJ (18 g fiber/1000 kcal), and 5–8 servings of FVs/d, depending on energy intake. In addition to using the methodologic strengths of a randomized clinical trial, the PPT provided an opportunity to discover whether free-living participants could make and maintain substantial changes in overall eating patterns over a long period of time (in this case, 4 y). Other trials aimed to change a single aspect of diet or 2 related factors

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Received May 23, 2000.

Accepted for publication December 13, 2000.

TABLE 1
Demographic characteristics of participants in the Polyp Prevention Trial at baseline[1]

Characteristic	Intervention group (*n* = 1037)	Control group (*n* = 1042)
Sex (%)		
Male	66 ± 1.5	64 ± 1.5
Female	34 ± 1.5	36 ± 1.5
Age (y)	61.4 ± 0.3	61.5 ± 0.3
Minority race (%)	12 ± 1.0	9 ± 0.9
Higher than high school education (%)	65 ± 1.5	65 ± 1.5
Married (%)	78 ± 1.3	79 ± 1.3
BMI (kg/m^2)	27.6 ± 0.1	27.5 ± 0.1
Current smoker (%)	14 ± 1.1	13 ± 1.0
Current aspirin user (%)	23 ± 1.3	22 ± 1.0
Vigorous and moderate activity (h/wk)	11.4 ± 0.4	12.3 ± 0.4

[1] $\bar{x}$ ± SEM. There were no significant differences between groups.

rather than the entire dietary pattern. For example, Dolecek et al (20) reported modifying total fat and unsaturated fat among free-living men. The Women's Health Trial (21) reported reductions in fat intake that were sustained for 24 mo. Other studies, such as the Dietary Approaches to Stop Hypertension Trial, attempted to alter eating patterns in a similar way to the PPT (reductions in fat and increases in FV intake), but accomplished this by preparing all food for the participants (22). The PPT was unique in supporting participants to alter their own food choices to effect changes in overall dietary patterns in a free-living situation. Although the PPT dietary intervention showed no effect on the percentage of participants with colorectal adenoma recurrence during the 4 y of the trial (23), this intervention continues to have broad relevance in that the recommended eating plan addressed 3 major dietary factors and required comprehensive changes in eating patterns similar to general recommendations for chronic disease prevention. This article presents the main dietary results of the PPT, including goal achievement and changes in intakes of specific nutrients and foods.

SUBJECTS AND METHODS

Enrollment and follow-up

The PPT included 2079 men and women aged ≥35 y (range: 35–89 y) with at least one histologically confirmed large-bowel adenomatous polyp removed during a colonoscopy procedure (the baseline procedure) within the previous 6 mo. To be eligible, participants could have no history of colorectal cancer, surgical resection of adenomas, bowel resection, polyposis syndrome, or inflammatory bowel disease; weigh no more than 150% of the recommended level; take no lipid-lowering drugs; and have no medical conditions or dietary restrictions that would substantially limit their ability to complete the study requirements. A more detailed description of the exclusion criteria is reported elsewhere (24). Recruitment activities occurred at 8 US clinical centers, starting in the spring of 1991 and ending in January 1994. The institutional review boards of the National Cancer Institute and each participating center approved the study. All participants provided written, informed consent.

Potential participants were asked to complete a 4-d food record (4DFR) and food-frequency questionnaire (FFQ) before being randomly assigned to ensure that their dietary patterns were not already similar to the intervention eating plan and to help determine whether they were willing to keep track of their dietary intake and capable of doing so. After their eligibility was confirmed by a clinical center, the participants were randomly assigned to either the intervention or control group. The baseline characteristics of trial participants by group are reported in **Table 1**.

Each randomly assigned participant was asked to remain in the study for 4 y. Those in the control group (*n* = 1042) were given a 2-page National Dairy Council "Guide to Good Eating" pamphlet immediately after being randomly assigned, but no further dietary information or support for change. The pamphlet described 3 steps for healthy eating [eat foods from all 4 food groups daily (milk, meat, FV, and grains), include a variety of foods, and practice moderation]; offered tips for reducing fat, energy, and sodium intakes and increasing fiber intake; and provided a chart with examples and recommended servings from each food group. Participants in the intervention group (*n* = 1037) were given an intensive program of instruction and support to adopt the PPT eating plan.

Intervention program

The objective of the intervention program was to provide the necessary instruction, support, and motivation to allow intervention participants to successfully adopt and maintain the PPT eating plan. Individual participant goals were based on energy intake calculated from the baseline FFQ (completed just before the subjects were randomly assigned), with the fat goal as 20% of energy and the fiber goal as 4.30 g/MJ (18 g/1000 kcal). Definitions of an FV serving and how daily FV goals were determined are provided in **Table 2**. Each participant received personal fat, fiber, and FV goals at the start of the intervention and retained these goals throughout the trial.

Intervention participants engaged in an intensive nutrition education and counseling program. The program was delivered at each clinical center by registered dietitians who had been trained in state-of-the-art techniques for facilitating dietary behavior change. The intervention program consisted of 4 key elements: *1*) nutrition skill building, *2*) behavior modification, *3*) self-monitoring, and *4*) the provision of standardized nutrition and behavior modification materials.

During year 1 of the trial, the intervention participants attended individual counseling sessions weekly for the first 6 wk, biweekly for the next 6 wk, and monthly thereafter for a total of 19 sessions. Most year 1 sessions were given on a one-to-one basis.

During year 2, the participants attended sessions every other month, with most sessions delivered in a group format. Nutritionists

TABLE 2
Fruit and vegetable (FV) goal determination in the Polyp Prevention Trial[1]

Baseline FFQ energy intake	Daily FV goal
<5.44 MJ	5 servings
5.44–7.11 MJ	6 servings
7.12–8.79 MJ	7 servings
>8.79 MJ	8 servings

[1] 1 FV serving = 1 medium whole fruit or vegetable; 0.5 cup raw or cooked fresh, frozen, or canned fruit or vegetable, except raw green leafy; 0.25 cup dried fruit or vegetable; 1 cup raw green leafy vegetables (such as lettuce); or 0.5 cup legumes or dried beans [fruit and vegetable juices (which contain little fiber) were not counted as servings]. SI unit examples are as follows: 0.5 cup boiled, sliced carrots = 78 g; 0.5 cup raw cauliflower = 85 g; 0.5 cup boiled cauliflower = 63 g; 1 cup iceberg lettuce = 55 g; 0.25 cup raisins = 34 g; and 0.5 cup cooked lentils = 100 g. FFQ, food-frequency questionnaire.

also contacted the participants by phone at least once per month to monitor their progress and to assist in resolving any difficulties with adherence to the PPT eating plan.

During years 3 and 4, participants attended sessions quarterly, with most delivered as group sessions. As in year 2, nutritionists contacted participants at least once monthly by phone. A more complete description of the intervention program and the specific topics covered is published elsewhere (25).

In addition to these individual and group sessions and contacts, 3 special intervention campaigns were launched during participant years 2–4 to boost adherence to one or more of the dietary goals. The first campaign focused on the fat goal (Take It Down Fat Campaign; February 1995 to July 1995), the second on the FV goal (Fruit & Veg-a-thon; May 1996 to October 1996), and the third on maintaining progress toward all 3 PPT goals during the last year of the trial (PPT On My Mind Campaign; February 1997 to September 1997). The campaigns were built on lessons learned in the fields of health behavior change and on advertising and market research on what makes people take action. Participant input about needs, interests, and potential obstacles to goal achievement were also incorporated. Key components of all campaigns included novelty, frequent contact, accountability, rewards, team effort, an action orientation, and an element of fun.

Dietary assessments

The PPT used 3 different dietary assessment measures to estimate intake and assess goal achievement: a modified Block–National Cancer Institute FFQ (26), 4DFRs, and 24-h dietary recalls. All participants (control and intervention) completed the FFQ and 4DFR at baseline and in conjunction with annual visits at the end of years 1, 2, 3, and 4. An additional 4DFR was collected from intervention participants after they had been in the trial for 6 mo to more closely monitor dietary change in the first year of the trial. Throughout each trial year, unannounced 24-h dietary recalls were collected in a random 10% sample (stratified by clinical center) of control and intervention participants.

At baseline, the participants viewed instructional videos demonstrating food portion size estimation and proper completion of the dietary assessments. Trained and certified nutrition staff members reviewed all completed FFQs and 4DFRs with the participants before the forms were submitted for analysis. The 24-h dietary recalls were collected by the same staff members. For each intervention participant, the dietary assessments were conducted and reviewed by nutrition staff members not involved with that individual's intervention counseling. Additionally, computer edits flagged out-of-range FFQ values and missing responses; these items were reviewed with the participants and revised to reflect corrected items before the data were finalized.

A 20% sample of 4DFRs was coded and analyzed immediately. This sample was identified randomly with stratification by clinical center. The remaining 80% of the 4DFRs were reviewed for completeness of information but were not analyzed because of cost considerations.

Biological measures

At the baseline visit and at subsequent annual visits at years 1, 2, 3, and 4, each participant was weighed and a fasting (overnight) venous blood specimen was collected. Serum carotenoids were analyzed by HPLC according to the method of Sowell et al (27). Total carotenoids were calculated as the summation of the major carotenoids in serum: lutein, zeaxanthin, β-cryptoxanthin, lycopene, β-carotene, and α-carotene. Total cholesterol in plasma was measured at the Johns Hopkins University, a laboratory certified by the Centers for Disease Control and Prevention for lipid analysis. The laboratory performed the lipid analysis with a commercially available enzyme method and a Hitachi (San Jose, CA) 704 Clinical Chemistry Analyzer (28).

Other relevant data collected

A health and lifestyle questionnaire was administered at baseline and at each annual visit. In addition to containing general health and lifestyle questions, this form was a means of collecting information about regularly used prescription medications and over-the-counter preparations, including vitamin and mineral supplements.

Statistical procedures

The intervention effect on continuous dietary measures was evaluated by using two-sample t tests. Intervention and control group means at each yearly data collection point were compared.

Changes over time were computed as the difference in group mean values at 2 time points. The difference in those changes between the intervention and control groups was compared by using two-sample t tests. The changes in group means between the 2 time points were computed by using results for participants with observations at either or both time points.

For baseline factors, the comparability of intervention and control group means was determined by two-sample t tests. When baseline variables were categorical (binary or more than 2), $2 \times k$ chi-square tests of independence were used to examine differences in distribution of the categories for the 2 groups.

All analyses were based on an intent-to-treat study design. Therefore, all relevant data for intervention participants were included, regardless of whether the individuals ceased active participation in the intervention. No analyses were based on imputed results for missing data or adjustment procedures for baseline covariates. All statistical analyses were done separately for men and women. In the tables, we highlight only those comparisons significant at the $P \leq 0.0001$ level; all these comparisons were still significant at the 5% level after applying Bonferroni's correction for multiple tests.

To determine the efficacy of the special intervention campaigns that occurred during trial years 2–4, we used a mixed linear model with covariance parameters that take repeated measurements into account (29) to compare dietary data collected during the campaigns with those collected during noncampaign times. The group and study year were included as fixed effects in the analysis. The effects of the campaigns on the intervention group were evaluated by testing the interaction of group × campaign period.

We compared longitudinal biomarker profiles across intervention and control groups by using mixed linear models for longitudinal data (30). The P values for testing differences in each set of biomarker profiles were computed by first testing for a significant group × visit interaction. If the interaction was significant, an overall test of the difference between profiles was based on a likelihood ratio test comparing a model with visit effects with a model with group × visit interaction terms (chi-square with 4 df). If the interaction effect was not significant, the overall test was based on testing the significance of the group effect in an additive model with visit and group effects (chi-square with 1 df).

TABLE 3
Fat, fiber, and fruit and vegetable (FV) intakes for men in the Polyp Prevention Trial at baseline and years 1–4[1]

	Baseline	Year 1	Year 2	Year 3	Year 4
Fat (% of energy)					
FFQ					
Control group	36.5 ± 0.3 [662]	34.9 ± 0.3 [633]	34.5 ± 0.3 [604]	34.6 ± 0.3 [586]	34.2 ± 0.3 [581]
Intervention group	35.9 ± 0.3 [689]	24.9 ± 0.3[2] [642]	24.5 ± 0.3[2] [609]	23.9 ± 0.3[2] [590]	23.8 ± 0.3[2] [605]
4DFR					
Control group	32.7 ± 0.6 [153]	32.1 ± 0.6 [147]	31.6 ± 0.6 [141]	30.9 ± 0.6 [141]	30.1 ± 0.7 [137]
Intervention group	32.7 ± 0.5 [150]	20.8 ± 0.6[2] [139]	20.9 ± 0.7[2] [128]	19.8 ± 0.7[2] [125]	20.2 ± 0.7[2] [125]
24-h Dietary recall					
Control group	—	32.2 ± 1.1 [66]	32.4 ± 1.3 [57]	31.0 ± 1.2 [51]	29.6 ± 1.1 [93]
Intervention group	—	20.5 ± 1.0[2] [69]	21.9 ± 1.4[2] [50]	20.0 ± 1.2[2] [50]	21.2 ± 0.9[2] [97]
Fiber (g/MJ)					
FFQ					
Control group	2.14 ± 0.03 [662]	2.31 ± 0.04 [633]	2.28 ± 0.04 [604]	2.29 ± 0.04 [586]	2.31 ± 0.04 [581]
Intervention group	2.31 ± 0.04 [689]	4.17 ± 0.06[2] [642]	4.09 ± 0.06[2] [609]	4.14 ± 0.06[2] [590]	4.11 ± 0.05[2] [605]
4DFR					
Control group	2.23 ± 0.06 [153]	2.26 ± 0.07 [147]	2.28 ± 0.07 [141]	2.32 ± 0.07 [141]	2.37 ± 0.08 [137]
Intervention group	2.27 ± 0.06 [150]	4.25 ± 0.14[2] [139]	4.10 ± 0.13[2] [128]	4.12 ± 0.15[2] [125]	4.09 ± 0.14[2] [125]
24-h Dietary recall					
Control group	—	2.01 ± 0.12 [66]	2.11 ± 0.15 [57]	2.18 ± 0.11 [51]	2.36 ± 0.10 [93]
Intervention group	—	3.93 ± 0.24[2] [69]	4.37 ± 0.29[2] [50]	3.96 ± 0.29[2] [50]	3.91 ± 0.20[2] [97]
FVs (servings/MJ)					
FFQ					
Control group	0.43 ± 0.01 [662]	0.46 ± 0.01 [633]	0.47 ± 0.01 [604]	0.47 ± 0.01 [586]	0.48 ± 0.01 [581]
Intervention group	0.46 ± 0.01 [689]	0.73 ± 0.01[2] [642]	0.71 ± 0.01[2] [609]	0.76 ± 0.01[2] [590]	0.79 ± 0.01[2] [605]
4DFR					
Control group	0.54 ± 0.02 [153]	0.57 ± 0.02 [147]	0.57 ± 0.02 [141]	0.59 ± 0.03 [141]	0.60 ± 0.03 [137]
Intervention group	0.55 ± 0.02 [150]	0.98 ± 0.04[2] [139]	0.95 ± 0.04[2] [128]	1.00 ± 0.04[2] [125]	1.04 ± 0.04[2] [125]
24-h Dietary recall					
Control group	—	0.48 ± 0.05 [66]	0.57 ± 0.06 [57]	0.58 ± 0.05 [51]	0.67 ± 0.06 [93]
Intervention group	—	0.94 ± 0.08[2] [69]	0.96 ± 0.06[2] [50]	0.94 ± 0.08[2] [50]	1.16 ± 0.07[2] [97]

[1] $\bar{x}$ ± SEM; *n* in brackets. FFQ, food-frequency questionnaire; 4DFR, 4-d food record.
[2] Significantly different from the control group, $P \leq 0.0001$. Significant at the 5% level after applying Bonferroni's correction for multiple tests.

RESULTS

Eighty-nine percent of the intervention participants and 88% of the control subjects remained in the trial for 4 y and provided year 4 dietary data. Of those lost to follow-up, ≈4% from each group died (4.1% in the intervention group and 4.4% in the control group). The remaining subjects were lost to follow-up for various reasons, including serious illness, moving from the clinical center area, and voluntary withdrawal from the trial.

Mean changes in dietary goals: intervention compared with control group

Shown in **Tables 3** and **4** are the mean fat, fiber, and FV intakes for men and women at baseline and for each year of the trial, by study group. At baseline, there were no significant differences between groups for any of the 3 dietary goals. By the end of the first year, however, intervention participants had made significant changes relative to the control group for all 3 dietary goals. These changes were sustained throughout the trial. Although the estimated values varied somewhat by method of dietary assessment, the magnitude of change was similar for each method.

Fat

By the end of the first year, the mean intervention group intake of fat for both men and women decreased markedly from baseline as measured by the FFQ and the 4DFR. Although the absolute percentage of energy from fat varied between measurement instruments, the magnitude of change (an ≈30% decrease) was similar by sex and by assessment tool. For all 4 study years, mean fat intake was significantly less in the intervention group than in the control group. Additionally, both the 4DFR and the FFQ data indicated that men and women sustained this fat reduction for all subsequent trial years with little or no drift. There was a modest, but not significant, decline in the percentage of energy from fat in the control group, similar to that observed in the national population during this time period. The absolute difference between the intervention and control groups in change in dietary fat as a proportion of total energy was 9.7% (95% CI: 9.0%, 10.3%).

The absolute mean FFQ values for percentage of energy from fat were consistently higher than the 4DFR values for both groups, in all trial years, regardless of sex. Because 24-h dietary recall measurement began at the 6-mo point, no baseline data are available for this measure. However, measurements obtained at year 1 and beyond were similar to those obtained from the 4DFR. The degree of change for all measurement instruments remained consistent at all annual measurement points.

Fiber

As with fat, mean baseline fiber values for the 2 groups were similar, with both groups reporting consuming slightly more than one-half of the 4.30-g/MJ (18-g/1000 kcal) goal. Whereas fiber intake in the control group increased only slightly (by

TABLE 4
Fat, fiber, and fruit and vegetable (FV) intakes for women in the Polyp Prevention Trial at baseline and years 1–4[1]

	Baseline	Year 1	Year 2	Year 3	Year 4
Fat (% of energy)					
FFQ					
Control group	35.2 ± 0.4 [380]	34.2 ± 0.4 [360]	33.4 ± 0.4 [343]	32.9 ± 0.4 [331]	33.2 ± 0.4 [335]
Intervention group	35.5 ± 0.4 [348]	24.1 ± 0.4[2] [326]	23.8 ± 0.4[2] [311]	23.2 ± 0.4[2] [303]	23.8 ± 0.4[2] [318]
4DFR					
Control group	31.9 ± 0.9 [69]	32.0 ± 0.8 [66]	30.9 ± 0.7 [64]	29.6 ± 0.8 [62]	30.2 ± 0.7 [64]
Intervention group	31.2 ± 0.8 [72]	22.0 ± 0.9[2] [67]	21.4 ± 1.0[2] [65]	21.9 ± 1.1[2] [65]	21.3 ± 1.0[2] [67]
24-h Dietary recall					
Control group	—	30.4 ± 1.5 [41]	29.4 ± 2.1 [32]	30.4 ± 1.3 [40]	31.1 ± 1.2 [63]
Intervention group	—	22.7 ± 1.8 [29]	22.4 ± 1.9 [28]	23.7 ± 1.6 [40]	21.4 ± 1.4[2] [60]
Fiber (g/MJ)					
FFQ					
Control group	2.49 ± 0.05 [380]	2.63 ± 0.05 [360]	2.63 ± 0.05 [343]	2.63 ± 0.05 [331]	2.59 ± 0.05 [335]
Intervention group	2.47 ± 0.05 [348]	4.33 ± 0.08[2] [326]	4.22 ± 0.08[2] [311]	4.19 ± 0.08[2] [303]	4.21 ± 0.08[2] [318]
4DFR					
Control group	2.52 ± 0.09 [69]	2.48 ± 0.09 [66]	2.50 ± 0.09 [64]	2.41 ± 0.08 [62]	2.59 ± 0.11 [64]
Intervention group	2.52 ± 0.10 [72]	4.22 ± 0.17[2] [67]	4.29 ± 0.20[2] [65]	4.28 ± 0.22[2] [65]	4.15 ± 0.16[2] [67]
24-h Dietary recall					
Control group	—	2.38 ± 0.17 [41]	2.45 ± 0.16 [32]	2.65 ± 0.20 [40]	2.69 ± 0.12 [63]
Intervention group	—	3.87 ± 0.41 [29]	3.73 ± 0.28[2] [28]	3.63 ± 0.29 [40]	3.74 ± 0.23[2] [60]
FVs (servings/MJ)					
FFQ					
Control group	0.57 ± 0.01 [380]	0.60 ± 0.01 [360]	0.60 ± 0.01 [343]	0.62 ± 0.01 [331]	0.63 ± 0.01 [335]
Intervention group	0.55 ± 0.01 [348]	0.87 ± 0.02[2] [326]	0.84 ± 0.02[2] [311]	0.86 ± 0.02[2] [303]	0.87 ± 0.02[2] [318]
4DFR					
Control group	0.70 ± 0.04 [69]	0.68 ± 0.03 [66]	0.69 ± 0.03 [64]	0.67 ± 0.03 [62]	0.77 ± 0.05 [64]
Intervention group	0.71 ± 0.04 [72]	1.12 ± 0.05[2] [67]	1.14 ± 0.05[2] [65]	1.19 ± 0.06[2] [65]	1.21 ± 0.06[2] [67]
24-h Dietary recall					
Control group	—	0.53 ± 0.06 [41]	0.70 ± 0.07 [32]	0.74 ± 0.09 [40]	0.98 ± 0.09 [63]
Intervention group	—	1.05 ± 0.11[2] [29]	1.23 ± 0.11[2] [28]	0.98 ± 0.11 [40]	1.27 ± 0.12 [60]

[1] $\bar{x}$ ± SEM; *n* in brackets. FFQ, food-frequency questionnaire; 4DFR, 4-d food record.
[2] Significantly different from the control group, $P \leq 0.0001$. Significant at the 5% level after applying Bonferroni's correction for multiple tests.

<0.24 g/MJ, or 1 g/1000 kcal) over the 4 trial years, intake in the intervention group (for both men and women) increased by 1.67–1.91 g/MJ (7–8 g/1000 kcal), a 75% increase overall. These changes were sustained for all 4 trial years, with average fiber intake for intervention participants consistently >4.06 g/MJ (17 g/1000 kcal) as measured by the FFQ and 4DFR and generally ≥3.82 g/MJ (16 g/1000 kcal) as measured by the 24-h dietary recall. The difference in fiber consumption between the 2 groups over the 4 y was 1.65 g/MJ (6.9 g/1000 kcal) (95% CI: 1.53, 1.74 g/MJ, or 6.4, 7.3 g/1000 kcal).

Unlike for fat, all 3 assessment instruments provided similar measures of fiber intake throughout the study. As for the changes in fat intake, intervention changes in fiber intake relative to the control group were similar by sex.

Fruit and vegetables

FV intake goals ranged from 5 to 8 servings/d, with a mean goal of 6.9 servings/d or 0.84 servings/MJ (3.5 servings/1000 kcal). FFQ baseline values for the control and intervention participants were virtually identical, with women consuming slightly more FVs than did men at the start of the trial. As for fat, there were measurement differences between the instruments, with the FFQ consistently indicating fewer FV servings relative to the 4DFR and 24-h dietary recall at all measurement points.

The intervention group showed significant increases in FV intake relative to the control group in all 4 trial years by the FFQ and 4DFR. For men, the 24-h dietary recall also indicated significant changes for all 4 y. Despite higher FV intakes by 24-h dietary recall in intervention women than in their control counterparts in years 3 and 4, these differences were not significant. Generally, the increase in FV intake from baseline to year 1 was similar in the intervention men and women. This increase of 0.36–0.48 servings/MJ (1.5–2.0 servings/1000 kcal) was sustained (or improved) during all trial years. Control intakes of FV varied little throughout the trial. The absolute difference between the 2 groups in the change in daily FV intake was 0.27 servings/MJ (1.13 servings/1000 kcal) (95% CI: 0.25, 0.29 servings/MJ, or 1.04, 1.21 servings/1000 kcal).

All goals

For all PPT dietary goals, intervention participants (both men and women) made the greatest changes in intake during their first year in the trial. In fact, the 4DFR completed by intervention participants after their first 6 mo in the trial indicated that most of the changes were achieved by that time. The 6-mo 4DFR showed average fat intake to be 20.7% of energy, fiber intake to be 4.18 g/MJ (17.5 g/1000 kcal), and FV intake to be 1.00 serving/MJ (4.2 servings/1000 kcal). After the first year, average changes were relatively small in magnitude.

Shown in **Figure 1** are the number of FV servings/MJ, grams of dietary fiber/MJ, and grams of dietary fiber from FVs/MJ for the control and intervention groups during trial years 2–4. To

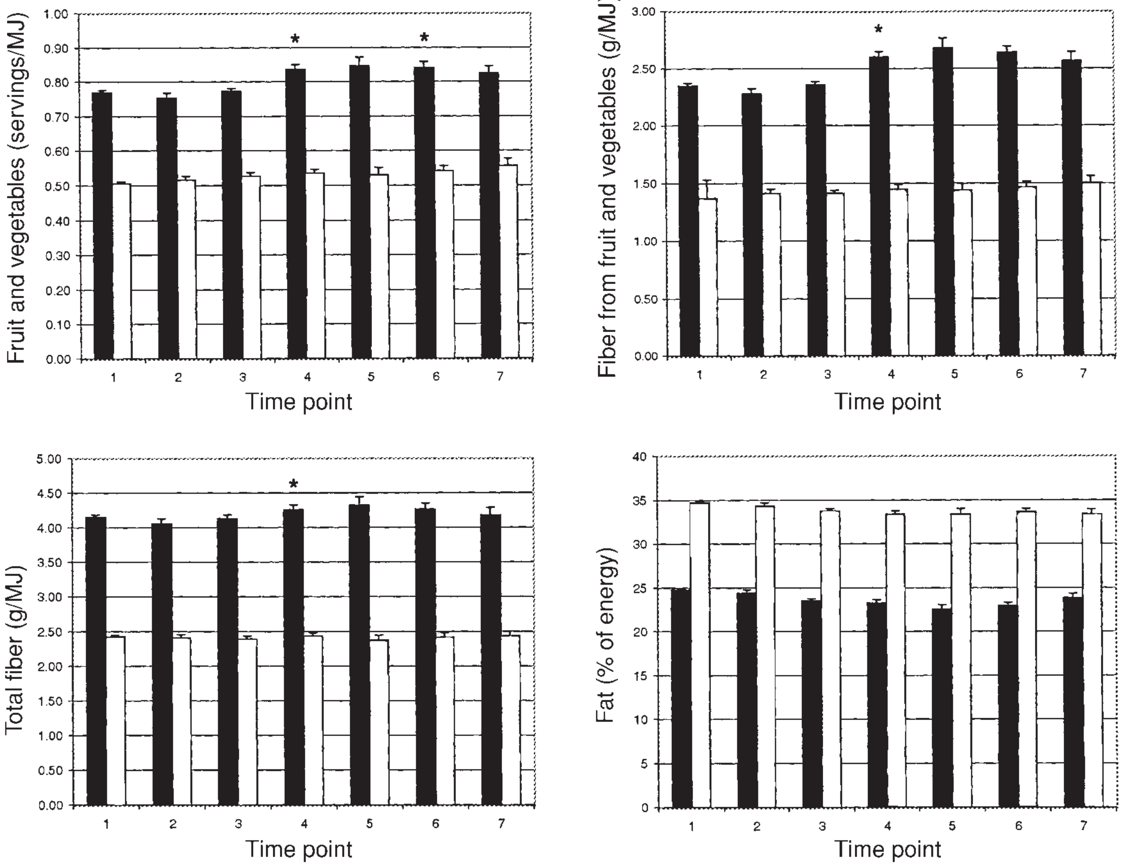

FIGURE 1. Mean (±SEM) changes in dietary intake during the campaign and noncampaign periods in the intervention (■) and control (□) groups of the Polyp Prevention Trial. The time points are as follows: 1, year 1 to the Take It Down Fat Campaign; 2, Take It Down Fat Campaign; 3, post–Take It Down Fat Campaign, pre–Fruit & Veg-a-thon; 4, Fruit & Veg-a-thon; 5, post–Fruit & Veg-a-thon, pre–PPT On My Mind Campaign; 6, PPT On My Mind Campaign; 7, post–PPT On My Mind Campaign. A mixed linear model with covariance variables that took repeated measures into account was used to compare dietary data collected during the campaign and noncampaign periods. *Significantly different between campaign and noncampaign periods, $P < 0.05$.

assess the effect of the campaigns that occurred during this same time period, data were averaged for 7 distinct, but continuous time points: 4 noncampaign periods (time points 1, 3, 5, and 7 in Figure 1) and each of the 3 intervention campaigns (the 6-mo Take It Down Fat Campaign, time point 2; the 6-mo Fruit & Veg-a-thon, time point 4; and the 8-mo PPT On My Mind Campaign, time point 6). For intervention participants, FV servings, fiber from FVs, and total dietary fiber intake were significantly higher during the Fruit & Veg-a-thon than during noncampaign periods. Similarly, FV servings and fiber from FVs, but not total fiber, were significantly higher during the PPT On My Mind Campaign than during the noncampaign periods. Although fat intake drifted down overall during years 2 through 4, there were no significant differences between the campaign and noncampaign periods for intervention participants. Intakes by control participants showed no significant differences in any goal area at any of the 7 time points, supporting the idea that the intervention program rather than any seasonal or secular events was responsible for the changes made by intervention participants.

Mean changes in nutrient and food group intakes

Because intervention participants made marked changes in their diet with respect to fat, fiber, and FV intakes, we expected concomitant changes in other nutrients and food groups. The intervention and control intakes of various nutrients at baseline, year 1, and year 4 in men and women are shown in **Tables 5–8**. The corresponding data for food groups are shown in **Tables 9–14**. The source of the data presented in Tables 5–14 is the FFQ. Data from years 2 and 3 are not shown because most changes in all nutrients and food groups occurred during the first year of the trial and were sustained throughout.

Many of the specific food groups and nutrients presented here have been associated with colorectal cancer risk and most are correlated with other chronic diseases (7–9, 11, 12, 31–39). Other nutrients and food groups are also reported because they are relevant to new food choices that PPT intervention participants made to achieve and maintain dietary changes.

Nutrient intake

There were no significant differences between the intervention and control groups in the intake of nutrients from food at baseline. In subsequent years, however, the intervention group made several changes relative to the control group; intake of relevant nutrients in the latter group stayed essentially the same throughout the trial.

Generally, changes in the intervention group were consistent with the PPT dietary goals. Fat intake decreased dramatically, with correspondingly large increases in carbohydrates (Tables 5 and 6). Protein intake also increased significantly in the men in

TABLE 5
Daily intake of energy and macronutrients for men in the Polyp Prevention Trial at baseline and years 1 and 4[1]

	Baseline (n = 662 control, 689 intervention)	Year 1 (n = 633 control, 642 intervention)	Year 4 (n = 581 control, 605 intervention)
Energy (MJ)			
Control group	8.84 ± 0.10	8.31 ± 0.09	8.5 ± 0.09
Intervention group	8.69 ± 0.09	8.09 ± 0.08	8.28 ± 0.08
Protein (% of energy)			
Control group	16.3 ± 0.1	16.4 ± 0.1	16.5 ± 0.1
Intervention group	16.5 ± 0.1	17.4 ± 0.1[2]	17.3 ± 0.1[2]
Carbohydrate (% of energy)			
Control group	45.1 ± 0.3	46.7 ± 0.3	47.1 ± 0.3
Intervention group	45.9 ± 0.3	57.5 ± 0.3[2]	58.3 ± 0.3[2]
Fat (% of energy)			
Control group	36.5 ± 0.3	34.9 ± 0.3	34.2 ± 0.3
Intervention group	35.9 ± 0.3	24.9 ± 0.3[2]	23.8 ± 0.3[2]
Fat (g)			
Control group	86.7 ± 1.3	77.9 ± 1.2	78.2 ± 1.2
Intervention group	83.7 ± 1.2	53.5 ± 0.8[2]	52.3 ± 0.8[2]
P:S			
Control group	0.521 ± 0.006	0.527 ± 0.007	0.506 ± 0.007
Intervention group	0.541 ± 0.007	0.528 ± 0.006	0.528 ± 0.006
Fiber from FV (g)			
Control group	10.0 ± 0.2	10.2 ± 0.2	10.9 ± 0.2
Intervention group	10.7 ± 0.2	18.3 ± 0.3[2]	20.2 ± 0.4[2]
Fiber from grains (g)			
Control group	9.4 ± 0.2	9.3 ± 0.2	8.8 ± 0.2
Intervention group	9.9 ± 0.2	17.2 ± 0.4[2]	15.9 ± 0.4[2]

[1] $\bar{x}$ ± SEM. Nutrient intakes are based on data from the food-frequency questionnaire. P:S, ratio of polyunsaturated to saturated fat.
[2] Significantly different from the control group, $P \leq 0.0001$. Significant at the 5% level after applying Bonferroni's correction for multiple tests.

TABLE 6
Daily intake of energy and macronutrients for women in the Polyp Prevention Trial at baseline and years 1 and 4[1]

	Baseline (n = 380 control, 348 intervention)	Year 1 (n = 360 control, 326 intervention)	Year 4 (n = 335 control, 318 intervention)
Energy (MJ)			
Control group	7.28 ± 0.12	6.93 ± 0.09	7.02 ± 0.10
Intervention group	7.50 ± 0.12	6.73 ± 0.10	6.98 ± 0.10
Protein (% of energy)			
Control group	17.0 ± 0.2	17.3 ± 0.2	17.3 ± 0.2
Intervention group	17.0 ± 0.2	17.7 ± 0.1	17.8 ± 0.1
Carbohydrate (% of energy)			
Control group	47.2 ± 0.4	47.9 ± 0.4	48.8 ± 0.5
Intervention group	47.1 ± 0.4	59.5 ± 0.4[2]	59.3 ± 0.5[2]
Fat (% of energy)			
Control group	35.2 ± 0.4	34.2 ± 0.4	33.2 ± 0.4
Intervention group	35.5 ± 0.4	24.1 ± 0.4[2]	23.8 ± 0.4[2]
Fat (g)			
Control group	69.2 ± 1.5	63.4 ± 1.2	62.5 ± 1.3
Intervention group	71.4 ± 1.5	43.0 ± 1.0[2]	44.0 ± 0.9[2]
P:S			
Control group	0.586 ± 0.010	0.570 ± 0.010	0.547 ± 0.010
Intervention group	0.571 ± 0.011	0.565 ± 0.010	0.553 ± 0.009
Fiber from FV (g)			
Control group	10.8 ± 0.3	10.9 ± 0.3	11.6 ± 0.3
Intervention group	10.5 ± 0.3	17.4 ± 0.4[2]	18.3 ± 0.5[2]
Fiber from grains (g)			
Control group	8.1 ± 0.2	8.4 ± 0.3	7.6 ± 0.2
Intervention group	8.9 ± 0.3	14.0 ± 0.4[2]	13.7 ± 0.5[2]

[1] $\bar{x}$ ± SEM. Nutrient intakes are based on data from the food-frequency questionnaire. P:S, ratio of polyunsaturated to saturated fat.
[2] Significantly different from the control group, $P \leq 0.0001$. Significant at the 5% level after applying Bonferroni's correction for multiple tests.

TABLE 7
Daily intake of micronutrients for men in the Polyp Prevention Trial at baseline and years 1 and 4[1]

	Baseline (n = 662 control, 689 intervention)	Year 1 (n = 633 control, 642 intervention)	Year 4 (n = 581 control, 605 intervention)
Folate (μg)			
Control group	322.5 ± 5.0	322.6 ± 4.9	329.6 ± 5.0
Intervention group	324.5 ± 4.7	424.7 ± 6.0[2]	439.7 ± 6.3[2]
Vitamin E from food (mg)			
Control group	8.7 ± 0.1	8.2 ± 0.1	8.2 ± 0.1
Intervention group	8.8 ± 0.1	8.5 ± 0.1	8.5 ± 0.1
Vitamin C from food (mg)			
Control group	139.0 ± 2.9	145.4 ± 3.1	147.9 ± 3.1
Intervention group	144.3 ± 3.0	195.9 ± 3.6[2]	209.8 ± 3.9[2]
Total carotenoids (μg)			
Control group	7802 ± 183	7831 ± 171	8320 ± 191
Intervention group	8513 ± 191	12044 ± 255[2]	13530 ± 292[2]
Calcium from food (mg)			
Control group	874.7 ± 16.1	828.7 ± 14.6	867.3 ± 16.2
Intervention group	872.1 ± 16.4	936.2 ± 16.3[2]	942.1 ± 16.6

[1] $\bar{x}$ ± SEM. Nutrient intakes are based on data from the food-frequency questionnaire.
[2] Significantly different from the control group, $P \leq 0.0001$. Significant at the 5% level after applying Bonferroni's correction for multiple tests.

the intervention group, but not in the women. Intake of all types of fat decreased, resulting in no significant change in the ratio of polyunsaturated to saturated fat in either sex. Postbaseline intakes of fiber from grains and fiber from FVs increased significantly, with both fiber sources contributing equally to the increased fiber intake in both men and women.

As a result of the increased intake of FVs, intakes of folate, vitamin C, and total carotenoids from food also increased significantly (Tables 7 and 8). In contrast, vitamin E from food did not differ significantly between the intervention and control groups. Among the men in the intervention group, calcium intakes from food increased significantly and this increase was maintained during years 2 and 3; calcium intake did not change significantly in the women.

There were no significant differences between the control and intervention groups in the use of supplements containing calcium, vitamin E, or vitamin C during the trial (either as the percentage of persons taking supplements or as the amount of supplement taken; data not shown). Although total fiber increased by ≈75% among intervention participants, there was a small but statistically significant reduction in fiber from fiber supplements (≈0.2 g on average) in the intervention group. A smaller proportion of intervention participants took fiber supplements during the trial (11% at baseline compared with 6–7% in all subsequent years), whereas control participants' fiber supplement intake was sustained throughout (≈11% in all years). This decrease was of no biological import, however, given the magnitude of increase in fiber intake from food in this group relative to the control group.

Food group intake

Like the changes in nutrient intake, most of the significant changes made by the intervention group relative to the control group were consistent with the PPT dietary goals and were similar (in most cases) between men and women. It is not surprising,

TABLE 8
Daily intake of micronutrients for women in the Polyp Prevention Trial at baseline and years 1 and 4[1]

	Baseline (n = 380 control, 348 intervention)	Year 1 (n = 360 control, 326 intervention)	Year 4 (n = 335 control, 318 intervention)
Folate (μg)			
Control group	288.8 ± 6.0	290.4 ± 5.8	293.7 ± 6.2
Intervention group	295.6 ± 6.5	370.0 ± 7.2[2]	385.8 ± 7.9[2]
Vitamin E from food (mg)			
Control group	7.9 ± 0.2	7.4 ± 0.1	7.3 ± 0.1
Intervention group	8.0 ± 0.2	7.2 ± 0.1	7.5 ± 0.1
Vitamin C from food (mg)			
Control group	140.3 ± 3.9	142.5 ± 4.0	144.5 ± 4.2
Intervention group	137.0 ± 4.1	175.7 ± 4.4[2]	183.1 ± 4.7[2]
Total carotenoids (μg)			
Control group	8519 ± 248	8545 ± 265	9568 ± 326
Intervention group	8508 ± 288	11662 ± 379[2]	12759 ± 430[2]
Calcium from food (mg)			
Control group	832.6 ± 25.4	823.1 ± 22.6	832.4 ± 19.7
Intervention group	862.0 ± 20.9	844.2 ± 20.5	909.9 ± 22.2

[1] $\bar{x}$ ± SEM. Nutrient intakes are based on data from the food-frequency questionnaire.
[2] Significantly different from the control group, $P \leq 0.0001$. Significant at the 5% level after applying Bonferroni's correction for multiple tests.

TABLE 9
Daily intake of fruit and vegetables (FVs) for men in the Polyp Prevention Trial at baseline and years 1 and 4[1]

	Baseline (*n* = 662 control, 689 intervention)	Year 1 (*n* = 633 control, 642 intervention)	Year 4 (*n* = 581 control, 605 intervention)
FVs and juices (g)			
Control group	561.3 ± 10.4	579.4 ± 10.9	603.8 ± 11.8
Intervention group	592.6 ± 11.1	835.6 ± 13.5[2]	918.7 ± 14.8[2]
Fruit (g)			
Control group	157.7 ± 4.9	166.1 ± 4.7	180.3 ± 5.5
Intervention group	173.7 ± 5.1	312.9 ± 6.8[2]	344.9 ± 7.7[2]
Vegetables (g)			
Control group	263.7 ± 5.0	264.3 ± 5.1	278.0 ± 5.6
Intervention group	275.9 ± 5.2	388.7 ± 7.0[2]	424.8 ± 7.4[2]
Legumes (g)			
Control group	14.3 ± 0.7	15.1 ± 0.7	16.7 ± 0.8
Intervention group	14.5 ± 0.7	46.4 ± 1.7[2]	52.1 ± 2.1[2]
Cruciferous vegetables			
Control group	23.6 ± 0.9	24.9 ± 0.9	24.7 ± 1.0
Intervention group	26.0 ± 1.0	40.7 ± 1.5[2]	44.2 ± 1.8[2]
Carotenoid-rich FVs (g)[3]			
Control group	248.3 ± 5.9	253.7 ± 6.1	267.4 ± 6.5
Intervention group	262.0 ± 6.2	345.4 ± 7.0[2]	385.0 ± 8.0[2]
Folate-rich FVs (g)[3]			
Control group	199.2 ± 5.1	203.4 ± 5.2	209.2 ± 5.4
Intervention group	199.2 ± 5.0	261.7 ± 5.8[2]	288.7 ± 6.5[2]
Green leafy vegetables (g)			
Control group	50.5 ± 1.6	49.9 ± 1.6	49.1 ± 1.6
Intervention group	50.0 ± 1.5	63.2 ± 1.9[2]	65.2 ± 1.9[2]

[1] $\bar{x}$ ± SEM. Nutrient intakes are based on data from the food-frequency questionnaire.
[2] Significantly different from the control group, $P \leq 0.0001$. Significant at the 5% level after applying Bonferroni's correction for multiple tests.
[3] Includes juices.

TABLE 10
Daily intake of fruit and vegetables (FVs) for women in the Polyp Prevention Trial at baseline and years 1 and 4[1]

	Baseline (*n* = 380 control, 348 intervention)	Year 1 (*n* = 360 control, 326 intervention)	Year 4 (*n* = 335 control, 318 intervention)
FVs and juices (g)			
Control group	572.8 ± 14.1	570.5 ± 13.8	600.7 ± 15.2
Intervention group	561.7 ± 15.0	778.7 ± 17.2[2]	817.3 ± 18.1[2]
Fruit (g)			
Control group	177.5 ± 6.8	180.1 ± 6.8	190.7 ± 7.5
Intervention group	165 ± 6.0	289.0 ± 8.1[2]	301.5 ± 8.9[2]
Vegetables (g)			
Control group	264.0 ± 6.7	267.0 ± 6.8	287.0 ± 7.9
Intervention group	267.2 ± 7.0	370.5 ± 9.1[2]	388.8 ± 9.8[2]
Legumes (g)			
Control group	11.9 ± 0.8	13.5 ± 0.8	15.0 ± 1.0
Intervention group	12.8 ± 1.0	41.7 ± 2.4[2]	42.3 ± 2.3[2]
Cruciferous vegetables (g)			
Control group	31.2 ± 2.0	33.1 ± 1.8	32.8 ± 1.9
Intervention group	33.3 ± 1.7	43.7 ± 2.2	44.2 ± 2.6
Carotenoid-rich FVs (g)[3]			
Control group	253.5 ± 7.4	258.1 ± 7.7	255.0 ± 9.0
Intervention group	248.5 ± 7.8	327.6 ± 9.6[2]	328.6 ± 10.1[2]
Folate-rich FVs (g)[3]			
Control group	188.5 ± 6.1	198.3 ± 6.4	196.4 ± 6.8
Intervention group	188.6 ± 6.4	239.9 ± 7.4[2]	251.9 ± 8.0[2]
Green leafy vegetables (g)			
Control group	53.7 ± 2.2	56.6 ± 2.3	54.4 ± 2.4
Intervention group	52.1 ± 2.1	59.7 ± 2.5	63.7 ± 2.9

[1] $\bar{x}$ ± SEM. Nutrient intakes are based on data from the food-frequency questionnaire.
[2] Significantly different from the control group, $P \leq 0.0001$. Significant at the 5% level after applying Bonferroni's correction for multiple tests.
[3] Includes juices.

TABLE 11
Daily intake of cereals for men in the Polyp Prevention Trial at baseline and years 1 and 4[1]

	Baseline (n = 662 control, 689 intervention)	Year 1 (n = 633 control, 642 intervention)	Year 4 (n = 581 control, 605 intervention)
Whole grains (g)			
Control group	78.4 ± 2.2	78.6 ± 2.3	74.9 ± 2.5
Intervention group	84.2 ± 2.4	123.0 ± 2.9[2]	117.0 ± 2.9[2]
Refined grains (g)			
Control group	131.8 ± 2.9	126.5 ± 3.0	129.1 ± 2.9
Intervention group	139.6 ± 3.2	117.3 ± 3.2	126.1 ± 3.4
Bran cereals (g)			
Control group	11.3 ± 0.7	12.3 ± 0.7	10.8 ± 0.7
Intervention group	12.0 ± 0.7	37.8 ± 1.2[2]	33.8 ± 1.2[2]

[1] $\bar{x}$ ± SEM. Nutrient intakes are based on data from the food-frequency questionnaire.
[2] Significantly different from the control group, $P \leq 0.0001$. Significant at the 5% level after applying Bonferroni's correction for multiple tests.

for example, that reported FV intake increased significantly in the intervention group across all 4 trial years (Tables 9 and 10). Intake of whole grains and bran cereals also rose (consistent with achievement of the fiber goal), with relatively little change in the consumption of refined grains (Tables 11 and 12), accounting at least in part for the overall increase in carbohydrate intake. Similarly, consumption of high-fat foods (such as high-fat dairy products, high-fat desserts, red meat, processed meat, and added fats) decreased significantly while intake of lower-fat alternatives correspondingly increased (Tables 13 and 14). Interestingly, both intervention men and women showed significant increases in FV juice consumption, even though these juices did not count toward the FV goal.

There were some small sex differences in food group intake in the intervention group. Although both men and women increased their intake of cruciferous vegetables, the increase compared with the control group was significant only for the men (possibly because women started at a higher level of consumption). Similarly, intervention men and women both increased their consumption of green leafy vegetables, but the difference was significant only for the men. The ratio of red meat to chicken and fish decreased significantly in all trial years for the men, whereas the decrease in the women was not significant. Again, this may have been because the baseline ratio for women was already low (2.2) compared with that for the men (2.9). There were no significant changes in fish intake throughout the trial; thus, all changes in the ratio of red meat to chicken and fish were a result of decreased red meat and increased chicken intakes.

Biological markers

Shown in **Table 15** are the mean measurements of plasma cholesterol, serum carotenoids, and weight at baseline and at years 1–4 for the control and intervention participants and the mean changes from baseline. The group × visit interaction was significant only for weight ($P < 0.0001$). There was no significant difference between groups in the mean change in plasma cholesterol. Plasma cholesterol values for both men and women were already relatively low at baseline, which is not surprising because individuals taking lipid-lowering drugs were not eligible for the trial. We observed a significant increase in total carotenoids in the intervention group compared with the control group ($P = 0.00063$). Carotenoids, widely distributed phytochemicals in vegetables and fruit, are measurable in human serum and thus have been suggested to be a biomarker of FV intake. The intervention group lost a modest, but significant amount of weight during the trial compared with the control group ($P = 0.0001$), but the gap between the 2 groups decreased over time ($P = 0.0001$).

DISCUSSION

Success of the PPT in promoting multifactor dietary change

Recent trials have examined adherence to a single dietary change over time periods from 6 mo to 6 y (40–43) or to more than one change over a short period of time, such as ≤6 mo (44). However, no trials to date have attempted to combine dietary

TABLE 12
Daily intake of cereals for women in the Polyp Prevention Trial at baseline and years 1 and 4[1]

	Baseline (n = 380 control, 348 intervention)	Year 1 (n = 360 control, 326 intervention)	Year 4 (n = 335 control, 318 intervention)
Whole grains (g)			
Control group	74.0 ± 2.9	75.0 ± 2.9	69.2 ± 2.9
Intervention group	81.3 ± 3.3	115.4 ± 3.8[2]	111.1 ± 3.7[2]
Refined grains (g)			
Control group	113.0 ± 3.1	114.9 ± 3.4	114.6 ± 3.3
Intervention group	114.3 ± 3.7	99.7 ± 3.7	103.3 ± 3.5
Bran cereals (g)			
Control group	8.9 ± 0.7	10.4 ± 0.9	6.9 ± 0.7
Intervention group	10.7 ± 1.0	29.4 ± 1.4[2]	28.5 ± 1.5[2]

[1] $\bar{x}$ ± SEM. Nutrient intakes are based on data from the food-frequency questionnaire.
[2] Significantly different from the control group, $P \leq 0.0001$. Significant at the 5% level after applying Bonferroni's correction for multiple tests.

TABLE 13
Daily intake of selected sources of fat for men in the Polyp Prevention Trial at baseline and years 1 and 4[1]

	Baseline (n = 662 control, 689 intervention)	Year 1 (n = 663 control, 642 intervention)	Year 4 (n = 581 control, 605 intervention)
Red and processed meat (g)			
Control group	110.4 ± 2.2	100.9 ± 2.0	107.2 ± 2.3
Intervention group	104.2 ± 2.1	82.0 ± 1.8[2]	82.6 ± 1.8[2]
Chicken, total (g)			
Control group	35.4 ± 1.0	33.9 ± 1.0	34.8 ± 1.1
Intervention group	37.0 ± 1.0	38.8 ± 1.1	43.1 ± 1.1[2]
Red meat/chicken and fish			
Control group	3.0 ± 0.2	2.9 ± 0.1	3.4 ± 0.2
Intervention group	2.9 ± 0.2	2.1 ± 0.1[2]	1.9 ± 0.1[2]
High-fat dairy products (g)			
Control group	194.1 ± 9.3	161.9 ± 7.6	146.9 ± 7.4
Intervention group	177.2 ± 9.1	92.2 ± 6.4[2]	71.7 ± 5.5[2]
Low-fat dairy products (g)			
Control group	160.0 ± 9.7	165.5 ± 9.3	199.7 ± 11.8
Intervention group	166.2 ± 9.4	275.3 ± 11.2[2]	290.5 ± 11.7[2]
Added fats (g)			
Control group	13.0 ± 0.4	11.7 ± 0.3	11.2 ± 0.4
Intervention group	12.6 ± 0.3	5.7 ± 0.2[2]	5.1 ± 0.2[2]
High-fat desserts (g)			
Control group	49.6 ± 1.9	44.9 ± 1.8	49.6 ± 1.9
Intervention group	47.3 ± 1.6	18.8 ± 1.0[2]	21.0 ± 1.1[2]
Low-fat desserts (g)			
Control group	17.3 ± 1.3	14.7 ± 1.1	16.4 ± 1.3
Intervention group	18.2 ± 1.3	35.4 ± 1.8[2]	31.8 ± 1.6[2]

[1] $\bar{x}$ ± SEM. Nutrient intakes are based on data from the food-frequency questionnaire.
[2] Significantly different from the control group, $P \leq 0.0001$. Significant at the 5% level after applying Bonferroni's correction for multiple tests.

TABLE 14
Daily intake of selected sources of fat for women in the Polyp Prevention Trial at baseline and years 1 and 4[1]

	Baseline (n = 380 control, 348 intervention)	Year 1 (n = 360 control, 326 intervention)	Year 4 (n = 335 control, 318 intervention)
Red and processed meat (g)			
Control group	75.1 ± 2.3	68.2 ± 1.9	71.0 ± 1.9
Intervention group	76.0 ± 2.4	59.1 ± 2.0	59.7 ± 2.0[2]
Chicken, total (g)			
Control group	37.6 ± 1.3	38.1 ± 1.3	36.8 ± 1.5
Intervention group	36.7 ± 1.4	34.0 ± 1.2	36.5 ± 1.6
Red meat/chicken and fish			
Control group	2.0 ± 0.1	1.9 ± 0.1	2.1 ± 0.1
Intervention group	2.2 ± 0.1	1.7 ± 0.1	1.7 ± 0.1
High-fat dairy products (g)			
Control group	119.6 ± 7.4	116.2 ± 8.4	102.6 ± 7.6
Intervention group	145.3 ± 9.6	70.2 ± 5.8[2]	69.3 ± 6.0
Low-fat dairy products (g)			
Control group	208.8 ± 17.2	211.4 ± 14.9	228.9 ± 13.9
Intervention group	195.1 ± 12.7	262.0 ± 13.9	297.4 ± 15.3
Added fats (g)			
Control group	12.5 ± 0.5	11.1 ± 0.5	10.3 ± 0.5
Intervention group	12.3 ± 0.5	5.1 ± 0.3[2]	4.9 ± 0.3[2]
High-fat desserts (g)			
Control group	36.4 ± 1.8	30.3 ± 1.5	32.7 ± 1.9
Intervention group	37.1 ± 1.8	12.9 ± 1.0[2]	15.2 ± 0.9[2]
Low-fat desserts (g)			
Control group	18.8 ± 1.7	18.8 ± 1.5	18.8 ± 1.8
Intervention group	17.8 ± 1.9	32.5 ± 2.1[2]	28.0 ± 1.9

[1] $\bar{x}$ ± SEM. Nutrient intakes are based on data from the food-frequency questionnaire.
[2] Significantly different from the control group, $P \leq 0.0001$. Significant at the 5% level after applying Bonferroni's correction for multiple tests.

TABLE 15

Plasma cholesterol, serum carotenoid, and body weight and changes in these biomarkers over time in the Polyp Prevention Trial[1]

	Plasma cholesterol		Serum carotenoids		Weight	
	Control group	Intervention group	Control group	Intervention group	Control group	Intervention group
	mmol/L		*mmol/L*		*kg*	
Year 1						
n	423	407	422	409	989	975
T0	5.15 ± 0.04	5.23 ± 0.05	1.69 ± 0.04	1.71 ± 0.04	80.89 ± 0.47	81.74 ± 0.48
T1	5.17 ± 0.04	5.12 ± 0.05	1.75 ± 0.04	1.95 ± 0.04	80.90 ± 0.47	79.78 ± 0.48
T1−T0	0.01 ± 0.03	−0.11 ± 0.03	0.06 ± 0.03	0.24 ± 0.03	0.01 ± 0.11	−1.96 ± 0.13
Year 2						
n	387	372	389	378	952	931
T0	5.15 ± 0.04	5.20 ± 0.05	1.68 ± 0.04	1.71 ± 0.04	81.02 ± 0.48	81.72 ± 0.49
T2	5.11 ± 0.05	5.11 ± 0.05	1.78 ± 0.04	1.88 ± 0.05	81.14 ± 0.48	80.45 ± 0.50
T2−T0	−0.04 ± 0.03	−0.09 ± 0.04	0.10 ± 0.03	0.18 ± 0.03	0.13 ± 0.13	−1.26 ± 0.15
Year 3						
n	376	365	380	368	937	919
T0	5.14 ± 0.04	5.22 ± 0.05	1.71 ± 0.04	1.73 ± 0.04	80.94 ± 0.48	81.80 ± 0.50
T3	5.07 ± 0.04	5.10 ± 0.05	1.74 ± 0.04	1.89 ± 0.04	81.28 ± 0.50	80.71 ± 0.51
T3−T0	−0.07 ± 0.03	−0.11 ± 0.04	0.04 ± 0.03	0.16 ± 0.03	0.34 ± 0.16	−1.09 ± 0.16
Year 4						
n	374	370	372	368	943	943
T0	5.15 ± 0.05	5.22 ± 0.05	1.68 ± 0.04	1.72 ± 0.04	80.95 ± 0.48	81.81 ± 0.49
T4	5.08 ± 0.05	5.09 ± 0.05	1.67 ± 0.04	1.81 ± 0.04	81.26 ± 0.50	81.16 ± 0.51
T4−T0	−0.07 ± 0.04	−0.13 ± 0.04	−0.01 ± 0.03	0.09 ± 0.04	0.31 ± 0.17	−0.65 ± 0.17
P	0.083		0.00063		0.0001	

[1] Differences in biomarker profiles (change from baseline) between the intervention and control groups were computed by using mixed linear models for longitudinal data. *P* values were computed by testing first for a significant group × visit interaction for each biomarker. The interaction was significant only for weight ($P < 0.0001$). The *P* values for testing for differences in the plasma cholesterol and serum carotenoid profiles between groups were based on a likelihood ratio test of the group effect in an additive model (chi-square test with 1 df). Because of the significant group × visit interaction, the *P* value for testing group differences in weight was computed based on a likelihood ratio test comparing a model with visit effects and a model with group × visit inteaction terms (chi-square test with 4 df).

change and behavior modification to the extent undertaken by the PPT in free-living adults.

Intake information from 3 separate dietary assessment instruments indicated that the PPT did effect multifactor dietary changes in the intervention group. Because each of the 3 instruments measures a different aspect of dietary intake (the FFQ measures usual food intake, the 4DFR measures current intake, and unannounced 24-h dietary recalls measure unanticipated intake), the consistency of the results provides some assurance that the estimated amount of change was accurate and sustained.

Because dietary interventions cannot be blinded and dietary assessments rely on self-report and recall, we also looked for reasonable biological measures to ascertain adherence. Although there are no perfect biomarkers for the PPT changes, plasma and serum cholesterol are considered effective markers of a low-fat, low-saturated-fat diet and plasma and serum carotenoids are used to measure changes in FV intake (the only carotenoid food source). There was no significant difference in plasma cholesterol concentrations between the intervention and control groups during the entire 4 y of the trial. However, the PPT emphasized total fat reduction, which resulted in a proportional decrease in all types of fat (saturated, monounsaturated, and polyunsaturated). It is also well established that decreases in plasma cholesterol are proportional to baseline concentrations; those with relatively low initial values (as in the PPT) have a limited capacity to respond, even when the dietary regimen is specifically focused on cholesterol lowering (45, 46). The increases in serum carotenoids relative to dietary carotenoid and FV increases in the PPT are consistent with other studies of FV intake (47–49), even though >50% of the FVs consumed by participants did not contain carotenoids. In addition to the significant increases in serum carotenoids, the small but significant differences in weight of the intervention group compared with the control group imply that some type of dietary change occurred. Activity levels were not a factor in weight change because they remained the same in both groups throughout the trial and there was no weight-control component to the intervention.

In contrast with other long-term trials in which participants did not maintain changes made during the first 6–12 mo over subsequent years (50, 51), the PPT intervention participants sustained dietary changes for the entire 4 y. The PPT combined counseling with the proven techniques of self-monitoring, social support, and behavior modification to achieve dietary change (52–55). Furthermore, a major factor in the continued PPT adherence relates to ongoing vigilance in monitoring goal attainment and the corresponding launching of new and different activities designed to rekindle flagging motivation as the need arose. Like previous studies, the PPT took advantage of initial participant enthusiasm to encourage early goal attainment. First-year activities included frequent, one-on-one sessions with a personal nutritionist, thereby incorporating a high level of accountability and many opportunities for problem resolution.

Not all goals were achieved by the end of year 1 and, predictably, some backsliding was observed early in year 2. Rather than accepting this as the inevitable course of behavior change, we stepped up our efforts, with the objective of boosting adherence through 3 separate intervention campaigns launched during participant years 2, 3, and 4 (C Daston, J Benson, E Lanza, et al, unpublished observations, 1997). It is noteworthy that goal attainment in PPT change areas generally improved (rather than diminished) in the later years of the trial. Significant increases occurred in 2 of the 3 goal areas (fiber and FV) and in the amount of fiber from FVs during the Fruit & Veg-a-thon. We saw similar increases in intakes of FV and of fiber from FVs during the PPT On My Mind Campaign, but no increase in total fiber intake. Although there were no significant decreases in fat intake during any campaign period, there was no significant upward drift in dietary fat after the first year in the trial.

Changes in food group and nutrient intakes: implications for disease prevention

When selecting new and different foods to meet fat, fiber, and FV goals, PPT participants also changed their intake of other foods and nutrients linked to both risk and prevention of colorectal cancer and other chronic diseases. Foods and nutrients linked to risk of colorectal cancer include a high intake of meat (39), a high intake ratio of red meat to fish and chicken (32, 33, 56), and high intakes of saturated fat (32). Nutrients associated with protection include dietary folate (57) and calcium (8). Although PPT intervention participants concurrently altered their intakes of nutrients and foods in directions previously associated with reduced colorectal cancer risk, these changes were usually not of the magnitude nor of the duration suggested by other studies to be protective. For example, the protective amount of calcium in Baron et al's study (8) was 1200 mg/d from supplements with some additional calcium from food; the average intake of calcium by PPT participants was <1000 mg, primarily from food. In observational studies of adenomas in men and women, Giovannucci et al (31) reported that higher folate intakes were associated with a protective effect, with quintile values ranging from <166 to >700 μg/d. In a later observational study with women, folate intakes of >400 μg/d (similar to PPT intakes) were protective against colon cancer, but only after 10–14 y (57).

In terms of overall eating pattern changes, intervention participants frequently substituted lower-fat alternatives for higher-fat options to meet fat goals (eg, they consumed more poultry and less red and processed meat and substituted low-fat dairy products and desserts for high-fat ones). To meet the fiber and FV goals, they increased their intake of foods that were rich sources of fiber (eg, whole grains, bran cereals, and legumes) and ate more of many different types of FVs, rather than substituting one food for another. High-fat foods were replaced by foods rich in fiber and by FVs. This was a strategy taught and reinforced throughout the intervention program, although the specific food choices were left to each participant. The trial was designed to obtain one-half the fiber from FVs and one-half from grains and this was achieved.

In summary, most of the dietary changes seen in the PPT were made during the intensive first 6 mo of the intervention and were then sustained with a less intensive program. The targeted campaigns introduced in the later years of the trial seemed to assist participants in sustaining changes and led to further progress for the fiber and FV goals. The PPT dietary changes are consistent in kind (if not in magnitude) with many of the components of a diet recommended for general good health (1, 2, 58, 59). The PPT showed that free-living individuals can alter their eating patterns in significant ways given appropriate support. Limitations to generalizing our findings are that participants with a diagnosed risk factor (adenomatous polyp) may be more highly motivated than the general population. Clinical trial volunteers also tend to be of a higher socioeconomic status and more highly educated than nonparticipants (Table 1), which may affect motivational constellation and the ability to make long-term changes. However, PPT control subjects, who had equal reason to change, did not, despite a wealth of nutrition information provided by the media and an initial dietary pamphlet.

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