Self-Rated Quality of Life Measures: Effect of Change to a Low-Fat, High-Fiber, Fruit and Vegetable Enriched Diet

Donald K. Corle, M.S.
National Cancer Institute

Carolyn Sharbaugh, M.S.
Westat

Donna J. Mateski, M.S.
Walter Reed Army Medical Center

Terry Coyne, Ph.D.
University of Pittsburgh

Electra D. Paskett, Ph.D.
Wake Forest University

Jack Cahill, M.A. and Cassandra Daston, M.A.
Westat

Elaine Lanza, Ph.D. and Arthur Schatzkin, M.D., Dr.P.H.
National Cancer Institute

The PPT Study Group

ABSTRACT

The Polyp Prevention Trial (PPT) was a multicenter, randomized clinical trial to determine the effect of a low-fat (20% of energy from fat), high-fiber (18 g/1000 kcal/day), high-fruit/vegetable (3.5 servings/1000 kcal/day) eating plan on the recurrence of large bowel adenomatous polyps. The PPT provided an opportunity to examine the impact of dietary changes on quality of life. At baseline and annually for 4 years, participants in the Quality of Life Substudy of PPT completed a Quality of Life Factors (QF) Questionnaire, a modified Block–National Cancer Institute Food Frequency Questionnaire, and a Health and Lifestyle Questionnaire. The 51-item QF Questionnaire assessed changes in nine domains: taste, convenience, cost, self-care, social, health assessment, health belief, health action, and life satisfaction. The analysis compared annual changes in domain scores for intervention (n = 194) and control (n = 200) participants. At Year 1, 363 (92%) completed a questionnaire, and 325 (82%) participants completed a Year 4 questionnaire. There were no statistically significant differences between treatment groups in the change from baseline to Year 1 for the convenience, cost, taste, health assessment, and life satisfaction domains. At Year 1, intervention participants rated the self-care ($p < .001$), health belief ($p = .021$), and health action ($p < .001$) domains significantly higher and the social domain significantly lower ($p < .001$) than control participants. These changes were consistent through Years 2, 3, and 4. This study provides evidence that, given appropriate support, free-living individuals can successfully alter their eating patterns in multiple ways without a negative impact on quality of life.

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INTRODUCTION

During the past 20 years, quality of life has emerged as an important consideration in disease prevention and treatment (1,2). A major goal in developing prevention and treatment strategies is to help individuals live longer and preserve their quality of life (3). It is important to understand the impact of the prevention or treatment approach on daily life because strategies with detrimental effects are not likely to be adopted and maintained. Although initial quality of life research centered on therapies with profound side effects, more recent efforts have looked at the impact of changes in everyday health habits, such as diet, on quality of life (4–10).

Dietary factors are associated with 5 of the 10 leading causes of death in the United States, including coronary heart disease, some types of cancer, stroke, noninsulin-dependent diabetes mellitus, and atherosclerosis (11). Decreasing fat and increasing fiber, fruits, and vegetables in the diets of Americans has become a national priority (11,12). For recommendations such as the *Dietary Guidelines for Americans* to be widely adopted, it is important to understand their impact on overall quality of life. Earlier studies on cholesterol- and fat-lowering interventions found higher death rates from suicides, homicides, and accidents (4,13–16), which may indicate unanticipated detrimental effects of the prevention strategy on various aspects of life. However, observational studies have had more ambiguous results (17–19), and recent randomized trials of the impact of cholesterol-lowering diet interventions on women (5) or

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Reprint Address: D. K. Corle, National Cancer Institute, Executive Plaza North, Suite 3131, 6130 Executive Blvd, MSC 7354, Bethesda, MD 20892–7354.

mixed-gender (6,7) cohorts have found no impact of the diet on mental health variables. Other studies suggest that healthier diets improve well-being and that improved well-being and adherence to a dietary regimen are related (8,9).

In assessing the true impact of dietary changes or dietary intervention activities on quality of life, one must investigate changes in physical and emotional well-being as well as look at other aspects of daily life that are affected by a major change in eating habits. These go beyond the "health" aspects of quality of life and include whether the food tastes good, whether the eating plan puts a crimp in one's social life, whether the food is difficult to prepare, and whether the eating plan costs too much.

The National Cancer Institute (NCI)-sponsored Polyp Prevention Trial (PPT) provided an ideal opportunity to examine a wide range of quality of life factors that may be influenced by changes in eating habits and to determine how attitudes toward these factors changed over time. In this randomized trial, participants in the intervention program were asked to make three concurrent dietary changes and to maintain these changes for 4 years, whereas the control participants were asked to continue with their usual eating habits. The purpose of this article is to evaluate the effects of a low-fat, high-fiber, and high-fruit and vegetable eating plan on nutrition- and health-related quality of life measures among PPT participants. The analysis is based on quality of life questionnaire data collected from a subgroup of PPT participants at baseline and Years 1 through 4; it focuses on changes in measures such as self-perceived physical and emotional well-being, satisfaction with the diet, and self-care.

METHOD

Overview of Study Design

The PPT study design, participant recruitment, randomization, and nutrition intervention program have been described in detail elsewhere (20,21). Briefly, the PPT was a multicenter, randomized clinical trial to test the effect of a low-fat, high-fiber, and high-fruit and vegetable eating plan on the recurrence of adenomatous polyps of the large bowel. Participants were 2,079 men and women, 35 years of age or older, who had one or more large bowel adenomatous polyps removed within 6 months before randomization. Participant recruitment and randomization occurred between June 1991 and January 1994. During the 4 years of participation in the study, intervention participants received ongoing nutrition and behavioral counseling to adopt an eating plan providing daily 20% of energy from fat, 18 g of dietary fiber per 1,000 kcal in their usual diet, and 3.5 servings of fruits and vegetables per 1,000 kcal (which ranged from five to eight servings per day, depending on energy intake). Control participants did not receive such counseling and were expected to maintain their usual eating pattern. Self-reported dietary, health and lifestyle data, and blood samples were collected at study entry and on an annual basis.

Planning for the Quality of Life (QOL) Substudy described in this article began early in 1993, more than 2 years after the main PPT study began. All 407 participants accrued and randomized into the trial between August 1993 and the end of the study were asked to complete the Quality of Life Factors (QF) Questionnaire at baseline and annually for 4 years, in addition to other PPT baseline and annual measurements. Of these, 394 (97%) agreed to participate and completed the questionnaire at baseline. Characteristics of participants in trials that accrue over several years may change over the course of the study, and substudies selected based on fixed time intervals of accrual may not be representative of the trial as a whole. Although addressing this question of potential bias is not critical to the analyses presented in this article, Table 1 shows the comparability of QOL Substudy to participants in the remainder of the PPT trial. Table 2 presents the demographic characteristics of the 200 control and 194 intervention participants completing a baseline QF Questionnaire. In general, substudy participants were White, married, well-educated nonsmokers with a mean age of 60.9 years at baseline. Thirty-seven percent of participants were

TABLE 1
Characteristics of Participants in the QOL Substudy and the Remainder of PPT

	Non-QOL[a]	*QOL*[b]
Intervention (%)	50.0 (1.2)	49.2 (2.5)
Age (*M*)	61.6 (0.2)	60.9 (0.5)
Men (%)	65.5 (1.2)	62.7 (2.4)
Minority (%)[c]	10.3 (0.7)	11.4 (1.6)
More than high school education (%)[d]	64.3 (1.2)	66.8 (2.4)
Smoking at baseline (%)	13.9 (0.8)	11.7 (1.6)
Body mass index (*M*)	27.6 (0.1)	27.5 (0.2)
Alive at Year 4 (%)	95.5 (0.5)	96.2 (1.0)

Note. Numbers in parentheses are standard errors. None of the differences between QOL and other PPT participants are statistically significant. QOL = Quality of Life; PPT = Polyp Prevention Trial.

[a]n = 1685. [b]n = 394. [c]Minorities include African Americans, Hispanics, Indians/Native Americans, Asians/Pacific Islanders, and others. [d]One participant with missing education data in non-QOL.

TABLE 2
Baseline Characteristics of Control and Intervention Participants in the QOL Substudy

Characteristic	*Control Group*[a]	*Intervention Group*[b]
Age (*M*)	61.6 (0.7)	60.2 (0.8)
Men (%)	61.0 (3.4)	63.4 (3.5)
Minority (%)[c]	9.0 (2.0)	13.9 (2.5)
More than high school education (%)	65.0 (3.4)	68.6 (3.3)
Smoking (%)	12.5 (2.3)	10.8 (2.2)
Body mass index (*M*)	27.4 (0.3)	27.6 (0.3)
Married (%)[d]	83.4 (2.6)	77.3 (3.0)

Note. Numbers in parentheses are standard errors. None of the differences between the intervention and control groups are statistically significant. QOL = Quality of Life.

[a]n = 200. [b]n = 194. [c]Minorities include African Americans, Hispanics, Indians/Native Americans, Asians/Pacific Islanders, and others. [d]One participant with missing marital status data in the control group.

women, and 9.0% of control participants and 13.9% of intervention participants were from minority populations.

Assessments

PPT QF Questionnaire. The QF Questionnaire was a 51-item, self-administered form completed by the participant at baseline and again at annual follow-up visits for 4 years. The purpose of the QF Questionnaire was to assess and monitor changes in nine domains related to diet and health: taste, convenience, cost, self-care, social, health assessment, health belief, health action, and life satisfaction. Loading questions for each domain (Table 3) provide a description of the main nutrition- and health-related issues addressed in each domain. These domains were selected because they focus on areas of everyday life assumed to be affected by the adoption of major changes in food consumption and eating behavior. The individual questions within each domain were scored on Likert scales, where higher scores represent greater satisfaction and higher quality of life.

All of the questions within the taste, convenience, cost, self-care, and social domains are from the Southeast Cholesterol Project QOL Questionnaire developed by Ammerman, DeVellis, Keyserling, and Simpson (7). Twenty-two of the questions had been tested for reliability with participants in the physician-directed diet treatment program. An additional 11 questions (7 in the social domain and 1 each in the self-care, taste, convenience, and cost domains) were under evaluation for validity and reliability at the time the QOL Substudy was being developed, and these were also included in the QF Questionnaire.

The 7-item health assessment domain includes four questions from the Medical Outcomes Study's 36-item Short-Form Health survey (22), two questions from the Health Locus of

TABLE 3
Internal Reliability and Description of Nine Domains Composing the QF Questionnaire

Domain	*No. of Items*	*Cronbach's* α	*Loading Questions*[a]
Taste	4	0.7	20. I enjoy most of the food I eat. 25. I am satisfied with the taste of the food I eat. (Responses: *Disagree a lot, Disagree a little, Agree a little, Agree a lot*)
Convenience	5	0.7	18. Is it hard or easy to shop for the kinds of food you or your family eat? 19. Is it hard or easy to plan and prepare the kinds of meals you or your family eat? (Responses: *Very hard, A little hard or don't know, Pretty easy, Very easy*)
Cost	5	0.8	36. The high cost of food is a problem for me. 37. Sometimes it's hard for me to pay for the kind of food I eat. (Responses: *Disagree a lot, Disagree a little, Agree a little, Agree a lot*)
Self-care	8	0.9	22. I feel like I'm doing something good for myself by eating the way I do. 29. Eating the way I do now makes me feel good about myself. (Responses: *Disagree a lot, Disagree a little, Agree a little, Agree a lot*)
Social	11	0.7	8a. I enjoy the foods I eat at holiday meals and parties. 8b. I enjoy getting together for meals with friends. (Responses: *Disagree a lot, Disagree a little, Agree a little, Agree a lot*)
Health assessment	7	0.8	13a. I have a lot of energy to accomplish what I need to. (Responses: *Disagree a lot, Disagree a little, Agree a little, Agree a lot*) 14. During the past month, how have you been feeling generally? (Responses: *Poor spirits, Fairly good spirits, Good spirits, Very good spirits, Excellent spirits*)
Health belief	3	0.9	11. How likely is it that food choices you can make will: 11b. Improve your health? 11c. Help you feel better? (Responses: *Very unlikely, Somewhat unlikely, Somewhat likely, Very likely*)
Health action	4	0.5	38. During the past month, how often have you received nutrition or health messages from the following sources: 38a. Media (television, radio, newspapers, magazines) 38d. Food labels (Responses: *Never, Sometimes, Often*)
Life satisfaction[b]	4	0.7	15. In general, how satisfying is your life? (Responses: *Very unsatisfying, Fairly unsatisfying, Fairly satisfying, Very satisfying*) 16a. Overall, during the past month, how much satisfaction have you gotten from your leisure time (Responses: *Does not apply, No satisfaction, A little satisfaction, A moderate amount of satisfaction, A good deal of satisfaction*)

Note. QF = Quality of Life Factors.
[a]Loading questions are the two questions in each domain that give maximal loading to the scale as determined by factor analysis. [b]Question on job satisfaction was not included as 40% of PPT population was retired.

Control Questionnaire (23), and one question from the Psychological General Well-Being Scale (24). The life satisfaction domain includes 4 items from the Bryant and Veroff QOL measure (25). The health belief domain includes questions on the perceived benefits of healthy food choices, based on Becker's Health Belief Model (26). The four questions in the health action domain, also based on the Health Belief Model, were adapted from a published scale developed by Connell and Crawford (27).

The reliability of each domain at baseline was assessed using Cronbach's alpha coefficient, which measures the internal consistency of the questions in the domain (28). Reliability was 0.7 to 0.9 at baseline (see Table 3) for all domains except health action, which had a reliability of 0.5. Because the health action domain includes separate queries on diverse sources of nutrition messages, we would not expect high intercorrelations among items.

Health and Lifestyle Questionnaire. This interviewer-administered questionnaire was used to assess a variety of demographic, clinical, and behavioral characteristics, including questions on food shopping and meal preparation responsibilities in the participant's household. The questionnaire was completed at baseline and annually for all PPT participants.

Food Frequency Questionnaire (FFQ). At baseline, and annually thereafter, all participants completed a modified Block–NCI FFQ (29). Modifications to the Block–NCI FFQ for the PPT, discussed in more detail elsewhere (21), included the addition of low-fat and nonfat food items and more high-fiber foods, such as dried fruit, high-fiber cereals, and legumes. The FFQ was self-administered at each annual visit, after which a specially trained nutrition staff member reviewed the completed questionnaire with the participant. Nutrient analysis of the completed FFQs was conducted using a modified Dietsys 2.0 program (30).

Data Analysis

For each item in the QF Questionnaire, scores were coded and standardized to a scale ranging from 0 (*worst quality of life*) to 1 (*best quality of life*). Missing responses to individual items, which were minimal (< 5%), were assigned a value of 0, the lowest value for the question. The total score for each domain was created by summing the responses to the individual questions in the domain, then dividing by the total number of domain questions and multiplying this value by 100. Therefore, the total score for each domain had a minimum value of 0 and a maximum value of 100, and each question had equal weight in creating the domain.

For each domain score, the mean and its standard error were calculated at baseline. Simple regression analysis quantified the relation of selected baseline demographic and behavioral variables to each domain score. The selected variables included gender, race, age, marital status, body mass index, educational level, and smoking status.

The change in each domain score from baseline to Year 1 was calculated for each participant. The difference between intervention and control in the mean change for each domain score was tested for significance using a two-sample *t* test. To determine whether the changes observed at the end of Year 1 were maintained, the changes in each domain score from baseline to Years 2, 3, and 4 were calculated for each participant. For those domains that showed significant group differences at Year 1, repeated measures analysis of variance was used to test the consistency of group differences over the 4 years of follow-up.

RESULTS

Domain Scores at Baseline

As shown in Table 4, mean scores for each domain ranged from 50.5 to 83.1 at baseline on a scale ranging from 0 (*worst quality of life*) to 100 (*best quality of life*). The taste, convenience, social, and health belief domains were all rated above 70. There were no significant differences between control and intervention participants for any domain except the taste domain. Control participants scored the taste domain a statistically significant (p = .005) 3.8 points higher on average than did intervention participants. We have no explanation for this difference, and as the randomized trial progressed, taste domain scores for control participants steadily decreased from the high baseline levels.

Relation of Baseline Demographic Characteristics to Baseline Domain Scores

Because there were minimal differences in domain scores between treatment groups at the beginning of the QOL, baseline scores for all participants were combined for the analysis of the relation of selected baseline demographic and behavioral variables to each domain. As presented in Table 5, women scored the convenience (p = .004) and social (p = .001) domains higher and the cost (p = .011) domain lower than did men. Participants older than 61 years of age rated themselves higher on the self-care domain (p < .001) compared to younger participants. Married participants more positively rated the cost (p = .009), social (p = .008), health assessment (p = .019), and life satisfaction (p < .001) domains than did their single counterparts. Similarly, the higher the educational level, the more participants re-

TABLE 4
Mean Baseline Domain Scores of Control and Intervention Participants in the QOL Substudy

Domain	*Control Group*[a]	*Intervention Group*[b]
Taste[c]	83.1 (0.9)	79.3 (1.0)
Convenience	72.7 (1.4)	72.1 (1.3)
Cost	66.1 (1.3)	65.7 (1.4)
Self-care	61.0 (1.3)	59.0 (1.3)
Social	74.5 (0.9)	73.1 (1.0)
Health assessment	64.0 (1.4)	62.8 (1.4)
Health belief	76.3 (1.6)	78.8 (1.5)
Health action	51.1 (1.4)	50.5 (1.4)
Life satisfaction	62.4 (1.0)	63.7 (1.0)

Note. Numbers in parentheses are standard errors. QOL = Quality of Life.

[a]n = 200. [b]n = 194. [c]Significant difference between groups, p = .005.

TABLE 5
Differences in Mean Levels of Baseline Domain Scores for Dichotomous Demographic Variables

	Domain								
	Taste	*Convenience*	*Cost*	*Self-Care*	*Social*	*Health Assessment*	*Health Belief*	*Health Action*	*Life Satisfaction*
Gender									
Female = 149	–2.38	–5.77	5.08	–1.79	–4.29	3.64	–4.80	–4.20	–0.21
Male = 245	(.092)	(.004)	(.011)	(.345)	(.001)	(.072)	(.036)	(.041)	(.888)
Race									
White = 349	1.32	–4.28	–4.97	2.25	–6.88	3.85	–3.65	1.26	1.24
Other = 45	(.541)	(.164)	(.103)	(.436)	(<.001)	(.213)	(.297)	(.688)	(.586)
Age									
≤ 61 years = 191	1.95	1.55	–1.38	7.22	–1.53	–2.95	–4.05	1.73	1.37
> 61 years = 203	(.155)	(.429)	(.479)	(<.001)	(.241)	(.133)	(.068)	(.387)	(.345)
Body mass index									
≤ 25 = 111	0.74	–1.65	–2.34	–5.14	2.16	0.80	–0.31	0.21	–2.45
> 25 = 283	(.626)	(.447)	(.279)	(.012)	(.136)	(.716)	(.899)	(.926)	(.129)
Education									
≤ High school = 131	–2.57	3.00	13.93	–4.77	3.47	3.76	0.04	–0.91	–0.62
College = 263	(.078)	(.148)	(< .001)	(.014)	(.012)	(.071)	(.986)	(.669)	(.687)
Smoker									
No = 348	–3.17	–1.39	–5.19	–9.84	–1.86	–4.90	0.26	–2.78	–3.61
Yes = 46	(.138)	(.649)	(.086)	(< .001)	(.360)	(.109)	(.941)	(.372)	(.110)
Marital status[a]									
Not married = 77	3.80	2.61	6.40	2.18	4.35	5.77	1.26	2.60	6.53
Married = 316	(.138)	(.290)	(.009)	(.346)	(.008)	(.019)	(.653)	(.299)	(<.001)

Note. Each factor was classified into two categories; the table entry is the difference between the means for the two categories. Values in parentheses are *p* values for a *t* test that the difference is equal to zero.

[a]One person had missing marital status at baseline.

TABLE 6
Self-Reported Daily Energy, Fiber, and Fruit and Vegetable Intake at Baseline, Year 1, and Year 4 in the Control (C) and Intervention (I) Groups in the Quality of Life Substudy

	Baseline		*Year 1*		*Year 4*	
	C[a]	*I*[b]	*C*[c]	*I*[d]	*C*[e]	*I*[f]
% energy from fat	35.3 (0.5)	35.2 (0.5)	33.5 (0.5)	24.2 (0.5)	33.2 (0.5)	23.5 (0.5)
Fiber (g/1000 kcal/day)	9.4 (0.2)	9.6 (0.2)	10.3 (0.3)	17.3 (0.4)	10.2 (0.3)	17.7 (0.4)
Servings of fruits and vegetables (per day)	3.7 (0.1)	3.9 (0.1)	3.9 (0.1)	5.9 (0.2)	4.3 (0.1)	6.3 (0.2)

Note. Table entries are means with standard errors in parentheses. Seven and 15 participants in QOL provided Food Frequency Questionnaire data at Year 1 and Year 4, respectively, but failed to complete the Quality of Life Factors Questionnaire.

[a]$n = 200$. [b]$n = 194$. [c]$n = 190$. [d]$n = 180$. [e]$n = 171$. [f]$n = 169$.

ported enjoying eating in restaurants or with family and friends ($p = .012$) and less often reported cost as a barrier to the purchase of food ($p < .001$).

Overweight participants (body mass index > 25) and participants with at least some college education had lower ratings on the self-care domain compared with lower weight participants ($p = .012$) and individuals with less education ($p = .014$). Smokers also reported lower scores on the self-care domain than nonsmokers ($p < .001$). Although non-Whites scored lower than Whites on the social domain ($p < .001$), there were no other significant differences in domain scores between White and non-White racial groups.

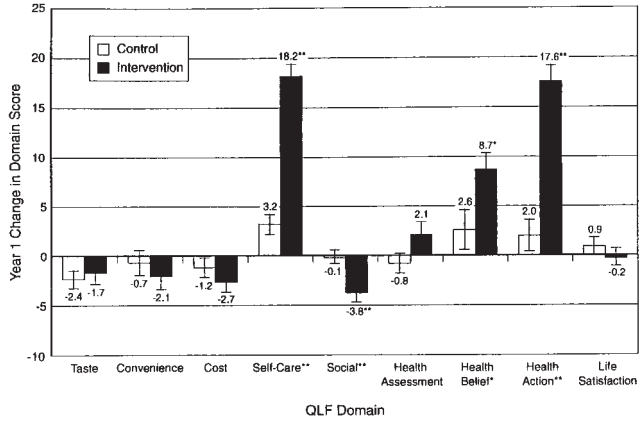
Reported Dietary Change

As shown in Table 6, intervention participants reported success in adopting the PPT eating plan by the end of Year 1 of the intervention and in maintaining the changes throughout the 4 years of the trial. Control participants did not report substantial changes in their diet. Because energy intake remained fairly constant, the Year 1 change in one of these dietary outcome measures was highly correlated with each of the remaining two. The three pairwise correlations among these factors ranged between .5 and .7, which were each significantly different from zero ($p < .001$). These results are comparable to those for the en-

tire PPT cohort, which have been discussed extensively elsewhere (31).

Changes at Year 1 in Domain Scores

Figure 1 presents the average changes in domain scores from baseline to Year 1 for 363 control and intervention participants that completed both surveys. There were no significant differences in the change from baseline to Year 1 between intervention and control participants for the taste, convenience, cost, health assessment, and life satisfaction domains. At Year 1, the change of –2.4 points from the baseline taste domain score in the control group was significant ($p = .006$). For intervention participants, the change of –1.7 points in taste score was not statistically significant. These changes in the taste domain were not statistically different between the treatment groups. The change of –2.7 in the cost domain score for the intervention group was statistically significant ($p = .010$). However, the changes in cost domain scores were not statistically different between the groups. There were significant differences between the treatment groups in baseline to Year 1 changes in scores for the self-care, social, health belief, and health action domains. In the self-care domain, both intervention and control participants reported significantly ($p < .002$) higher ratings at Year 1 than at baseline. The increase in the self-care domain score of 18.2 points in the intervention group was significantly higher than the 3.2-point increase in the control group ($p < .001$). The social domain was the only domain the intervention group rated significantly lower than the control group after Year 1 on the PPT eating plan. The social domain score for intervention participants decreased by 3.8 points in Year 1, and this decrease was significantly different ($p < .001$) from the negligible decrease in the mean score for control participants.



* p = .02
** p < .001 Statistical significance of differences in changes between intervention and control groups.

FIGURE 1 Mean change in domain scores from baseline to Year 1 for the control and intervention groups in the Quality of Life Substudy (limits are 1 SEM).

Consistency of Changes in Domain Scores Over Follow-Up Years

Figure 2 shows the control and intervention mean domain scores over the 4-year study period for those four domains showing significant group differences at Year 1. To test the consistency of changes in each domain over the entire follow-up period, we

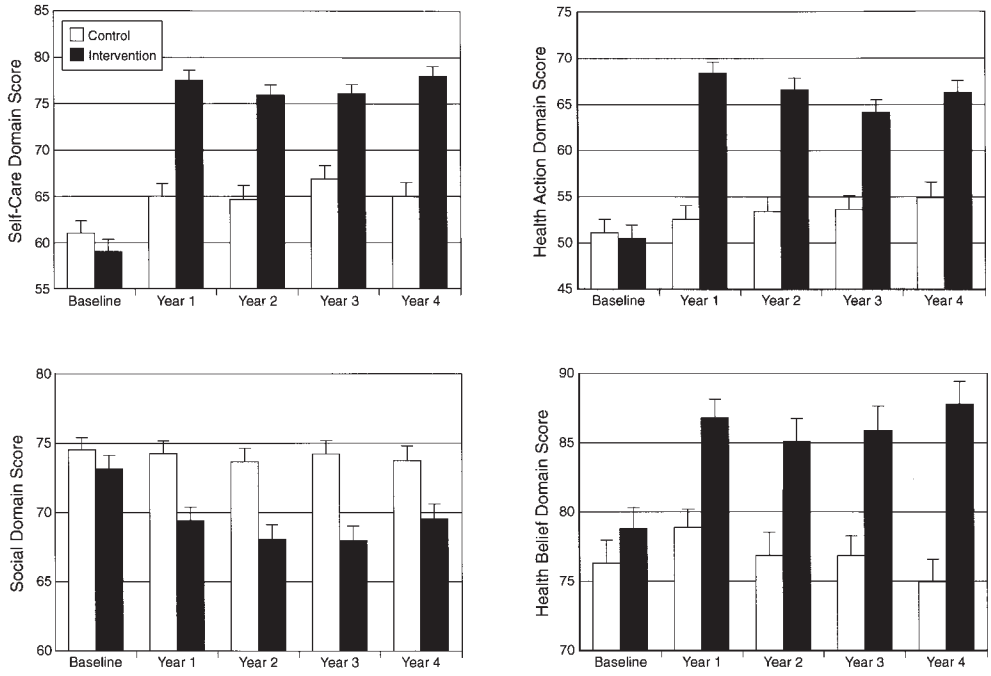


FIGURE 2 Mean baseline through Year 4 domain scores for intervention and control participants in the Quality of Life Substudy (limits are 1 SEM).

TABLE 7
Baseline Characteristics of QOL Participants With Complete (Baseline and Year 4 QF Questionnaire) and Incomplete Data Points

	Complete[a]	*Incomplete*[b]
Intervention (%)	48.6 (2.8)	52.2 (6.0)
Age (*M*)	60.8 (0.6)	61.6 (1.3)
Men (%)	63.1 (2.7)	60.9 (5.9)
Minority (%)[c]	12.3 (1.8)	7.2 (3.1)
More than high school education (%)	67.1 (2.6)	65.2 (5.7)
Smoking (%)	10.2 (1.7)	18.8 (4.7)
Body mass index (*M*)	27.5 (0.2)	27.4 (0.5)

Note. No differences are statistically significant between completers and noncompleters. Numbers in parentheses are standard errors. QOL = Quality of Life; QF = Quality of Life factors.

[a]$n = 325$. [b]Incomplete are those not completing the Year 4 questionnaire; $n = 69$. [c]Minorities include African Americans, Hispanics, Indians/Native Americans, Asians/Pacific Islanders, and others.

computed the change from baseline as each participant's observed value of score change at each of the four annual follow-up visits. Because some of the 394 participants in the QOL Substudy failed to complete a questionnaire at all time points, we used a mixed model repeated-measures analysis procedure that permits some missing data. To adjust for potential biases induced by missing observations, we adjusted for three factors. Table 7 shows characteristics of those 69 missing a Year 4 QF Questionnaire compared to the remaining 325 in the QOL Substudy. Of the 69 missing, 15 died prior to their Year 4 visit. We adjusted on gender, minority status, and smoking status because some imbalances in these three factors are suggested. We entered the three adjustment and group effects as indicator variables and follow-up time as a linear trend. We also tested for an interaction between group and time. The repeated-measures analysis indicated differences in the effect due to group assignment for the self-care ($p < .001$), social ($p < .001$), health action ($p < .001$), and health belief ($p = .051$) domain scores. We noted a significant ($p = .028$) negative time effect for the health belief domain. A hint of an interaction between group and time ($p = .044$) was seen for the health action domain. For each of the four domain scores, a model based contrast to test the group difference at Year 4 indicated each significantly different from zero ($p < .002$).

DISCUSSION

Our findings suggest that a low-fat, high-fiber, and fruit- and vegetable-enriched eating plan can be adopted without negative impact on overall perception of quality of life. In fact, many positive changes in quality of life perceptions were reported by QOL Substudy participants. The ongoing challenge of maintaining the eating plan in social situations was the only reported negative perception. At baseline and prior to intervention counseling, we found significant associations between selected demographic and lifestyle characteristics and self-perceived overall health; enjoyment of the social aspects of food; care of personal health; and satisfaction with food taste, food cost, and the convenience of buying and preparing food.

Positive Influences of Eating Pattern Changes on QOL

In this study, people encouraged to adopt a low-fat, high-fiber, and fruit- and vegetable-enriched eating pattern were as satisfied with the taste and enjoyment of food and the ease of grocery shopping, meal planning, and meal preparation as on their previous diet when compared with a control group. Intervention participants reported significantly and substantially greater confidence in their ability to care for their health compared with control group participants. Those in the intervention program reported more awareness of nutrition and health messages from health professionals and food labels, and they expressed greater belief that food choices would improve health.

The overall positive impact of the PPT eating plan is consistent with the results of several other studies. Hyman, Flora, Reynolds, Johannsson, and Farquhar (32) examined the effects of dietary changes to improve cholesterol levels among community participants with elevated cholesterol levels. General well-being (e.g., self-rating of health, level of anxiety or depression, energy level, and enjoyment of foods eaten) did not change among those who made dietary changes to reduce cholesterol levels. In a 4-month dietary treatment program to lower blood cholesterol, Ammerman et al. (7) found that the intervention group showed substantial and significant improvement on a self-care index relative to controls. This intervention group also had slight but significant increases in scores for the taste, cost, and convenience indices, compared with the control group. Bowen, Kestin, McTiernan, Carrell, and Green (5) reported that women who lowered dietary fat intake in a breast cancer prevention clinical trial experienced more positive psychological function than the control group; by the Year 1 follow-up, the intervention participants reported less anxiety, less depression, more vigor, and more positive perceptions of current health and health outlook than the control participants.

These results contrast with previous reports identifying potential negative outcomes of cholesterol- and fat-lowering interventions. Earlier randomized trials provided evidence that lowering serum cholesterol levels in men may result in increased rates of death by violent means, including suicides, homicides, and accidents (3,16,17). In our study, both men and women received a dietary-only intervention to reduce fat and increase dietary fiber, fruit, and vegetable intake. The intervention did not focus on lowering cholesterol. Although we did not administer a full battery of mental health scales, our data suggest that participants did not experience a negative impact on general feelings of overall well-being and general satisfaction with life, family relationships, and leisure activities. The overall death rate and the rate of deaths resulting from accidents and injury were comparable between the PPT control and intervention groups. Our data suggest that diet-based, fat-lowering interventions can be recommended without fear of negative mental health sequelae.

Our results also contrast with reported barriers to adopting and maintaining a low-fat eating plan. In prior studies, people

adopting low-fat eating patterns to reduce cardiovascular disease risk have reported that a low-fat diet does not taste as good (8,33,34), costs more (9,33), and makes food shopping and meal preparation difficult (33,35–37). Contrary to these common perceptions, cost and convenience ratings did not change significantly during 4 years of participation in the PPT intervention program. Intervention participants did not rate the overall cost or difficulty in shopping for and preparing foods as significantly different from their previous diet, and their ratings on these factors were not significantly different from those of control participants. After each year of participation in the intervention program, participants rated their satisfaction with the taste and enjoyment of food as similar to their level of satisfaction with their previous diet. At baseline, control participants rated taste 3.8 points higher than did intervention participants ($p = .005$). We have no explanation for this difference. However, comparing the change in taste scores from baseline to Year 1 (see Figure 1) showed no difference in the amount of change between the intervention and control groups. Also, the multivariate analysis across all years of the study showed no significant difference in taste scores between intervention and control participants. We conclude that participation in the PPT intervention program did not result in an overall decline in this quality of life domain.

We speculate that the standardized PPT nutrition intervention program, which included more than 60 hr of counseling on behavior modification techniques and nutrition skills building in Year 1 (21), helped participants overcome some of the commonly perceived barriers (e.g., cost, convenience, taste of food) to adopting a healthier diet. The frequent face-to-face and telephone contact with PPT nutritionists were intended to provide social support for adopting and maintaining the eating plan and help participants with problem solving. The counseling stressed self-monitoring, positive self-talk, practical meal preparation, and recipe modification. The cost savings of increasing the complex carbohydrate content of the diet while decreasing fat were discussed. In addition, the emphasis on increased fruit, vegetable, and fiber intake was intended to provide a more positive message compared to interventions focusing mainly on reducing fat. We also believe that the increased availability of a wide range of low-fat food products in the marketplace (38) may have made adopting the PPT eating pattern more convenient for participants.

Negative Influences of Eating Pattern Changes on QF

Several studies (8,9,33–36) have identified difficulty eating away from home or dining with family and friends as barriers to adopting and maintaining a low-fat diet. After Year 1 on the PPT eating plan, intervention participants indicated that eating in social situations was more difficult on the PPT plan than on their previous diet, and their ratings on this domain were more negative than those of control participants. The social domain section of the QF Questionnaire included questions about eating with family and friends and eating at holidays, parties, and restaurants. There were also questions about eating differently than others and difficulty eating with others.

Of the 11 items within the social domain, 2 in particular were affected by adoption of the PPT eating pattern. After Year 1, intervention participants were significantly ($p < .001$) more likely to state that the way they ate was different from the eating pattern they observed in others. This may represent an accurate comparison between the intervention eating pattern and the dietary choices made by the average American. Intervention participants were also significantly more likely ($p < .001$) to report difficulty in eating with others as a result of their modified eating patterns. This suggests that they did experience some degree of challenge in maintaining their intervention eating pattern when dining with other people. However, responses to questions about the intervention participant's enjoyment in eating meals with family, with friends, or at restaurants were not different from those of controls.

By recognizing that eating away from home and eating with others are major social aspects of life, the PPT intervention may have helped participants maintain their enjoyment of eating with friends and family. Strategies for meeting the challenge of maintaining the PPT eating plan while eating away from home and during holidays and celebrations were integrated throughout the 4-year intervention. Approximately 25% of the written materials were devoted specifically to developing participant skills for social situations such as eliciting support from family and friends, planning ahead for social occasions, making appropriate restaurant menu selections, making and refusing requests, and meeting the challenge of vacations and travel. However, the limited selection of healthier menu items at most restaurants was a frequent complaint of participants and also of study nutritionists.

Demographic and Lifestyle Differences in QF Domains

Our data suggest that self-perceived physical and emotional well-being and satisfaction with diet and self-care vary considerably among demographic groups and lifestyles. At baseline, older participants, those who were not overweight, nonsmokers, and those with less education reported being better able to care for their health, compared with younger participants, those who were overweight, smokers, and those with more education. We were surprised by the inverse relation of education level to the self-care domain. We speculate that participants with higher levels of education score themselves lower on the self-care domain at baseline because they have a greater knowledge of healthful habits but may not have adopted them. Compared to men, women found it easier to shop for and prepare meals, reported more concerns about the cost of food, and reported greater enjoyment of meals with family and friends. Married participants had higher assessments of their overall health, life satisfaction, the taste of food, and enjoyment of the social aspects of eating and were less concerned about food cost than their single counterparts.

Other studies have found significant associations between demographic and lifestyle characteristics and the adoption of a healthier eating pattern. In a diet and exercise intervention, poor compliance was linked with smoking and younger age (38). There was a significant decline in dietary satisfaction among men, but not women, with kidney disease following the adop-

tion of a low-protein diet (10). Male gender and fewer than 13 years of education are documented risk factors for low fruit and vegetable consumption (39,40). Responsibility for food selection, purchase, and preparation were related to both short- and long-term success in adopting a low-fat diet in the Women's Health Trial (41).

These studies support the importance of addressing the relations between demographic and lifestyle factors and attitudes and beliefs about food and health early in the intervention process. Targeted strategies should be developed to help people with specific demographic characteristics, lifestyle characteristics, or both to overcome barriers to adopting a healthier eating pattern. For example, unmarried people and those who smoke or are overweight may require additional customized intervention counseling to address negative attitudes and health beliefs.

SUMMARY

In this study, the dietary intervention incorporated nutrition skills building, behavior modification techniques, self-monitoring, and extensive professional counseling and support to help participants overcome barriers to adopting and maintaining major changes in their eating habits. Before enrollment and randomization in this study, an eligible individual was required to commit to making a major change in his or her usual eating habits. In addition, the individual agreed to attend more than 60 hr of individual and group counseling, keep extensive food intake records, and participate in regular telephone counseling between in-person sessions. This considerable personal commitment resulted in the successful adoption of a low-fat, high-fiber, and high-fruit and vegetable eating plan and did not negatively affect overall perceptions of quality of life. In fact, the enhancement of several quality of life factors was documented.

Participants who adopted and maintained the PPT eating plan for 4 years reported greater confidence in their ability to care for their health, greater belief that food choices would improve health, and more awareness of health and nutrition messages. Contrary to common perceptions of low-fat diets, participants did not report any detrimental effects of the eating plan on taste, cost, the convenience of shopping for and preparing foods, their overall health assessment and general well-being, or satisfaction with life. Difficulty in eating in social situations was the only reported detrimental impact of the eating plan. This finding highlights the need to develop additional strategies to facilitate the maintenance of a modified dietary pattern while eating with others or dining out. These data provide evidence that the adoption of a low-fat, high-fiber, and high-fruit and vegetable eating plan can be recommended without fear of negative quality of life sequelae.

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APPENDIX

The PPT Study Group also includes L. S. Freedman, C. Clifford, and J. Tangrea of the National Cancer Institute; M. R. Cooper, S. Quandt, C. DeGraffinreid, K. Bradham, L. Kent, M. Self, D. Boyles, D. West, L. Martin, N. Taylor, E. Dickenson, P. Kuhn, J. Harmon, I. Richardson, H. Lee, and E. Marceau of the Bowman Gray School of Medicine; M. P. Lance, J. R. Marshall (currently at the University of Arizona), D. Hayes, J. Phillips, N. Petrelli, S. Shelton, E. Randall, A. Blake, L. Wodarski, M. Deinzer, and R. Melton of the State University of New York at Buffalo; F. L. Iber, P. Murphy, E. C. Bote, L. Brandt-Whittington, N. Haroon, N. Kazi, M. A. Moore, S. B. Orloff, W. J. Ottosen, M. Patel, R. L. Rothschild, M. Ryan, J. M. Sullivan, and A. Verma of the Edward Hines Jr. Hospital, Veterans Administration Medical Center; B. Caan, J. V. Selby, G. Friedman, M. Lawson, G. Taff, D. Snow, M. Belfay, M. Schoenberger, K. Sampel, T. Giboney, and M. Randel of the Kaiser Foundation Research Institute; M. Shike, S. Winawer, A. Bloch, J. Mayer, R. Morse, L. Latkany, D. D'Amato, A. Schaffer, and L. Cohen of the Memorial Sloan-Kettering Cancer Center; J. Weissfeld, R. Schoen, R. R. Schade, L. Kuller, B. Gahagan, A. Caggiula, C. Lucas, S. Pappert, R. Robinson, V. Landis, S. Misko, and L. Search of the University of Pittsburgh; R. W. Burt, M. Slattery, N. Viscofsky, J. Benson, J. Neilson, R. McDivitt, M. Briley, K. Heinrich, and W. Samowitz of the University of Utah; J. W. Kikendall, R. Wong, E. Stoute, V. Jones-Miskovsky, A. Greaser, S. Hancock, and S. Chandler of the Walter Reed Army Medical Center; and M. Hasson, B. Brewer, T. Zimmerman, B. O'Brien, L. Cranston, N. Odaka, K. Umbel, J. Pinsky, H. Price, and A. Slonim of the Data and Nutrition Coordinating Center (Westat). The central pathologists for the trial are K. Lewin (University of California, Los Angeles) and H. Appelman (University of Michigan). The PPT laboratory scientists are P. S. Bachorik and K. Lovejoy (Johns Hopkins University) and A. Sowell (Centers for Disease Control and Prevention). Members of the PPT Data and Safety Monitoring Committee are E. R. Greenberg, chair (Dartmouth University); E. Feldman (Augusta, GA); C. Garza (Cornell University); R. Summers (University of Iowa); S. Weiand (through June 1995, University of Minnesota); and D. DeMets (beginning June 1995, University of Wisconsin).