HHS Public Access

Author manuscript

Psychooncology. Author manuscript; available in PMC 2015 May 12.

Published in final edited form as:

Psychooncology. 2005 February ; 14(2): 85–93. doi:10.1002/pon.822.

Quality of life and diet intervention in individuals at risk for recurrence of colorectal adenomas

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Summary

The effect of participation in a diet intervention study on self-reported quality of life (QOL) with subjects at risk of recurrence of colorectal adenomas was explored in 77 men and women, aged 18-80 years, with a history of adenomatous polyps. Participants were randomly assigned to intervention and control groups and followed for one year. Dietary goals for the intervention group included reduced intake of fat and increased intakes of fiber, calcium, and vegetables and fruit. Diet counseling was provided by telephone. Anthropometric measurements were obtained and dietary intakes were assessed at baseline, six and 12 months. The Quality of Life Factors questionnaire (QF), designed to explore the absolute effects of the diet intervention on participants' perceived QOL, was administered at baseline and study end. Based on repeated 24-hour dietary recalls, the intervention group reported significantly higher consumption of vegetables, fruit, low-fat dairy products, fiber, and calcium at 12 months. There were no significant differences in total QF scores for the two groups at study end, and no significant changes within groups between baseline and study end. Findings suggest that even though the intervention participants made significant modifications in their eating behavior, these changes did not impact their perceived QOL negatively.

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Introduction

Diet plays an important role in the prevention and treatment of several types of cancer as well as other chronic diseases [WCRF/AICR 1997]. With the growing evidence for a biological link between dietary constituents and carcinogenesis [WCRF/AICR 1997], cancer prevention and control efforts continue to examine and test the effects of dietary interventions [Dwyer, 2001; Weed, 97]. Colorectal cancer, in particular, is considered a preventable disease because research suggests that 85-90% of all cases may be derived from environmental and dietary factors [Vargas, 1992; Greenwald, 1992; Potter, 1992; Sandler, 96]. Colon cancer is expected to account for 11% of cancer cases and 10% of cancer deaths in the U.S. in 2003 [Jemal et al, 2003]. While much attention has been paid to the effects of dietary change on the initiation, maintenance and progression of colon cancer, few studies have addressed the effects of diet modification efforts on the quality of life for the individual at risk.

As an aspect of everyday life, diet is central to a person's overall health, well-being and quality of life. Knowledge about the association between the desired behavior change and quality of life outcomes is essential in assuring the sustained success of dietary interventions. While a growing body of research suggests that disease prevention and treatment efforts should be focused on quality of life outcomes [Sanders et al, 1998], few have paid attention to the absolute effect of dietary change on the overall quality of life. Food is not only a fundamental human need, but it is also a source of pleasure and satisfaction and is an integral part of an individual's social life. Most studies that have a dietary component have evaluated more traditional outcomes, such as patient's well-being, with measures that assess health-related quality of life. One such study is The Dietary Approaches to Stop Hypertension (DASH) trial that examined the effects of three types of diets on health-related quality of life, assessing the extent to which physical health or emotional problems interfere with daily activities [Plaisted et al, 1999]. At the end of the eight-week intervention period, the DASH trial researchers found improvement in health-related quality of life scores in all treatment groups. Similar findings were reported from another study that examined the effects of a prepared meal plan on weight loss and cardiovascular risk factors [Metz et al, 2000]. Similar to the DASH study, the investigators found improvements in quality of life in the intervention group.

In contrast, there are studies that suggest subjects participating in diet intervention studies may report a decline in their quality of life [Cummings & Psaty, 1994; Pekkanen et al, 1989]. It could be argued that participating in studies that require strict adherence to dietary goals, in addition to data collection procedures and frequent clinic visits, could be burdensome, thus adversely affecting perception of well being. However, in order to know whether the dietary intervention component of a study is actually introducing high subject burden, it would be misleading to rely on studies that evaluate overall or health related quality of life. While informative, these outcomes do not take into account the individual, social and cultural aspects of eating to evaluate the impact of modification of the dietary pattern.

In order to evaluate the absolute impact of a dietary change on quality of life, it is necessary to look beyond physical and emotional well-being and to examine changes in all aspects of daily life that may be influenced by the desired changes in eating habits [Corle et al, 2001]. Diet intervention and prevention programs may demand an overall lifestyle change by requiring more time for food selection and preparation and by complicating one's ability to eat away from home or to attend social gatherings. Other challenges that a diet intervention program introduces include the increased cost or the need for developing and maintaining a taste for new flavors. Only a focused approach addressing the individual, social, and cultural aspects of food preparation and consumption can illuminate the relationship between dietary change for disease prevention and quality of life. One of the few studies that evaluated the absolute effects of dietary changes on eating-related quality of life is the Polyp Prevention Trial (PPT) [Corle et al, 2001]. The participants completed a Quality of Life Factors (QF) questionnaire at baseline and yearly for four years, and their findings indicated that, with the exception of the social domain, intervention versus control participants rated all domains of QF higher in each study year.

The purpose of this study was to explore the relationship between dietary changes and self-reported quality of life outcomes in 77 adults who were at risk of recurrence for colorectal adenomas. The subjects in this study participated in a feasibility study that aimed to determine whether individuals with a history of adenomatous polyps could change their diets in order to reduce their risk for recurrence, and we assessed the effects of the diet intervention efforts on participants' quality of life. Even though the subjects in the intervention group were asked to make significant changes in their usual dietary patterns, we hypothesized that, compared to the participants in the control group, there would be no detectable effects on quality of life.

Methods

Subjects

Individuals recruited into this study were adult men and women who were recruited by physician referral. Patients at two major local hospitals in San Diego, California who had undergone a colonoscopy and whose pathology report indicated they would qualify for the study comprised the eligible pool. Participants were eligible for the study if they had an adenoma or malignant polyp diagnosed and fully resected, with no evidence of invasion, within the previous six months; had undergone colonoscopy with the entire large bowel seen and judged to be free of further polyps; had no prior invasive cancer within the past 5 years other than non-melanoma skin cancer; were in good health; could provide dietary and historical information; and were accessible geographically and by telephone for participation. Subjects were excluded if they were diagnosed with familial polyposis; had a history of invasive large bowel cancer; or had a malabsorption syndrome or any other condition that might be worsened by the protocol or diet intervention. This report includes all participants for whom dietary intake data and QF scores were available at baseline and 12 months, when the study was terminated.

Study design

Participants were 77 adult men and women who have had at least one histologically confirmed adenoma or a malignant polyp diagnosed and removed from the large bowel. Subjects were stratified into six groups based on gender and on whether they had one non-malignant polyp, two or more non-malignant polyps, or a malignant polyp. Polyp classification was obtained from the pathology report provided by the referring physician. Upon enrollment into the study and at 6 and 12 months, participants were scheduled for clinic visits to obtain relevant study information on dietary intake patterns and supplement usage. At these visits, height and weight were obtained by standard procedures, and BMI (weight (kilogram)/height (square meters)) was calculated. Subjects were trained to estimate serving sizes with food models to enhance their accuracy when describing food intake. Baseline demographic variables, family history, and health status were determined by self-report. Physical activity levels were assessed with 11 questions taken from the Thoughts and Feelings Questionnaire, developed for the Women's Health Initiative Clinical Trial and Observational Study [1998].

Participants were randomly assigned to intervention or control groups and were followed for one year. The intervention group was asked to make changes in their usual eating patterns in order to meet the study dietary goals, which included consuming lower levels of fat and increased amounts of fiber, vegetables and fruits, and calcium. Dietary intake data were collected at baseline and six and 12 months.

Quality of Life Questionnaire

The quality of life questionnaire utilized in the current study was identical to the Quality of Life Factors questionnaire used at the Polyp Prevention Trial [PPT QF - Corle et al, 2001]. The data on quality of life were collected at baseline and study end. The 51-item self-administered questionnaire includes questions about perceived satisfaction with diet and overall health status. The participant responses to the questionnaires were entered into the computer and scored electronically. Items were scored on a four-point Likert scale with higher scores indicating better functioning.

Changes in diet-related quality of life were assessed in nine domains that have been previously identified in the PPT QF; taste, convenience, cost, self-care, social, health assessment, health belief, health action and life satisfaction [Corle et al, 2001]. Detailed background information on loading questions and a full description of the nine domains addressing nutrition and health-related matters are described in Corle et al [2001]. For the present study, all items that were identified for each particular domain [Corle et al, 2001] were selected to calculate the reliabilities for each domain. The nine domains address behaviors, beliefs and thoughts related to various health and food-related issues. These include, but are not limited to, satisfaction with flavors, meal enjoyment alone and/or with friends, ease of food shopping or meal preparation, affordability, as well as overall health and life satisfaction. The reliabilities for the overall scale and individual domains were assessed using Cronbach's alpha coefficient, an indicator of the internal consistency of the items. At baseline, the QF questionnaire utilized in the current study had good overall inter-item reliability (Cronbach's α=0.9). The reliabilities for the nine domains ranged from 0.3 to

0.9 (Table 1). The reliability for most domains compare favorably to those in the PPT with the exception of the Health Assessment domain (Cronbach's $\alpha = 0.3$). The questions that make up this domain include statements about overall well being as well as feelings within the past month.

Diet Intervention

The target daily diet for the intervention group was 7 to 9 servings of vegetables or vegetable juice equivalents, 3 servings of fruit or fruit juice equivalents, 3 servings of lowfat dairy products or equivalents, at least 30 to 35 g fiber, and 20 to 25 percent of energy from fat. One vegetable serving was defined as ½ cup of chopped or shredded vegetables, 1 cup of raw leafy vegetables, or 4 fluid ounces of vegetable juice. One fruit serving was defined as 1 medium sized fruit; ½ cup of chopped, cooked, or canned fruit; ¼ cup of dried fruit; or 4 fluid ounces of fruit juice. The three servings of low-fat dairy products were expected to result in the intake of at least 1200 to 1500 milligrams of dietary calcium. The fiber goal was expected to be reached by the consumption of 8 vegetable servings, 2 fruit servings, 2 whole grain servings, and 1 serving of cooked dry beans, lentils, or peas (1 serving equals ½ cup cooked). A whole grain serving consists of 1 slice of bread, ½ bagel, ¼ cup of bran, ¾ cup of dry cereal, ½ cup of cooked cereal, rice, or pasta.

Individual diet counseling for the intervention group involved telephone counseling and was based on social cognitive theory [Bandura, 1986; Pierce et al, 1997]. The control group was provided the current general dietary guidelines for reducing cancer risk. The schedule for diet monitoring for the control group was the same as that for the intervention group, but no telephone counseling was provided.

Dietary Assessment

The primary method of collecting dietary intake data was through repeated 24-hour dietary recalls obtained by telephone interview. These recalls were completed by a trained dietary assessor using an interactive computer-assisted, telephone technique. Four 24-hour dietary recalls were collected on randomly selected days (2 weekday and 2 weekend days) from each participant over a two-week period. Information about dietary supplement use was collected along with dietary intake during these phone interviews.

Analysis

Data were examined for normality, and when necessary, values were log- transformed to improve normality. Frequencies and univariate statistics were generated to describe the sample. Chi-square statistics were performed to evaluate group differences. Within group and between group differences were evaluated for intervention and control groups for change in mean values of selected variables at baseline and study end with two-sample t-tests. A P-value ≤ 0.05 was considered statistically significant. Data was analyzed using SPSS for Windows, Version 10.01 [1999].

Results

Participant Characteristics

Of the total study group of 77 participants, 69 were non-Hispanic white (Table 2), and the mean age of the group at diagnosis was 64.5 years. All participants entered the study within six months from the time of polyp excision. Four participants dropped out prior to study end. The mean body mass index (BMI) of the group was 29.0 kg/m^2 (29.3 kg/m^2 for the intervention and 28.8 kg/m^2 for the control group). The majority of the subjects were married, and many had completed college or higher levels of education. There were no significant differences between intervention and control groups for ethnic distribution, age, BMI, the ratio of men to women, and polyp number and classification at diagnosis (Table 2).

Based on results from t-tests, compared to the male participants, females in the study had lower BMI at study entry ($P < 0.01$), and they reported lower levels of fiber ($P < 0.01$) and calcium intake ($P < 0.01$) at baseline. Reported fiber intake at study end for females continued to be lower than levels reported for male participants ($P < 0.05$) at study end (Table 3).

Quality of Life Factors Questionnaire (QF)

Between group differences were assessed for total QF score at study end for participants in the intervention and control groups. Based on t-tests, there were no significant differences in total QF scores for the two groups at the 12-month interval (Table 4). Similarly, between group differences were assessed for each of the nine domain scores at study end for participants in the intervention and control groups. The findings indicate that the scores for the intervention group were significantly higher for the health action domain ($P < 0.01$). This domain asks to specify the sources of health/nutrition information, including the media, friends and family, health care professionals and food labels. There were no significant differences in mean scores for the remainder of the domains for the two groups at study end (Table 4).

Within group differences in total QF scores at baseline and endpoint was also assessed separately for the participants in each group. Significant changes in QF scores were not observed in either the intervention or the control groups. For the intervention group, the mean QF scores increased at the level of marginal significance: 153.9 (SD: 21.2) at baseline and 157.6 (SD: 18.9) at endpoint ($P = 0.058$). For the participants in the control group the mean values were 154.5 (SD: 15.6) at baseline and 156.9 (SD: 15.7) at study end (NS). Similarly, within group differences in QF scores for each of the nine domains were evaluated at baseline and endpoint for intervention and control participants separately. For the participants in the intervention group, the results indicated that the mean QOL scores for two domains changed significantly between baseline and study end. One was the health action domain (averaging 8.3 at baseline and 9.2 at endpoint, $P < 0.01$) which asks about utilizing sources of health/nutrition information. Self-care domain was the other one in which a significant change in QF scores between baseline and study end was observed. This domain includes questions about one's perceived ability to take care of one's own health as well as their thoughts on whether following the intervention program is beneficial to health

and well being. According to the findings, the baseline mean QF scores were significantly lower ($P < 0.01$) than scores at study end. For the participants in the control group, the only significant change in QF scores between baseline and study end was noted for the life satisfaction domain ($P < 0.05$). This domain asks about the perceived level of satisfaction with life in general, in addition to level of satisfaction at work or home, during leisure time and in relationship with family members.

The relationship between a number of participant characteristics at study end were evaluated for those scored above or below the mean QF score of 157 (Table 5). There were no differences in QF scores of male and female participants. Subjects with lower BMI scores had higher endpoint QF scores ($P < 0.01$). Similarly, participants had higher QF scores at endpoint if they reported more dietary supplement usage ($P< 0.01$) and higher levels of physical activity ($P < 0.05$) (walking and strength training) measured as metabolic equivalents (MET-h/week).

Diet Intervention

Based on data from repeated 24-hour dietary recalls, the intervention group reported a significantly higher consumption of vegetables, fruit, low-fat dairy products, fiber, and calcium at 12 months (Table 6).

Discussion

Adherence to dietary recommendations for disease management can often be hindered by a complex number of factors, one of which is the perceived reduction in QOL. Efforts directed at examining the impact of dietary interventions on QOL outcomes would provide valuable information for developing successful cancer prevention and control programs.

The results from the current study indicate that men and women with a history of adenomatous polyps can alter their diets without adverse effects on their perceived quality of life. Participants in the intervention group, compared to the control group, increased their intake of vegetables, fruits, fiber, and calcium, and decreased their fat consumption. Making these changes was not apparently regarded as burdensome by participants as indicated by lack of a decline in their overall QF scores at study end. In fact, the scores of the participants in the intervention group increased between baseline and endpoint and the difference was marginally significant. Furthermore, as indicated by the higher endpoint scores on the health action domain, compared to the controls, participants in the intervention group appear to have felt empowered by changing their diets as prescribed in the intervention program. They reported becoming more attuned to the health messages they encounter in the media, in their conversations with friends and family as well as in their interaction with health care professionals. They also indicated paying attention to food labels, regarding them as a source of health and/or nutrition information. Higher endpoint scores for the self-care domain for the intervention group is another indicator that the proposed diet intervention in the current study was perceived to be beneficial and not burdensome.

We further explored the differences in participant characteristics between those with higher versus lower QF scores at study end. Participants with higher QF scores appear to be more

health conscious, as evidenced by higher levels of physical activity, a lower BMI and higher numbers of supplement usage. These data also suggest that healthful habits can be achieved without a negative impact on one's quality of life.

In contrast to studies that report enhanced quality of life in association with a diet intervention program [Metz et al, 2000; McCarron, 1997], the participants in the intervention group in this study did not observe a marked increase in their quality of life. Higher level of education and socioeconomic status of the participants in both groups may have been the neutralizing factor. Previous research shows that adults with higher levels of education and above the age of 50 years may be better able to change their diets, when compared to other subgroups [Smith-Warner et al, 2000]. More importantly, the quality of life measures utilized in these other studies assessed health-related quality of life concepts such as bodily pain, mental health, vitality and general health perceptions. In contrast, the QF measure utilized in the current study is designed to evaluate quality of life outcomes specific to diet-related behaviors, such as the ease with which one can shop for or purchase the target foods, time and energy spent for meal preparation, and food enjoyment alone or with friends and family. In order to evaluate effectiveness of dietary interventions, more studies with dietary components need to explore the absolute effects of diet on quality of life, in addition to assessing traditional outcomes such as clinical measurements of a patient's well being. Furthermore, Schlettwein-Gsell [1992] suggests that the value of food intake for social structure, self esteem and enjoyment gradually increases for older populations. The current challenge for disease prevention efforts would be to evaluate the absolute effects of a dietary intervention for different age groups and under a number of different circumstances.

According to the findings, the participants with higher quality of life scores at study end also reported lower BMI scores, and higher levels of physical activity. Coupled with such characteristics, the dietary changes achieved by the intervention group in the current study may provide a means to reduce risk for cancer and other chronic diseases. From a public health perspective, achieving dietary change without negative effects on quality of life for persons at risk for cancer recurrence could have a significant impact on meeting the Year 2010 objective of reducing cancer incidence [US DHHS, October 2002].

Acknowledgments

Research supported by NIH/NCI grant number PO1 CA72092.

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Table 1

Inter item reliabilities for nine domains at baseline for the Quality of Life Factors questionnaire (QF) utilized in the current study and Quality of Life Factors questionnaire used in the Polyp Prevention Trial (PPT-QF; Corle et al, 2001).

Domains	QF Cronbach's α	PPT-QF Cronbach's α
Taste	0.7	0.7
Convenience	0.7	0.7
Cost	0.9	0.8
Self-Care	0.8	0.9
Social	0.8	0.7
Health Assessment	0.3	0.8
Health Belief	0.9	0.9
Health Action	0.5	0.5
Life Satisfaction	0.6	0.7
Total scale	0.9	NA

Table 2

Participant characteristics at baseline for intervention (n = 37) and control (n = 40) groups.

	Intervention n (%)	Control n (%)
Gender		
Male	27 (73)	27 (68)
Female	10 (27)	13 (32)
Age (years)		
<60	9 (24)	12 (30)
60-69	15 (41)	18 (45)
70-81	13 (35)	10 (25)
Race/Ethnicity		
Non-Hispanic white	34 (92)	35 (88)
Other	3 (8)	5 (22)
Education		
High school graduate	11 (30)	18 (45)
College graduate	22 (70)	21 (35)
Marital status		
Married	27 (73)	30 (75)
Single	10 (27)	10 (25)
Degree of obesity (BMI)		
Normal (25 kg/m^2)	6 (16)	12 (30)
Overweight (25-25.99 kg/m^2)	17 (46)	16 (40)
Obese (30 kg/m^2)	14 (38)	12 (30)
Number of adenomas		
One	26 (70)	27 (68)
Two or more	9 (24)	12 (30)
Malignancy	2 (5)	1 (2)

Table 3

Gender differences.

	Females		Males	
	Baseline Mean (SD)	**Study end Mean (SD)**	**Baseline Mean (SD)**	**Study end Mean (SD)**
Body mass index	26.8 (4.8)	NA	30.2 (6.0) *	NA
Fiber intake	18.2 (7.4)	19.7 (7.8)	23.2 (8.4) *	24.4 (9.5) *
Calcium intake	633.0 (227.6)	823.6 (343.0)	873.6 (326.0) +	949.9 (439.8)

* $p < 0.01$

+ $p < 0.05$

Table 4

Mean endpoint domain scores of intervention and control participants for the Quality of Life Factors questionnaire.

Domain	Intervention Group Mean (SD)	Control Group Mean (SD)	Significance (P value)
Taste	12.9 (2.1)	13.4 (1.9)	0.30
Convenience	5.6 (2.1)	5.9 (1.9)	0.54
Cost	9.9 (1.2)	10 (1.8)	0.86
Self-care	24.8 (3.8)	23.6 (3.7)	0.18
Social	6.9 (1.5)	6.9 (1.5)	0.76
Health assessment	19.3 (3.4)	19.9 (2.9)	0.37
Health belief	9.7 (1.7)	9.5 (2.2)	0.65
Health action	9.2 (1.4)	7.8 (1.9)	0.001
Life satisfaction	11.4 (3.5)	12.5 (2.6)	0.15
Total QF score	157.6 (18.9)	156.9 (15.7)	0.90

Table 5

Participant characteristics and Quality of Life Factors (QF) scores at study end.

Participant characteristics	QF scores ≥157 Mean (SEM)	QF scores < 157 Mean (SEM)
BMI	27.1 (1.6)	31.5 (1.7)*
Number of supplements	3.9 (0.5)	2.2 (0.3)*
Physical activity levels as metabolic equivalents	1140.6 (197.8)	514.3 (89.3)*

* $p \leq 0.05$

Table 6

Dietary intake values by study group assignment.

Nutrient/Food Group	Baseline Dietary Intake Mean (SEM)	12-Month Dietary Intake Mean (SEM)
Total Vegetables [svg/d]: Intervention	2.9 (0.3)	5.3 (0.5)*
Control	2.7 (0.3)	2.4 (0.2)
Total fruit [svg/d]: Intervention	4.7 (0.7)	6.0 (0.5)*
Control	3.5 (0.4)	3.9 (0.4)
Total fiber [g/d]: Intervention	22.4 (1.4)	27.7 (1.6)*
Control	21.9 (1.4)	18.9 (1.3)
Calcium [mg/d]: Intervention	836 (48.1)	1,101 (77.8)*
Control	809 (55.9)	742 (52.8)
Percent energy from fat: Intervention	31.2 (1.3)	27.5 (1.2)*
Control	31.1 (1.2)	31.7 (1.3)

*$p < 0.05$