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Long-term Dietary Outcomes of the FRESH START Intervention for Breast and Prostate Cancer Survivors

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Abstract

Background—Cancer survivors are at increased risk for secondary cancers and other diseases. Healthy dietary practices may improve cancer survivors' health and well-being.

Objective—The durability of the effects of the FRESH START intervention, a program of sequentially-tailored mailed materials, and standardized mailed materials (for controls) on cancer survivors' dietary outcomes was assessed over a 2-year period. Greater dietary gains were expected for FRESH START participants relative to controls.

Design—Participants were randomized to receive tailored vs. standardized 10-month mailed print interventions promoting diet and exercise behaviors. Data were collected at baseline and 1- and 2-year follow-ups.

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Participants/setting—Breast and prostate cancer survivors (N = 543) were recruited from 39 states and two provinces within North America. A total of 489 participants completed the 2-year follow-up assessment (10% attrition).

Intervention—Participants were randomly assigned to either a 10-month program of tailored mailed print materials promoting fruit and vegetable (F&V) consumption, reduced total and saturated fat intake, and/or increased exercise or to a 10-month program of publicly-available mailed materials on diet and exercise.

Main outcome measures—Telephone surveys (supported with blood biomarkers) assessed dietary habits at baseline and 1- and 2-year follow-ups.

Statistical analyses performed—Paired-samples t-tests were conducted to examine the durability of the intervention's effects on dietary outcomes within each study arm. Arm differences in follow-up outcomes were then tested with the general linear model, controlling for the baseline value of the outcome.

Results—Both arms reported decreased saturated fat intake, increased servings of F&V, and better overall diet quality at year 2 relative to baseline. However, FRESH START participants reported better overall diet quality and lower total and saturated fat intake compared to controls at the 2- year follow-up.

Conclusions—Results suggest that mailed material interventions, especially those that are tailored, can produce long-term dietary improvement among cancer survivors.

Keywords

breast carcinoma; prostate carcinoma; survivorship; diet

Advances in early detection and treatment of cancer have led to increases in the number of cancer survivors (1–2). Currently, there are more than 12 million cancer survivors in the United States, comprising roughly 4% of the population (3). Over 4.5 million of these survivors were diagnosed with breast or prostate cancer (4). The number of cancer survivors is expected to continue to grow due to the aging population and further improvement in cancer detection and care (1). Although the increase in cancer survivors is a positive trend, cancer and its treatment are associated with negative health-related sequelae. Relative to persons without a cancer history, cancer survivors are at increased risk for developing secondary cancers and other diseases or conditions, such as heart disease, osteoporosis, diabetes, and functional impairment (5–7).

A healthy diet and regular exercise may reduce cancer survivors' comorbidities (4–5, 8–9). Some evidence suggests that a healthful diet also may reduce cancer-associated biomarkers and risk of cancer recurrence, although findings have been mixed (10–15). Furthermore, a cancer diagnosis provides a teachable moment during which many individuals are motivated to improve their diet and other health behaviors (16–21). Harnessing the teachable moment, lifestyle interventions have been effective in improving cancer survivors' dietary behaviors (22–26).

Current dietary recommendations for cancer survivors, as well as the population at large emphasize a plant-based diet high in fruits and vegetables and low in fat (27–29). Specifically, adults' daily total fat intake should not exceed 20%–35% of their kcal, whereas saturated fat intake should not exceed 10% of their kcal (27, 29). The current FRESH START trial tested the efficacy of an intervention that was designed to promote both additive (fruits and vegetables) and reductive (low-fat) dietary practices among cancer survivors (30).

FRESH START was the first diet and exercise intervention for cancer survivors to be delivered exclusively through mailed print materials (30). This intervention was designed to promote behavioral goals including consumption of 5 or more fruits and vegetables (F&V) per day, reduction of total and saturated fat intake to less than 30% and 10% of kcal, respectively, and 150+ minutes of moderate to vigorous exercise per week. Individuals randomly assigned to the intervention arm received sequentially-tailored mailed print materials and those assigned to the control arm received diet and exercise materials available in the public domain. At the 1-year follow-up, the intervention and control arms demonstrated significant increases in diet quality and F&V consumption and decreased fat intake (30). However, the intervention arm showed greater improvement in these areas and reduced body mass index (BMI) relative to controls. The current research examines the durability of the FRESH START and control interventions' effects on dietary outcomes and body mass index over a 2-year period and compares the efficacy of the interventions at 2 years post-baseline. It was hypothesized that the intervention arm would show greater sustained improvement in dietary behaviors (less saturated and total fat intake, more F&V intake, and better overall diet quality) and lower BMI compared to the control arm.

METHODS

Participants

Individuals diagnosed with early-stage (in situ, localized, or regional) breast or prostate cancer within the prior 9 months participated in the FRESH START trial between July 2002 and October 2005. Individuals were excluded from participation if they had conditions precluding unsupervised exercise (recent myocardial infarction, uncontrolled angina or congestive heart failure, plans for hip or knee replacement surgery, pulmonary difficulties requiring oxygen use or hospitalization, or walker or wheelchair use) or if they had conditions that prohibited a high F&V diet (chronic warfarin use or renal failure). Potential participants also were excluded if they had advanced cancer or an additional primary cancer or lacked English fluency.

Procedure

The FRESH START trial design and methods were published previously (30–33). Following approval of study methods by the Duke University Health System Institutional Review Board, participants were recruited via self-referral, cancer registries of participating medical centers, or oncology practices in 39 states and 2 provinces in North America. Written informed consent was obtained prior to study participation. Survivors were identified and underwent eligibility screening within 9 months of diagnosis. Eligible individuals began the intervention following receipt of primary treatment. Survivors were excluded from the intervention trial if they met two or more goal behaviors (exercising 150+ minutes per week, eating 5 or more servings of F&V each day, limiting total and saturated fat intakes to less than 30% and 10% of kcal, respectively). Participants were randomized to receive one of two 10-month interventions designed to improve diet and exercise practices. The interventions involved an initial workbook followed by a series of seven newsletters at 6-week intervals. Between mailings, participants in both study arms received brief surveys and a \$5 incentive for each returned survey. The surveys for control participants assessed the perceived helpfulness of the brochures, whereas the surveys for experimental participants assessed current diet and exercise practices and readiness to change these practices. Information from the surveys was used to individually tailor each newsletter and provide feedback to experimental participants. The FRESH START intervention was based upon Social Cognitive Theory (34) that emphasizes confidence building and goal setting. Mailings were tailored to the experimental participants' demographic characteristics (age, race, and sex) (30), cancer coping style (e.g., 'fighting spirit,' 'anxious preoccupation') (35),

stage of readiness (36), barriers to lifestyle changes, and progress toward goal behaviors (150+ minutes of exercise, adherence to a low fat or high F&V diet) (31). Each experimental participant received two 5-month mailings on F&V consumption, low fat dietary practices, or exercise and only received materials in areas where they did not meet the goal behavior. Participants who did not adhere to any goal behaviors at baseline were randomly assigned to two of the three mailings. Additional newsletter content included information on the health benefits of lifestyle change.

Control participants received an initial workbook that included the "Facing Forward" booklet from the National Cancer Institute and subsequent materials on exercise, F&V consumption, and low fat dietary practices that are available in the public domain (31). These materials were mailed on a similar schedule to the FRESH START intervention arm. Current smokers in both study arms were sent the American Lung Association 'Quitting for Life' brochure (2003PS96328).

Measures

Computer-assisted telephone interviews of 45 to 55 minutes each were conducted at baseline and 1- and 2-year follow-ups and included measures of weight status and the Diet History Questionnaire (37–38), which was modified to include regional cuisine (e.g., okra, hominy). Reliability and validity of the DHQ has been demonstrated (37–38). The DHQ assesses dietary fat intake and consumption of a variety of foods and nutrients over the past year. Dietary outcome variables for the current research included the 100-point Diet Quality Index-Revised score (39), with higher numbers indicating better adherence to dietary recommendations, number of daily servings of F&V, and percentages of kcal from fat and saturated fat. On a 23% subset, anthropometric measures (height and weight), and blood samples were drawn and tested for plasma carotenoids. Measured values confirmed those of self report, i.e., BMI and fruit and vegetable consumption.

Throughout the study, participants reported adverse events by calling a toll-free number. Adverse events also were reported during the 1- and 2-year follow-up interviews and were classified as serious (life-threatening, permanently debilitating, or requiring hospitalization overnight) or non-serious (all other events) by research team members blinded to random assignment status.

Data Analysis

Paired-samples t-tests were used to determine the durability of the intervention's effects on dietary outcomes and body mass index within each study arm. The extent to which these outcomes were stable between the 1- and 2-year follow-up assessments and improved at year 2 relative to baseline values was examined. Our hypothesis that the intervention arm would show better outcomes than the control arm at 2 years post-baseline was tested with the general linear model, controlling for the baseline value of the outcome. All reported *p* values were two-tailed, and a *ps* value < .05 was considered statistically significant. Data were analyzed with SPSS statistical software (version 18.0, 2009, SPSS, Chicago, IL).

Two potential moderators of the intervention's effects were examined and excluded from the final analyses. Gender, a variable confounded with cancer type, and body mass index (normal weight vs. overweight) did not significantly interact with study arm to predict outcomes (data not shown).

RESULTS

Sample Characteristics

Descriptions of the sample and statistical analyses of the accrual procedures have been previously reported (30). To summarize, significant differences (all *p* values < 0.01) were found between participants and non-participants with respect to gender (54% vs. 46% female, respectively), race (19% vs. 38% minority, respectively), and age (58 vs. 62 years, respectively).

A total of 306 breast cancer patients and 237 prostate cancer patients participated in the randomized trial. Participants were primarily Caucasian (83%) or African American (13%) and well educated (88% with at least some college) (see Table 1). The average age of participants was 57 years (SD = 10.8) and the average time since diagnosis was 3.8 months (SD = 2.7) at the point of study entry. Most participants (85%) had undergone surgery and received adjuvant treatment, including radiation (44%), chemotherapy (27%), and hormonal therapy (38%).

Attrition and Adverse Events

An excellent retention rate (90%) was observed, with 519 patients completing the 1-year follow-up and 489 patients completing the 2-year follow-up. Reasons for attrition included participant withdrawal (n = 17), death (n = 8), familial illness (n = 7), and inability to reach the participant (n = 22). Attrition did not differ by sex or level of education; however, ethnic minority participants had a significantly higher attrition rate than Caucasians (16% vs. 9%, respectively, p = .02). Reasons for attrition among ethnic minority participants included inability to reach the participant (n = 9), death (n = 4), and familial illness (n = 1). In addition, the intervention arm had a significantly higher attrition rate than the control arm (13% vs. 7%, respectively, p = .02).

No differences in adverse events were found between study arms; intervention participants reported 211 total events (41 serious and 170 non-serious), and control participants reported 238 total events (56 serious and 182 non-serious).

Change in Dietary Outcomes and Body Mass Index

Baseline and follow-up data for study variables are listed in Table 2. Demographic and medical variables and dependent measures did not differ between study arms at baseline. As previously reported (30), both arms showed increased F&V consumption, decreased total and saturated fat intake, and better overall diet quality at the 1-year follow-up (all *p*-values < .01). However, significantly greater improvement in dietary outcomes occurred in the intervention arm, which also showed a significant reduction in BMI at the 1-year follow-up relative to controls (-0.2 vs. +0.1 kg/m², respectively, p < .01).

Although both arms significantly increased their total fat intake between the 1- and 2-year follow-ups (*p-values* < .001), only the intervention arm continued to show a reduction in total fat intake compared to baseline (p < .001). Other dietary outcomes showed sustained improvement relative to baseline in both arms. Specifically, both groups maintained their increased F&V intake, reduced saturated fat intake, and enhanced overall diet quality at the 2-year follow-up (see Figures 1, 2, and 3; all *p-values* < .01). Overall diet quality and total and saturated fat intake continued to be better for the intervention arm relative to controls (see Table 2). Weight status was fairly stable; both the intervention and control arms reported small increases in BMI over the study period (+0.2 vs. +0.1).

DISCUSSION

This study examined the durability of dietary outcomes of the FRESH START intervention at two years post-baseline. FRESH START was the first diet and exercise intervention for cancer survivors delivered exclusively through mailed print materials. At the 2-year followup, both the intervention and control arms showed greater F&V intake, lower saturated fat intake, and better overall diet quality relative to baseline. However, intervention participants showed lower total and saturated fat intake and better overall diet quality compared to controls at the 2-year follow-up. These results did not vary by cancer type or body mass index. In addition, although both arms increased their total fat intake between the 1- and 2year follow-ups, only the intervention arm showed a sustained reduction in total fat intake relative to baseline. These findings suggest that tailored intervention materials resulted in better long-term dietary outcomes than standard materials, although both fostered improved adherence to healthy dietary behaviors in cancer survivors. Results are consistent with evidence that tailored interventions are more effective than standardized interventions in modifying various lifestyle practices, including mammography, smoking, exercise, and dietary behaviors (24, 40–43). Tailored messages are thought to produce behavior change by providing personally relevant information.

Although this trial did not focus on weight loss, the intervention group showed a significant decrease in BMI when compared to the control group at the 1-year follow-up. Both study arms, however, reported small increases in BMI over the 2-year study period. These increases in BMI were roughly half that generally observed for the adult population over a 2-year time period (44), which suggests that the interventions may have promoted weight stability.

Although a number of diet and exercise interventions have focused on cancer survivors (12, 45–48), the FRESH START trial is noteworthy for a variety of reasons. First, FRESH START accrued a large North American sample of cancer survivors, whereas most trials accrued a smaller sample from one institution. Second, the FRESH START intervention targeted both prostate and breast cancer survivors, whereas most lifestyle intervention trials have targeted survivors of a single cancer type. In addition, the intervention was delivered exclusively via mailed print materials, whereas most studies have examined hospital-based or telephone-based interventions. Other strengths of this trial include the use of a rigorous attention control group, the long-term follow-up assessments, and the low attrition rate.

Several extensions of the present findings warrant future research attention. First, the extent to which booster materials may help cancer survivors sustain reductions in fat intake and improve other dietary outcomes should be evaluated. Second, technology-based delivery of lifestyle interventions (e.g. text, podcast, or Web-based approaches) should be explored, as the majority of U.S. adults have Internet access (49). The feasibility of these approaches with older adults warrants further study. Finally, the health events and health care costs associated with mailed material interventions such as FRESH START and technology-based interventions should be examined to determine their potential cost savings.

Limitations of this study also should be noted. Although a large North American sample was recruited, ethnic minorities, older adults, and individuals of lower educational attainment were underrepresented. Future research is needed to evaluate the effects of similar interventions in samples that are entirely representative of the population of cancer survivors. In addition, differential dropout occurred as a function of study arm (13% in the intervention arm and 7% in the control arm) and race (16% for ethnic minority participants and 9% for Caucasian participants). However, given the low overall attrition rate, this limitation may be a minor issue. The primary reason for dropout of ethnic minority

participants was an inability to reach them, which may be due to passive refusal or changes in contact information. Cultural tailoring of intervention materials may increase retention of ethnic minority individuals. Finally, study outcomes were self-reported. Although selfreported dietary outcomes were strongly supported by biomarker data (e.g., plasma alphacarotene) from a 23% subsample at the 1-year follow-up (30), further collection of biomarker data from a larger subsample would have been desirable.

Conclusions

Our findings inform clinical care by showing that a minimal, mailed intervention can produce long-term dietary improvement among cancer survivors. This print intervention may be readily disseminated to geographically dispersed survivors. Further research is needed to examine the cost-effectiveness of mailed material approaches and to compare their efficacy to that of less expensive technology-based approaches (e.g., Web-based interventions).

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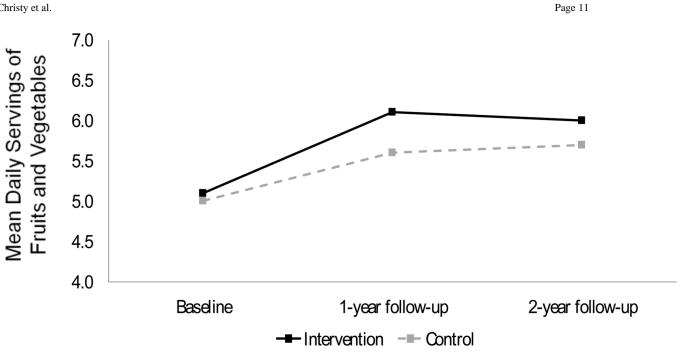
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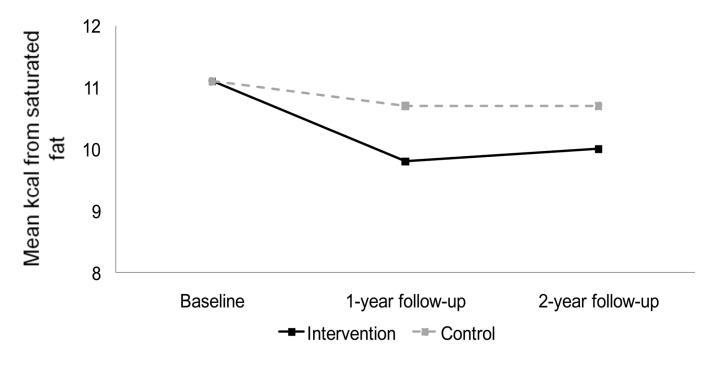
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Time

Figure 1. Change in number of daily servings of fruits and vegetables by study arm

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Time

Figure 2. Change in total percentage of calories from saturated fat by study arm

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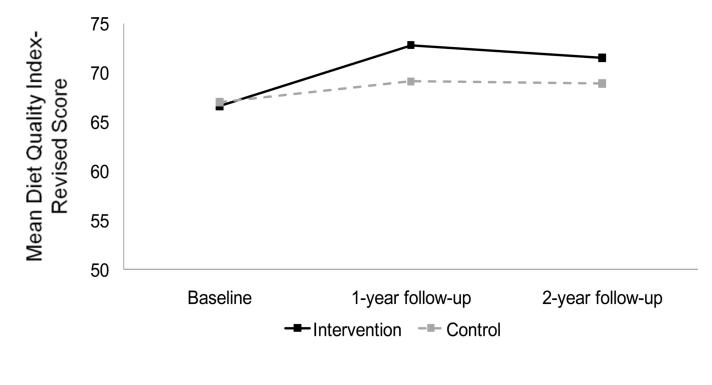




Figure 3. Change in overall diet quality by study arm

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Table 1

Baseline characteristics of study participants

	Total Sample (N = 489)		FRESH START Intervention (n = 236)		Attention Control (n = 253)	
Characteristic	No. of participants	%	No. of participants	%	No. of participants	%
Age, years						
Mean		57.2		57.4		57.1
SD		10.7		10.1		11.2
Range		22–85	ŝ	30–78		22-85
Race						
White	413	85	200	85	213	84
Black	59	12	25	11	34	13
Other	17	4	11	S	9	2
Source of ascertainment						
Self-referral	185	38	06	38	95	38
Cancer registry	304	62	146	62	158	63
Type and clinical stage of cancer						
Breast						
Stage 0	39	14	18	13	21	15
Stage I	148	53	78	57	70	50
Stage II	78	28	33	24	45	32
Stage III	13	5	8	9	5	4
Prostate						
Stage I	83	39	41	41	42	38
Stage II	111	53	51	52	60	54
Unknown	17	8	7	L	10	6
Treatment						
Surgery	416	85	206	87	210	83
Radiation therapy	221	45	108	46	113	45
Chemotherapy	127	26	64	27	63	25

	Total Sample (N = 489)		FRESH START Intervention (n = 236)		Attention Control (n = 253)	
Characteristic	No. of participants	%	No. of participants	%	No. of participants	%
Hormonal therapy	195	40	66	42	96	38
Other	17	4	7	3	10	4
No. of comorbid conditions						
Mean	(1	2.1		2.0		2.2
SD		1.7		1.8		1.7
Range	0	0-11	0	0-10		0-11
Education						
≤ High school graduate	56	11	28	12	28	11
Some college or associate	145	30	64	27	81	32
College graduate/postgraduate	288	59	144	61	144	57

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Table 2

Changes in outcome measures over time between the intervention and attention control arms

	FRESH START Intervention (n = 236)	LART tion 6)	Attention Control $(n = 253)$	tion 53)	P (Interv Attention	P (Intervention vs. Attention Control)
	Mean	SD	Mean	SD	1 Year	2 Years
Diet Quality Index-Revised score ^a					<.001	<.001
Baseline	66.6	11.1	67.0	9.4		
1-year follow-up	72.8	10.6	69.1	10.8		
2-year follow-up	71.5	10.5	68.9	10.6		
Total % calories from fat					<.001	.001
Baseline	38.0	5.7	37.8	5.6		
1-year follow-up	33.6	5.8	35.7	4.6		
2-year follow-up	36.5	6.6	38.0	5.4		
Total % calories from saturated fat					<.001	<.001
Baseline	11.1	2.1	11.1	2.0		
1-year follow-up	9.8	2.3	10.7	2.2		
2-year follow-up	10.0	2.1	10.7	2.1		
No. of daily servings of F&V					.014	.152
Baseline	5.1	2.7	5.0	2.3		
1-year follow-up	6.1	2.8	5.6	2.5		
2-year follow-up	6.0	2.7	5.7	2.8		
BMI, kg/m ²						
Baseline	27.2	5.1	27.6	5.4	.008	.710
1-year follow-up	27.0	5.0	27.7	5.4		
2-year follow-up	27.5	5.2	27.8	5.3		

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Abbreviations: SD, standard deviation; F&V, fruits and vegetables; BMI, body mass index.

 $^{a}\mathrm{A}$ 100-point scale with higher scores indicating better diet quality.