VOLUME 25 · NUMBER 19 · JULY 1 2007

JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

Main Outcomes of the FRESH START Trial: A Sequentially Tailored, Diet and Exercise Mailed Print Intervention Among Breast and Prostate Cancer Survivors

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Submitted January 7, 2007; accepted April 5, 2007.

Supported by Grants No. CA81191, CA74000, CA63782, and M01-RR-30 from the National Institutes of Health and also by the American Institute of Cancer Research and the Susan G. Komen Foundation (W.D.-W.).

Presented in part at the 42nd Annual Meeting of the American Society of Clinical Oncology, June 2-6, 2006, Atlanta, GA.

Authors' disclosures of potential conflicts of interest and author contributions are found at the end of this article.

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0732-183X/07/2519-2709/$20.00

DOI: 10.1200/JCO.2007.10.7094

ABSTRACT

Purpose
Cancer survivors are at increased risk for cardiovascular disease, diabetes, osteoporosis, and second primary tumors. Healthful lifestyle practices may improve the health and well-being of survivors. The FRESH START trial tested the efficacy of sequentially tailored versus standardized mailed materials on improving cancer survivors' diet and exercise behaviors.

Methods
Five hundred forty-three individuals with newly diagnosed locoregional breast or prostate cancer were recruited from 39 states and two provinces within North America. Participants were randomly assigned either to a 10-month program of tailored mailed print materials promoting fruit and vegetable (F&V) consumption, reducing total/saturated fat intake, and/or increasing exercise or to a 10-month program of nontailored mailed materials on diet and exercise available in the public domain. Telephone surveys conducted at baseline and 1 year assessed body mass index (BMI), dietary consumption, physical activity, and other psychosocial/behavioral indices. Clinical assessments were conducted on a 23% subsample; information was used to validate self-reports.

Results
Five hundred nineteen participants completed the 1-year follow-up (4.4% attrition; sample characteristics: 57 ± 10.8 years old, 83% white, 56% female, 64% overweight/obese, and 0% underweight). Although both arms significantly improved their lifestyle behaviors ($P < .05$), significantly greater gains occurred in the FRESH START intervention versus the control arm (practice of two or more goal behaviors: +34% *v* +18%, $P < .0001$; exercise minutes per week: +59.3 *v* +39.2 minutes, $P = .02$; F&V per day: +1.1 *v* +0.6 servings, $P = .01$; total fat: −4.4% *v* –2.1%, $P < .0001$; saturated fat: −1.3% *v* –0.3%, $P < .0001$; and BMI: −0.3 *v* +0.1 kg/m^2, respectively, $P = .004$).

Conclusion
Mailed material interventions, especially those that are tailored, are effective in promoting healthful lifestyle changes among cancer survivors. Further study is needed to determine sustainability, cost to benefit, and generalizability to other cancer populations.

J Clin Oncol 25:2709-2718. © 2007 by American Society of Clinical Oncology

INTRODUCTION

In the United States, a diagnosis of breast or prostate cancer is rendered almost every minute.[1] The good news is that most of these patients will be diagnosed with early-stage disease, for which 5-year relative survival rates exceed 98%.[1,2] The bad news is that cancer survivors are at increased risk for secondary cancers and other chronic conditions, such as cardiovascular disease, osteoporosis, and functional decline.[2-15]

A healthful diet and regular exercise can reduce cancer survivors' comorbidities,[2,4,7,16-19] and new evidence suggests that healthful lifestyle practices can protect against recurrence and cancer-specific mortality.[20-24] Furthermore, the cancer diagnosis provides a teachable moment, or a time when motivation for lifestyle change is especially high.[7,25-27] However, hospital-based programs have limited appeal for this older and geographically dispersed population.[17,18,25,28] Instead, home-based mailed print interventions are most preferred,[25,28] are likely to be

well accepted, and also may be more cost effective than one-on-one counseling or group classes.

The FRESH START trial aimed to improve the diet and exercise practices of newly diagnosed breast and prostate cancer survivors and tested the efficacy of a sequentially tailored mailed print intervention against standardized health education materials.[29] The central hypothesis was that the tailored intervention would promote significantly greater changes in behavior and higher proportional attainment of at least two of the following behavioral goals: 150+ min/wk of moderate to vigorous exercise; consumption of five or more servings of fruits and vegetables (F&V) a day; and restriction of total and saturated fat to less than 30% and 10% of energy intake, respectively.[29,30]

METHODS

Study Design

The FRESH START trial design and methods were published previously.[29] This behavioral intervention study was a randomized, single-blind, parallel group, attention control and active treatment controlled phase II clinical trial with a 10-month treatment phase and a blinded poststudy follow-up at 1 year. The study was conducted from July 2002 to October 2005, approved by the Duke University Medical Center Institutional Review Board, and reported according to Consolidated Standards of Reporting Trials guidelines.[31]

Study Population

Early-stage (in situ, localized, or regional) breast and prostate cancer patients were identified within 9 months of diagnosis via self-referral, rapid case ascertainment from participating cancer registries,[32,33] or large oncology practices throughout North America. Permission to contact patients was secured from their oncologists (Fig 1). Approved patients were sent letters of invitation that included the following: a toll-free telephone number to field questions regarding the trial; two consent forms (one for signature and return and the other for the respondent to keep); a preaddressed, postage-paid return envelope; and a brief screening questionnaire designed to exclude individuals who had conditions precluding unsupervised exercise (uncontrolled congestive heart failure or angina, recent myocardial infarction, or breathing difficulties requiring oxygen use or hospitalization; walker or wheelchair use; or plans to have hip or knee replacement), had conditions precluding a high F&V diet (kidney failure or chronic warfarin use), had progressive cancer or additional primary tumors, or were non-English speakers/writers. Ineligible participants received a thank you letter and a complementary brochure; eligible participants participated in the baseline assessment and were subsequently screened out if they practiced two or more goal behaviors (exercised 150+ min/wk or adhered to a low-fat or high-F&V diet).

Measures

Data were collected largely via telephone interview, with physical measures (phlebotomy, height, and weight) performed on a 23% subsample of patients residing within 60 miles of Duke University Medical Center to validate self-reported data. Two computer-assisted telephone interviews of 45 to 55 minutes each were conducted with participants at baseline and at follow-up;

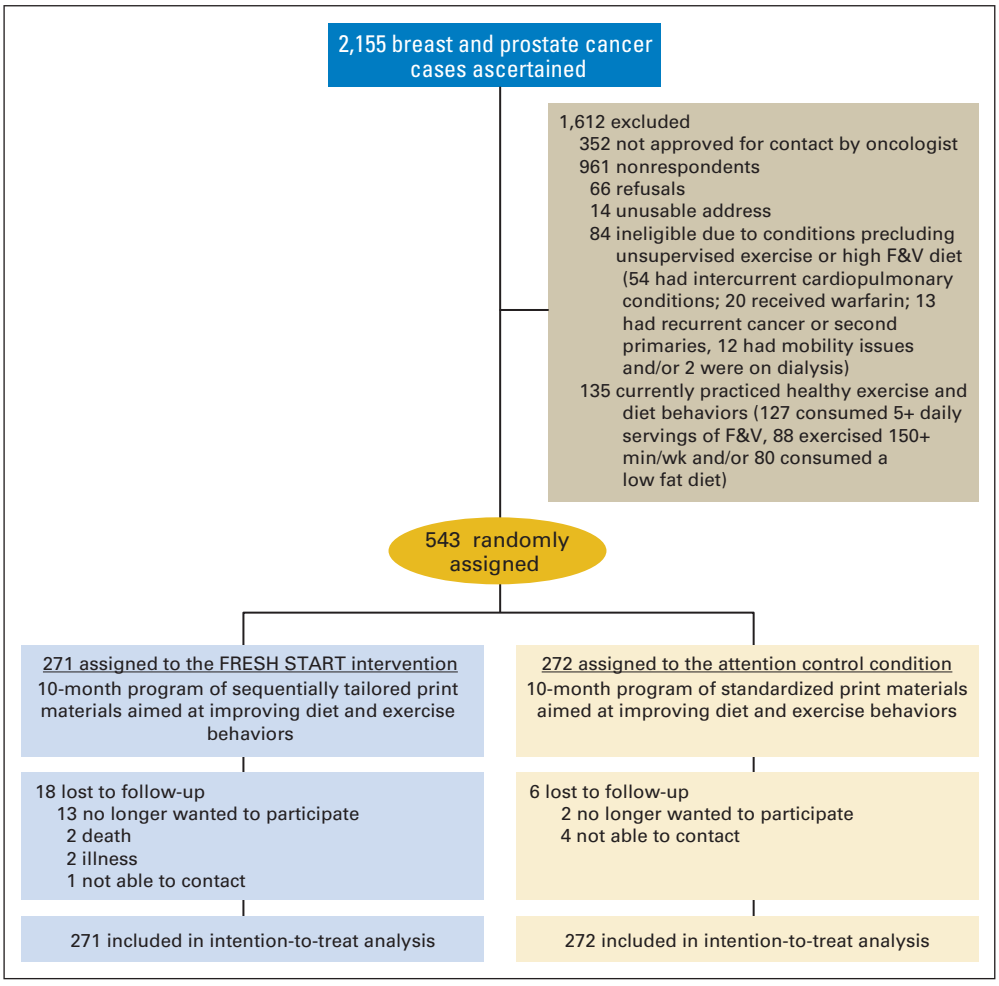

Fig 1. FRESH START trial flow diagram. F&V, fruits and vegetables.

interviews were scheduled 1 year apart to reduce confounding as a result of seasonality.[34-37] The 7-Day Physical Activity Recall[38,39] and the Diet History Questionnaire[40,41] were administered, and output specific to the practice of goal behaviors was used to evaluate intervention success (ie, minutes per week of moderate, hard, or very hard physical activity of at least 5 metabolic equivalents [kcal/kg/h] pursued for the purpose of fitness, number of F&V servings per day, and % kcal from fat and saturated fat). At these time points, we also assessed quality of life[42,43]; risk for depression[44]; social support[45]; comorbidity[46]; perceived health[47]; self-efficacy for exercising 150+ min/wk, eating five or more servings of F&V a day, and eating a low-fat diet[48]; stage of readiness for undertaking dietary and exercise change [49]; tobacco use[50]; and weight status. Sociodemographic information, cancer coping style,[51] and barriers to exercise and eating a low-fat, high-F&V diet were assessed only at baseline. Data related to adverse events were collected continuously via participant report to a toll-free number and were systematically elicited during the year 1 survey; events were categorized by a committee blinded to random assignment status as serious (life threatening, permanently debilitating, or requiring hospitalization overnight) or nonserious (all other events). Participants' opinions regarding the helpfulness of specific intervention materials in promoting behavior change (5-point Likert scale from completely to not at all helpful) were also assessed at the year 1 follow-up.

Measured heights and weights were performed on the 23% subsample at both time points using a wall-mounted stadiometer and a calibrated platform scale; weight status was expressed as body mass index (BMI; kg/m^2). Phlebotomy was performed after a fast of 4+ hours; blood samples were protected from light and centrifuged within 1 hour of collection. Plasma was stored at −80°C until batch analyzed for the following: total and high-density lipoprotein cholesterol and high-sensitivity C-reactive protein using a Hitachi 911 clinical analyzer with standard chemistries by Roche Diagnostics (Indianapolis, IN); insulin via radioimmunoassay (Linco, St Charles, MO); and interleukin-6 via enzyme-linked immunosorbent assay (Invitrogen, Carlsbad, CA).[52] Alpha-carotene and other carotenoids were quantified using the high-performance liquid chromatography method originally described by Bieri et al[53] and subsequently modified and described in detail by Gamboa-Pinto et al.[54]

Random Assignment

Participants who met all criteria after the baseline survey were randomly assigned with equal allocation to either the intervention or attention control arm. Block randomization within eight strata defined by cancer (breast/prostate), race (white/nonwhite), and number of goal behaviors practiced at study entry (zero/one) was used. Random assignment lists were generated by a project statistician using the software of the Cancer and Leukemia Group B. The process of random assignment was implemented in blinded fashion and at an office that was physically removed from the main study office. Study participants were never formally informed whether they received the tailored intervention or the standardized intervention; however, some may have deduced their assignment on receipt of the materials.

Interventions

The interventions are detailed in previous publications.[29,55,56] Briefly, both interventions aimed to improve diet and exercise behaviors, were 10 months in duration, and involved an initial personalized workbook followed by a series of seven newsletters at 6-week intervals. Between mailings, participants in both study arms received brief surveys that, when completed and returned, yielded a $5.00 incentive; surveys for the attention control arm elicited information regarding the perceived helpfulness of the brochures, whereas surveys targeting the experimental arm elicited information on current health practices and readiness to pursue lifestyle change. Current smokers in both arms received the American Lung Association "Quitting for Life" brochure (2003PS96328).

FRESH START intervention (experimental arm). Participants in this arm received workbooks and newsletters that were individually tailored on barriers, stage of readiness, and progress toward goal attainment of exercising 150+ min/wk, eating five or more servings of F&V a day, or restricting total and saturated fat intakes to less than 30% and 10% of kcal, respectively[29]; cancer coping style[51]; and basic demographic characteristics (age, race, and sex).[56] Information from brief mailed surveys was used to tailor the newsletters, such that participants received continually updated feedback. Each participant received two 5-month modules on F&V, dietary fat restriction, or exercise; participants only received materials in areas where they did not meet goal behavior; modules were presented one at a time to allow participants time and opportunity to gain needed skills before tackling behavior change in another area. Participants not practicing any goal behaviors at baseline were randomly assigned to two of the three modules. The FRESH START intervention was based on Social Cognitive Theory that emphasizes confidence building and skills development[48]; the Transtheoretical Model also was used to frame messages on participants' stage of readiness to motivate behavior change.[49] Figure 2 features an illustration of the FRESH START intervention materials (People Designs, Durham, NC).

Standardized intervention (attention control arm). Participants assigned to this arm received a personalized workbook that included the "Facing Forward" booklet (National Cancer Institute) and, in subsequent mailings, additional health education materials on a healthful diet and exercise available in the public domain.[29]

Statistical Analysis

The primary outcome of this trial was the percentage of patients who achieved goal behavior in at least two of the three behavioral domains. The design of this trial ensured that 265 patients per arm would give 89% power (two-sided alpha = .05) to detect a difference of 5% in the attention control arm (estimated Hawthorne effect)[57] versus 13% in the FRESH START intervention arm. Although this sample size allowed for dropout of about 30 patients total, all randomly assigned patients were included in intent-to-treat analyses by imputing no change in behavior across time for dropouts.

Arm difference in the percentage of patients achieving goal behavior was tested with the logistic regression model. Arm difference in number of behaviors practiced at goal level was tested with the ordinal logistic regression model, controlling for number of behaviors practiced at baseline. Arm differences on continuous outcomes measured at 12 months were tested with the general linear model, controlling for the baseline value of the outcome. Intraclass correlation coefficients were used to examine the agreement between self-reported and clinically assessed BMI, and Spearman correlation coefficients were used to examine the association between alpha-carotene from self-reported dietary intake and plasma levels, partialling out plasma cholesterol levels to achieve lipid-adjusted values. Alpha-carotene was specifically selected for analysis because previous studies have shown stronger correlations with diet and responsiveness to F&V interventions.[58,59]

RESULTS

Participant Disposition

Of the 2,155 cancer patients identified, 83.6% were approved for contact. Several oncologists reported that the Health Insurance Portability and Accountability Act precluded them from referring patients despite a protocol that was compliant with the Health Insurance Portability and Accountability Act.[60] Of the 1,789 patients (14 patients had unusable addresses) contacted for study, 42% expressed an interest in participating and submitted consent forms and screening surveys. Respondents differed significantly from nonrespondents with respect to age (58 *v* 62 years, respectively; $P < .0001$), race (19% *v* 38% minority, respectively; $P < .0001$), and sex (54% *v* 46% female, respectively; $P = .001$). Of the respondents screened, 29% were ineligible; leading reasons for exclusion were the current practice of healthful lifestyle behaviors (accounting for 62% of ineligibility) and cardiopulmonary conditions that precluded unsupervised exercise (accounting for 25% of ineligibility; Fig 1). The overall Recruitment Index (mean number of days to accrue and randomly assign each participant) was 1.42 days; Recruitment Indexes for various subgroups were as follows: white breast cancer survivors = 2.45 days; white prostate

Fig 2. FRESH START intervention materials.

cancer survivors = 3.61 days; minority breast cancer survivors = 11.60 days; and minority prostate cancer survivors 30.60 days.[61]

Trial participants were recruited from 39 states and two provinces within North America (Fig 3). Participants were generally white, married, and college educated (Table 1). Most participants were ascertained from cancer registries and had stage I or II cancers that were treated with surgery. Roughly equal numbers of breast and prostate cancer survivors were represented, with most exhibiting fatalistic cancer coping styles[51] and moderate numbers of comorbidities. At baseline, roughly half of our sample practiced goal behavior in one domain, with the consumption of five or more servings of F&V most likely to be practiced. Most participants were very to extremely confident that they could make changes in their diet and exercise behaviors, with most being in the preparation or action stages of readiness.

Adherence, Attrition, and Adverse Events

All participants received the assigned intervention materials. Of the seven brief surveys interspersed between intervention mailings, completion rates were 5.2 ± 2.4 surveys in the intervention arm and 6.1 ± 1.8 surveys in the control arm ($P < .0001$). Intervention participants who completed more interim surveys had higher proportional goal attainment; survey completion rates averaged 5.9 *v* 5.1 surveys among participants achieving two or more goal behaviors versus participants achieving fewer goals, respectively ($P = .005$). No differences in survey completion rates were observed over time or between modules. Overall, an exceptionally low attrition rate (4.4%) was observed. Attrition did not differ by age, race, sex, or educational status; however, significant differences were observed between arms (6.6% in the intervention arm *v* 2.2% in the attention control arm, $P = .01$). No differences in adverse events were observed between arms; intervention participants reported 137 total events (35 serious and 102 nonserious), and attention control participants reported 142 total events (39 serious and 103 nonserious).

Change in the Primary End Point

At follow-up, a significant difference was observed between arms in the practice of two or more goal lifestyle behaviors, with a combined frequency of 34% noted in the intervention arm and 18% noted in the attention control arm (Table 2, Fig 4).

Change in Secondary End Points

The attention control arm experienced significant increases ($P < .05$) in exercise and F&V consumption and decreases in fat intake; however, the intervention arm achieved far greater improvements (Table 2). The intervention arm also had much greater improvements in diet quality. Participants' ratings of the helpfulness of materials in motivating their behavior change differed between arms, with 32% to 61% (depending on the behavior) of intervention participants reporting that the tailored workbook and newsletters were quite a bit or completely helpful (compared with not at all, a little, or somewhat helpful) and 34% to 50% of these participants reporting that the tailored surveys also provided them with motivation. In the attention control arm, rated helpfulness for standardized brochures and surveys was 19% to 31% and 18% to 26%, respectively. Little change in quality of life was observed for either arm over the study period; however, baseline levels were high. Although the numbers of smokers were small, a trend ($P = .10$) toward decreased smoking was observed in the intervention arm. Although the intervention was not aimed at weight loss, a healthful diet and exercise are helpful in regulating body weight.[29,30] At baseline, no participants in the sample were underweight, and 64% were overweight. Significant differences between arms were observed for BMI and the proportion of individuals

Fig 3. Geographic distribution of FRESH START study participants. Participants were recruited from yellow-shaded states and regions.

classified within their ideal weight range (BMI, 18.5 to 24.9 kg/m^2).[62] Among all participants, 6% (33 of 543 participants) changed BMI categories over the study period, with the intervention arm experiencing significantly more shifts from overweight to normal weight than the control arm (75% *v* 29%, respectively; $P = .01$). Intraclass correlations between self-reported and clinically measured BMI were 0.996 (baseline) and 0.994 (follow-up), suggesting an almost perfect correlation. Significant associations also were observed between dietary and plasma alpha-carotene (baseline: $r = 0.30$, $P = .001$; follow-up: $r = 0.31$, $P = .001$). Small changes in health-related biomarkers were observed over the study period (eg, plasma cholesterol decreased by 5.1 mg/dL in the intervention arm *v* 0.3 mg/dL in the control arm); however, we were underpowered to detect significant differences within the 23% subsample with regard to total, low-density lipoprotein, and high-density lipoprotein cholesterol, interleukin-6, insulin, and C-reactive protein.

DISCUSSION

FRESH START is the first reported trial of a distance medicine-based diet and exercise intervention in cancer survivors delivered exclusively via mailed print materials. Data show that the FRESH START intervention was effective in increasing the number of lifestyle behaviors practiced at recommended levels and increasing the weekly number of minutes exercised, daily intake of F&V, and overall diet quality, as well as decreasing intakes of fat and saturated fat. Furthermore, although the intervention was not aimed specifically at weight loss, like the results of the Canadian Diet and Breast Cancer Prevention Study[63] and the Women's Intervention Nutrition Study,[20] the improvement in diet and exercise behaviors resulted in a significant loss of weight. Data from self-report were solidly supported by objective data for which correlations were either in the range (our correlations between dietary and plasma alpha-carotene were 0.30 to 0.31, $P = .001$, compared with reported correlations of 0.28 to 0.35, $P < .0001$)[58,59] or surpassed findings of previous studies (our correlations between self-reported and measured BMIs were 0.994 to 0.996, $P < .0001$, compared with correlations of 0.936 to 0.947, $P < .0001$, reported in the European Prospective Investigation into Cancer and Nutrition study).[64]

To date, there have been more than 40 diet and exercise interventions targeting cancer survivors. Most of these studies have been effective in improving lifestyle behaviors, with exercise interventions showing benefit in cardiorespiratory fitness, quality of life, and reduced fatigue and dietary interventions showing reductions in body weight and increased levels of dietary biomarkers, such as carotenoids.[7,17,18,65-67] Preliminary findings from the Women's Intervention Nutrition Study suggest that a low-fat diet may be effective in decreasing breast cancer recurrence, especially in women with estrogen receptor–negative disease.[20] Thus, the FRESH START intervention is not unique with respect to its reported efficacy. However, it is exceptional from the following standpoints: it targeted survivors of both breast and prostate cancer, whereas most extant trials have targeted only breast cancer survivors; it intervened on multiple behaviors (diet and exercise), whereas most others have focused solely on one

Table 1. Characteristics of Study Participants

Characteristic	Total Sample (N = 543)		FRESH START Intervention (n = 271)		Attention Control (n = 272)	
	No. of Participants	%	No. of Participants	%	No. of Participants	%
Age, years						
Mean	57.0		57.0		56.9	
SD	10.8		10.4		11.2	
Range	22-85		30-79		22-85	
Race						
White	452	83	226	83	226	83
Black	72	13	32	12	40	15
Other	19	4	13	5	6	2
Source of ascertainment						
Self-referral	209	38	106	39	103	38
Cancer registry	334	62	165	61	169	62
Type and clinical stage of cancer						
Breast						
Stage 0	41	8	19	7	22	8
Stage I	157	29	82	30	75	28
Stage II	90	17	40	15	50	18
Stage III	18	3	12	4	6	2
Prostate						
Stage I	94	17	47	18	47	17
Stage II	124	23	62	23	62	23
Unknown	19	3	9	3	10	4
Treatment						
Surgery	460	85	234	86	226	83
Radiation therapy including brachytherapy	240	44	120	44	120	44
Chemotherapy	145	27	74	27	71	26
Hormonal therapy	210	39	106	39	104	38
Other	13	5	13	5	12	4
No. of comorbid conditions						
Mean	2.10		2.01		2.18	
SD	1.72		1.77		1.67	
Range	0-11		0-10		0-11	
Education						
< High school graduate	64	12	30	11	34	13
Some college or associate	164	30	79	29	85	31
College graduate/postgraduate	315	58	162	60	153	56
Risk for depression according to CES-D						
Mean	3.7		3.5		3.9	
SD	2.5		2.3		2.6	
Perceived health						
Excellent	153	28	76	28	77	28
Good	304	56	153	56	151	56
Fair	69	13	35	13	34	12
Poor	17	3	7	3	10	4
Cancer coping style						
Fighting spirit	204	38	104	38	100	37
Fatalist	297	55	152	56	145	53
Cognitive avoider	23	4	8	3	15	6
Anxious preoccupier	18	3	6	2	12	4
Helpless/hopeless	1	<1	1	<1	0	0
Current smoker	34	6	15	6	19	7
Self-efficacy for exercise						
Not at all sure	18	3	8	3	10	4
A little sure	42	8	15	6	27	10
Somewhat sure	142	26	74	27	68	25
Very sure	138	26	71	26	67	25
Extremely sure	202	37	103	38	99	36
Stage of readiness for exercise						
Precontemplator	49	9	23	9	26	10
Contemplator	55	10	25	9	30	11
Preparation	365	67	182	67	183	67
Action	74	14	41	15	33	12

(continued on following page)

Table 1. Characteristics of Study Participants (continued)

Characteristic	Total Sample (N = 543)		FRESH START Intervention (n = 271)		Attention Control (n = 272)	
	No. of Participants	%	No. of Participants	%	No. of Participants	%
Self-efficacy for eating more F & V						
Not at all sure	7	1	0	0	7	3
A little sure	39	7	17	6	22	8
Somewhat sure	145	27	78	29	67	25
Very sure	157	29	83	31	74	27
Extremely sure	194	36	92	34	102	37
Stage of readiness to increase F & V						
Precontemplator	44	8	19	7	25	9
Contemplator	7	1	4	2	3	1
Preparation	329	61	169	62	160	59
Action	163	30	79	29	84	31
Self-efficacy for fat restriction						
Not at all sure	7	1	2	1	5	2
A little sure	30	6	17	6	13	5
Somewhat sure	147	27	70	26	77	28
Very sure	174	32	86	32	88	32
Extremely sure	185	34	96	35	89	33
Stage of readiness for fat restriction						
Precontemplator	60	11	33	12	27	10
Contemplator	15	3	9	3	6	2
Preparation	221	41	92	34	129	47
Action	247	45	137	51	110	41

Abbreviations: SD, standard deviation; CES-D, Center for Epidemiologic Studies Depression Scale; F & V, fruits and vegetables.

behavioral domain; it used a distance medicine-based approach that was delivered exclusively through mailed print materials, whereas most trials have relied on hospital-based programs; and it accrued a North American sample of 543 participants, whereas most trials have accrued smaller samples from one institution. FRESH START also is distinguished by its exceptionally low rate of attrition and the use of an attention control arm that served as a rigorous comparison group. Indeed, the fact that, unlike others,[19,30,65,67] we did not observe improvements in quality of life may be explained by positive changes inherent with intervention delivery. Ceiling effects offer another plausible explanation because scores were high at baseline. Another area in which we did not observe significant change was in plasma biomarkers because our effect sizes may have been too small to detect within the 23% subsample.

The fact that participants in the attention control arm also made significant positive changes in their behavior suggests that individuals with newly diagnosed cancers are a population eager for lifestyle interventions. Indeed, capitalizing on the teachable moment prompted by a cancer diagnosis has been the subject of many reports,[26-28] although more research is needed to determine whether intervention uptake differs between cancer populations and populations with other diseases or between newly diagnosed and long-term survivors. The fact that we saw significant improvements in behaviors with a series of seven standardized brochures and surveys provides evidence that minimal interventions may produce significant changes in behavior.

Clearly, the tailored intervention was significantly more effective than standardized materials, and even the brief interim surveys that specifically assessed progress in select behavioral domains were viewed by intervention participants as more helpful than standardized surveys. Moreover, exploratory data suggest that the tailored intervention also may be associated with benefit in health events and body weight status. Future studies are needed that will prospectively and systematically examine health events and health care costs associated with interventions such as FRESH START to determine their potential cost savings. In addition, other channels of delivery should be explored. Interventions delivered via Web-based approaches are a natural extension of this work, especially because we found that 80% of the sample had Internet access at the time of the follow-up survey.

FRESH START had limitations that should be considered when interpreting its findings. First, although the trial had excellent uptake and accrued participants throughout North America, the representation of minorities, elders, and those of lower educational attainment was proportionally lower than among the general population. Although findings of a recent review of 28 lifestyle intervention trials among cancer survivors suggests that more than two thirds of trials have minority representation of less than 10%, it is notable that FRESH START achieved a greater degree of diversity.[68] However, recruitment of minorities was a challenge for us as well and reduces the external validity of our findings. Differential dropout between study arms (ie, 6.6% in the intervention arm and 2.2% in the attention control arm) served as another limitation. However, given that our overall attrition was exceedingly low (less than half the average rate of 13.3%),[68] this is less of an issue. Among the 13 intervention participants who discontinued follow-up, one of the primary reasons for dropout was that the participant "just couldn't comply" with the diet or exercise regimen and "felt guilty" about being in the study (a feeling that may have been exacerbated by the intermittent surveys that asked about their health behavior practices). Thus, this study might have

Table 2. Baseline and 1-Year Follow-Up Self-Reported Outcomes Observed With the FRESH START Versus Attention Control Interventions

Factor	FRESH START Intervention		Attention Control		*P*	
	Baseline (n = 271)	1-Year Follow-Up (n = 253)	Baseline (n = 272)	1-Year Follow-Up (n = 266)	Unadjusted	Adjusted
No. of behaviors practiced at goal level					< .001	< .001
0						
No. of patients	116	59	115	90		
%	43	23	42	34		
1						
No. of patients	155	109	157	128		
%	57	43	58	48		
2						
No. of patients	0	70	0	41		
%	0	28	0	15		
3						
No. of patients	0	15	0	7		
%	0	6	0	3		
Physical activity, min/wk					.02	.02
Mean	53.4	112.7	44.6	83.8		
SD	112.7	126.6	89.1	119.1		
Range	0-715	0-650	0-675	0-960		
Diet Quality Index–Revised, score					< .001	< .001
Mean	66.3	72.8	66.9	68.7		
SD	11.3	10.6	9.5	10.9		
Range	29-87	45-91	35-85	34-90		
Total % calories from fat					< .001	< .001
Mean	38.0	33.6	37.8	35.7		
SD	5.6	5.6	5.6	4.6		
Range	17.6-51.4	13.8-50.3	20.3-51.7	15.7-50.0		
Total % calories from saturated fat					< .001	< .001
Mean	11.2	9.9	11.1	10.8		
SD	2.1	2.3	2.0	2.2		
Range	5.1-20.1	4.0-16.6	6.1-17.8	4.8-19.7		
No. of daily servings of F & V					.01	.01
Mean	5.1	6.2	5.0	5.6		
SD	2.7	2.8	2.3	2.6		
Range	0.-17.2	1.1-19.0	1.1-14.5	1.1-17.3		
BMI, kg/m^2					.008	.004
Mean	27.4	27.1	27.7	27.8		
SD	5.0	5.0	5.4	5.3		
Range	17.4-48.2	17.4-45.3	15.8-48.8	18.9-46.4		
Quality of life, FACT-G score					.18	.16
Mean	90.5	93.0	90.7	93.5		
SD	13.1	12.4	14.3	11.9		
Range	38-108	36-108	41-108	41-108		

Abbreviations: SD, standard deviation; F & V, fruits and vegetables; BMI, body mass index; FACT-G, Functional Assessment of Cancer Therapy–General.

benefited from upfront instructions that emphasized the importance of follow-up over that of adherence. Another limitation is the discrepancy in measurement windows of the Diet History Questionnaire and the 7-Day Physical Activity Recall (1 year *v* 1 week, respectively), although the foremost consideration in selecting these instruments was validity, reliability, and sensitivity to behavioral change, rather than consistency in measurement window.[38-41] Finally, more objective biomarker data on a larger subset would have been desirable, as would have been prospectively collected documentation of health care costs. Future studies are needed that will collect such information and that will test similar interventions in other samples of cancer survivors, especially among elders, minorities, and so on. Also, comparison of interventions delivered via various modalities (eg, computer based) is needed to ascertain optimally effective interventions and those that are most cost effective.

Newly diagnosed cancer survivors are a vulnerable population who are eager to pursue healthful lifestyle change. Home-based interventions may offer a superior channel in terms of acceptance and cost effectiveness for this geographically dispersed and relatively older population. FRESH START, a 10-month intervention of sequentially tailored print mailed materials, was effective at improving the diet and exercise behaviors of cancer survivors. Further studies are needed to assess the durability of such interventions, to prospectively measure associated cost to benefit, and to test print mailed material approaches against others that offer additional cost savings (eg, Web-based interventions).

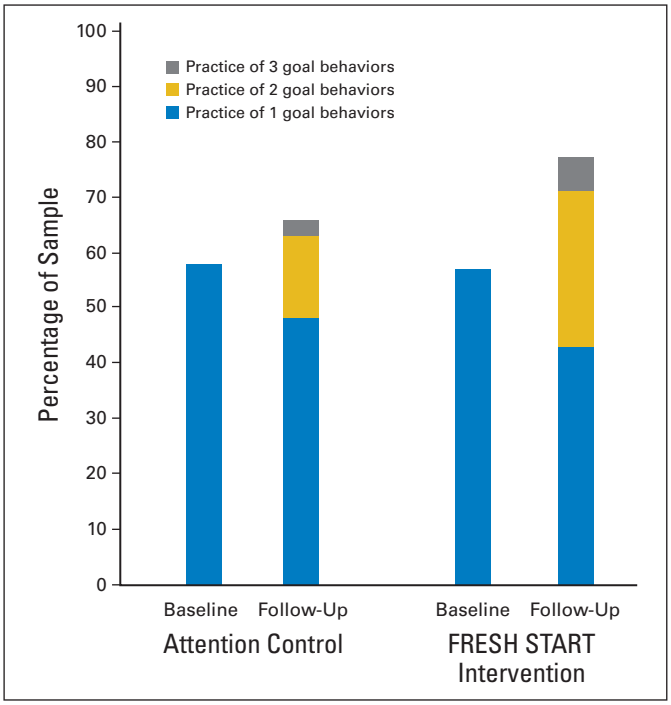

Fig 4. Change from baseline to 1-year follow-up in the practice of one or more goal lifestyle behaviors (150+ minutes of exercise per week; five or more servings of fruits and vegetables a day; and dietary fat restriction: total fat < 30% of kcal and saturated fat < 10% of kcal).

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

The author(s) indicated no potential conflicts of interest.

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Acknowledgment

The Acknowledgment is included in the full-text version of this article, available online at www.jco.org. It is not included in the PDF version (via Adobe® Reader®).