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Cancer Survivors' Uptake and Adherence in Diet and Exercise Intervention Trials: An Integrative Data Analysis

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Abstract

BACKGROUND—The health benefits of diet and exercise interventions for cancer survivors are well documented. However, little is known regarding demographic and medical predictors of survivors' willingness to participate in diet and exercise intervention trials, study enrollment, intervention adherence, and study completion. To assist in interpreting the generalizability of trial findings as well as to improve the design of future trials, we examined predictors of these process measures.

METHODS—An integrative data analysis was performed on data from three of the largest home-based diet and exercise intervention trials for cancer survivors ($N=23,841$). Demographic and medical factors (i.e., gender, race, age, time since diagnosis, and cancer type) were examined as predictors of willingness to participate, study enrollment, intervention adherence, and study completion in the pooled sample. A 99% confidence interval was used to determine statistical significance.

RESULTS—Across trials, 11.1% of contacted survivors were willing to participate and 5.7% were eligible and enrolled. Among enrollees, 53.4% demonstrated 75% adherence to the intervention and 91.1% completed the study. Race (Caucasian vs. others), age, time since diagnosis, and cancer type predicted survivors' willingness to participate (p -values<.01). All examined predictors were associated with the likelihood of study enrollment (p -values<.01). No significant predictors of intervention adherence or study completion were found among study enrollees (p -values .01).

CONCLUSIONS—Cancer survivors’ demographic and medical characteristics predicted their interest and participation in diet and exercise intervention trials. These findings have implications for the generalizability of results and can help guide procedures used in future trials to enhance patient representation.

Keywords

neoplasms; survivorship; intervention studies; adherence; diet; exercise

Cancer survivors are at increased risk for secondary cancers, medical comorbidities, accelerated functional decline, and poor health-related quality of life (HRQOL).^{1–8} A healthy diet and regular exercise have been found to reduce disease risk and physical decline in this population.^{2, 9, 10} However, similar to adults in the general population, many cancer survivors do not meet national dietary and exercise guidelines.^{1–3}

Lifestyle intervention trials have been conducted to improve the dietary and exercise behaviors of cancer survivors.¹¹ In randomized controlled trials (RCTs), combined diet and exercise interventions have resulted in improved diet quality, increased exercise, better physical functioning, decreased obesity, and increased HRQOL among recently diagnosed and long-term cancer survivors.^{12, 13}

Although the health benefits of diet and exercise interventions for cancer survivors are well documented, little is known regarding demographic and medical predictors of survivors’ willingness to participate in intervention trials, study enrollment, adherence to diet and exercise interventions, and study completion.^{14–16} CONSORT standards for reporting trial methods¹⁷ do not require that authors report characteristics of individuals who do not: 1) agree to an eligibility assessment; 2) enroll in the study; 3) adhere to the intervention; and 4) complete the study. Although some lifestyle intervention trials for cancer survivors have reported demographic and medical predictors of adherence,^{14, 16} data on upstream events, such as willingness to participate in trials, are often not collected. Subsequently, studies have not combined data across trials for these analyses—a necessary step because the representation of participants from low base rate groups (e.g., racial minorities) is often too small to justify analysis. Thus, the goal of the present study was to examine demographic (i.e., gender, race, age) and medical (i.e., time since diagnosis, cancer type) predictors of willingness to participate in lifestyle intervention trials, study enrollment, intervention adherence, and study completion using pooled data from three large diet plus exercise RCTs for breast, colorectal, and prostate cancer survivors. The outcome of this analysis has implications for the generalizability of trial findings. Furthermore, if certain demographic or medical subgroups are less likely to participate in different aspects of research, investigators may modify these aspects to enhance their appeal or effectiveness for these groups. In this analysis, we focused specifically on Project LEAD (Leading the Way in Exercise And Diet),¹⁸ FRESH START,¹⁹ and RENEW (Reach-out to Enhance Wellness)²⁰ because all three of these large trials relied heavily on population-based approaches to recruit participants through state cancer registries or multiple institutions, thus reducing potential bias involved with single institution studies. Moreover, all of the interventions were

delivered and evaluated using home-based strategies; thus the barriers of time and travel were similarly reduced in each of these trials.

Materials and Methods

Samples and Procedure

Data from three home-based diet and exercise RCTs for cancer survivors (i.e., Project LEAD,¹⁸ FRESH START,¹⁹ and RENEW²⁰) were used in the current analyses. Complete descriptions of trial methods have been published.^{18–20} Institutional review boards approved all trial procedures, which are summarized in Table 1. All trials relied on state cancer registries or medical records of multiple institutions to identify potential participants; other commonalities included a home-based approach for delivering and evaluating the intervention, and similar means of approaching potential participants, i.e., through a mailed letter of invitation, which included consent forms, a return envelope, and a screening questionnaire designed to exclude individuals who (1) routinely exercised (150 minutes per week of moderate to vigorous physical activity) or adhered to a healthy diet (5 fruit and vegetable servings per day); (2) had progressive cancer or additional primary tumors; or (3) had conditions precluding full participation in the intervention. Sample characteristics and statistics regarding recruitment, enrollment, completion, and adherence within and across trials appear in Table 2.

Study Variables

The four study outcomes were dichotomous variables. Survivors who completed and returned the eligibility screener and consent form via postal mail were considered *willing to participate*. Survivors who were willing to participate and eligible were considered *enrolled*. Participants who demonstrated at least 75% adherence to the intervention (i.e., completed 75% of telephone counseling sessions for the RENEW or Project LEAD studies or returned 75% of their mailed update cards for FRESH START) were considered *adherent*. Adherence was computed for intervention groups only, including the delayed intervention comparison group in RENEW. Participants who remained enrolled in the study after the intervention and who completed follow-ups were considered to have *completed the study*.

Baseline predictors of study outcomes were gender, race (white versus racial minority), age, years since diagnosis, and cancer type.

Statistical Analyses

Integrative data analysis of the three trials was used to examine predictors of willingness to participate, study enrollment, intervention adherence, and study completion. Integrative data analysis involves pooling original data sets for simultaneous analysis of multiple studies.²¹ Research suggests that analysis of primary data is superior to an analysis of study-level summary data (i.e., meta-analysis) when studying relationships between patient-level characteristics and trial outcomes.^{22, 23} Advantages of analyzing primary data include increased statistical power and sample heterogeneity.^{22–24} A fixed-effects model-based procedure was employed in this study rather than a random-effects model because of the small number of studies.²¹ Study membership was included as a covariate to control for

differences in eligibility criteria across studies that affected the probability of an individual being sampled.

After pooling the data sets, univariate logistic regression analyses were run in SPSS to examine relationships between each predictor and outcome, controlling for study membership (i.e., Project LEAD, FRESH START, or RENEW). Relations of time since diagnosis and cancer type to each outcome were examined twice: once with the RENEW trial sample only and once with the Project LEAD and FRESH START study samples combined. These analyses were run separately because these variables differed between RENEW and other studies (see Table 1). For RENEW analyses, two orthogonal contrast codes for cancer type were included in the same analysis. Across trials, only data from study enrollees were included when examining intervention adherence and study completion. To reduce Type I error, a 99% confidence interval was used to determine statistical significance.

Results

Sample characteristics are shown in Table 2. Data from 23,841 survivors were included in analyses.

Predictors of willingness to participate

Predictors of survivors' willingness to participate in the studies appear in Table 3. White survivors were more likely to show interest than racial minority survivors. In addition, for every 1-year increase in age, there was a 5% decrease in survivors' likelihood of showing interest in the study. Women were more likely to show interest than men, though this result fell short of significance. Furthermore, time since diagnosis was not significantly related to survivors' willingness to participate in Project LEAD and FRESH START; however, in the RENEW trial, for every 1-year increase in time since diagnosis, there was a 5% decrease in survivors' likelihood of showing interest in the study. Additionally, cancer type was not a significant predictor of survivors' willingness to participate in Project LEAD and FRESH START. However, in the RENEW trial, breast and prostate cancer survivors were more willing to participate than colorectal cancer survivors, and breast cancer survivors were more willing to participate than prostate cancer survivors.

Predictors of study enrollment

Predictors of enrollment status also were examined (see Table 3). Among all individuals approached for study participation, women and white survivors were more likely to be eligible and subsequently enroll than men or racial minorities. Furthermore, for every 1-year increase in age, there was a 5% decrease in survivors' likelihood of enrolling. Similar to interest in the study, enrollment was not associated with time since diagnosis in Project LEAD or FRESH START; however, in the RENEW trial, for every 1-year increase in time since diagnosis, survivors' likelihood of being eligible and subsequently enrolling decreased by 7%. Additionally, in the RENEW trial, breast and prostate cancer survivors were more likely to enroll than colorectal cancer survivors and, in all trials, breast cancer survivors were more likely to enroll than prostate cancer survivors.

Predictors of intervention adherence

Predictors of intervention adherence were examined among study enrollees only (see Table 3). None of the demographic and medical variables predicted survivors' likelihood of adhering to the intervention.

Predictors of study completion

Predictors of study completion also were examined among study enrollees only (see Table 3). There were no significant predictors of survivors' likelihood of completing the study.

Discussion

When approached for participation in diet and exercise intervention trials, cancer survivors' background characteristics predicted their likelihood of expressing interest in participation and enrolling in the study. Given that less than 2% of clinical studies report demographic characteristics of individuals who decline study participation,²⁵ this is one of the first reports regarding protocol implementation. In our analysis of over 23,000 cancer survivors, race, gender, age, time since diagnosis, and cancer type predicted survivors' likelihood of expressing interest in trial participation or enrolling in the trial. Many investigators have reported low enrollment of racial minorities in clinical trials by comparing the racial composition of clinical trial cohorts with population-based norms,^{26, 27} rather than performing statistical comparisons. Given historical discrimination and unethical treatment of minority groups in research trials,^{28–30} distrust of research and medicine might explain minority survivors' lack of interest in participation. Furthermore, culture-specific barriers and those related to socioeconomic status, such as low literacy, inflexible work schedules, or childcare demands, can reduce minority participation.³¹

Regarding participant gender, women were more likely to enroll in the trials. Women also tended to show greater interest in trial participation, but this finding fell short of statistical significance. Women's higher enrollment in diet and exercise intervention trials relative to men is unsurprising given their greater use of healthcare services in general.³² Similarly, breast cancer survivors were more likely to enroll in Project LEAD and FRESH START than prostate patients, but there was no statistically significant difference in interest in participation. Because trial enrollment was confounded with eligibility status in the examined studies, another explanation for the gender/cancer type difference is the higher prevalence of certain health conditions, such as cardiovascular disease, among men,³³ which may preclude participation in unsupervised exercise. Moreover, men tend to be more physically active,³⁴ as well as less likely to report deficits in physical functioning³⁵ and thus were screened-out of two of the three trials analyzed.

Regarding cancer type, in the RENEW trial, breast and prostate cancer survivors were more likely to show interest and subsequently enroll than colorectal cancer survivors. Differences in physical symptoms by cancer type that affect lifestyle practices provide one potential explanation for these findings.

Age and time since diagnosis also were found to predict survivors' willingness to participate in the studies and subsequent enrollment. Specifically, older survivors were less likely to

show interest in the studies and enroll. Low enrollment of older adults is commonly reported; however, it is often attributed to physicians' age bias^{27, 36} rather than higher rates of refusal by older adults, as were found in this study. Potential explanations for these age differences include older adults' perceived barriers to exercise, such as fear of falling and the belief that their health conditions preclude exercise.^{37, 38} Additionally, one study of older adults suggested that they may prefer learning about studies via face-to-face contact rather than methods used in the current trials (i.e., telephone and print materials).³⁹ Age was positively correlated with time since diagnosis in the RENEW study, which may help explain the lower likelihood of showing interest in the study and enrolling among survivors farther out from diagnosis. Alternatively, survivors may perceive less benefit from lifestyle changes as their illness becomes less salient over time; however, all survivors approached for the RENEW trial were long-term survivors (> 5 years post-diagnosis). In contrast, time since diagnosis did not predict interest in study participation and enrollment in trials of more recently diagnosed survivors (i.e., FRESH START and Project LEAD). However, given that the period from diagnosis to contact was fairly compressed, it is likely that insufficient variation in time since diagnosis in these two trials precluded the ability to observe significant differences.

None of the examined demographic or medical factors predicted intervention adherence or study completion, suggesting that, once survivors are enrolled, engagement in diet and exercise interventions does not differ by these factors. Of note, in all of the analyzed studies, survivors had to return a screener by mail in order to enroll in the trial. As a result, recruitment rates were quite low (see Table 2), and study enrollees may have had greater motivation for health behavior change than the typical cancer survivor, leading to high adherence and retention rates across demographic and medical subgroups.

Although this integrative analysis has several strengths, e.g., a large and diverse sample, a population-based approach, and similar methods across the combined studies, limitations should be noted. Our analyses examined only five predictors; therefore, other survivor characteristics that might impact the likelihood of participation in all phases of lifestyle intervention trials warrant examination. In addition, our analyses focused on the only three home-based diet and exercise intervention trials for cancer survivors, all of which used recruitment mailings; thus, the findings may not generalize to survivors approached for trials using more active recruitment strategies or testing other types of lifestyle interventions. Furthermore, all three trials were conducted by a single research group, and participants were primarily from the Southern U.S. Findings warrant replication across research groups and geographical areas. Finally, reasons for survivors' non-participation in the trials were not collected and would enhance our understanding of barriers to trial enrollment.

Results point to the need to increase representation of racial minorities and older adults in future diet and exercise intervention trials with cancer survivors. Regarding minority participation, researchers may partner with "cultural insiders" from community-based organizations, approaches that have increased minority enrollment in other types of health research.^{29, 30} Within these organizations, passive recruitment strategies (e.g., disseminating information and allowing prospective participants to contact study staff) result in higher recruitment rates than proactive strategies (e.g., approaching patients) and also are far less

expensive.^{30, 40} In addition, clinicians and researchers should be sensitive to cultural differences when referring patients to trials.

Regarding older adults' trial participation, research suggests that referral and recommendation by clinicians might yield higher recruitment rates.³⁹ Additionally, older adults prefer face-to-face contact rather than recruitment via telephone or flyers.^{39, 41} During recruitment, clinicians and researchers may probe for age-specific barriers to trial participation. Determining the most effective methods to engage older cancer survivors in lifestyle intervention trials is critical, as they comprise the largest group of cancer survivors and are at greater risk of poor health outcomes than the general older adult population.⁴⁻⁸

In addition to researching strategies to reduce racial and age differences in trial participation, publication of sample characteristics at all phases of lifestyle and other intervention trials is needed to better understand the degree to which findings are generalizable and to inform the design of future trials. Determining who participates in clinical trials and who does not is the first step in designing interventions with high reach and the potential for reducing health disparities.

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Table 1

Summary of diet and exercise intervention trials included in the pooled analysis

Parameter	Project LEAD	FRESH START	RENEW
No. of patients	182	543	641
Intervention arm	89	271	319
Control arm	93	272	322
Major inclusion criteria	Early-stage breast or prostate cancer survivors within 18 months of diagnosis; aged 65 years; non-adherent to physical activity and/or dietary recommendations	Early-stage breast or prostate cancer survivors within 9 months of diagnosis; aged 18 years; non-adherent to physical activity and/or dietary recommendations	Breast, prostate, or colorectal cancer survivors at least 5 years post-diagnosis; aged 65 years; BMI between 25–40; non-adherent to physical activity recommendations
Intervention arm	Personalized workbook; 20- to 30- minute telephone counseling sessions about dietary and exercise goals every 2 weeks for 6 months	Receipt of mailed print materials that included tailored feedback and encouragement regarding dietary and exercise goals every 6 weeks for 10 months	Personalized workbook; tailored quarterly newsletters; 8 automated telephone prompts and fifteen 15- to 30-minute telephone counseling sessions to monitor dietary and exercise goals over the 12-month intervention period
Control arm	Non-personalized workbook; 20- to 30-minute telephone counseling sessions every 2 weeks for 6 months about health promotion topics unrelated to diet and exercise	Receipt of non-tailored mailed print materials on health promotion topics every 6 weeks for 10 months	Delayed intervention following completion of 1-year follow-up
Intervention goals	Improved functional status; increased quality of life; better diet quality and physical activity level	30 minutes of exercise per day at least 5 days a week; 5 servings of fruits and vegetables per day; < 30% of calories from fat	15 minutes of strength exercise every other day; 30 minutes of endurance exercise per day; 7 servings of fruit and vegetables per day for women and 9 servings of fruit and vegetables per day for men; < 10% total calories from saturated fat; approximately 10% weight loss
Timing of follow-up interviews	6 and 12 months post-baseline	1 and 2 years post-baseline	1 and 2 years post-baseline

Table 2

Characteristics of recruitment pools

	Project LEAD	FRESH START	RENEW	Pooled Sample
	No. of Patients (%)	No. of Patients (%)	No. of Patients (%)	No. of Patients (%)
Number of cases approached	2,023(100)	1803(100)	20,015(100)	23,841(100)
White	1,574(77.8)	1,269(70.4)	16,636(83.1)	19,479(81.7)
Female	985(48.7)	888(49.3)	9,043(45.2)	10,916(45.8)
Prostate	1,038(51.3)	915(50.8)	8,949(44.7)	10,902(45.7)
Breast	985(48.7)	888(49.3)	6,976(34.9)	8,849(37.1)
Colorectal	N/A	N/A	4,090(20.4)	4,090(17.2)
Mean age	73.4	60.7	76.0	74.6
SD	5.7	11.4	5.9	7.6
Mean years since diagnosis	0.9	0.3	9.4	8.0
SD	0.5	0.2	2.5	4.0
Willing to participate	688(34.0)	762(42.3)	1,208(6.0)	2,658(11.1)
Enrolled in the study	182(9.0)	543(30.1)	641(3.2)	1,366(5.7)
Adhered to the intervention ^a	71/82(86.6)	188/253(74.3)	262/641(40.9)	521/975(53.4)
Missing	7/89(7.9)	18/271(6.6)	0/641(0.0)	25/1,001(0.02)
Completed the study ^b	168/182(92.3)	519/543(95.6)	558/641(87.1)	1,245/1,366(91.1)

^a Participants who completed 75% of the intervention were considered to be adherent. For the intervention adherence outcome, data were only included from participants receiving the intervention condition, including the delayed intervention in RENEW.

^b Participants who remained enrolled in the study at the end of the intervention period and completed follow-up assessments were considered to have completed the study.

Table 3

Logistic regression analyses predicting willingness to participate, study enrollment, intervention adherence, and study completion

Variable	Willing to Participate			Enrolled in Study			Adhered to Intervention			Completed Study		
	OR	99% CI	p	OR	99% CI	p	OR	99% CI	p	OR	99% CI	p
Female ^a	1.05	0.99 to 1.11	.05	1.22	1.13 to 1.31	<.01	1.19	1.00 to 1.42	.01	1.05	0.82 to 1.35	.58
Age	0.95	0.94 to 0.96	<.01	0.95	0.94 to 0.96	<.01	1.03	1.00 to 1.05	.02	0.99	0.95 to 1.02	.33
White ^b	1.36	1.26 to 1.48	<.01	1.41	1.27 to 1.58	<.01	1.17	0.90 to 1.53	.13	1.10	0.77 to 1.56	.51
Time Since Diagnosis ^c	0.95	0.75 to 1.21	.58	0.86	0.61 to 1.23	.28	0.73	0.19 to 2.82	.55	1.34	0.30 to 6.07	.62
Time Since Diagnosis ^d	0.95	0.92 to 0.98	<.01	0.93	0.89 to 0.97	<.01	1.03	0.95 to 1.11	.34	1.05	0.93 to 1.19	.26
Cancer Type ^e	0.97	0.89 to 1.06	.34	1.22	1.09 to 1.36	<.01	1.12	0.80 to 1.58	.39	1.15	0.75 to 1.77	.40
Cancer Type ^f	1.08	1.01 to 1.15	<.01	1.17	1.06 to 1.29	<.01	0.92	0.75 to 1.11	.24	0.85	0.61 to 1.19	.21
Cancer Type ^g	1.10	1.01 to 1.20	<.01	1.20	1.07 to 1.34	<.01	1.23	0.98 to 1.54	.02	1.01	0.74 to 1.40	.92

Note. Two bivariate covariates for study membership (i.e., Project LEAD vs. RENEW and FRESH START vs. RENEW) were included in the analyses regarding gender, age, and race. For analyses regarding cancer type for RENEW, two orthogonal contrast codes were included in the same analysis. For the intervention adherence and study completion outcomes, data were only included from participants who enrolled in the studies. For the intervention adherence outcome, data were only included from participants receiving the intervention condition, including the delayed intervention in RENEW. Participants who adhered to the intervention completed 75% of intervention requirements. Participants who completed the study were enrolled in the study at the end of the intervention period and completed follow-up assessments. OR—odds ratio; CI—confidence interval. A 99% confidence interval was used to determine statistical significance.

^aCoded (male -1, female +1).

^bCoded (non-white -1, white +1).

^cData from Project LEAD and FRESH START only. Study membership was included as a covariate.

^dData from RENEW only.

^eData from Project LEAD and FRESH START only. Coded (Prostate cancer -1, Breast cancer +1).

^fData from RENEW only. Contrast code reported (Colorectal cancer -2, Prostate and Breast cancer +1).

^gData from RENEW only. Contrast code reported (Colorectal cancer 0, Prostate -1, Breast +1).