

Short Communication

Differences in Baseline Characteristics and Outcomes at 1- and 2-Year Follow-up of Cancer Survivors Accrued via Self-Referral versus Cancer Registry in the FRESH START Diet and Exercise Trial

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Abstract

Participant accrual to research studies is a challenge; oftentimes, advertisements are used to supplement cases ascertained through clinic caseloads and cancer registries. It is unknown, however, if cases ascertained through these two sources differ. In this study, we compared self-referred ($n = 209$) and registry-ascertained ($n = 334$) participants enrolled in FRESH START, a randomized controlled trial promoting a healthy diet and increased exercise among breast and prostate cancer survivors. The two groups were compared on baseline characteristics, adherence, attrition, and outcomes by study arm. Compared with participants enrolled from registries, self-referrals were significantly younger (54.1 ± 10.4 versus 58.7 ± 10.7 years), more likely to have later-stage disease and to have received chemotherapy (40% versus 19%), and more likely to report "fighting spirit" coping styles (50% versus 30%), lower quality-of-life (88.2 ± 15.1 versus 92.0 ± 12.9), fewer comorbid conditions ($1.87 \pm$

1.60 versus 2.24 ± 1.78), and lower consumption of five or more daily servings of fruits and vegetables (35% versus 45%; P values <0.05). Although no differences in behavior change were observed between self-referred and registry-ascertained cases assigned to the tailored intervention arm, this was not the case within the attention control arm. Among those who received the attention control intervention of standardized materials in the public domain, self-referred versus registry-ascertained participants showed significantly greater increases in exercise at 1-year follow-up and significantly greater increases in fruit and vegetable consumption at both 1- and 2-year follow-up (P values <0.05). Several differences exist between self-referred and registry-ascertained participants, including motivation to respond to standardized educational materials, which appears significantly greater in self-referred populations. (Cancer Epidemiol Biomarkers Prev 2008;17(5):1288–94)

Introduction

Recruitment to research trials is challenging (1, 2). Fewer than 5% of cancer patients participate in clinical trials (3). Institutional constraints and privacy issues contribute to the costly and labor-intensive process of subject recruitment (2). Furthermore, cancer registry policies regarding patient education and physician involvement deter researchers' ability to notify patients about research opportunities (1, 4). These barriers affect recruitment strategies, design, and cost (2).

Researchers may diversify recruitment strategies to expand the subject pool for clinical trials (5). Although recruitment through advertisement has been commonly used for clinical trials targeting diseases, such as diabetes and hypertension, which affect 20% to 30% of American adults (6, 7), to date, such means have not been frequently pursued in oncology trials primarily due to low cancer prevalence (3–4%) (8). However, the Internet now makes it possible to reach cancer survivors (newly diagnosed and long-term) for clinical trials. The differences between survivors responding to these solicitations, compared with those recruited from cancer registries, however, are not known. No studies have reported differences in characteristics or outcomes in behavioral interventions among self-referred versus registry-ascertained cancer study subjects, although such differences have been documented in other health conditions (5, 9, 10). For example, differences in motivation have been observed among people who self-referred to a weight management program versus those

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ascertained from clinics (11). Furthermore, self-referred problem drinkers were more likely to reduce alcohol consumption with bibliotherapy (self-help) than those identified through at-risk screening (12). Advertisement may yield cost savings by reducing recruitment duration (5); however, such strategies might yield biased samples whose characteristics and study performance are not generalizable to populations of interest (9, 10).

We compared cancer survivors accrued from two sources, self-referral and cancer registry, enrolled in a two-arm randomized behavioral lifestyle intervention trial entitled FRESH START, testing the efficacy and durability of sequentially tailored versus standardized print materials in improving diet and exercise behaviors of breast and prostate cancer survivors (13, 14). We hypothesized that, compared with participants ascertained from cancer registries, those who self-referred might differ with regard to cancer coping style (that is,

manifest higher proportions of “fighting spirits” versus “fatalists”) and also have higher levels of interest, readiness, and self-efficacy to pursue lifestyle change at baseline. In addition, we speculated that self-referred participants would show greater levels of adherence once enrolled in the intervention.

Materials and Methods

Subjects. The methods and main outcomes for this trial have been reported elsewhere (13, 14). Briefly, potential study participants who were within 9 months of diagnosis with early-stage female breast or prostate cancer (*in situ*, localized, or regional) were identified using two accrual sources: (a) cases rapidly ascertained through cancer registries with subsequent approval from their oncology care physicians and (b) self-referrals responding to study flyers, magazine articles, Internet

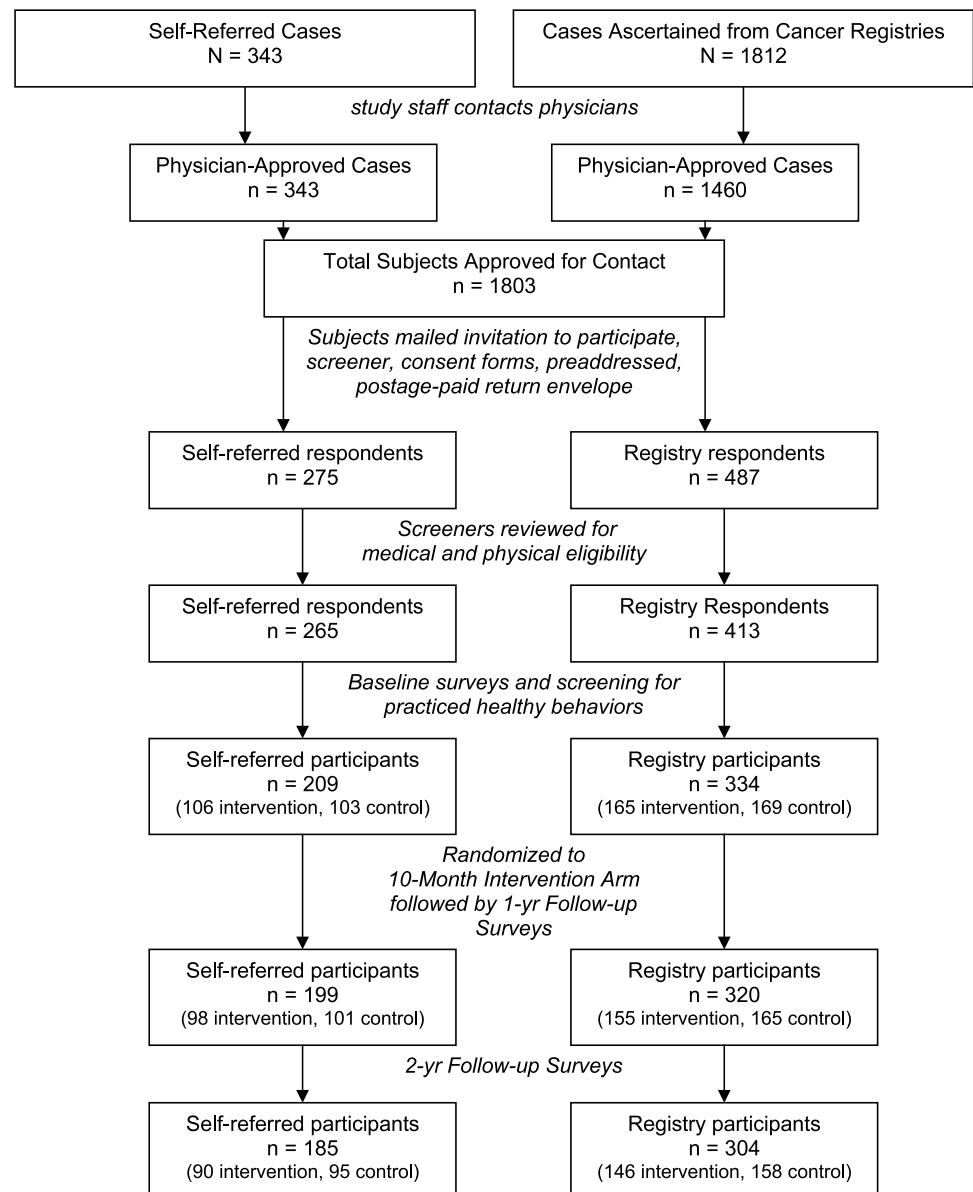


Figure 1. Cancer survivor participation in FRESH START by accrual source.

sites, targeted list-serves (e.g., NexCura©, Inc.), support groups, national meetings, and word of mouth. Institutional review boards at all participating institutions approved the study, which complied with the Health Insurance Portability and Accountability Act guidelines.

From July 2002 to August 2004, a total of 762 survivors responded with interest (42% response rate), provided written consent, and were screened to exclude individuals with medical or physical conditions precluding unsupervised exercise or a high fruit and vegetable diet (13, 14). Individuals also were excluded if they practiced at least two of the following behaviors: (a) consumption of five or more daily servings of fruits and vegetables, (b) adherence to a diet <30% of energy from fat, and/or (c) participation in >150 min of exercise weekly. After screening, 543 participants were enrolled.

Measures. Participants completed two computer-assisted telephone interviews of 45 to 55 min each at baseline and at 1- and 2-year follow-up. Minutes per week of moderate, hard, and very hard exercise of at least five metabolic equivalents (MET-kcal/kg/h) were captured using the 7-day Physical Activity Recall (15). Servings per day of fruits and vegetables and percent energy from fat (total and saturated) were derived using the Diet History Questionnaire (16). Additionally, at baseline, the following additional measures were collected: sociodemographic characteristics (treatment, education, and income); cancer coping style (modified Mini-Mental Adjustment to Cancer subscale); barriers to exercise and eating a low-fat, high fruit and vegetable diet; quality-of-life (Functional Assessment of Cancer Therapy); risk for depression (Center for Epidemiologic Studies of Depression); social support (Duke Social Support Index); comorbidity; perceived health; self-efficacy and stage of readiness for exercising \geq 150 min/wk, eating five or more servings of fruits and vegetables per day and consuming a low-fat diet; smoking; and weight status (12).

Interventions. The interventions are described in detail elsewhere (13, 17, 18). Briefly, participants in both groups received a personalized workbook and additional information to improve diet and exercise behaviors. The intervention arm received sequentially tailored mailed materials over a 10-month period sent as a series of seven newsletters every 6 weeks for each behavior being addressed. The attention control arm received standardized print materials in the public domain on diet and exercise (13). Both groups also received a brief survey between each mailing.

Statistical Analyses. Self-referred participants were compared with registry participants on variables measured at baseline, 1 year, and 2 years. The 1- and 2-year outcomes included lifestyle practices, adherence, and attrition rates. Differences between self-referred and registry participants on baseline measures, adherence, and attrition rates were tested using *t* tests or the χ^2 tests, as appropriate. Comparison of the tailored intervention and attention control study arms by self-referral versus registry patients on 1- and 2-year outcome data were tested in separate regression models, one model for each outcome variable and each time point. Logistic regression was used to test for accrual group differences in attainment of each of the three goal behaviors (yes/no);

ordinal logistic regression was used to test for a group difference in number of goal behaviors achieved; and the general linear model was used to test for group differences on each of the continuous outcome variables. The following baseline variables were controlled for in all models: study arm, the outcome under study, percent energy from dietary fat, number of servings of fruits and vegetables, exercise minutes, the number of behaviors already practicing at baseline (0 or 1), gender, race, and social support. All analyses were done using SAS (version 9.1, 2003; SAS Institute).

Results

A total of 543 individuals were accrued, including 209 self-referred and 334 registry ascertained. Self-referred subjects were more likely than registry subjects to respond with interest (80% versus 33%, respectively; $P = 0.001$; Fig. 1). When compared with registry participants, self-referred participants were significantly younger, more likely to have received chemotherapy (owing to more aggressive disease among women with breast cancer), more likely to identify with the "fighting spirit" cancer coping style, more likely to report greater self-efficacy for fat restriction, a greater stage of readiness to exercise and restrict fat, lower quality-of-life, fewer comorbid conditions, and lesser frequency of eating five or more daily fruits and vegetables (Table 1).

There were no significant associations between accrual source and study arm, adherence, adverse health events, or attrition (dropouts) at either follow-up time point. Means (SD) for adherence for self-referred versus registry participants were 5.6 (2.3) and 5.5 (2.3), respectively. Approximately 52% of self-referred participants compared with 55% of registry participants reported at least one health event. Ninety-five percent of participants (regardless of accrual source) completed 1 year of the study, whereas by 2 years the rate declined to 89% and 91% for self-referred and registry participants, respectively.

Table 2 presents change scores for frequencies and means (SE) from baseline to 1-year follow-up by study arm and accrual source for the 519 subjects who completed the 1-year assessment. Comparing self-referred and registry participants in the intervention arm, there were no significant differences in weekly exercise minutes, percent energy from fat, fruit and vegetable daily servings, or number of behaviors practiced at goal levels (data not shown) at 1-year follow-up. Within the control arm, self-referred participants showed significantly greater increases in exercise and fruit and vegetable consumption after 1-year follow-up (P values <0.05) and also experienced significantly more durable effects with regard to fruit and vegetable consumption after 2-year follow-up when compared with registry participants (+1.25 versus +0.38 daily servings, respectively; $P = 0.007$). Self-referred participants in the control arm also significantly increased the numbers of behaviors practiced at goal levels at 1-year follow-up compared with registry participants (0 goal achievement = -15.9% versus -3.6%; 1 goal achievement = -10.8% versus -9.1%; 2 goal achievement = 20.8% versus 12.1%; and 3 goal achievement = 5.9% versus 0.6%, respectively; $P = 0.01$).

Table 1. Characteristics of self-referred versus registry-solicited participants in the FRESH START trial

Characteristics	Self-referred (n = 209)	Registry (n = 334)	P
Age			
Mean (SD)	54.1 (10.4)	58.7 (10.7)	<0.0001
Range	30-75	22-85	
Gender, % (n)			
Male	39 (81)	47 (156)	0.07
Race, % (n)			
White	83 (173)	83 (279)	0.81*
Black	12 (26)	14 (46)	
Other	5 (10)	3 (9)	
Type/clinical cancer stage, % (n)			
Breast			
0	8 (10)	17 (31)	<0.0001
I	44 (56)	57 (101)	0.06 [†]
II	41 (53)	21 (37)	
IIIA	7 (9)	5 (9)	
Prostate			
I	49 (39)	35 (55)	
II	44 (36)	57 (88)	
Unknown	7 (6)	8 (13)	
Marital status, % (n)			
Single	6 (12)	5 (16)	0.74 [‡]
Married or stable union	78 (164)	77 (258)	
Divorced or widowed	16 (33)	18 (60)	
Education, % (n)			
High school or less	9 (19)	13 (45)	0.09
Some college or associate	29 (61)	31 (103)	
College graduate/postgraduate	62 (129)	56 (186)	
Income, % (n)			
<\$20,000	5 (10)	9 (28)	0.12
\$20,000 to <\$40,000	15 (32)	16 (53)	
\$40,000-60,000	21 (43)	21 (66)	
>\$60,000	59 (122)	54 (174)	
Cancer coping style, % (n)			
Fighting spirit	50 (105)	30 (99)	0.001
Fatalistic	43 (89)	62 (208)	
Other (cognitive avoider, anxious preoccupier, helpless-hopeless)	7 (15)	8 (27)	
Treatment, % (n)			
Surgery	84 (175)	85 (285)	0.62
Radiation therapy (including brachytherapy)	46 (97)	43 (143)	0.41
Chemotherapy	40 (83)	19 (62)	<0.0001
Hormonal therapy	39 (82)	38 (128)	0.83
Other	5 (11)	4 (14)	0.56
No. comorbid factors, mean (SD)	1.87 (1.60)	2.24 (1.78)	0.01
Risk for depression (Center for Epidemiologic Studies of Depression), mean (SD)	2.84 (4.05)	2.24 (3.46)	0.07
Social support (Duke Social Support Index), mean (SD)	27.7 (2.6)	28.0 (3.7)	0.22
Perceived health, % (n)			
Good/excellent	81 (168)	86 (287)	0.14
Fair/poor	19 (39)	14 (47)	
Quality-of-life (Functional Assessment of Cancer Therapy), mean (SD)	88.2 (15.1)	92.0 (12.9)	0.002
Self-efficacy for exercise, mean (SD)	3.95 (1.08)	3.80 (1.12)	0.12
Stage of readiness for exercise, % (n)			
Precontemplator	6 (12)	11 (37)	0.05 [§]
Contemplator	10 (21)	10 (34)	
Prepared	84 (176)	79 (263)	
Self-efficacy for fat restriction, mean (SD)	4.05 (0.93)	3.84 (0.99)	0.02
Stage of readiness for fat restriction, % (n)			
Precontemplator	7 (14)	14 (46)	0.02
Contemplator	3 (7)	2 (8)	
Prepared	90 (188)	84 (280)	
Self-efficacy for eating ≥5 fruits and vegetables, mean (SD)	4.01 (0.92)	3.85 (1.06)	0.05
Stage of readiness for eating ≥5 fruits and vegetables, % (n)			
Precontemplator	6 (12)	10 (32)	0.09
Contemplator	1 (2)	1 (5)	
Prepared	93 (195)	89 (297)	
Current practice of goal lifestyle behaviors, % (n)			
≥5 servings of fruits and vegetables per day	35 (74)	44 (149)	0.03

(Continued on the following page)

Table 1. Characteristics of self-referred versus registry-solicited participants in the FRESH START trial (Cont'd)

Characteristics	Self-referred (n = 209)	Registry (n = 334)	P
<30% calories from fat (<10% from saturated fat)	8 (16)	5 (16)	0.17
≥150 min of exercise per week	12 (25)	10 (33)	0.45
Nonsmoker	96 (200)	93 (309)	0.15
Body mass index <25.0	37 (77)	36 (121)	0.88

*White versus others.

†Stage I versus II.

‡Married versus others.

§P < 0.05.

Discussion

To our knowledge, this is the first trial comparing the characteristics and performance of self-referred versus registry-ascertained cancer survivors in a lifestyle intervention trial. Our findings have implications for the utility of diverse recruitment strategies in expanding the available population for cancer research studies.

Self-referral sources may be particularly useful to bolster both response rate and accrual for home-based behavioral intervention studies and may offer a cost-effective approach to recruitment. By adding self-referral sources to the standard registry-ascertained cases, we reduced the time required for sample accrual and also achieved some measure of cost savings. However, self-referral sources also introduced bias, because these participants were younger and reported lower quality-of-life and fewer comorbid conditions. Despite these differences, we were surprised to find no observed differences between accrual groups with regard to income, education, and minority status. This was a similar finding to Henrikson et al., who reported that participants who self-referred to a genetics registry were comparable in terms of demographic characteristics (except education) to an actively recruited population-based sample, whereas psychosocial differences existed between the groups (10). FRESH START, however, like many diet and exercise interventions that target cancer survivors, accrued a mostly White (83%) and upper socioeconomic sample (19). Our ability to observe a differential in socioeconomic diversity may have been limited.

Our findings also are similar to those of Scholle et al., who enrolled bipolar disorder registry members via diverse recruitment sources that included health professionals, the Internet, support groups, and general marketing (5). Their data suggest that the cost per participant accrued was substantially lower for registrants accrued via support groups and Internet sources than those ascertained via health professionals and general marketing. Unlike our study, these investigators found that both strategies yielded a more highly educated sample; however, like our study, participants accrued via the Internet were significantly younger than registrants from all other groups. Further, in a study of irritable bowel syndrome subjects, Lee et al. found that the type of recruitment method used (advertisement versus clinic referral) affected patient characteristics, including demographics, physical and psychological symptoms, and quality-of-life (9).

Perhaps the most important finding of this secondary analysis was that whereas self-referred and registry

participants performed similarly in the tailored intervention arm, self-referred participants performed significantly better than registry participants in the attention control arm (receiving standardized materials) in terms of exercise and fruit and vegetable consumption. One could intuit that individuals who actively seek enrollment into a behavioral intervention trial might be more motivated than those who are solicited from a cancer registry. Binks and O'Neil also found greater levels of motivation for weight loss among individuals who self-referred compared with individuals who were physician-referred to a weight loss program (11). However, these findings differ from FRESH START in that they found no differences in weight loss by accrual source. Indeed, our study may be similar to a meta-analysis by Apodaca and Miller, who found that self-help bibliotherapy was less effective among drinkers who were identified through at risk screening than those who were self-referred (12). Whereas self-referred populations may benefit from standardized health promotion materials that are low in cost, populations that do not actively seek health promotion opportunities (that is, cases solicited from

Table 2. Comparison of intervention and attention control study arms by self-referred versus cancer registry solicited participants from baseline to 1-y follow-up and change in behavioral outcomes

	Change from baseline to year 1		
	Self-referral	Registry	P*
Achieved exercise goal: ≥150 min/wk, % (n)			
Intervention [†]	+23 (22)	+18 (28)	0.11
Attention control [‡]	+25 (25)	+7 (12)	0.002
Exercise (min/wk), mean (SE)			
Intervention	+64 (16)	57 (11)	0.26
Attention control	+60 (15)	+26 (9)	0.004
Achieved fat goal: <30% of energy from fat, % (n)			
Intervention	+17 (17)	+19 (29)	0.76
Attention control	+2 (2)	+4 (7)	0.71
% Energy fat, mean (SE)			
Intervention	-4 (0.6)	-5 (0.5)	0.59
Attention control	-2 (0.5)	-2 (0.4)	0.30
Achieved fruits and vegetables goal: ≥5 servings per day, % (n)			
Intervention	+27 (26)	+17 (26)	0.23
Attention control	+22 (22)	+6 (9)	0.04
Daily servings of fruits and vegetables, mean (SE)			
Intervention	+1.5 (0.3)	+0.8 (0.2)	0.18
Attention control	+1.1 (0.2)	+0.4 (0.2)	0.02

*P values reflect the difference between recruitment sources within each treatment arm.

†Intervention arm, self-referred (n = 98) and registry (n = 155).

‡Attention control arm, self-referred (n = 101) and registry (n = 165).

registries and clinics) may require tailored interventions to achieve behavior change.

In conclusion, researchers must continue to devise efficient, low-cost, high-yield recruitment strategies to achieve targeted accrual. At the same time, researchers must work toward broader dissemination of lifestyle interventions to the growing population of cancer survivors. Efforts must be made to recruit representative populations and craft interventions that enable behavior modification. Although it was less costly and more efficient to enroll participants who self-referred to FRESH START, researchers should consider potential differences in characteristics and outcomes at the time of recruitment planning and study implementation.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

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