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Proactive versus reactive recruitment to a physical activity intervention for breast cancer survivors: Does it matter?

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Background There is a gap in the current breast cancer survivorship literature identifying potential sample biases that may result from recruiting participants via different methods.

Purpose To document whether participant recruitment method influences baseline demographic or psychosocial variables and trial participation among breast cancer survivors recruited for a physical activity intervention trial.

Methods Participants were recruited for the trial via either a reactive method (letters mailed through their oncologist's office inviting them to contact the research staff) or a proactive method (referred in person by their oncologist at a clinic appointment). The groups of participants recruited via the two methods were compared based on baseline sociodemographic characteristics, weight, time since diagnosis, stage of disease, treatment, motivational readiness for physical activity, level of physical activity, self-reported physical and mental health, willingness to receive the intervention, and study retention.

Results Participants recruited proactively were closer to the point of diagnosis (mean = 2.5 years, standard deviation (SD) = 1.9 years) than participants recruited reactively via letter mailings (mean = 3.4 years, SD = 2.3 years; $p < .05$). The two groups were similar with respect to all other baseline characteristics and retention.

Limitations Recruitment via the two methods was not concurrent. Also, proactive recruitment occurred at a single hospital site. Mailings were made by the oncologists; we are unable to estimate how many letters were mailed. Similarly, we have no information for the patients who were not referred to the study during proactive recruitment.

Conclusions Despite the potential for differences in characteristics and degree of trial participation between trial participants recruited proactively and reactively, in this investigation, the two groups were similar. Information from other trials in other conditions may confirm or modify our conclusion. *Clinical Trials* 2013; **10:** 587–592. http://ctj.sagepub.com

Introduction

Breast cancer is the most frequently diagnosed cancer in women in the United States; an estimated 232,620 women had this diagnosis in 2011 [1]. As a result of significant improvements in awareness,

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early detection, and treatment options, the 5-year relative survival rate for those diagnosed with breast cancer has increased dramatically, to 90% [1]. Longer survival has resulted in a growing population of breast cancer survivors who are faced with the difficult task of adjusting to life, post cancer diagnosis [2].

Mounting evidence suggests that psychosocial care of cancer survivors is a critical aspect of improving the quality of cancer survivorship [3]. Recent literature has suggested that more work is required to evaluate the specifics of intervention content and delivery to optimize efficacy [4]. Evidence for physical and psychological benefits of physical activity among cancer survivors [5,6] has led to the development of interventions to increase physical activity among survivors [7–9].

The timing and setting of the recruitment effort are important factors with respect to enrollment of cancer survivors in intervention research [10,11]. There have been few evaluations of success and yield of proactive (e.g., approaching patients in person) compared with reactive recruitment (e.g., mailing letters) methodology. Even less research has focused on whether these recruitment strategies are associated differentially with consent to study enrollment, characteristics of enrollees, psychosocial profiles, participation in the intervention, and retention to study completion. Irwin et al. [6] documented different recruitment methods (self-referral and cancer registry) but did not elaborate fully on the impact of these methods on participant characteristics and behaviors. A factor that may influence psychosocial sample characteristics in breast cancer survivorship research has been participant bias due to failure to enroll a representative sample of participants [12]. Thus, recruitment method may be associated with participant characteristics and degree of trial participation.

Letter mailings to cancer survivors from state registries have yielded a response rate of about 10% [13,14], with 3% of the mailings resulting in an eligible participant who was randomized into the study [14]. Mailings from cancer centers or oncologists' offices have resulted in better recruitment, yielding a 50% (cancer center mailing) [15] and 33% (oncologist's office) [16] rate of participant study enrollment. This latter approach may be more effective and may result in a lower cost per enrolled participant. Telephoning candidate participants directly has been reported to result in 35% accrual at an estimated cost per participant of US$156 [17]. The use of mailed letters in the same study resulted in 2% accrual and an estimated cost per participant of US$1967 [17].

Using data from an intervention trial designed to improve levels of physical activity in breast cancer survivors [18], we have compared (1) psychosocial and medical characteristics and physical activity variables and (2) whether recruitment strategy was associated with baseline psychosocial profile, differential receipt of the intervention, participant retention, and physical activity for participants recruited proactively and reactively.

Methods

Participants and recruitment strategies

Target participants were breast cancer survivors for a randomized controlled trial to compare the efficacy of health-care practitioner advice plus telephone counseling for increasing physical activity levels versus health-care practitioner advice plus calls that controlled for telephone contact [18]. Participants were recruited primarily via (1) proactive or (2) reactive methods. (1) Proactively, breast cancer survivors who were expected to live for $\geq$12 months were approached by study personnel at a hospital-based oncology clinic after being identified as having completed breast cancer treatment and having attended a nonurgent follow-up appointment that day. (2) Reactively, health-care providers at hospitals and private practices identified women who had completed breast cancer treatment, were expected to live for $\geq$12-months, and were scheduled for a follow-up appointment in the coming months. The medical offices mailed letters that described the study to these women. Letters were mailed approximately 3 months prior to follow-up appointment; women interested in study participation were asked to contact the study staff.

Eligible women were $>$18 years of age, had completed primary and adjuvant treatment for breast cancer (patients on hormone treatment, such as tamoxifen, were eligible), were less than 5 years posttreatment, were fluent in English, provided consent for a medical chart review, could walk without assistance, were not regular exercisers, and had access to a telephone. Exclusion criteria for the randomized controlled trial were history of other cancers, current medical illness, or current treatment for a psychiatric illness. Enrollees signed a consent form approved by the Institutional Review Boards at The Miriam Hospital and Women and Infants Hospital of Providence, Rhode Island.

Measures

Participants in this study were evaluated at baseline, 3 months, 6 months, and 12 months. Demographic characteristics, measurements of height and body weight, demographic findings from psychosocial questionnaires, and breast cancer–specific

information (e.g., stage of disease) from medical chart review were recorded at baseline.

Seven-day physical activity recall

This interviewer-administered measure assessed the number of hours the participant spent in activities, including sleep and moderate, hard, and very hard physical activity over the course of the past week [19]. We used the total minutes spent in at least moderate intensity physical activity as an outcome variable for comparing recruitment methods.

Functional assessment of cancer therapy-breast (FACT-B)

The FACT-B was used to assess quality of life in four domains: emotional, functional, physical, and social/family for breast cancer survivors [20]. Higher scores indicate better quality of life.

Center for Epidemiologic Studies Depression (CES-D) Scale

The CES-D is a 20-item self-report scale that evaluates depressive symptomatology over the course of the past week [21]. Higher scores indicate higher levels of depression.

Stage of motivational readiness for physical activity

This measure evaluated the participant's motivational readiness for physical activity [22] by classifying her into one of five stages of readiness for physical activity: precontemplation, contemplation, preparation, action, and maintenance.

Analytic strategies

Analyses were conducted with PASW Statistics (SPSS) 19.0. To evaluate baseline differences between recruitment strategies with respect to demographic, psychosocial, and outcome data, we utilized independent samples *t*-tests (for continuous variables) and chi-squared tests (for categorical variables). To evaluate the relationship between method of recruitment and physical activity during follow-up, linear regression analyses were conducted while controlling for demographic variables that were ($p < .10$) associated with method of recruitment and baseline physical activity. Only the participants assigned to the intervention group who provided physical activity data at all time-points were included in the regression analysis models.

Results

A total of 351 women who were informed about the intervention study through proactive or reactive methods completed eligibility telephone screens [18]. Of these 351 women, 192 were deemed eligible and enrolled in the study. The other 159 screenees either were deemed to be ineligible (n = 81) or chose not to participate (n = 78). Of the 78 screenees who chose not to participate in the study, 27 (35%) were invited to participate through a proactive approach, while 44 (56%) were invited to participate through a reactive approach. Reasons for choosing not to participate included no interest (n = 18), too busy (n = 18), family issues (n = 5), medical issues (n = 4), lost contact (n = 8), other reasons (n = 11), and unknown (n = 14).

Of the 192 participants enrolled in the physical activity trial, 19 were excluded from the current analysis because they were recruited through methods other than proactive or reactive means (e.g., community events, word of mouth). Of the remaining 173 women, 80 (46%) were recruited proactively and 93 (44%) were recruited reactively. Twenty-seven of the 173 participants withdrew or were dropped (due to a lack of response from the participant) from the trial during the 12-month study period.

The only baseline characteristic that differed between women recruited proactively and reactively was time since diagnosis of breast cancer ($p < 0.01$). Women recruited reactively were a mean of 3.4 years (SD = 2.3 years) postdiagnosis compared to women recruited proactively who were 2.5 years (SD = 1.9 years) postdiagnosis (Table 1). Recruitment method did not influence retention or intervention receipt. After controlling for time since diagnosis and baseline level of physical activity, regression analysis of the physical activity outcome indicated that method of recruitment was not a predictor of level of physical activity reported at any follow-up time.

Discussion

In a randomized trial for breast cancer survivors in which the goal of the intervention was to increase physical activity, women who enrolled after recruitment via proactive versus reactive methods were comparable across a broad spectrum of demographic, psychosocial, and physical activity variables at baseline and physical activity during the follow-up period. These findings are consistent with existing literature conducted in the general population, which demonstrated that different recruitment methods did not result in a different demographic or psychosocial participant profile [23]. However, in this limited literature evaluating the potential

Table 1. Comparison of characteristics of 173 breast cancer survivors recruited to a randomized trial of a physical activity counseling intervention by method of recruitment

Baseline demographic and psychosocial variables	Proactive recruitment (% of overall sample) n = 80	Reactive recruitment (% of overall sample) n = 93
Age (years), mean (SD)	54.7 (8.7)	57.2 (11.1)
Race, n (%)		
Non-Hispanic White	77 (96)	90 (97)
African-American	3 (4)	3 (3)
Marital status, n (%)		
Single/separated/divorced/widowed	25 (31)	25 (27)
Married/living with partner	55 (69)	68 (73)
Income,[a] n (%)		
≤US$29,999	10 (14)	10 (12)
US$30,000–US$49,999	20 (28)	21 (24)
≥US$50,000	42 (58)	56 (64)
Education, n (%)		
Some high school/high school	16 (20)	16 (17)
Vocational/trade school	6 (8)	4 (4)
Some college	19 (24)	29 (31)
Associate degree	11 (14)	8 (9)
Bachelor's degree	12 (15)	17 (18)
Graduate school	16 (20)	19 (20)
Weight, pounds,[a] mean (SD)	167.9 (34.2)	166.9 (37.8)
Time since diagnosis (years), mean (SD)	2.5 (1.9)	3.4 (2.3)**
Stage of disease, n (%)		
0	12 (15)	12 (13)
1	23 (29)	42 (45)
2	37 (46)	34 (37)
3	8 (10)	5 (5)
Treatment,[b] n (%)		
Lumpectomy	63 (79)	65 (70)
Lumpectomy and node dissection	46 (58)	41 (44)
Mastectomy	23 (29)	33 (35)
Mastectomy and reconstruction	3 (4)	9 (10)
Radiation	59 (74)	63 (68)
Chemotherapy	51 (64)	50 (54)
Hormone treatment	48 (60)	68 (73)
FACT-B, mean (SD)		
Physical well-being	23.3 (4.3)	24.1 (3.3)
Social/family well-being	15.9 (3.6)	16.0 (4.2)
Emotional well-being	19.4 (3.2)	20.0 (3.5)
Functional well-being	20.6 (6.4)	21.2 (5.8)
CES-D, mean (SD)	12.7 (8.7)	11.4 (8.5)
Stage of motivation for physical activity at baseline,[c] n (%)		
Precontemplation	0 (0)	1 (1)
Contemplation	57 (71)	78 (84)
Preparation	17 (21)	13 (14)
Action/Maintenance	6 (7.5)	1 (1)
Outcomes		
Physical activity/week (minutes),[d] mean (SD)		
Baseline	44.0 (61.7)	39.3 (54.9)
3 months	119.7 108.6)	135.2 (100.4)
6 months	94.7 (121.7)	112.2 (99.9)
12 months	81.3 (93.9)	84.1 (72.5)

(continued)

Table 1. (Continued)

Baseline demographic and psychosocial variables	Proactive recruitment (% of overall sample) n = 80	Reactive recruitment (% of overall sample) n = 93
Intervention receipt,[d] mean (SD)		
Total number of calls received	9.2 (2.3)	9.1 (2.5)
Total call time (minutes)[a]	112.0 (69.6)	111.3 (51.8)

FACT-B: Functional Assessment of Cancer Therapy–Breast Cancer; CES-D: Center for Epidemiologic Studies Depression Scale; SD: standard deviation.
[a]Not all participants provided data; thus, total number < 173.
[b]Most participants had received more than one treatment; percentages add to >100.
[c]Participants in the action and maintenance stages (other) were not included in analyses as it is not expected that they would be in either stage prior to the intervention, which targeted breast cancer survivors in the precontemplation, contemplation, or preparation stages of motivational readiness.
[d]Only participants in the physical activity counseling intervention arm were evaluated. Sample sizes decrease with follow-up time.
[**]$p = .013$.

impact of recruitment strategy on sample characteristics, there has been contradictory evidence suggesting that differing recruitment approaches may result in unique samples [24]. In our study, the only baseline difference between the groups recruited by the two methods was time from breast cancer diagnosis to trial enrollment, with women recruited proactively at the oncologist's office having more recent diagnosis. This is likely an artifact of our study design, as time elapsed between when women who were recruited reactively were identified by their health-care providers, letters were mailed out to the women, and they enrolled in the trial. The absence of important differences by recruitment method in our study should prove encouraging for clinical trial investigators, as they typically seek to recruit trial candidates by using multiple recruitment approaches. Of women screened who were eligible but chose not to participate, 56% were recruited via letters from the oncologists (reactively) versus 35% recruited in the oncology clinic (proactively), underscoring the importance of engaging physicians in the recruitment process.

Study limitations

Our analysis has several limitations. First, proactive recruitment occurred at a single hospital site with good patient flow. Second, proactive and reactive recruitment did not occur concurrently. Third, the mailings were performed by the oncologists' offices so that we are unable to estimate how many letters were mailed. Fourth, there were differences in the resources demanded by these different recruitment methods. Finally, our sample size was small, particularly for the analysis of the effect of recruitment method on the primary outcome.

Conclusion

Given the relative paucity of published comparisons of participant characteristics in breast cancer intervention trials by recruitment methods, we did not have conclusive reasons to hypothesize that differential recruitment methods would result in important differences in sociodemographic, psychosocial, medical, or trial participation characteristics. Of note, participants recruited proactively had more recent diagnoses and, when found to be eligible for the study, more often consented to participate than women recruited reactively.

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Conflict of interest

None declared.

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