original report

Promoting Breast Cancer Surveillance: The EMPOWER Study, a Randomized Clinical Trial in the Childhood Cancer Survivor Study

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abstract

PURPOSE The aim of the current study was to increase the uptake of screening mammography among high-risk women who were treated for a childhood cancer with chest radiotherapy.

PATIENTS AND METHODS Two hundred four female survivors in the Childhood Cancer Survivor Study who were treated with chest radiotherapy with 20 Gy or greater, age 25 to 50 years, and without breast imaging in the past 24 months were randomly assigned 2:1 to receive a mailed informational packet followed by a tailored telephone-delivered brief motivational interview (intervention) versus an attention control. Primary outcome was the difference in the proportion of participants who completed a screening mammogram by 12 months as evaluated in an intent-to-treat analysis. Stratum-adjusted relative risk (RR) and 95% CI were estimated using the Cochran-Mantel-Haenszel method. Secondary outcomes included the completion of screening breast magnetic resonance imaging (MRI) and barriers to screening and moderating factors.

RESULTS Women in the intervention group were significantly more likely than those in the control group to report a mammogram (45 [33.1%] of 136 *v* 12 [17.6%] of 68; RR, 1.9; 95% CI, 1.1 to 3.3). The intervention was more successful among women age 25 to 39 years (RR, 2.2; 95% CI, 1.1 to 4.7) than among those age 40 to 50 years (RR, 1.4; 95% CI, 0.6 to 3.2). The proportion of women who reported a breast MRI at 12 months was similar between the two groups: 16.2% (intervention) compared with 13.2% (control; RR, 1.2; 95% CI, 0.6 to 2.5). Primary barriers to completing a screening mammogram and/or breast MRI included lack of physician recommendation, deferred action by survivor, cost, and absence of symptoms.

CONCLUSION Use of mailed materials followed by telephone-delivered counseling increased mammography screening rates in survivors at high risk for breast cancer; however, this approach did not increase the rate of breast MRI. Cost of imaging and physician recommendation were important barriers that should be addressed in future studies.

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INTRODUCTION

By age 50 years, one in three women who were treated for a childhood cancer with chest radiotherapy will be diagnosed with breast cancer, a risk equivalent to that of *BRCA1* carriers.[1] Because early detection of breast cancer is strongly associated with survival in the general population, breast cancer surveillance with annual screening mammography and breast magnetic resonance imaging (MRI) is recommended for female survivors of childhood cancer who were treated with chest radiotherapy, starting at age 25 or 8 years after chest radiation, whichever occurs last.[2-4] As we have previously documented, the majority of women in this risk group is not adherent to these recommendations.[5,6] Magnifying this problem, most survivors of childhood cancer are unaware of their risks,[5,7] are no longer observed at a cancer center,[8,9] and are instead observed by primary care providers (PCPs) who rarely receive a survivorship care plan for these survivors and, as a result, are poorly informed about recommended follow-up care.[10-12]

Our preliminary studies suggested that an educational intervention with a recommendation for annual mammography may lead to increased surveillance rates.[13] Furthermore, our data suggested that inclusion of a behaviorally based method to address screening self-efficacy and other related individual factors would enhance the intervention and facilitate the initiation and maintenance of screening.[5,14,15] This approach, which is especially relevant for women who require a more intensive and personalized health-related, behavior-based intervention, can optimally be delivered by telephone via a brief motivational interview.[16-20]

Thus, we conducted the two-arm, unblinded, randomized controlled EMPOWER study (ClinicalTrials.gov identifier:

ASSOCIATED CONTENT

Appendix

Data Supplements

Author affiliations and support information (if applicable) appear at the end of this article.

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Clinical trial information: NCT01579552.

NCT01579552) among high-risk female survivors age 25 to 50 years to test the efficacy of mailed educational materials, followed by a telephone-delivered brief motivational interview, on completing breast cancer screening—primarily with mammography and secondarily with breast MRI—compared with an attention control group.

PATIENTS AND METHODS

Study Design and Participants

Participants were recruited for this institutional review board–approved study from the Childhood Cancer Survivor Study, a 31-institution retrospective cohort that consists of 24,363 long-term childhood cancer survivors who were diagnosed before age 21 years, between 1970 and 1999, surviving at least 5 years from diagnosis and living in the United States or Canada. The Childhood Cancer Survivor Study cohort methodology and study design have been previously described in detail.[21,22] Survivors were eligible to participate in the EMPOWER study if they were female, treated with chest radiotherapy with 20 Gy or greater, at least 8 years from chest radiation, age 25 to 50 years at time of enrollment, English speaking, did not have a personal history of breast cancer or myocardial infarction, and had not undergone a mammogram or other breast imaging in the previous 24 months.

Random Assignment and Study Interventions

After the receipt of informed consent, participants were enrolled from October 7, 2010, through April 1, 2014, and were randomly assigned 2:1 via a computer algorithm using a permuted block randomization scheme with a block size of four to the targeted intervention or attention control group. On the basis of our previous findings of lower screening mammography rates among women younger than age 40 years, we stratified randomization by age at enrollment (25 to 39 and 40 to 50 years).[5] We also stratified on the basis of race and ethnicity. The baseline survey completed by participants is available at https://ccss.stjude.org/tools-and-documents/questionnaires.html.

The intervention consisted of mailed informational print materials followed by a tailored telephone-delivered brief motivational interview. The intervention was guided by two health behavior theories, the Health Belief Model[23-25] and the Transtheoretical Model.[26-30] The marriage of the Health Belief Model and Transtheoretical Model models has been particularly successful with mammography interventions.[31-37] The mailed packet (Data Supplement) included a cover letter that provided information in lay terms about the risks associated with the woman's previous chest radiotherapy and the clinical guideline recommendation for annual screening mammography and breast MRI. Four other components included were a one-page description of the potential benefits and other considerations of breast cancer screening for women with a similar cancer history, two laminated cards—one for the participant and one to give to her PCP—highlighting the recommendations, a list of low-cost options for mammography, and a letter template that could be used to obtain approval for coverage of breast MRI from an insurance company, if needed. Two to four weeks later, women were contacted by telephone and a brief motivational interview[16,17,38-41] with computer-assisted telephone interviewing was conducted by a trained counselor. The 30- to 45-minute brief motivational interview was tailored to the stage of readiness. Overarching goals of the session were to answer questions about the mailed materials, elicit intrinsic motivation for breast cancer surveillance, create and resolve ambivalence, develop an action plan, and strengthen client commitment to initiate and maintain regular screening. The attention control group received the same number of contacts, but mailed information and telephone calls focused on cardiac health rather than breast cancer risk (Data Supplement). After the completion of the study, women in the control group were provided with the breast cancer–related informational materials sent to the intervention group.

Assessment of Study Outcomes

Primary outcome in the protocol was screening mammography by 12 months after random assignment. As a result of difficulties in obtaining medical record confirmation (described below), we analyzed self-reported completion of a mammogram by 12 months. Secondary

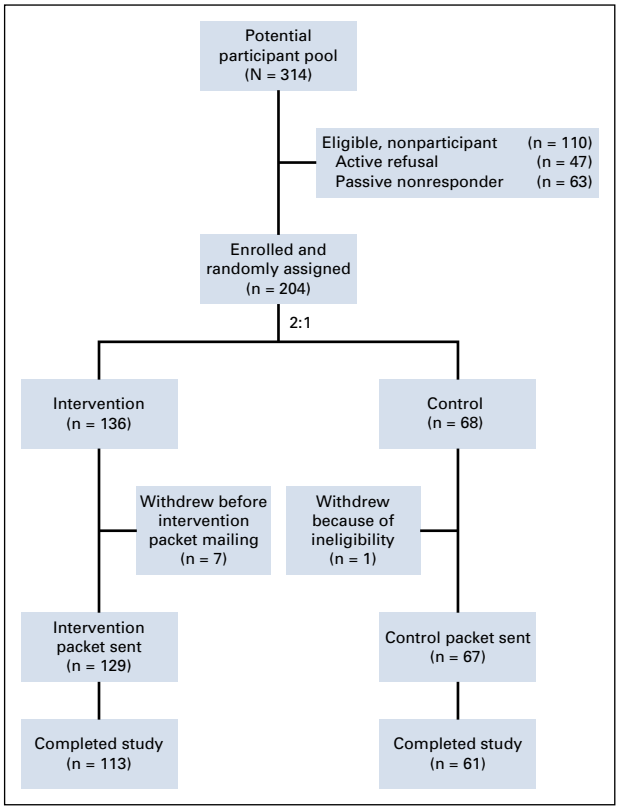

FIG 1. EMPOWER study CONSORT diagram (ClinicalTrials.gov identifier: NCT01579552).

aims included moderating factors that predict mammogram completion, the proportion of women who completed a breast MRI, and perceived barriers to completing surveillance imaging. For this latter variable, we asked the question, "How important were each of the following reasons for not having a mammogram?" After this question was a list of items, based on our previous studies,[5] using a five-point Likert scale (not at all, a little bit, moderately, quite a bit, extremely). A similar question was used for breast MRI.

Statistical Analysis

The trial was powered to detect a difference of 15% between the intervention and attention control arms, assuming that the proportion of women in the control arm having a mammogram by 12 months would be 10% to 15%.[5] We planned to enroll 360 women (intervention, n = 240; control, n = 120) to have at least 85% power and a Type I error rate of 0.05 using a two-sided test. However, the accrual rate was less than anticipated and the study closed with a total of 204 participants enrolled. Sociodemographic characteristics were compared between participants and nonparticipants using Fisher's exact test and the Wilcoxon rank-sum test for categorical and continuous covariates, respectively.

Primary analysis was an intent-to-treat analysis that included all women who were randomly assigned to the study. Participants who did not complete the 12-month assessment were considered to not have had a mammogram. Intervention and control groups were compared using the Cochran-Mantel-Haenszel test stratifying by the randomization strata. In secondary analyses, we restricted our analyses to the subsets of participants who completed the 12-month assessment.

We examined factors that potentially moderated the efficacy of the intervention using Poisson regression models with a log link function and robust SEs to estimate relative risks (RRs). Fitting separate models for each moderating factor, we modeled the probability of obtaining a mammogram within 12 months as a function of the intervention, factor, interaction between the intervention and the factor, and randomization strata. Similar analyses were performed for receipt of breast MRI. Potential moderating factors, informed by our previous work,[5,13-15] included age, race/ethnicity, education level, health insurance status, household income, presence of chronic health conditions, having a cancer treatment summary, and knowledge that chest radiation increases the risk of breast cancer.

Among women who completed the 12-month assessment who did not report a mammogram, the proportions of women who listed key barriers to obtaining a mammogram were compared between arms by modeling the barrier as a function of group and randomization strata also using Poisson models.

All statistical analyses were performed using SAS (SAS/STAT User's Guide, Version 9.4, 1990; SAS Institute, Cary, NC) or StataSE 15.0 for Windows (STATA, College Station, TX; Computing Resource Center, Santa Monica, CA) using two-sided tests and a significance level of $P \leq .05$.

TABLE 1. Baseline Demographic and Clinical Characteristics of Participants in the EMPOWER Study: Women at Risk for Breast Cancer After ≥ 20 Gy of Chest Radiotherapy for a Childhood Cancer; Attention-Control Group (control) or Intervention Group (intervention)

Characteristic	Control (n = 68)	Intervention (n = 136)
Age at baseline assessment, years		
25-39	50 (73.5)	102 (75.0)
40-50	18 (26.5)	34 (25.0)
Race and ethnicity		
White, non-Hispanic	57 (83.8)	114 (83.8)
Minority	11 (16.2)	22 (16.2)
Education level		
High school graduate or less	12 (17.6)	17 (12.5)
Post–high school training/some college	12 (17.6)	31 (22.8)
College graduate/postgraduate	43 (63.2)	81 (59.5)
Unknown/missing	1 (1.6)	7 (5.2)
Household income, US $		
< 20,000	10 (14.7)	11 (8.1)
20,000-60,0000	24 (35.3)	50 (36.7)
≥ 60,000	27 (39.7)	59 (43.4)
Unknown/missing	7 (10.3)	16 (11.8)
Health insurance		
Yes or Canadian	61 (89.7)	110 (80.9)
None	6 (8.8)	19 (14.0)
Unknown/missing	1 (1.5)	7 (5.1)
Primary cancer diagnosis		
Hodgkin lymphoma	52 (76.5)	90 (66.2)
Other cancers	16 (23.5)	46 (33.8)
Age at cancer diagnosis, years		
0-9	18 (26.5)	40 (29.4)
≥ 10	50 (73.5)	96 (70.6)

NOTE. Data are given as No. (%).

RESULTS

Of the 314 women living in the United States or Canada who were eligible and successfully contacted with the introductory study packets, 204 (65.0%) consented and were randomly assigned—68 to the attention control group and 136 to the intervention group (Fig 1). Forty-three women (13.7%) were successfully contacted but did not consent to participate (active nonparticipants) and another 67 women (21.3%) did not respond to the study invitation (passive nonparticipants). Nonparticipants were modestly older than participants (38.7 years *v* 35.8 years,

respectively; $P < .001$). There were no significant differences on the basis of race/ethnicity, attained educational level, household income, or health insurance status, according to status at last contact (Appendix Table A1, online only).

Of the 136 women who were randomly assigned to the intervention group, 80% (109 of 136) received all components of the intervention. Of the 68 women in the control group, 90% (61 of 68) received all components. In total, 174 women (85%) completed the 12-month measurements (intervention group, n = 113 of 136; control group, n = 61 of 68). Intention-to-treat analysis included all randomly assigned participants.

Of the 204 women who were randomly assigned, mean age was 35.8 years, 16.2% were a racial/ethnic minority, and 10.3% had a household income of less than $20,000 (Table 1). Most had some form of insurance (83.8%), although 32% reported a large deductible.

Primary and Secondary Outcomes

Women in the intervention group were more likely than those in the attention control group to report a mammogram by 12-months (intent-to-treat analysis; 33.1% [45 of 136] *v* 17.6% [12 of 68]; RR, 1.9; 95% CI, 1.1 to 3.3; Table 2). When restricting the analysis to those who completed the 12-month measurements, the difference between the two groups was slightly greater. Women in the intervention group (45 [39.8%] of 113) were more likely to complete the mammogram than women in the control group (12 [19.7%] of 61; RR, 2.0; 95% CI, 1.2 to 3.4).

Although the intervention was associated with increased mammography rates, the proportion of women who reported a breast MRI was similar between the two groups (intervention, 16.2%; control, 13.2%; intention-to treat RR, 1.2; 95% CI, 0.6 to 2.5).

Consistent with the low breast MRI completion rate, only 13.2% of women who were randomly assigned to the intervention group and 10.3% of women in the control group completed both a screening mammogram and breast MRI (intention-to-treat: RR, 1.3; 95% CI, 0.6 to 2.9). When comparing the completion of at least one breast imaging study (mammogram or breast MRI), women who were randomly assigned to the intervention group were 75% more likely to report any screening test than women in the control group (intention-to-treat: RR, 1.7; 95% CI, 1.1 to 2.9).

Of 63 women who reported a screening test, we obtained medical confirmation of breast imaging for 54 of them (85.7%; 12 of 14 in the control group and 42 of 49 in the intervention group). Reasons for the inability to confirm the imaging study included a lack of information regarding the imaging facility, the facility being unable to locate records, and the facility sending only partial information. When we repeated the analysis including only women with a medically confirmed imaging study, results were not substantively different.

Factors Moderating the Efficacy of the Intervention

Several factors moderated the efficacy of the intervention (Table 3 and Fig 2). The intervention was more successful among women age 25 to 39 years (RR, 2.2; 95% CI, 1.1 to 4.7) than among those age 40 to 50 years (RR, 1.4; 95% CI, 0.6 to 3.2). Similarly, the intervention seemed to be more efficacious among women with a lower household income, a lower educational attainment, those without a cancer treatment summary, or a lack of awareness of their breast cancer risk before the study. Indeed, less than 10% of women in the control group who had a lower level of education or who were unaware of their breast cancer risk completed a mammogram, whereas more than 35% in the intervention group completed one. Thus, it seems that the intervention was particularly efficacious among the more vulnerable women.

In contrast, none of these factors moderated the efficacy of the intervention on completing a breast MRI (Fig 2 and Appendix Table A2, online only).

Barriers to Breast Cancer Surveillance

Because primary barriers differed by age group, results are presented separately in Figure 3. Among women in the intervention group age 25 to 39 years, primary barriers to completing a mammogram were “put it off” (36.0%), “too expensive” (34.3%), and “doctor didn’t order it” (29.4%). Among women age 40 to 50 years, primary barriers were “too busy” (50.0%), “haven’t had any problems” (46.7%),

TABLE 2. Proportion of Women Completing Recommended Screening With RR and 95% CI

Screening Modality	Control, %	Intervention, %	Adjusted RR* (95% CI)	*P*
Mammography				
Intention to treat	17.6	33.1	1.9 (1.1 to 3.3)	$P = .018$
Completed 12-month survey	19.7	39.8	2.0 (1.2 to 3.4)	$P = .007$
Breast MRI				
Intention to treat	13.2	16.2	1.2 (0.6 to 2.5)	$P = .59$
Completed 12-month survey	15.0	19.5	1.3 (0.6 to 2.6)	$P = .49$

Abbreviations: MRI, magnetic resonance imaging; RR, relative risk.

*RR was estimated using Mantel-Haenszel method and adjusted for randomization strata: age at study category (25-39 and 40-50 years) and race/ethnicity (white non-Hispanic and minority).

TABLE 3. Association of the Intervention With the Proportion of Women Who Reported a Screening Mammogram During Study by Potential Moderating Factors

Characteristic	No Mammogram (n = 147), No. (%)	Completed Mammogram (n = 57), No. (%)	RR*	95% CI	*P*
Age at baseline assessment, years					
25-39					
Intervention	70 (68.6)	32 (31.4)	2.2	1.1 to 4.7	.03
Control	43 (86.0)	7 (14.0)	1.0	Ref	
40-50					
Intervention	21 (61.8)	13 (38.2)	1.4	0.6 to 3.2	.45
Control	13 (72.2)	5 (27.8)	1.0	Ref	
Race and ethnicity					
White, non-Hispanic					
Intervention	74 (64.9)	40 (35.1)	1.7	0.9 to 2.9	.07
Control	45 (78.9)	12 (21.0)	1.0	Ref	
Minority					
Intervention	17 (77.3)	5 (22.7)	3.3	0.8 to 7.7	.26
Control	11 (100.0)	0 (0.00)	1.0	Ref	
Education level†					
≤ HS graduate ± additional					
Intervention	33 (68.7)	15 (31.2)	3.9	1.0 to 15.0	.05
Control	22 (91.7)	2 (8.3)	1.0	Ref	
≥ College graduate					
Intervention	51 (63.0)	30 (37.0)	1.5	0.8 to 2.9	.16
Control	33 (76.7)	10 (23.3)	1.0	Ref	
Health insurance†					
Yes or Canadian					
Intervention	67 (60.9)	43 (39.1)	2.1	1.2 to 3.8	.01
Control	50 (81.9)	11 (18.0)	1.0	Ref	
None					
Intervention	17 (89.5)	2 (10.5)	0.7	0.1 to 5.0	.70
Control	5 (83.3)	1 (16.7)	1.0	Ref	
Household income, US $†					
< 60,000					
Intervention	44 (72.1)	17 (27.9)	4.7	1.1 to 19.2	< .03
Control	32 (94.1)	2 (5.9)	1.0	Ref	
≥ 60,000					
Intervention	32 (54.2)	27 (45.8)	1.2	0.7 to 2.1	.53
Control	17 (63.0)	10 (37.0)	1.0	Ref	
Chronic health condition†					
None					
Intervention	33 (62.3)	20 (37.7)	2.5	0.9 to 6.7	.07
Control	23 (85.2)	4 (14.8)	1.0	Ref	
Any grade 1 or 2					
Intervention	14 (73.7)	5 (26.3)	1.2	0.3 to 5.2	.80
Control	6 (75.0)	2 (25.0)	1.0	Ref	

(continued on following page)

TABLE 3. Association of the Intervention With the Proportion of Women Who Reported a Screening Mammogram During Study by Potential Moderating Factors (continued)

Characteristic	No Mammogram (n = 147), No. (%)	Completed Mammogram (n = 57), No. (%)	RR*	95% CI	P
Any grade 3 or 4					
Intervention	33 (62.3)	20 (37.7)	1.7	0.8 to 3.7	.19
Control	24 (80.0)	6 (20.0)	1.0	Ref	
Cancer treatment summary†					
No or don't know					
Intervention	48 (68.2)	28 (36.8)	2.6	1.2 to 5.7	.02
Control	39 (86.9)	6 (13.3)	1.0	Ref	
Yes					
Intervention	35 (67.4)	17 (32.7)	1.4	0.6 to 3.3	.46
Control	16 (76.2)	5 (23.2)	1.0	Ref	
Chest RT increases BC risk‡					
Correct knowledge					
Intervention	58 (60.4)	38 (39.6)	1.7	0.9 to 3.0	.09
Control	31 (75.6)	10 (24.4)	1.0	Ref	
Incorrect knowledge					
Intervention	9 (56.2)	7 (43.7)	4.2	1.0 to 17.5	.05
Control	18 (90.0)	2 (10.0)	1.0	Ref	

Abbreviations: BC breast cancer; HS, high school; Ref, reference; RT, radiotherapy; RR, relative risk.

*Poisson regression model with indicator for treatment group, moderator variable, and its interaction. The model is also adjusted for stratification factor age at random assignment and race/ethnicity.

†At baseline enrollment in the EMPOWER study.

‡At 12 months.

"put it off" (43.8%), "doctor didn't order it" (37.5%), and "too expensive" (37.5%). Barriers to completing a breast MRI were similar (Fig 3).

DISCUSSION

Recognizing that the cumulative incidence of breast cancer in this population is 30% by age 50 and that mortality after second breast cancers is substantially elevated,[1] breast cancer surveillance is an essential component of risk-based health care among women who were treated for a pediatric cancer with chest radiotherapy.[2,3] To our knowledge, this is the largest multicenter randomized controlled trial to date aimed at increasing breast cancer surveillance rates in a high-risk population. We determined that women who received a mailed informational packet followed by a telephone-delivered brief motivational interview were twice as likely to report completing a mammogram within 12 months. Furthermore, the intervention may have been more efficacious among younger women and among more vulnerable women (eg, lower level of education or household income or lack of knowledge of risk); however, this subgroup analysis was limited by sample size. Despite the efficacy of the intervention, the overall proportion of high-risk survivors in the intervention group who completed a mammogram remained relatively low at less than 40%. In addition, the intervention did not substantively increase the rate of breast MRI. Key barriers to completing these breast imaging studies included patients' doctors not ordering the test(s), putting testing off, cost, and the absence of symptoms.

We are aware of only one other randomized trial aimed at increasing breast cancer surveillance among this high-risk population. Bloom et al[42] previously conducted a single-institution randomized trial among 157 survivors of Hodgkin lymphoma who were treated with chest radiotherapy before age 35 years and compared mammography rates after a risk notification letter (control) with the letter plus telephone counseling (intervention). Breast MRI rates were not evaluated. Nearly one half of women (47%) reported a mammogram in the 14 months before study enrollment. Among the 133 women who completed the 6-month study, telephone counseling, compared with control, was associated with a 3.6-fold increased likelihood of being in mammography maintenance. Notable differences from our study were the inclusion of women who were already undergoing mammography before enrollment and not using an intent-to-treat analysis. Nevertheless, these two randomized trials found that an informative letter

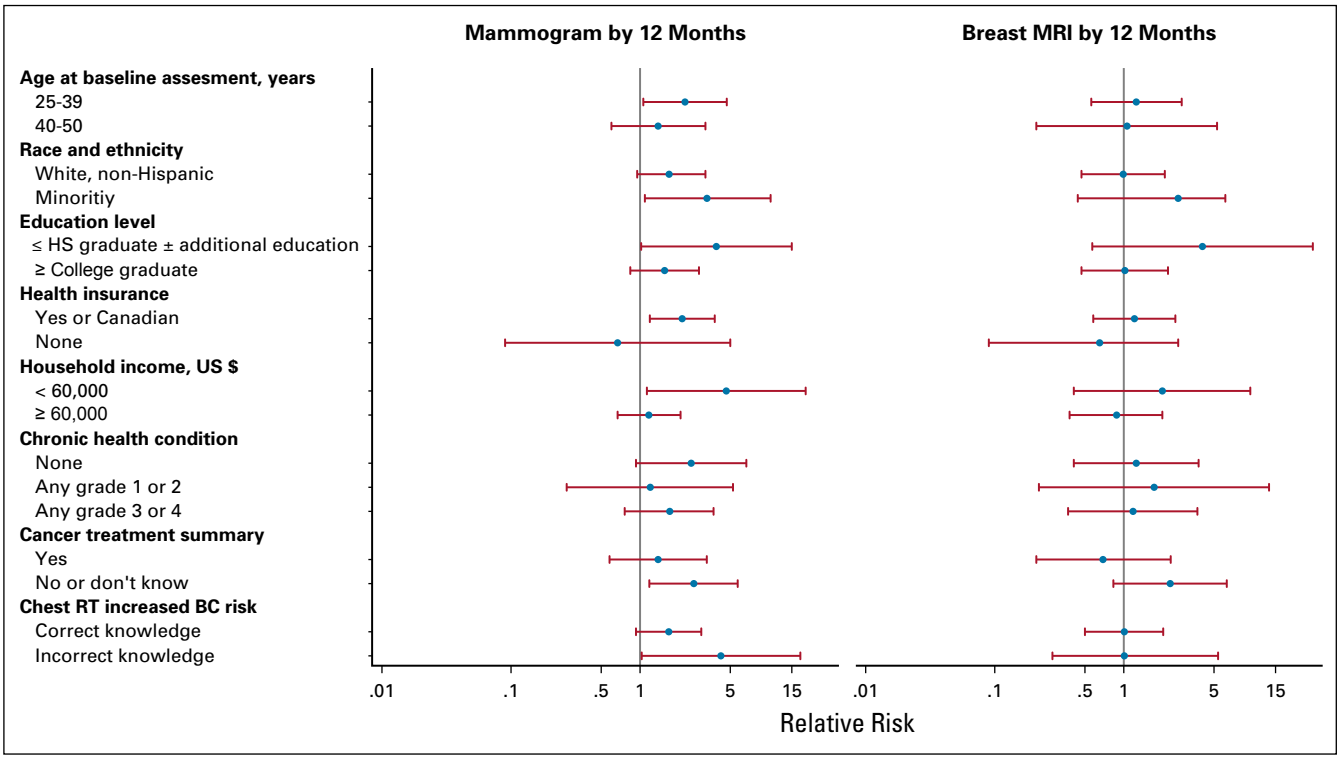

FIG 2. Association of the intervention with the proportion of women who reported a screening mammogram during study by potential moderating factors. BC, breast cancer; HS, High School; MRI, magnetic resonance imaging; RT, radiotherapy.

followed by telephone counseling is an effective strategy by which to increase the likelihood of beginning or continuing mammography in this high-risk population.

A novel contribution of this study is exploring factors that moderate the efficacy of the intervention. Although caution is recommended when interpreting these findings on the basis of relatively small subgroup analyses, there seemed to be some important moderators. The intervention may have been more efficacious among women who might be considered less likely to begin screening—younger women, lower household income, or lower level of education—or who were unaware of their risk. Indeed, as our control group illustrates, having these factors of vulnerability was associated with a low likelihood of completing a mammogram without the intervention.

Despite the efficacy of the intervention on mammography rates, this approach led to only a modest increase in screening breast MRI rates. Breast MRI with mammography has been shown to be superior to either test alone among women with a hereditary risk for breast cancer,[43-47] or among survivors of Hodgkin lymphoma who were treated with chest radiotherapy.[48,49] Recognizing that radiotherapy may be associated with an increased mammographic breast density,[2,3] thereby rendering mammography somewhat less sensitive, breast MRI is an essential tool for early breast cancer detection in this young, high-risk population. Indeed, Hodgson et al[50] simulated the benefit of breast MRI among women who were treated with chest radiotherapy and observed that approximately 80 women would need to be invited to MRI-based screening to prevent one breast cancer death.

Thus, to build upon the efficacy of our intervention that increases screening mammography and to identity new ways with which to increase the rate of breast MRI use among this high-risk group, it is important to consider the barriers to breast MRI that women face in our trial. Although cost is an obvious barrier, there are several strategies that may help lessen its impact. First, most insurance companies cover the cost of a screening breast MRI among women with a lifetime risk of breast cancer that exceeds 20%.[4] In the informational packet, we provided women with a template letter to be sent to insurance companies, if needed; we do not know how often this letter was used by their PCPs. In addition, the Right Action for Women/Christina Applegate Foundation provides low- to no-cost breast MRI for young women with an elevated risk of breast cancer. This avenue should be explored in future studies.[51]

In addition to cost, three other barriers must be addressed to improve breast cancer surveillance rates among these women: "put it off," "too busy," and "doctor didn't order it." Studies of different methods of patient and physician activation are warranted. Recognizing that our intervention seemed to be more successful among younger women completing a mammogram, additional efforts may be needed for women older than age 40.

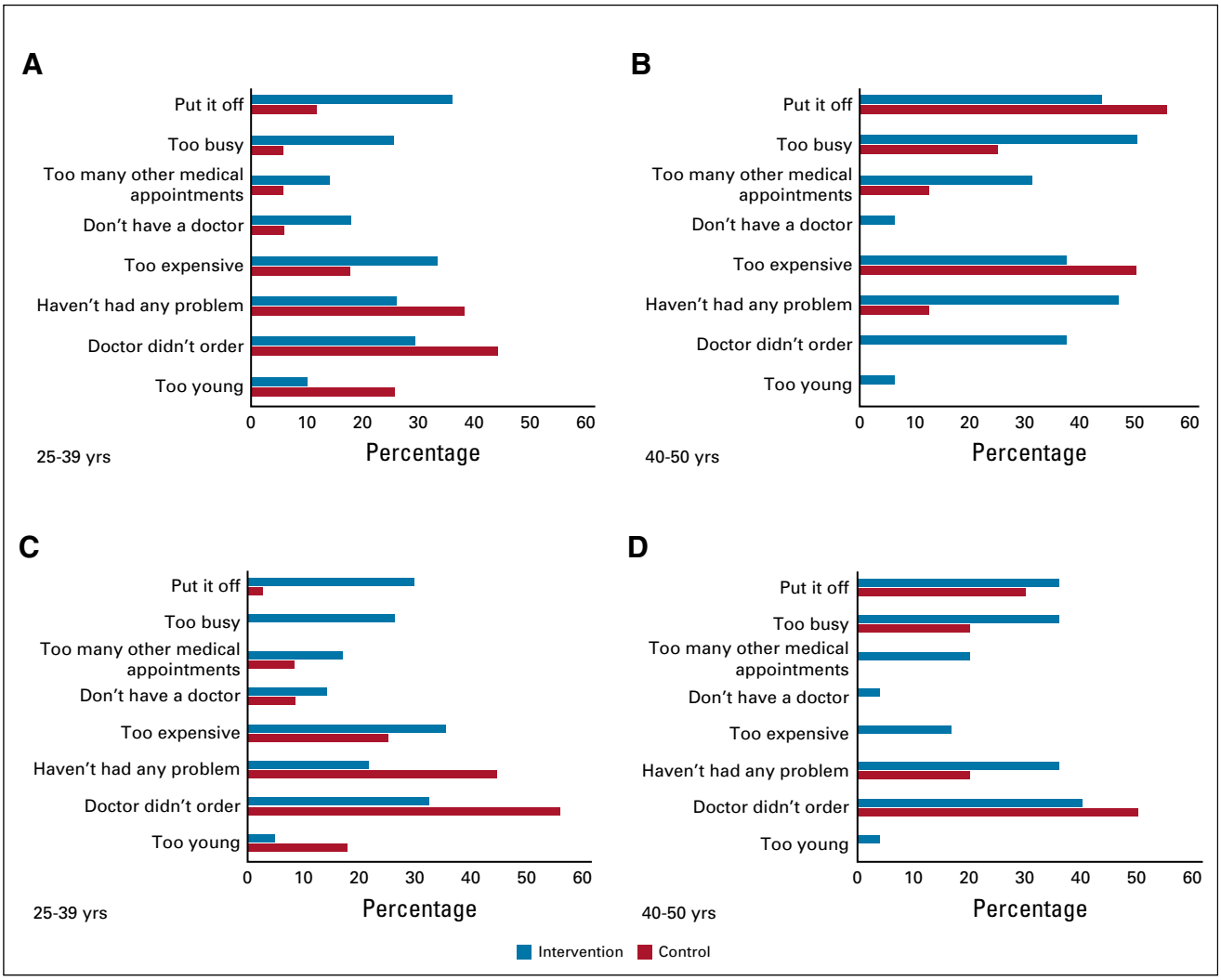

FIG 3. Barriers (quite a bit/extremely) to obtaining (A and B) a screening mammogram or (C and D) breast magnetic resonance imaging (MRI)among women who did not complete the recommended surveillance. (NOTE. Participants could have had more than one reason for not completing the breast imaging study.)

This study has several strengths, including being the largest randomized controlled trial completed to date; using a conceptually based approach; and enrolling a racially, socioeconomically, and geographically diverse group of women with an elevated risk of breast cancer. There were also limitations that should be considered when interpreting the results. Women who participated in this study are part of a cohort study and may be more informed about their risks than other women with similar histories; however, in a population with lower awareness, the intervention may be more effective. Second, we relied on self-reported imaging for our primary analyses. Using self-reported mammography is associated with an overestimation of completion rate.[52-54] As noted above, restricting the analysis to include only medical record–confirmed imaging studies did not change the findings. Lastly, 14% of women in the intervention group did not complete the telephone-based brief motivational interview. These limitations are important not only for interpreting the findings of the study, but also for planning future studies.

In summary, an intervention that consisted of a mailed informational packet followed by a telephone-delivered brief motivational interview was associated with a doubling of the screening mammography rate while having minimal impact on breast MRI rate. Recognizing the high risk of breast cancer and breast cancer–specific mortality among women who are treated for a childhood cancer with chest radiotherapy, testing of other approaches aimed at enhancing breast cancer surveillance are urgently needed.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Promoting Breast Cancer Surveillance: The EMPOWER Study, a Randomized Clinical Trial in the Childhood Cancer Survivor Study

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APPENDIX

TABLE A1. Baseline Demographic and Clinical Characteristics of Nonparticipants in the EMPOWER Study: Active Refusal, Nonresponder, Lost Contact

Characteristic	Participants (n = 204)	Nonparticipants (n = 110)	Active Refusal (n = 43)	Passive Nonresponder (n = 67)	*P**
Mean age at the time of invitation, years (SD)	35.8 (6.0)	38.7 (6.0)	39.7 (6.3)	38 (5.7)	< .001
Race and ethnicity					.742
White, non-Hispanic	171 (83.8)	90 (81.8)	37 (86.0)	53 (79.1)	
Minority	33 (16.2)	15 (13.6)	5 (11.6)	10 (14.9)	
Missing	0	5 (4.6)	1 (2.3)	4 (6.0)	
Education level					.178
≤ High school graduate	29 (14.2)	13 (11.8)	5 (11.6)	8 (11.9)	
Post–high school training/some college	43 (21.1)	34 (30.9)	3 (7.0)	31 (46.3)	
College graduate	86 (42.2)	37 (33.6)	20 (46.5)	17 (25.4)	
Postgraduate	38 (18.6)	25 (22.7)	15 (34.8)	10 (15.0)	
Unknown/missing	8 (4.0)	1 (0.9)	0 (0.0)	1 (1.5)	
Household income, US $					.792
< 20,000	21 (10.3)	11 (10.0)	1 (2.3)	10 (14.9)	
20,000-60,0000	74 (36.3)	31 (28.2)	12 (27.9)	19 (28.4)	
≥ 60,000	86 (42.2)	43 (39.1)	23 (53.5)	20 (29.9)	
Unknown/missing	23 (11.3)	25 (22.7)	7 (16.3)	18 (26.9)	
Health insurance					.99
Yes or Canadian	171 (83.8)	77 (70.0)	36 (83.7)	41 (61.2)	
No	25 (12.2)	11 (10.0)	1 (2.3)	10 (14.9)	
Unknown/missing	8 (4.0)	22 (20.0)	6 (14)	16 (23.9)	
Primary cancer diagnosis					.99
Hodgkin lymphoma	142 (69.6)	77 (70.0)	31 (72.1)	46 (68.7)	
Other cancers	62 (30.4)	33 (30.0)	12 (27.9)	21 (41.3)	

NOTE. Data are given as No. (%) unless otherwise noted.
Abbreviation: SD, standard deviation.
*Comparing participants with nonparticipants. *P* value was calculated with complete data.

TABLE A2. Association of the Intervention With the Proportion of Women Who Reported a Screening Breast MRI During Study by Potential Moderating Factors

Characteristic	Did Not Complete (n = 179), No. %	Completed Breast MRI (n = 25), No. %	RR*	95% CI	*P*
Age at baseline assessment, years					
25-39					
Intervention	84 (82.3)	18 (17.7)	1.2	0.6 to 2.8	.57
Control	43 (86.0)	7 (14.0)	1.0	Ref	
40-50					
Intervention	30 (88.2)	4 (11.7)	1.1	0.2 to 5.3	.94
Control	16 (88.9)	2 (11.1)	1.0	Ref	
Race and ethnicity					
White, non-Hispanic					
Intervention	96 (84.2)	18 (15.8)	1.0	0.5 to 2.1	.99
Control	48 (84.2)	9 (15.8)	1.0	Ref	
Minority					.39
Intervention	18 (81.8)	4 (18.2)	2.6	0.4 to 6.1	
Control	11 (100.0)	0 (0.0)	1.0	Ref	
Education level†					
≤ HS graduate ± additional					
Intervention	41 (85.4)	7 (14.6)	4.1	0.6 to 29.1	.11
Control	23 (95.8)	1 (4.2)	1.0	Ref	
≥ College graduate					
Intervention	66 (81.5)	15 (18.5)	1.0	0.5 to 2.2	.96
Control	35 (81.4)	8 (18.6)	1.0	Ref	
Health insurance†					
Yes or Canadian					
Intervention	90 (81.8)	20 (18.2)	1.2	0.6 to 2.5	.60
Control	52 (85.2)	9 (14.7)	1.0	Ref	
None					
Intervention	17 (89.5)	2 (10.5)	0.6	0.1 to 2.6	1.00
Control	6 (100.0)	0 (0.0)	1.0		
Household income, US $†					
< 60,000					
Intervention	53 (86.9)	8 (13.1)	2.0	0.4 to 9.6	.39
Control	32 (94.1)	2 (5.9)	1.0	Ref	
≥ 60,000					
Intervention	45 (75.3)	14 (23.7)	0.9	0.4 to 2.0	.85
Control	20 (74.1)	7 (25.9)	1.0	Ref	
Chronic health condition†					
None					
Intervention	43 (81.1)	10 (18.9)	1.3	0.4 to 3.8	.72
Control	23 (85.2)	4 (14.8)	1.0	Ref	
Any grade 1 or 2					
Intervention	15 (78.9)	4 (21.0)	1.7	0.2 to 13.3	.60
Control	7 (87.5)	1 (12.0)	1.0	Ref	

(continued on following page)

TABLE A2. Association of the Intervention With the Proportion of Women Who Reported a Screening Breast MRI During Study by Potential Moderating Factors (continued)

Characteristic	Did Not Complete (n = 179), No. %	Completed Breast MRI (n = 25), No. %	RR*	95% CI	*P*
Any grade 3 or 4					
Intervention	45 (84.9)	8 (15.1)	1.2	0.4 to 3.7	.78
Control	26 (86.7)	4 (13.3)	1.0	Ref	
Cancer treatment summary†					
No or don't know					
Intervention	61 (80.3)	15 (19.7)	2.3	0.8 to 6.3	.11
Control	41 (91.1)	4 (8.9)	1.0	Ref	
Yes					
Intervention	45 (86.5)	7 (13.5)	0.7	0.2 to 2.3	.55
Control	17 (80.9)	4 (19.0)	1.0	Ref	
Chest RT increases BC risk‡					
Correct knowledge					
Intervention	75 (78.1)	21 (21.9)	1.0	0.5 to 2.0	.97
Control	32 (78.0)	9 (21.9)	1.0	Ref	
Incorrect knowledge					1.00
Intervention	15 (93.7)	1 (6.2)	1.0	0.3 to 5.4	
Control	20 (100.0)	0 (0.0)	1.0	Ref	

Abbreviations: BC breast cancer; HS, high school; MRI, magnetic resonance imaging; Ref, reference; RT, radiotherapy; RR, relative risk.

*Poisson regression model with an indicator for treatment group, moderator variable, and its interaction. The model is also adjusted for stratification factor age at random assignment and race/ethnicity.

†At baseline enrollment in the EMPOWER study.

‡At 12 months.