Why do breast cancer survivors decline a couple-based intimacy enhancement intervention trial?

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Abstract

Recruitment challenges hinder behavioral intervention research in cancer survivors. The purpose was to examine the reasons for declining and intervention preferences of study-eligible breast cancer survivors declining a trial of a four-session couple-based Intimacy Enhancement intervention (refusers) and explore whether refusers differed from participants on key characteristics. Partnered, post-treatment breast cancer survivors reporting sexual concerns who were eligible for but declined participation in the intervention trial were approached to complete a standardized 5-min telephone survey assessing reasons for declining and support preferences. Demographic, clinical, and sexual concerns information were collected during screening. Trial participants and refusers were compared on key variables of age, race, hormone therapy use, time since treatment, level of sexual concerns, and recruitment method using *t*-tests or chi-square tests. Among the 31 women who declined the trial and completed the survey, the most common reasons for declining were time commitment (74%) and partner noninterest (32%). Most (61%) reported that the telephone format played little to no role in their refusal. Eighty-one percent wanted their partners involved in a program addressing sexual concerns. The two most preferred resources were informational websites (45%) and meeting with a professional (26%). Trial participants and refusers did not differ on any key factors examined. Developing intimacy interventions that are very brief, partner-optional, or that use stepped care may bolster uptake. The methods used to examine study-eligible candidates' needs and preferences could be employed in other health populations, thus having broader implications for research design.

Keywords

Breast neoplasms, Couples therapy, Interventions, Sexuality

INTRODUCTION

Recruiting cancer survivors to studies of behavioral interventions is challenging [1]; these challenges are often amplified when recruiting to studies of interventions that are couple-based [2] or that focus on sexuality [3]. Given the key role of the intimate relationship in breast cancer survivors' sexual experiences [4–8], a couple-based intervention that systematically involves the partner may be a highly effective approach for addressing these concerns. Yet a trial of a couple-based intervention focusing on sexuality could encounter considerable recruitment challenges both in requiring the participation

of survivors and their partners and in dealing with a

Implications

Practice: Although couple-based interventions appeal to many breast cancer survivors who have sexual problems, interventions that are very brief, partner-optional, and use stepped care could enhance uptake.

Policy: Funding is needed for studies that examine multiple approaches to delivering evidence-based interventions for addressing sexual problems in cancer survivors.

Research: Future research could use similar methods to examine the needs and preferences of study-eligible candidates for other health issues and populations and thereby inform the design of behavioral intervention research broadly.

highly sensitive topic. With this in mind, in designing a recent pilot trial of a couple-based intervention addressing breast cancer survivors' sexual concerns [9], we planned a substudy focused on understanding the needs and preferences of study-eligible survivors who, despite their eligibility, declined to participate. We surmised that the findings of this substudy could have broader research implications by informing the development of behavioral intervention trials in cancer.

The objectives of the present study, which comprises a substudy of the separate pilot trial [9], were thus to examine reasons for nonparticipation and identify preferences for sexual support for breast cancer survivors who were study-eligible but declined participation. The intervention tested in the pilot trial was a four-session couple-based intervention delivered via telephone called Intimacy Enhancement (IE). The IE intervention was designed to address women's sexual concerns and enhance their relationship intimacy through education and couples' skills training [9, 10] and was compared in the trial against an active educational condition

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equating for therapist time and attention [9]. In the present study, we were particularly interested in identifying potential features of the IE intervention that could be modified, such as partner involvement, delivery format, and intervention length. Given that study-eligible refusers reported sexual concerns during screening yet declined to participate, we also examined the preferences of this group for sexual support: were they likely to seek help elsewhere, and if so, what support would they prefer? Finally, to understand whether certain features of the study population were associated with declining, we compared trial refusers with those who accepted (participants) on key characteristics such as sociodemographic or clinical factors, method of recruitment, and level of sexual concerns.

METHODS

Participants

To participate in the survey study, women had to meet eligibility for but decline the IE intervention trial. Adult female breast cancer survivors were eligible if they lived with a romantic partner for ≥ 6 months, had nonrecurrent Stage I–III breast cancer for which they had completed acute treatment 6 months–5 years ago (use of endocrine therapy was acceptable), and reported sexual concerns, denoted by a score ≥ 3 (range 0–10) on an item adapted from the Patient Care Monitor for breast cancer [9, 11]. Women were excluded if they had a history of any cancer other than non-melanoma skin cancer, an ECOG performance score > 2 [12] or were too ill to participate, for overt cognitive dysfunction or psychiatric disturbance, pregnancy, current participation in couple therapy, or if the patient or partner had a hearing impairment or could not speak English. No exclusions were made for sexual orientation.

Procedures

All study procedures were approved by the Institutional Review Board at Fox Chase Cancer Center (IRB # 15–8007). Women who screened eligible for the randomized controlled pilot trial of the four-session IE intervention, described in detail elsewhere [9], but declined participation were offered the opportunity to participate in a separate survey study by the recruiter. Oral consent and the survey were completed via telephone usually within the same phone call. Women received a \$10 gift card in the mail for participating.

Measures

Sociodemographic and clinical information including age, age at diagnosis, partner age, engagement in marital therapy, past cancer diagnoses, metastatic disease status, treatments obtained, and current status were obtained verbally during trial screening.

With patients' permission, disease stage and length of time since acute treatment ended were confirmed by checking patients' medical records. Sexual concerns were assessed using the sexual concerns screening item described above. Women's race and ethnicity were asked in the oral survey, described next. Reasons for nonparticipation and support preferences were assessed through a 6-item standardized survey using questions developed for this study through review of recruitment literature and review of study team experts (see [Supplementary Material](#)). To maximize acceptance, the survey was designed to be focused and brief.

Statistical analysis

Study sample characteristics were first analyzed descriptively. Then, those who refused versus consented to the trial were compared on demographic and clinical variables (age; age at diagnosis; race, dichotomized as White versus non-White; current use of hormonal therapy; length of time since treatment completion in months), and sexual concerns using independent samples *t*-tests or chi-square tests, as appropriate. Responses on survey items using a 0–10 scale were categorized: 0 = no/not at all; 1–3 = a little bit; 4–6 = somewhat; 7–10 = very/very much.

RESULTS

Characteristics of trial refusers

The study flow diagram is shown in [Fig. 1](#). Data on the flow of the randomized pilot trial itself are described elsewhere [9]. Briefly, of the 91 eligible survivors, 31 enrolled in the trial and 40 declined; 18 were eligible and did not outright decline, but could not be reached for follow-up. Of 35 refusers approached for the survey study, 31 (89%) agreed. Five trial refusers could not be approached for the developmental survey because they declined via voicemail messages and did not return the recruiter's calls. Data are described for trial refusers who completed the survey. Their mean age was 55.8 ($SD = 8.7$). The majority were white (87.1%) and non-Hispanic or Latina (93.5%). Most had a diagnosis of either Stage I or II breast cancer (83.9%) and were taking hormonal therapy (80.6%). The mean length of time since treatment completion was 29.9 months ($SD = 16.0$), and the mean sexual concerns score was 6.5 ($SD = 2.1$). No significant differences were found between these refusers and study participants in age, race, stage of disease, hormone therapy use, or level of sexual concerns ($p \geq .11$). The same percentage of refusers and participants were recruited through mailings (84%) as via the clinic. We also examined whether trial refusers who agreed to complete the survey would differ from those who did not complete the survey ($n = 27$); no differences were seen in

Fig 1 | Study flow diagram

age, stage of disease, hormone therapy use, level of sexual concerns, or method of recruitment ($p > .11$).

Reasons for nonparticipation

As shown in Table 1, the most common reason given for declining was time commitment/scheduling difficulties, followed by a perceived lack of partner interest or willingness, topic too personal, and uncertainty about the study or its usefulness. More than half of the refusers reported that the telephone-based nature of the program did not factor at all in their decision not to participate versus just over one third of the sample who reported that the telephone format factored “very much” into this decision.

Likelihood of seeking help, and support preferences

The vast majority (90%) reported wanting their partners included in a program addressing sexual or intimacy concerns at least “a little bit” (see Table 1); over half (55%) wanted their partners involved either “quite a bit” or “very much,” and 10% did not want their partner involved at all. The majority reported that they were at least “a little bit” likely to seek help for sexual or intimacy concerns elsewhere; however, almost 40% reported being “not likely at all” to do so. The most commonly desired source for help was a gynecologist, followed by a psychologist/mental health professional. Less common responses included oncologists and primary care clinicians

(PCPs). The most appealing sources of information were an informational website, followed by meeting one-on-one with a professional. The least appealing sources were a support group and written materials. Most refusers wanted a one-on-one program addressing sexual/intimacy concerns to be delivered by a social worker/psychologist or gynecologist, followed by nurse, another breast cancer survivor, oncologist, or a PCP.

DISCUSSION

Findings of the study indicated that survivors who declined the IE intervention did not differ from those who agreed to participate in key sociodemographic, clinical, or recruitment factors, or in sexual concerns. Rather, time commitment or scheduling difficulties emerged as the most commonly cited reason for declining the study, followed by partner participation. This is notable in light of several features of the IE intervention, including its brevity (it consisted of four hour-long sessions) and its telephone delivery, eliminating the burden of travel. For breast cancer survivors with sexual concerns who face significant time limitations, either a very brief (i.e., one-session) intervention or a stepped care approach may be critical elements to further reduce time as a barrier to seeking assistance.

It is also possible that some survivors may have had sexual problems that fell below a critical threshold of bother to warrant the study’s time commitment.

Table 1 | Survey responses from trial refusers ($N = 31$)

Item	N (%)
What are some of the reasons you are not interested in participating in the program? (multiple responses allowed)	
Too much of a time commitment/scheduling difficulties	23 (74.2)
Partner unwilling or uninterested	10 (32.3)
Topic too personal/not ready to address these issues	4 (12.9)
Unsure what study is about/did not think it would be useful	2 (6.5)
Other—(want a psychologist to deliver the intervention, not enough incentive)	2 (6.5)
How much did the telephone-based nature of the program figure in to your decision not to participate, if at all?	
0 (not at all)	16 (51.6)
1–3	3 (9.7)
4–6	2 (6.5)
7–10 (very much)	10 (32.3)
How likely are you to seek help for sexual or intimacy concerns elsewhere through a different source?	
0 (not at all)	12 (38.7)
1–3	8 (25.8)
4–6	6 (19.4)
7–10 (very)	5 (16.1)
Where might you go to seek help for this? (open-ended question)	
Gynecologist	10 (32.3)
Not applicable (not interested in seeking help)	10 (32.3)
Psychologist/mental health professional	5 (16.1)
Cancer support network	2 (6.5)
Primary care clinic/physician	2 (6.5)
Which one of the following appeals to you MOST?	
Informational website	14 (45.2)
Meeting one-on-one with a professional	8 (25.8)
Written material	7 (22.6)
Support group	2 (6.5)
Which one of the following appeals to you LEAST? ^a	
Written material	13 (43.3)
Support group	13 (43.3)
Meeting one-on-one with a professional	3 (10.0)
Informational website	1 (3.3)
How much would you want your partner to be included in a program addressing sexual or intimacy concerns?	
Not at all	3 (9.7)
A little bit	3 (9.7)
Somewhat	8 (25.8)
Quite a bit	11 (35.5)
Very much	6 (19.4)
If you were to participate in a one-on-one program to address sexual/intimacy concerns, who would you want to deliver it?	
Social worker or psychologist	9 (29.0)
Gynecologist	8 (25.8)
No preference/other	5 (16.1)
Nurse	3 (9.7)
Another breast cancer survivor/peer	3 (9.7)
Oncologist	2 (6.5)
Primary care physician	1 (3.2)

^aOne data point was missing for this item, so percentages are calculated out of an N of 30.

Although refusers had similarly high sexual concerns scores as participants, almost 40% of the refusers said that they were “not at all” likely to seek help for sexual concerns, suggesting a potentially intriguing disconnect between women’s reported

level of sexual concerns and their willingness to engage in a study of a potentially helpful behavioral intervention addressing such concerns. Thus, for some breast cancer survivors with sexual concerns, these concerns may not be enough of a priority to

overcome the time burden or emotional discomfort involved in seeking help for sexual concerns and/or discussing sexuality. Moreover, some women may acknowledge having sexual concerns but may have partners who are unwilling to acknowledge or act on such concerns, complicating the prospect of seeking help. Compounding this low priority may be the relative clinical neglect of women's sexual concerns in the context of cancer care [13]: half as many women with cancer when compared with men have received information about how their treatments will affect their sexual function and communication is also rare in follow-up [14]. Though speculative, it is possible that the message that sexual health is of low importance may filter to women's own thinking, leading to a lower priority ascribed to addressing their own sexual concerns and potentially less willingness to engage sexual support.

We explored whether the need for partner participation may have been a key reason for refusal. Perceived partner unwillingness or disinterest was a reason why one third of the refusers declined the study, yet most refusers reported wanting their partners involved in addressing sexual concerns. The decision to use a couple-based approach was guided by evidence that such interventions can be effective in addressing breast cancer survivors' sexual problems [15]. These findings support a couple-based approach while also suggesting the need for survivor-only or partner-optional interventions. In future research, it would be interesting to examine whether partners' nonparticipation was due to lack of availability versus interest and whether partners might agree if approached directly.

Interesting findings also emerged with regard to the IE intervention's telephone-based format and intervention preferences. First, given that few couple-based interventions for cancer survivors have used a telephone format [6], there is little information available on whether this format poses a recruitment challenge. For most refusers, the telephone-based nature of the intervention was *not* a major reason for refusal, supporting this method of delivery for interventions for breast cancer survivors and their partners. Second, when asked about other preferred sources of information, responses were mixed, although the most appealing option was an informational website. Research-tested internet-based interventions addressing sexual concerns for cancer survivors [16, 17] hold promise for survivors who prefer this format. Third, when selecting from a list of health professionals who survivors would most want to deliver a one-on-one intervention addressing sexual concerns, the most common responses were a social worker/psychologist or a gynecologist; oncologists and PCPs were mentioned least commonly. Nevertheless, most cancer patients want sexual health to be discussed in their care [18] and clinical oncology guidelines recommend that

sexual health be discussed clinically for all patients with cancer [19].

This study has several limitations that warrant discussion. First, given that the parent study was a small pilot study, the number of refusers we were able to survey for this study was also small. However, 89% of study refusers who were approached about the survey agreed to complete it, indicating the feasibility of collecting information about reasons for study refusal in this manner. We were unable to reach a number of women who did not enroll on the trial and thus could not capture the reasons these women had for not participating. The use of mail and telephone recruitment for the trial may have contributed to our inability to survey these women. It is possible that had we approached them in person they may have been more likely to complete a brief survey even if they refused the larger trial, although this would need to be tested in a larger study. In addition, our survey assessed reasons for refusal, support preferences, and sociodemographic characteristics, whereas other factors could also be of interest to assess in relation to study refusal. For instance, some research has found that factors such as relationship satisfaction are associated with participation in couples' cancer research [20, 21]. We plan to examine such factors in a larger trial we are planning to evaluate the IE intervention.

Despite limitations, findings from this study contribute to the understanding of recruitment challenges in conducting trials of behavioral interventions with cancer survivors, with particular relevance to couple-based interventions and those addressing sexuality. Furthermore, the methods used in this study to systematically examine the needs and preferences of study-eligible candidates could be employed in trials of behavioral intervention for other health populations and of those addressing other types of health-related concerns, thus having potentially broader implications for research design.

SUPPLEMENTARY MATERIAL

Supplementary data are available at *Translational Behavioral Medicine* online.

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Compliance with Ethical Standards

Conflict of Interest: Authors Reese, Sorice, Oppenheimer, Smith, Bober, Bantug, Schwartz, and Porter declare that they have no conflicts of interest to report.

Authors' Contributions: All authors were involved in the preparation of this manuscript and read and approved the final version.

Ethical Approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration

and its later amendments or comparable ethical standards.

Informed Consent: Informed consent was obtained from all individual participants included in the study.

Welfare of Animals: This article does not contain any studies with animals performed by any of the authors.

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