Recruitment and Retention Challenges in Breast Cancer Survivorship Research: Results from a Multisite, Randomized Intervention Trial in Women with Early Stage Breast Cancer

Sharon R. Sears, Annette L. Stanton, Lorna Kwan, Janice L. Krupnick, Julia H. Rowland, Beth E. Meyerowitz, and Patricia A. Ganz

Department of Psychology, University of California, Los Angeles, Los Angeles, California 90095-1563 [A. L. S.]; Department of Psychology, University of Kansas, Lawrence, Kansas 66045 [S. R. S.]; University of California Los Angeles, Division of Cancer Prevention and Control Research, School of Public Health and Jonsson Comprehensive Cancer Center, Los Angeles, CA 90095-6900 [L. K., P. A. G.]; Georgetown University Medical Center, Department of Psychiatry, Washington, DC 20007-2197 [J. L. K.]; Office of Cancer Survivorship, National Cancer Institute, Rockville, Maryland 20852 [J. H. R.]; and Department of Psychology, University of Southern California, Los Angeles, California 90089-1061 [B. E. M.]

Abstract

The Moving Beyond Cancer trial is a multisite randomized, controlled trial of an individualized psychoeducational intervention for women with early stage breast cancer. Recruitment early in the cancer trajectory and assessment of retention at multiple points are notable features of the research, offering a unique opportunity to examine recruitment, retention, and predictors of participation. Patients were registered for the study within 6 weeks after definitive surgery and followed until primary medical treatment completion, whereupon they were enrolled, administered baseline measures, and randomized to one of three arms. Of 2242 women referred, 41% were ineligible. Of eligible women, 42% elected participation through the point of randomization (n = 558). Participants did not differ from nonparticipants on initial self-reported physical functioning and mental health status, employment status, cancer history, cancer treatment plan, or previous cancer-related research participation. Women who were over 65 years of age, of racial minority status, unmarried, or less educated were less likely to participate through the point of randomization. Thus, several patient characteristics predicted trial participation, indicating the need for targeted recruitment attempts.

Introduction

Recruitment and retention of participants present a challenge for medical and behavioral intervention trials. Reports of the recruitment process in RCTs often are incomplete (1, 2) and fail to compare retained and dropped participants on demographic and psychosocial characteristics, a practice that would yield information regarding generalizability of findings. In this report, we describe prospective data collection on participant recruitment and retention in the Moving Beyond Cancer trial, a multisite RCT of an individualized psychoeducational intervention for women with early stage breast cancer. This trial required early identification of potential participants to deliver the intervention soon after treatment completion. Our goals were to identify characteristics of women likely to enroll in the trial, and to examine medical, demographic, and quality of life variables as predictors of retention.

Materials and Methods

Researchers at UCLA coordinated the trial; other sites were DC and KS. Investigators at each site contacted 22 medical treatment centers to request patient referrals; 16 provided them (UCLA, n = 8; DC, n = 5; and KS, n = 3). IRB approval was obtained from all of the institutions.

Referral. Research staff provided medical personnel with written information on participant eligibility criteria. Referral sites were asked to provide contact information (i.e., name, address, and phone number) for consecutive, eligible patients within 5 weeks after definitive surgery for breast cancer. Referral mechanisms varied across centers, and included physicians, nurses, administrative assistants, and research staff obtaining patient contact and eligibility information by confidential fax, phone, and pathology reports. Research staff regularly reminded medical personnel to provide referrals.

Registration. Research staff mailed an introductory letter to women under the letterhead and signature of the referring physician between 1 and 5 weeks after surgery, and called women for registration 2–6 weeks after surgery. Women were considered “passive refusers” if research staff was unable to reach them after at least 3 telephone call attempts and messages within 6 weeks of surgery (3 attempts with messages was the maximum allowed by the IRB of one institution). To increase the chance of contact, calls occurred on different days of the week at different times of day. Registration began in 1999 and continued through December of 2001.

During the call, research staff invited the woman to con-

1 The abbreviations used are: RCT, randomized, controlled trial; UCLA, University of California, Los Angeles; DC, Georgetown University; KS, University of Kansas; IRB, Institutional Review Board; DCIS, ductal carcinoma in situ; LCIS, lobular carcinoma in situ.
consider registering for a study that was “examining the transition women go through as they complete their active treatments for breast cancer” and asked if she might consider participating at treatment completion. If she was not interested, we were unable to collect any additional data per an IRB ruling.

At registration and other contact points (enrollment and randomization), eligibility was determined based on diagnostic-related, treatment-related, logistic, and other criteria. Diagnosis-related eligibility included having a first diagnosis of Stage I or II invasive breast cancer (no DCIS/LCIS, inflammatory, or metastatic disease). Treatment-related eligibility included having no prior adjuvant treatment for another cancer, no neoadjuvant chemotherapy, no more than one completed chemotherapy cycle, and no planned bone marrow/stem cell transplant. Regarding logistics, women were eligible if they had undergone primary surgery within the past 6 weeks at registration, lived within 1 h of the treatment center, could read/write English, would complete medical treatment by the end of trial enrollment, and were not participating in other quality of life research or genetic testing. Other eligibility criteria included being female and having no apparent psychosis/serious mental disturbance; this category also included ineligible patients for whom the reason inadvertently was not recorded. For eligible women, staff obtained demographic, treatment plan, and quality of life data (Physical Functioning and Mental Health sub-scales of the MOS-SF-36; Refs. 3, 4) and mailed a study information brochure. High scores on the 10-item Physical Functioning scale indicate self-reported ability to perform “physical activities including the most vigorous without limitations because of health” (p. 3-5; Ref. 4). High scores on the five-item Mental Health scale reflect feeling peaceful, happy, and calm, and not nervous or blue (4).

Enrollment and Baseline Assessment. Women who underwent only surgery proceeded directly to study enrollment at the end of the registration call. For women planning adjuvant medical treatment, staff called the patient periodically until she completed medical treatment and then proceeded with enrollment. Only women who had completed medical treatment within approximately the past month were eligible. Multiple enrollment call attempts were conducted (e.g., 3-10). During the call, staff described the full study.

Women who agreed to enroll were asked to complete and return the informed consent form and baseline questionnaire by mail. Reminder calls were initiated if the questionnaire was not received within 2 weeks. Those who did not return the baseline questionnaire within 1 month of enrollment were considered passive refusers.

Randomization. Eligible women who returned the baseline questionnaires were immediately randomized. From July 1999 to July 2002, randomization was performed by the coordinating center at UCLA, stratified by study center, whether the woman received chemotherapy, and whether she was married/in committed relationship. Participants were randomized to receive: (a) standard written information (National Cancer Institute publication “Facing Forward”; Ref. 5); (b) “Facing Forward” plus videotape that modeled approach-oriented coping (e.g., active acceptance and problem-solving) and provided information about what to expect in the transition from patient to survivor; or (c) “Facing Forward,” videotape, and manual-guided educational sessions (one in-person session and one phone follow-up call) with a trained cancer educator, and an in-depth written resource guide/workbook. In the sessions, women reviewed their cancer-related concerns, identified a primary concern, and developed an approach-oriented action plan. Interventions were delivered within ~2 weeks of randomization.

Analyses. We describe eligibility, refusal, and participation at each recruitment point through randomization. We then use demographic (i.e., age, race, marital status, education, and employment status), medical (i.e., surgery type, treatment plan, additional serious medical problems, previous cancer, and previous research participation), and SF-36 data collected at registration to predict willingness to participate at enrollment and randomization. Because the IRB prohibited data collection with women not willing to register, we were unable to predict willingness to participate at registration. We conducted analyses with backward stepwise logistic regression, including all of the predictors in initial models. Several predictors were dichotomized for analysis (see Table 3). Final models included variables that met the $P < 0.05$ significance level.

Results

Description of Participation and Sample Characteristics. Medical personnel provided a total of 2242 referrals over ~30 months. Of these, 41% ($n = 928$) were deemed ineligible before randomization. Reasons for ineligibility were 29% diagnosis-related (e.g., metastatic disease), 13% treatment-related (e.g., neoadjuvant treatment), 48% logistic (e.g., surgery >4 weeks before registration), and 9% other (e.g., male). Of 1314 eligible women, 58% ($n = 756$) were active or passive refusers. Table 1 displays participant reasons for refusal across recruitment periods. Of refusals, the majority (56%) were passive (i.e., unreachable by phone or did not complete baseline questionnaire within 1 month). Patterns of reasons for study refusal were relatively consistent across recruitment points, although being unreachable by phone was a particularly frequent (54%) reason for refusal at registration, and not returning the baseline questionnaire accounted for the majority of refusals (82%) at randomization.

Of eligible women, 42% ($n = 558$) participated through randomization. Table 2 displays characteristics of consenting participants. At registration, women ranged in age from 24 to 87 years. Most were white, married, and college-educated. Most received breast-conserving surgery and adjuvant therapy. Women reported SF-36 Physical Functioning similar to and Mental Health slightly below general population norms for United States females (Physical Functioning $M = 82.86$ for women aged 45–54 and 73.09 for women aged 55–62; Mental Health $M = 74.36$ for women aged 45–54 and 73.40 for women aged 55–64; Ref. 4).

Predictors of Trial Participation. Initial $\chi^2$ analyses were conducted to assess whether the sites differed in participant

<table>
<thead>
<tr>
<th>Reason</th>
<th>$n$</th>
<th>%</th>
</tr>
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<tbody>
<tr>
<td>Unreachable by telephone</td>
<td>305</td>
<td>40</td>
</tr>
<tr>
<td>Did not return baseline questionnaire in 1 month</td>
<td>121</td>
<td>16</td>
</tr>
<tr>
<td>Not interested</td>
<td>108</td>
<td>14</td>
</tr>
<tr>
<td>Too busy</td>
<td>65</td>
<td>9</td>
</tr>
<tr>
<td>Other</td>
<td>61</td>
<td>8</td>
</tr>
<tr>
<td>Too personal/stressful</td>
<td>49</td>
<td>6</td>
</tr>
<tr>
<td>Unwilling/unable to travel</td>
<td>31</td>
<td>4</td>
</tr>
<tr>
<td>Too sick</td>
<td>16</td>
<td>2</td>
</tr>
</tbody>
</table>

Table 1 Reasons for refusal across recruitment periods ($n = 756$)

Women were considered to be passive refusers if the research staff was unable to contact them by phone or if they did not return the baseline questionnaire within 1 month.
retention. Only analyses for race (P < 0.01) and education (P < 0.05) were significant. KS (31%) and UCLA (34%) had lower attrition of African American and other minority women at enrollment than did DC (62%). KS (16%) had lower attrition of women with less than a college education at enrollment than did UCLA (31%) or DC (28%).

Table 3 displays results of logistic regressions. Dependent variables were refusal versus consent to enroll, and participation in randomization versus nonparticipation (including all of the women eligible at enrollment less women ineligible at randomization). First, logistic regression analyses revealed that age, minority status, and marital status predicted refusal (n = 195) versus consent (n = 714) to enroll. Women who were >65 years of age, of minority status, or not married were less likely to enroll than were women <65 years, white, or married (ORs, 1.9, 3.5, and 1.6, respectively).

Minority status and education predicted refusal (n = 195 + 148 = 343) versus participation (n = 558) in randomization among all of the women eligible at enrollment. Minority women or those with less than a college degree were less likely to continue through randomization (OR, 2.9 and 1.9, respectively) than were white women or women with at least a college degree.

Discussion
Of all women referred to this psychoeducational RCT for women with breast cancer, 41% were ineligible. This high rate results in large part from registration occurring early in the cancer trajectory. Early identification of women was a unique strength of the trial, allowing us to collect mental and physical health data before adjuvant treatment and to recruit women whose treatment included only surgery. However, it resulted in a short period within which to obtain referrals. Medical personnel were asked to provide referrals within 5 weeks after surgery, and, hence, it is not surprising that the primary reason for ineligibility at registration was receiving the referral too late. Furthermore, ~200 women were ineligible because they had DCIS/LCIS or received neoadjuvant therapy. The reentry transition of these groups requires empirical attention.
Recruitment in Cancer Survivorship Research

Table 3 Predictors of nonparticipation at enrollment and randomization

<table>
<thead>
<tr>
<th>Predictor</th>
<th>ENR OR (95% CI)</th>
<th>RAND OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>1.8 (1.3, 2.8)</td>
<td>—</td>
</tr>
<tr>
<td>Race</td>
<td>3.5 (2.5, 5.1)</td>
<td>2.9 (2.1, 4.0)</td>
</tr>
<tr>
<td>Marital status</td>
<td>1.6 (1.1, 2.3)</td>
<td>—</td>
</tr>
<tr>
<td>Education</td>
<td>—</td>
<td>1.9 (1.4, 2.5)</td>
</tr>
</tbody>
</table>

a Among those who refused (n = 195) versus consented (n = 714) at enrollment.

b Among all eligible women who entered less eligible women at randomization, those who refused (n = 343) versus participated in randomization (n = 558).

Of eligible women, 42% elected participation through randomization, a figure like that reported for an RCT of a group intervention for women with metastatic cancer (2). Psychosocial RCTs for women with breast cancer do not routinely include a detailed description of the recruitment process (6), or they use procedures in which women call the researcher to indicate interest in the study (7), rendering comparisons of randomization rates across studies difficult. The majority of refusals were “passive:” women either were unreachable after multiple call attempts or did not return baseline questionnaires after reminders. The three maximum call attempts with messages for registration allowed by the IRB of one institution may have inflated the “passive” refusal rate. Nonetheless, attempts to contact potential participants considered considerable staff time, costs for which should be factored in to RCT design and funding. Accrual of large (n > 500) samples for intervention trials may best be conducted through collaborative efforts across sites. Whether in-person, on-site recruitment at medical facilities is more effective and cost-efficient than mail and phone recruitment requires study.

Women who were >65 years of age, from minority backgrounds, unmarried, and less educated were less likely to participate at enrollment and/or randomization. Women from minority ethnic backgrounds comprised 24% and 15% of the registration and randomization samples, respectively. The findings for age (8), ethnic background (9–12), and education (6) are consistent with previous research in medical and psychosocial clinical trials for cancer and other diseases. They contrast with the Helgeson et al. (6) finding that women who refused randomization in that trial were more likely (rather than less likely) to be married, perhaps reflecting the low perceived need by married women for a group intervention format or less flexibility in their schedules to accommodate a fixed meeting time in that trial.

Although recruiting and retaining individuals from diverse demographic backgrounds remained a challenge in this trial, these rates compare favorably with those for another large RCT of a psychosocial intervention (6). Shavers et al. (12) offer strategies for retaining individuals from under-represented populations, such as acknowledging under-representation in research and discussing specific plans to assure participant protection. Providing transportation, childcare, and flexible appointment times also may bolster participation.

Employment status, participation in previous research, cancer history, cancer treatment plan, and quality of life indicators did not predict participation or retention. The finding that quality of life indicators did not predict recruitment or retention is particularly noteworthy. If the most distressed or physically challenged individuals refuse RCT participation, trialists do not have the opportunity to intervene with those who may be most likely to benefit. Because an IRB ruling precluded gathering data from women who initially declined study registration, generalizability is limited to those who were receptive to considering research participation.

Although we cannot systematically examine the effectiveness of our recruitment strategies, we believe that establishing several treatment centers with many referring physicians and sending participants an introductory letter under the letterhead of the physician communicated endorsement by the physician of the research and, thus, promoted recruitment. Given that referring practices were busy, and research was not a top priority, furnishing medical personnel with written information on eligibility criteria and maintaining close contact with them also appeared helpful. On-site, in person recruitment might have enabled even more effective recruitment early in the cancer trajectory, although it also might have been more costly. Our findings indicate that, depending on eligibility criteria as well as the nature and timing of the intervention, researchers testing psychoeducational interventions may need to anticipate and figure in to trial expenses the need to screen two to four times as many individuals as required to attain the targeted sample size. Certainly, methods to promote the most efficient and successful recruitment procedures for psychosocial clinical trials require additional empirical consideration.

References


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