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A pilot randomized controlled trial testing a minimal intervention to prepare breast cancer survivors for recovery

Dr Katherine Regan Sterba, PhD, MPH, Mr Kent Armeson, MS, Ms Regina Franco, NP, Dr Jennifer Harper, MD, Ms Rebecca Patten, BS, Ms Stacey Kindall, MPH, Dr James Bearden, MD, and Dr Jane Zapka, ScD

Department of Public Health Sciences, Medical University of South Carolina, Charleston, South Carolina (Drs Sterba and Zapka, Mr Armeson and Ms Patten); Greenville Health System Cancer Institute, Greenville, South Carolina (Ms Franco); Department of Radiation Oncology, Medical University of South Carolina, Charleston, South Carolina (Dr Harper); Gibbs Cancer Center, Spartanburg Regional Healthcare System, Spartanburg, South Carolina (Dr Bearden and Ms Kindall)

Abstract

Background—Interventions addressing cancer survivors' post-treatment concerns can be time-intensive and require specialized staff. Research is needed to identify feasible minimal intervention strategies to improve survivors' quality of life after treatment.

Objectives—The objectives of this study were to evaluate the feasibility and short-term impact of a minimal clinic intervention on breast cancer survivors' quality of life, unmet needs, distress and cancer worry.

Interventions/Methods—In this randomized controlled pilot trial, we enrolled breast cancer survivors at the end of treatment and administered baseline surveys. Participants were randomized to study arm (4-week video plus educational booklet intervention group and usual care group) and completed follow-up surveys at 10 weeks. Linear regression was used to examine intervention effects on quality of life outcomes controlling for clinical and demographic factors. Open-ended questions were used to examine program satisfaction and obtain feedback to improve the intervention.

Results—We enrolled 92 survivors in the trial. Participants rated the intervention highly and reported feeling less isolated and having more realistic expectations about their recovery after completing the program. Despite positive qualitative findings, no significant intervention effects were observed for quality of life, unmet needs, distress or cancer worry in unadjusted or adjusted analyses.

Conclusions—Future research is needed to define optimal intervention elements to prepare breast cancer survivors for the post-treatment period.

Correspondence: Katherine Regan Sterba, PhD, MPH, Department of Public Health Sciences, Medical University of South Carolina, MSC 955, Charleston, SC USA, (sterba@musc.edu).

Conflicts of Interest

The authors have no conflicts of interest to disclose.

Implications for Practice—Effective survivorship interventions may require more intensive components such as clinical input and longer follow-up periods.

Keywords

Breast cancer; survivorship; quality of life; intervention

Introduction

Advances in early detection and treatment for breast cancer have led to improved survival and a growing priority to advance our understanding of long-term survivorship needs.^{1,2} Breast cancer survivors comprise 22% of all cancer survivors and approximately 2.5 million breast cancer survivors were living in the United States in 2012.³ The post-treatment effects of breast cancer can be considerable and include physical (e.g., fatigue, pain), psychological (e.g., fear of recurrence, body image concerns), social (e.g., communication) and spiritual challenges.^{1,4–10} Research has pinpointed the transition from primary treatment to the post-treatment period as especially challenging¹¹ highlighting the importance of identifying feasible, cost-effective intervention strategies. Addressing long-term survivorship concerns early in a patient's cancer care may set the stage for improved clinical and psychosocial outcomes over time.

As the field of cancer survivorship research grows, we are learning more about interventions focused on the transition after treatment completion.¹¹ One key randomized, controlled trial showed that an educational video improved breast cancer survivors' vitality at 6-month follow-up, especially in women who felt unprepared for the end of treatment.¹² Other interventions have focused on promoting healthy behaviors such as improved diet, physical activity and smoking cessation,^{13–15} seeking to capitalize on the teachable moment provided by the cancer diagnosis.^{16,17} Finally, an emerging area of research is focused on survivorship care planning interventions as a way to promote care coordination, but few trials have been published to date.^{18,19}

Many of the survivorship interventions that have been tested are resource-intensive. Key challenges to implementation, for example, can include time and the need for staff with special clinical skills.²⁰ Few survivorship-focused interventions have been implemented during treatment when oncology staffing resources are still in place. Introducing survivorship topics at the end of treatment may be particularly beneficial because this transition^{16,17} offers the opportunity to improve understanding of evidence-based follow-up care guidelines and lifestyle modification recommendations,²¹ to provide guidance concerning physical and emotional well-being and to prepare survivors to initiate discussions with their health care providers. As we seek to identify strategies to improve long-term outcomes in breast cancer survivors, we need to consider creative, feasible, cost-effective ways to incorporate survivorship interventions into the clinic at the end of treatment.

In the current pilot research, we tested a minimal intervention at the end of adjuvant therapy to prepare breast cancer survivors for the next phase of their cancer experience. The objectives of this study were to evaluate the feasibility of implementing a 4-week

educational intervention and to examine the potential impact of the intervention on quality of life (QOL), unmet needs, distress and cancer worry in South Carolina breast cancer survivors at the transition from primary treatment to the post-treatment phase. We adapted existing, tested educational resources^{12,22} for our target population and changed the delivery style to meet the needs and preferences of South Carolina breast cancer survivors. We hypothesized that women receiving the intervention would have better QOL, fewer unmet needs and lower distress and cancer worry at follow-up when compared to women receiving usual care. In this pilot work, we focused on short-term psychological factors important to survivors at the end of treatment^{1,11} and also examined participants' satisfaction with program elements and suggestions for use in improving and expanding the program in the future.

Methods

Setting and study participants

Women with stage I, II and III breast cancer at two regional cancer centers in the southeastern United States were identified using administrative clinic databases. Potential participants were approached in the clinic and provided with written study information during routine treatment appointments from July 2011 to March 2012. Participants were recruited 2–3 weeks before completing radiation therapy following a protocol approved by the Institutional Review Boards of participating cancer centers. We excluded women with stage IV cancer and those with a prior cancer due to the significantly different treatment and follow-up care experiences in these groups.²¹ Interested participants signed informed consent and Health Insurance Portability and Accountability Act (HIPAA) forms at study enrollment and were mailed giftcards upon completion of study activities to thank them for their study efforts. Study recruitment, data collection and intervention activities are outlined in Figure 1.

Study design and data collection

After a developmental period with input from breast cancer survivors to adapt and refine the intervention materials and delivery, we used a two-arm randomized controlled trial design to test the impact of the intervention on short-term outcomes. Enrolled participants completed a baseline survey by telephone or in person and were randomized to the intervention or usual care group; randomization at each site was stratified by age (< 50 or >50) and race (white or non-white). All participants completed a mailed or telephone follow-up survey 10 weeks from the end of treatment date. Intervention group participants also completed a telephone process evaluation during the intervention as well as an additional section in the follow-up survey to provide feedback on the intervention. Usual care group participants received a delayed mailed intervention.

Video and print booklet intervention

The intervention consisted of two components, an in-person video session at the cancer care site and weekly mailings of educational booklets for three weeks. All study activities were delivered by research staff at each center who completed a one-day in-person training session and participated in weekly meetings during the course of the project. In a private

study room at each clinic, research staff introduced the National Cancer Institute video “Moving Beyond Breast Cancer” (<http://www.cancer.gov/cancertopics/coping/survivorship/beyond-cancer-video>)¹² using a structured script describing the purpose and goals of the video. Next, the study participant and research staff watched the 23-minute video together. This video observes four diverse breast cancer survivors as they complete breast cancer treatment. The video includes a module on physical, emotional and interpersonal concerns, as well as life changes. Following the video, using a scripted protocol, the participant was encouraged to think about and discuss her own worries or concerns about completing treatment, given the video to take home and provided with brief print materials with local support resources.

Following this session, each participant received a weekly mailer for 3 weeks with printed educational booklets reinforcing messages in the video. Booklets were adapted from the National Cancer Institute’s Facing Forward: Life after Cancer Treatment resource guide (NIH Publication 10-2424).^{22,23} This 61-page booklet for survivors of various cancer types has demonstrated a beneficial impact on stress management behaviors and increased attendance at support groups for breast, colorectal, thoracic and prostate cancer survivors.²² We adapted this booklet to develop three 12–14 page educational booklets focused on breast cancer for a lower literacy population but maintaining much of the same content, format and quotes with additional content adapted with permission from materials from the American Cancer Society²⁴ and Living Beyond Breast Cancer.²⁵ Some of the original information was adapted slightly so the messages were delivered from the perspectives of peer breast cancer survivors. Research shows that women often report desiring to talk with someone who has been through cancer.²⁶ This mentoring approach is grounded in Social Learning Theory²⁷ and relies on the provision of encouragement and advice from survivors who have first-hand knowledge of the challenges patients experience.²⁸ After drafting the adapted booklets, we convened advisory groups comprised of breast cancer survivors at both cancer centers (n=10 at each site) who had completed treatment for breast cancer within the past 2 years with diverse demographic and clinical characteristics to review and provide feedback about the intervention delivery and educational booklets. Table 1 highlights themes from this process that resulted in finalized intervention protocol and educational booklets.

Trial measures

Outcome variables—Cancer-specific quality of life (physical, functional, emotional, social) was assessed at baseline and follow-up using the Functional Assessment of Cancer Therapy general and breast cancer modules.^{29,30} After reverse scoring negative items, a summary score was calculated for overall and breast cancer-specific QOL with higher scores reflecting higher QOL. Cronbach’s alphas in the current study sample were 0.92 for overall and 0.69 for breast cancer-specific QOL at baseline.

Unmet needs were assessed at baseline and follow-up using an adapted version of the Cancer Survivors Unmet Needs instrument.³¹ After pilot testing the instrument with staff and volunteers, we modified the wording of several items and the response options. Respondents rated 30 items concerning whether they currently needed help with

comprehensive care, information, QOL, existential survivorship and relationship issues (yes or no). Total number of unmet needs was calculated.

Distress was assessed at baseline and follow-up using the National Comprehensive Cancer Network Distress Thermometer.^{32,33} Participants viewed a thermometer that illustrated distress levels ranging from 0 (no distress) to 10 (extreme distress) and were asked to select the number that best represented their current distress.

Cancer worry was assessed at baseline and follow-up using a summary score from the 5-item Assessment of Survivor Concerns instrument.³⁴ This instrument is typically used as two subscales but because the Cronbach's alpha in the current study sample was 0.91 for one subscale, we averaged the 5 items for each participant.

Other psychosocial and symptom variables—Survivorship readiness was assessed at baseline and follow-up using two items developed in previous research¹² assessing the extent to which women felt prepared for the next phase of their breast cancer experience and the extent to which they believed their health care team had prepared them for what to expect during their recovery. These two items were averaged for a total score and Cronbach's alpha in the current study sample was 0.77 at baseline.

Symptoms were assessed at baseline and follow-up with the MD Anderson Symptom Inventory.³⁵ Participants completed 13 items rating the presence and severity of cancer-related symptoms and 6 items rating the extent to which their current symptoms interfered with aspects of their daily living. Cronbach's alphas in the current study sample were 0.92 for symptom severity and 0.93 for symptom interference at baseline.

Sociodemographic variables—We assessed age, race/ethnicity, education, and marital, employment, and insurance status at baseline.

Care variables—At follow-up, all participants were asked to report whether they had discussed survivorship issues with their health care providers, received a survivorship care plan or other survivorship materials, or sought out survivorship information or resources.

Clinical variables—Using a standardized abstraction form, data were collected from the electronic medical record at each site, including cancer site, cancer stage, date of diagnosis, previous (e.g., surgery and chemotherapy) and future (e.g., hormone therapy) treatments, family history of cancer, body mass index, smoking status and comorbid medical conditions. We also examined all care visits after the final treatment date for each participant to assess whether survivorship concerns were discussed and whether survivorship materials or resources were distributed.

Intervention process variables and program satisfaction—Using detailed tracking logs, we assessed the delivery of the intervention (length of video session and booklet reminder phone calls, whether caregivers attended the video session, what questions were asked and topics discussed at the video session and during booklet reminder calls). We assessed participants' satisfaction with the video session and educational booklets using

ratings of overall satisfaction as well as satisfaction with the extent to which the video and booklets made participants feel better emotionally and practically (1=strongly disagree to 6=strongly agree). In addition, we assessed participants' ratings of the appropriateness of the timing of the video session and educational booklets (1=strongly disagree to 6=strongly agree). Women also reported whether they watched the video again or shared it with others and whether they discussed any of the intervention materials or questions raised by the materials with their health care providers. Finally, we used open-ended questions to assess preferences concerning a future, more intensive intervention.

Data analysis

Participant characteristics were summarized and compared across the intervention and usual care groups at baseline. Age and number of comorbid health conditions were compared using a t-test and Wilcoxon rank-sum test, respectively, and counts were compared across groups using the Fishers exact test. To examine intervention effects (intervention versus usual care) on our five outcome variables at follow-up (overall and breast cancer-specific QOL, unmet needs, distress and cancer worry), we used unadjusted t-tests (or Wilcoxon rank-sum tests) and linear regression models adjusting for a variety of clinical, demographic and psychosocial factors. Covariate selection for final adjusted models were carried out through exhaustive screening (iterating through all combinations) of the candidate covariates for each model using the glmulti package^{36,37} in R v2.13.2³⁸ for each of the outcome variables independently. Interactions with time were included in the screening for those covariates measured at baseline and follow-up. The best model was defined as the one with the lowest Akaike information criteria (AIC). Also calculated was a model average importance of terms (of all models in which a term appeared), defined as the sum of the relative evidence weights, $\exp(-AIC/2)$, where AIC is the difference in AIC between a model and the best model. The final model for each outcome variable included a set of core variables (baseline level of the dependent variable, age, cancer stage, and cancer center site); the set of variables in the best (lowest AIC) model for that outcome; and the set of variables with average importance ≥ 0.8 for that outcome. The variables included in the selection process were (in addition to the core variables listed above): symptom severity (baseline and follow-up), number of unmet needs (baseline and follow-up), education, insurance status (Medicaid alone or other), race (white or other), marital status, type of surgery (lumpectomy or mastectomy), hormonal treatment (yes or no), number of comorbid health conditions, body mass index and chemotherapy receipt (yes or no).

To further examine whether intervention effects varied by demographic or cancer care factors, we explored several interaction terms in our final models (including intervention group by age, cancer center site, symptom severity, unmet needs and type of treatment). Finally, we used descriptive statistics and content analysis to explore participant use of and satisfaction with the video and educational booklets as well as preferences regarding intervention improvements.

Results

Ninety-eight potential participants were approached for the study and 92 enrolled (94%); reasons for declining included being overwhelmed (n=4) or disliking research (n=2). All participants completed baseline surveys and were randomized to the usual care or intervention groups but two participants were excluded from the data analysis because they were found to be ineligible at a later date due to having a prior cancer or being unavailable to participate in the intervention due to other health concerns. This report therefore includes 46 usual care and 44 intervention group participants at baseline; one participant from each group did not complete the follow-up survey leaving a final sample size for longitudinal analyses of 45 usual care and 43 intervention group participants.

Participants' characteristics varied widely, but did not differ significantly between the two groups for any demographic or clinical characteristics (Table 2). One-third of participants were African American and approximately half had stage I cancer. Approximately half of participants had chemotherapy while about three-fourths had hormonal therapy. There were no differences in baseline levels of overall or breast cancer-specific QOL, unmet needs, distress or cancer worry by treatment group. As shown in Table 3, higher overall and breast cancer specific QOL as well as lower unmet needs, distress and cancer worry were found in both treatment and intervention groups at follow-up.

No significant intervention effects were observed for overall or breast cancer-specific QOL, unmet needs, distress or cancer worry in unadjusted comparisons or in models controlling for sociodemographic and clinical characteristics and baseline levels of each dependent variable (Table 3). When we explored treatment group interactions with cancer center site, age, symptom severity, treatment type and unmet needs to determine whether the intervention had different effects on various subgroups, for all five models, the treatment group interaction terms were not significant ($p > .05$). Likewise, no significant group differences were found in the extent to which participants discussed survivorship issues with their health care providers, received survivorship materials, or sought out additional survivorship information or resources on their own.

Only 5 (12%) intervention group participants (N=43) brought a caregiver to the video session with them. The average length of discussion about participants' concerns about recovery after watching the video was 14 minutes (range 3–50 minutes). Several participants described feeling like they could relate to the issues the women described in the video and also brought up questions about their current symptoms and about hormonal therapy. Twenty-one percent of intervention group participants reported watching the video again at home and 35% shared the video with others.

Sixty-seven percent of intervention participants reported reading the weekly educational booklets in their entirety, while 30% read the booklets partially and 1 participant reported not reading the booklets at all. Intervention use factors (e.g., length of discussion after video, extent to which participants read educational booklets, whether participants watched video again or shared with family members) were not significantly associated with QOL but trends

in the expected direction were seen (e.g., participants who read the booklets completely versus those who read them partially or not at all reported higher QOL).

Overall, participants reported being satisfied with the program (69% excellent, 26% good, and 5% fair ratings). Participants also reported satisfaction with the timing of the video session and educational booklets (65% and 58% of participants strongly agreed that the timing of the video session and booklets was appropriate, respectively). Participants consistently rated the video and educational booklets highly; the majority of participants moderately or strongly agreed that the video (77%) and booklets (80%) made them feel prepared for the post-treatment period. Most participants also moderately or strongly agreed that the information provided in the video was helpful emotionally (82%) and practically (81%). Participants also rated the educational booklets highly; the majority of participants moderately or strongly agreed that the information provided in the booklets was helpful emotionally (83%) and practically (83%). However, only 21% of intervention participants talked to their health care providers about the intervention materials.

Responses to open-ended questions about the intervention are summarized in Table 4 with illustrative quotes. Participants reported that the intervention made them feel less isolated and helped them identify questions for their health care providers. Participants reported gaining a better understanding after completing the intervention about what to expect after finishing treatment. Few participants offered suggestions about ways to improve the program; some described preferring additional informational about nutrition and depression or having group sessions to watch the video so they could share experiences with other survivors.

Discussion

Minimal interventions are appealing due to the barriers implicit in implementing more complex, time and resource-intensive interventions in the busy cancer clinic environment. In this pilot study, we tested the short-term impact of a 4-week educational intervention on breast cancer survivors' QOL, unmet needs, distress and cancer worry. We hypothesized that the intervention would lead to beneficial short-term outcomes due to its timing and content. We delivered this intervention which required low time and staffing resources in the clinic as women were approaching the end of treatment. Thus, they were still actively receiving oncology care and the intervention aimed to activate them to start thinking about the next phase of their cancer experience and to talk to their health care providers about their concerns. We found no intervention effects on our primary outcomes of interest at 10-week follow-up. We also found no differences in the effect of the intervention on higher risk groups, including younger women, women who received chemotherapy or hormonal therapy, and those who had more unmet needs or felt less prepared for the post-treatment period. In contrast, individuals who participated in the intervention reported high satisfaction with the program, rated the timing of the intervention positively and reported feeling less isolated and more realistic about their recovery after receiving the intervention.

There may be several reasons for the discrepant qualitative and quantitative findings in this pilot intervention. It is possible that while participants reported high satisfaction with the

video and educational booklets provided in this minimal intervention, their participation was not sufficient to facilitate improvements in their QOL experiences. In particular, because the intervention was not focused directly on building self-management skills or providing clinical referrals, this may explain the lack of change in the multidimensional construct of QOL which encompasses physical, functional, emotional, social and breast cancer-specific well-being.^{4,39} For example, Social Cognitive Theory emphasizes the important concepts of self-efficacy, goal-setting, skill-building and reinforcement to adequately facilitate behavior change.²⁷ Likewise, while our intervention included repeated messages for survivors to reach out to their health care providers, our results highlight that clinicians may need to be more actively involved in the intervention delivery process to sufficiently impact women's needs and concerns.

It is also possible that outcomes other than those selected for this study were impacted by the intervention. The extent to which QOL outcomes are modifiable at the end of treatment is unknown given the physical challenges that may persist at this time.^{1,6,40} Specifically, physical concerns that may arise from hormonal therapy⁴¹ and some worries such as fear of recurrence may be expected to be stable at the end of treatment. Other outcomes emerging from participants' responses to open-ended questions included feeling less isolated and having more realistic expectations about recovery after participating in the intervention; these outcomes are distinct from health-related QOL and were not measured in this study. In addition, it is possible that the study data collection procedures impacted participants' responses in different ways across the two groups.⁴² Finally, the intervention may have impacted future outcomes that we missed by administering our follow-up survey at 10 weeks. Whether the intervention improved knowledge and this later translated to better coping outcomes is unknown based on the design of this pilot work.

Our findings are surprising in light of previous studies demonstrating positive effects from delivery of the video used in our study on breast cancer survivors' vitality¹² and the positive effects of the Facing Forward booklet from which our materials were adapted, on stress management behaviors and use of support services.²² However, both of these evaluations did involve longer follow-up periods and targeted different outcomes and these intervention delivery details and study designs may partially explain the differences in findings. While it is difficult to compare other more extensive survivorship interventions directly to the minimal intervention we tested in this study due to differences in intervention components, study questions and designs, some observations can be considered. Several more intensive psychoeducational interventions have demonstrated positive effects on QOL outcomes in breast cancer survivors. The scope and focus of these interventions have varied and included a combination of face-to-face, telephone and small group counseling^{43,44} or a combination of educational materials with telephone counseling^{45,46} with longer-term follow-up when compared to the current intervention. Other successful interventions have targeted specific behaviors such as mindfulness-based stress reduction⁴⁷ or clinician-directed interviewing and care planning.⁴⁸ This emerging survivorship intervention literature suggests that a more comprehensive intervention with a stepped delivery approach to reinforce messages, improve self-efficacy and address the dynamic nature of the recovery process may be appropriate to address survivors' needs at the end of treatment. Because breast cancer

survivors are a highly activated group,⁴⁹ a more intensive intervention may be needed simply to supplement the widely available existing resources and provider practices.

Limitations of the current pilot study include its small sample size, short follow-up period and a lack of follow-up in those who were in the usual care group receiving a delayed intervention. Despite these limitations, our study had a strong study design, was conducted at multiple clinics, included a diverse sample and used mixed methods.

Conclusions

While this minimal educational intervention was well-received by participating breast cancer survivors, no intervention effects were found at 10 weeks on participants' short-term QOL outcomes when compared to usual discharge care. Further study is needed to understand the discrepancies we found in our quantitative and qualitative findings. Relying on social science theory, a more detailed consideration of the mechanisms underlying improvements in breast cancer survivors' QOL at the end of treatment⁵⁰ is needed to inform the development of effective interventions.

Practice implications

Results from this study highlight remaining questions about clinic interventions at the end of treatment. Oncology nurses are likely to play a critical role in delivering survivorship interventions at the end of treatment and our results suggest that more intensive interventions with greater involvement of the clinical team may be important to improve short-term outcomes in survivors. This research also pointed to the importance of assessing and addressing survivors' concerns at the end of treatment and beyond. A focus on discussing women's expectations at the end of treatment and addressing concerns about isolation may be helpful as survivors transition to the post-treatment period and clinical encounters occur less frequently. Future research should test more intensive intervention elements with greater involvement of the clinical team and identify key outcome measures and follow-up periods for the study of minimal interventions to improve QOL in breast cancer survivors.

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Figure 1.
Study recruitment, data collection and intervention activities and timeline

Table 1

Advisory Group Findings and Implications for Intervention

Theme	Descriptive Quotes	Intervention Implications
<u>Confirmed interest in survivorship program:</u>		
<ul style="list-style-type: none"> Reported feeling isolated and needing support at the end of treatment 	<ul style="list-style-type: none"> "You feel a great sense of love when you go to get your chemo, to get your radiation... You just feel this connection, this kind of love. And then suddenly there is this hole." "When you're in care, you are treated like a fragile little egg; you feel so safe... then when everything is finished, they just roll you out..." 	<ul style="list-style-type: none"> Intervention messages were presented from the perspective of other survivors to make participants feel less isolated.
<u>Intervention Timing:</u>		
<ul style="list-style-type: none"> Reported wanting to hear about survivorship earlier (after surgery) 	<ul style="list-style-type: none"> "It is eye opening, and it would give me hope, to know from the beginning that I am considered a survivor." 	<ul style="list-style-type: none"> Planned to deliver intervention before the end of radiation therapy.
<u>Intervention Materials:</u>		
<ul style="list-style-type: none"> Reported that booklets should be short and include bullets, pictures and brief text. Reported that they would value personalized messages from other survivors. 	<ul style="list-style-type: none"> "Literacy is a concern; use definitions, plain language." "Very plain written things-stories from survivors could have helped me." "Add a note-taking section to the back of the booklet." "It was simple, but when I was in treatment, I needed simple. I like the personal touch in the booklets." "Each page is different, a wonderful way to keep your interest; the to-do lists are good; add color and pictures." 	<ul style="list-style-type: none"> Information was presented in three booklets by topic (emotional, physical, interpersonal concerns). Adopted reader-friendly design used with bulleted text and pictures. Used quotes from advisory group to personalize booklets.

Table 2

Participant Characteristics

	Usual Care Group (N=46)	Intervention Group (N=44)	Overall (N=90)	p value
Age, median (range)	58 (33–73)	53 (40–77)	55 (33–77)	.83
50, n (%)	16 (35)	15 (34)	31 (34)	
>50, n (%)	30 (65)	29 (66)	59 (66)	
Race, n (%)				1
African American	14 (30)	13 (30)	27 (30)	
White	32 (70)	31 (70)	63 (70)	
Marital Status, n (%)				.38
Partnered	31 (69)	26 (59)	57 (64)	
Not Partnered	14 (31)	18 (41)	32 (36)	
Unknown	1	0	1	
Education, n (%)				.50
<12 years	3 (7)	4 (9)	7 (8)	
12 years	12 (26)	7 (16)	19 (21)	
>12 years	31 (67)	33 (75)	64 (71)	
Insurance Status, n (%)				.98
Medicare Only	4 (9)	3 (7)	7 (8)	
Medicaid Only	9 (20)	7 (16)	16 (18)	
Medicare + Medicaid	1 (2)	1 (2)	2 (2)	
Private + Medicare/Medicaid	5 (11)	6 (14)	11 (12)	
Private Only	27 (59)	27 (61)	54 (60)	
Stage, n (%)				.57
I	23 (50)	24 (55)	47 (52)	
II	14 (30)	15 (34)	29 (32)	
III	9 (20)	5 (11)	14 (16)	
Comorbidities, Mean (SD)	3.4 (2.1)	2.6 (1.9)	3.0 (2.0)	.11
Chemotherapy, n (%)				.41
No	23 (50)	18 (41)	41 (46)	
Yes	23 (50)	26 (59)	49 (54)	
Hormone Therapy, n (%)				.81
No	12 (26)	10 (23)	22 (24)	
Yes	34 (74)	34 (77)	68 (76)	

Table 3

Baseline (T1) and Follow-up (T2) Dependent Variables and Difference Scores by Group with Unadjusted and Adjusted Linear Regression Models

Dependent Variable ^a (scale range)	Usual Care Group (N=45)			Intervention Group (N=43)			Unadjusted p-value ^b	Adjusted p-value ^d
	T1	T2	T2-T1	T1	T2	T2-T1		
Overall QOL (0–108)	84.6	86.5	1.9	86.4	86.7	0.3	.51	.98 <i>ii,iii,iv,vi</i>
Breast cancer QOL (0–40)	27.2	28.5	1.3	26.7	26.7	0.1	.33	.88 <i>i,ii,vi,vii,viii</i>
Unmet needs (0–30)	6.20	3.73	-2.47	6.86	5.67	-1.19	.57 ^c	.49 <i>vi,vii</i>
Distress (0–10)	3.11	2.62	-0.49	2.79	2.67	-0.12	.52	.46 <i>i,iii,v,vi</i>
Cancer worry (1–5)	2.28	2.04	-0.24	2.23	2.15	-0.08	.30	.31 <i>iii,iv,vi,vii</i>

Abbreviations: QOL, quality of life; T1, baseline; T2, follow-up.

^a Higher scores indicate higher levels of the dependent variable^b t-test or^c Wilcoxon rank-sum test^d Adjusted for core variables (baseline level of the dependent variable, age, cancer stage, and cancer center site) plus the following:*i* symptom interference T1,*ii* symptom interference T2-T1,*iii* unmet needs T1,*iv* unmet needs T2-T1,*v* insurance status,*vi* type of surgery,*vii* hormonal treatment,*viii* race

Table 4

Qualitative Ratings of Intervention (N=43)

Theme	Illustrative Quotes
Intervention helped participants to feel less isolated	<ul style="list-style-type: none"> • "I expected to feel better sooner and now know better what to expect." • "Survivors' stories helped me to relate better and realize that the feelings I was having were common." • "Yes, because real women with some of the same thoughts I had were shedding light those issues. It made me feel normal." • "I'm able to identify with what they were saying. It's helpful to know that others have the same thoughts and feelings."
Intervention introduced questions about survivorship	<ul style="list-style-type: none"> • Questions raised about follow up care, when to get another MRI: "I will talk to [my doctor] today." • "I would really like to get involved in a support group, because now that this is all over I am very worried."
Intervention helped participants to have realistic expectations	<ul style="list-style-type: none"> • "I am in denial and don't want to deal with the fact that it isn't over." • "I feel more prepared because the video taught me that I was expecting too much of myself and I will not be able to jump back into everything immediately."
Intervention helped participants consider their caregivers' perspectives	<ul style="list-style-type: none"> • "I wish I would have brought my kids and husband because they don't understand." • "I plan to share this video with my family... some just don't have a clue." • "My daughter expressed one day when I was not in a good mood that she was glad that she watched the video with me because she felt she knew where my moodiness was coming from."
Program satisfaction	<ul style="list-style-type: none"> • "The thoroughness and the timing. I felt let down when [the booklets] stopped coming. Short, easy read." • "Easy to read... enjoyable. Real life experiences from women; could relate to them." • "I feel like I wrote these books myself; word for word I was able to relate. Now I have the assurance that I am not alone. The booklets helped me think of new ways to cope with stress. Some things are still a struggle but the books are a great resource. I really enjoyed them all and I plan to make my husband and daughter read them." • "The people in the video were honest and positive."
Suggestions for improving program	<ul style="list-style-type: none"> • "I'd like more survivors' stories and specifics on what helped them." • "I had done a lot of research so I only found a few comments in each booklet to be helpful. I had read everything I could get my hands on so I am very well-informed." • "It would be good to have the video session in a group setting with other survivors." • "Could go through stages of what to expect in greater detail." • "I suggest that all women should talk to a professional 'cause even if they say they are okay they are not." • "More information on nutrition and genetics."