

Outcomes From the Moving Beyond Cancer Psychoeducational, Randomized, Controlled Trial With Breast Cancer Patients

Annette L. Stanton, Patricia A. Ganz, Lorna Kwan, Beth E. Meyerowitz, Julianne E. Bower, Janice L. Krupnick, Julia H. Rowland, Beth Leedham, and Thomas R. Belin

From the Division of Cancer Prevention and Control Research, Jonsson Comprehensive Cancer Center at University of California, Los Angeles (UCLA); Department of Psychology; Department of Psychiatry and Biobehavioral Sciences, David Geffen School of Medicine at UCLA; Cousins Center for Psychoneuroimmunology, UCLA Neuropsychiatric Institute; UCLA Schools of Medicine and Public Health; Department of Psychology, University of Southern California, Los Angeles; Encino, CA; Department of Psychiatry, Georgetown University Medical Center, Washington, DC; Office of Cancer Survivorship, National Cancer Institute, Bethesda, MD.

Submitted September 23, 2004; accepted June 2, 2005.

Supported by funding from the National Cancer Institute (R01-CA63028). Supported through an American Cancer Society Clinical Research Professorship (P.A.G.).

Presented in part at the 40th Annual Meeting of the American Society of Clinical Oncology, June 5-8, 2004, New Orleans, LA, and the Annual Meeting of the American Psychological Association, July 28-August 1, 2004, Honolulu, HI.

Authors' disclosures of potential conflicts of interest are found at the end of this article.

Address reprint requests to Annette L. Stanton, PhD, Department of Psychology, 1285 Franz Hall, Box 951563, University of California, Los Angeles, Los Angeles, CA 90095-1563; e-mail: astanton@ucla.edu.

© 2005 by American Society of Clinical Oncology

0732-183X/05/2325-6009/\$20.00

DOI: 10.1200/JCO.2005.09.101

A B S T R A C T

Purpose

Evidence suggests that the re-entry phase (ie, early period after medical treatment completion) presents distinct challenges for cancer patients. To facilitate the transition to recovery, we conducted the Moving Beyond Cancer (MBC) trial, a multisite, randomized, controlled trial of psychoeducational interventions for breast cancer patients.

Methods

Breast cancer patients were registered within 6 weeks after surgery. After medical treatment, they completed baseline measures and were randomly assigned to standard National Cancer Institute print material (CTL); standard print material and peer-modeling videotape (VID); or standard print material, videotape, two sessions with a trained cancer educator, and informational workbook (EDU). Two primary end points were examined: energy/fatigue and cancer-specific distress. Secondary end points were depressive symptoms and post-traumatic growth. Perceived preparedness for re-entry was analyzed as a moderator of effects.

Results

Of 558 women randomly assigned to treatment, 418 completed the 6-month assessment and 399 completed the 12-month assessment. In analyses controlling for study site and baseline depressive symptoms, VID produced significant improvement in energy/fatigue at 6 months relative to CTL, particularly among women who felt less prepared for re-entry at baseline. No significant main effect of the interventions emerged on cancer-specific distress, but EDU prompted greater reduction in this outcome relative to CTL at 6 months for patients who felt more prepared for re-entry. Between-group differences in the primary outcomes were not significant at 12 months, and no significant effects emerged on the secondary end points.

Conclusion

A peer-modeling videotape can accelerate the recovery of energy during the re-entry phase in women treated for breast cancer, particularly among those who feel less prepared for re-entry.

J Clin Oncol 23:6009-6018. © 2005 by American Society of Clinical Oncology

INTRODUCTION

Breast cancer is the most common cancer in women, and 86% of patients survive for at least 5 years after diagnosis, yielding more than two million women living with a history of the disease in the United States.¹ Thus, preparation for favorable survivorship is a realizable goal for most women. The

transition from patient to survivor, also termed the re-entry transition,^{2,3} is an understudied period.⁴⁻⁷ Accordingly, we tested two psychoeducational interventions in the Moving Beyond Cancer (MBC) trial for breast cancer patients in re-entry.

Themes of the re-entry phase are remarkably similar across accounts by cancer patients,^{2,3,8,9} health professionals,⁸⁻¹² and

qualitative researchers.^{4,13-16} Once treatment ends, patients no longer interact frequently with the medical team and may lose the accompanying sense of protection.⁸ Cancer patients also often cite a downturn in emotional support at this time.^{14,17} They often must address fears about cancer recurrence¹⁸⁻²² and the pace at which persistent decrements in physical functioning will diminish.^{18,23-25} In a sample of 223 women treated for breast cancer within the prior year,²⁰ the most frequent concerns were fear of cancer recurrence, pain, death, harm from adjuvant treatment, and medical bills.

The literature documents unmet needs for information that persist after treatment. Luker et al²⁶ found that 105 breast cancer patients at diagnosis reported receiving new information from medical professionals. Almost 2 years later, however, the sample reported receiving new information primarily from popular media and reported discomfort requesting information from medical providers. Most (66%) reported information needs that had not been met. Psychoeducational interventions developed for cancer patients primarily have been conducted during rather than after medical treatment.²⁷⁻²⁹ During development of the MBC trial, we could locate no published intervention trial directed specifically at cancer patients at re-entry. In light of evidence that most cancer patients adjust well over the long term (eg, Dorval et al,³⁰ Ganz et al,³¹ and Shimozuma et al³²), we reasoned that intensive intervention might not be necessary. Rather, brief intervention delivered at this pivotal point may hasten recovery and set the stage for adaptive long-term survivorship. Hence, we initiated the MBC trial, a multisite randomized, controlled intervention trial with three arms involving a peer-modeling videotape, two educational sessions, and a control condition.

The development of the intervention approaches was guided by research and theory in stress and coping,³³⁻³⁸ self-regulation,^{39,40} and social learning.^{41,42} These theories suggest that a breast cancer survivor will recover well if her goal expectancies for re-entry are realizable and she possesses the resources to achieve them. Unrealistic or unconfirmed expectations have been shown to undermine self-change efforts^{43,44} and adjustment.⁴⁵ Furthermore, studies of cancer patients at diagnosis and re-entry document the utility of approach-oriented coping (eg, active acceptance, seeking social support, emotional expression).^{33,36,37,46,47} In addition to providing information regarding what to expect during re-entry, the interventions were designed to increase active, approach-oriented coping skills through peer modeling in the videotape intervention and guided practice in the educational sessions.

We hypothesized that both the videotape and the brief counseling would promote improved functioning relative to a control condition on two a priori specified primary end points: fatigue/energy and cancer-specific distress. We selected these outcomes because they are cited in the literature

as frequent, unexpected experiences in re-entry,^{20,25} and they emerged as common problems in focus groups conducted in preparation for the trial with breast cancer patients who had recently completed medical treatments at the three trial sites. As secondary end points, we selected depressive symptoms (an outcome examined frequently in intervention trials; eg, Antoni et al⁴⁸ and Jacobsen et al⁴⁹) and post-traumatic growth^{50,51} to include an indicator of positive aspects of the cancer experience. In light of the evidence that many cancer patients do not anticipate the challenges of re-entry, we also hypothesized that perceived preparedness for this phase would moderate intervention effects. Specifically, we predicted that the interventions would be particularly effective for women who reported feeling unprepared for re-entry.

METHODS

Recruitment Procedures and Study Eligibility

Detailed descriptions of recruitment are provided elsewhere.^{52,53} With institutional review board approval, patients were recruited in Los Angeles, CA (University of California, Los Angeles, Los Angeles [LA]), Washington, DC (Georgetown University [DC]), and Kansas City/Lawrence, KS (University of Kansas [KS]) from practices of collaborating oncologists. Potentially eligible patients with newly diagnosed stage I or II breast cancer were sent a letter of invitation from their physician, followed by a call from the research staff who introduced the study. During this call, women were registered onto the study if they permitted us to contact them again to determine when their treatment was completed.

Inclusion criteria for registration were definitive primary surgery within the last 6 weeks; invasive epithelial cancer histology; any tumor size; any nodal status; surgery as initial therapy; and reconstructive surgery if it was completed within approximately 6 months. Exclusion criteria were prior history of breast cancer; noninvasive breast cancer; metastatic or inflammatory breast cancer; planned use of neoadjuvant chemotherapy or of high-dose chemotherapy with bone marrow or stem-cell rescue; protracted reconstructive surgery or surgical complications; severe physical, cognitive, or psychiatric illness; inability to read and write in English; or participation in another clinical trial with a quality-of-life intervention.

Enrollment and Randomization Procedures

Registered participants were tracked by phone until treatment completion, whereupon they were mailed informed consent forms and baseline questionnaire packets. Participants had to return their completed materials within 8 weeks after medical treatment completion to remain eligible for participation in the study. When the baseline packet was returned, the woman was assigned randomly, based on a random number-generated list, to one of three study arms. Intervention assignment was stratified by study site, whether the woman had received chemotherapy, and marital status (married/living as married *v* other). Random assignment to treatment was revealed to research staff after the participant's baseline questionnaire was received, and was conducted from July 1999 through June 2002, with all 12-month follow-up

assessments completed by August 2003. Personnel performing data checking were unaware of condition assignment.

Description of the Intervention Arms

Within 2 weeks after random assignment, the three arms were initiated as follows: women randomly assigned to the standard print control (CTL) condition were mailed a personalized letter thanking them for completion of the baseline survey and reminding them of the upcoming assessment points. The mailing included a copy of the 1994 National Cancer Institute publication *Facing Forward*.⁵⁴ This 43-page booklet contains general information for cancer survivors and focuses on health care after cancer treatments, managing emotions, and financial issues.

Women assigned to the videotape intervention (VID) received the personalized letter and *Facing Forward*, as well as an author-developed and professionally filmed videotape entitled, *Moving Beyond Cancer* (free copies can be ordered by contacting the National Cancer Institute's Cancer Information Service, toll-free in the United States at 1-800-4-CANCER [1-800-422-6237], or online at www.cancer.gov). This 23-minute film addressed re-entry challenges in four life domains: physical health, emotional well-being, interpersonal relations, and life perspectives. Designed to promote adaptive peer modeling, the film observes four breast cancer survivors as they describe their experience in each of the four domains, as well as active coping skills they used to meet associated challenges. The film also depicts an African American breast cancer support group in which the members discuss the experiences of re-entry and model active coping. It includes commentary by an oncologist expert in breast cancer (Susan Love, MD) on the re-entry experience and on active methods for approaching problems during re-entry.

Women assigned to psychoeducational counseling (EDU) participated in one individually conducted in-person session and one telephone session with trained cancer educators (eg, social worker, psychologist), all of whom had a masters- or PhD-level education and had been trained in a full-day session by the researchers (B.E.M., B.L., A.L.S., and J.H.R.) using a detailed manual at each site. In the first session of approximately 80 minutes, women reviewed their cancer-related concerns in the four life domains described previously, identified a primary concern and their associated goals, developed an approach-oriented action plan to address that concern (eg, getting more information, seeking social support), and addressed barriers to their plan. At this session, they also were given the *Moving Beyond Cancer* videotape and an author-constructed 60-page manual entitled, *Moving Beyond Cancer: Your Guide to a Successful Recovery*. Developed from an extensive literature review, focus groups with patients who had completed treatment recently, and input from the research team, the manual provided information on what to expect during re-entry, encouraged an active approach, and offered a list of cancer-related resources specific to that study site. The manual was organized to conform to the four life domains. For example, the chapter on the physical domain provides information on and suggestions for managing fatigue, menopausal symptoms, sexual issues, weight gain, vaginal dryness, lymphedema, symptoms at the surgical site, and pregnancy after breast cancer. Conducted 2 weeks later by the same educator for individual participants and lasting approximately 30 minutes, the second telephone-delivered session was designed to focus on reactions to and questions on the videotape and manual, evaluate progress on and revise the action plan, and address generalization of strategies to other re-entry challenges.

Instruments and Assessment Points

The baseline assessment included standardized questionnaires and author-constructed instruments. Similar questionnaires were completed at 2 months, 6 months, and 12 months after random assignment. The 2-month questionnaire included measures to assess whether VID and EDU participants had watched the videotape. This report focuses on the following measures.

Primary end points. The four-item Short Form-36 (SF-36) Vitality subscale⁵⁵ from the Medical Outcomes Study SF-36 items, is a reliable and valid measure of both positive (eg, "feel full of pep") and negative (eg, "feel worn out") aspects of vitality (ie, energy and fatigue).⁵⁶ To assess comparability of groups at baseline, we also examined the SF-36 summary scales: Physical Component Summary and Mental Component Summary (MCS).⁵⁷ They are standardized to the US population with a mean score of 50 and a standard deviation (SD) of 10.

The psychometrically adequate Revised Impact of Events Scale (IES-R)^{58,59} was used to assess cancer-specific distress. Participants rated how distressing 22 experiences (ie, intrusive thoughts, avoidance, hyperarousal) had been "during the past 7 days with respect to your breast cancer" (eg, "I had waves of strong feelings about it") on 5-point response scales (ie, "not at all" to "extremely"). The internal consistency estimate of reliability for the total score in our sample ranged from $\alpha = .88$ to $.89$ across the three assessment points. Responses were skewed toward lower scores, and they conformed to a more normal distribution when a logarithmic transformation was applied. Thus, analyses were conducted with $\log(\text{IES-R} + 1)$.

Secondary end points. The Center for Epidemiologic Studies-Depression Scale (CES-D) contains 20 items to measure depressive symptoms during 1 week and has excellent reliability and validity.⁶⁰ Responses are rated on a 4-point scale, with total scores ranging from 0 to 60. It has been used in studies of healthy women^{61,62} and breast cancer patients.^{31,63,64}

The Posttraumatic Growth Inventory (PTGI)⁵¹ contains 21 items that reflect positive changes (eg, enhanced relationships, life appreciation) after stressful experiences. Women rated items with regard to cancer as the life stressor (0 = "I did NOT experience this change as a result of my experience with cancer"; 5 = "I experienced this change to a VERY GREAT degree. . ."). Breast cancer patients report greater growth on the PTGI than matched healthy counterparts.⁶⁵

Perceived preparedness for re-entry. Perceived preparedness for re-entry was assessed at baseline with two author-constructed items: "Overall, I feel very well-prepared for what to expect during my recovery" and "Overall, I feel the medical team has done a great deal to prepare me for what to expect during my recovery from breast cancer treatment." Responses were rated on a 0 to 4 scale (ie, not at all, a little, a fair amount, much, very much). The items were highly correlated ($n = 415$; $r = 0.84$; $P < .0001$) and were averaged to create a total score.

Intervention fidelity and adherence. One researcher (B.E.M.) listened to and rated approximately 25% of the audiotaped EDU sessions, and a second researcher (A.L.S.) listened to 25% of those. Fourteen mixed-response items were constructed to assess fidelity to the intervention (eg, "Did the educator follow the outline of the session?") and other aspects of competence (eg, "Educator appeared prepared"). On each item, we set a criterion for adequate intervention delivery. For example, on the item, "Did educator follow the outline of the session?" the educator must have received a minimum rating of "Yes, with few omissions or additions" and

not a rating of “Educator made several omissions or additions” or “Outline was not followed” to demonstrate adequate delivery on that item.

To assess adherence to the intervention, we assessed whether women attended the two EDU sessions. To assess self-reported adherence to the VID condition, women reported at the 2-month assessment whether they had obtained information from the videotape from this study.

Sample Size Calculation and Statistical Analysis

Analyses first were conducted to assess participation during the trial and baseline differences among randomized conditions. Categorical variables were examined using χ^2 or Fisher’s exact tests; continuous variables were compared using analysis of variance.

To determine sample size, the original analytic plan called for pairwise comparisons across the three treatment groups on change scores from baseline to the 6-month assessment for two primary outcomes: SF-36 Vitality and log (IES-R + 1). We called for a Bonferroni adjustment using $\alpha = .05/6 = .00833$ to address the planned six pairwise comparisons (CTL ν VID, CTL ν EDU, VID ν EDU on each outcome). The original study design noted that 146 women per condition, which is close to the number of patients available at the 6-month assessment ($n_{CTL} = 143$; $n_{VID} = 139$; $n_{EDU} = 136$; Fig 1), would yield 90% power to detect as significant a standardized effect size of 0.46. This effect size was targeted based on the effect on cancer-related distress attained in another psychosocial intervention trial.⁶⁶

Because analyses of baseline data revealed significant between-group differences, we selected two baseline variables for inclusion as covariates in outcome analyses. Included to promote demographic diversity, the three geographic sites indeed did yield a number of significant between-site differences at baseline (eg, education, race, income⁵²), and study site was included as a covariate. As explained in Results, the baseline CES-D score also was included as a covariate. Thus, in primary analyses, regression analyses were conducted including the two covariates and study condition as two dummy variables, with the CTL condition as the referent group on change scores (baseline to 6 months and baseline to 12 months) on the dependent variables. To examine effects of the proposed moderator variable (ie, baseline perceived preparedness for re-entry), preparation scores first were centered around the group mean (ie, each patient’s score was subtracted from its condition mean), in accordance with a standard procedure for analyzing interaction effects.⁶⁷ Centered scores then were entered in the regression model as a main effect of perceived preparedness as well as interaction terms with study condition (ie, preparedness-VID, preparedness-EDU). Finally, to assess the sensitivity of findings to incomplete data, we produced multiple imputations for missing values using SAS PROC MI (SAS Institute, Cary, NC) and imputed versions of each primary outcome at each time point were reanalyzed using SAS PROC MIANALYZE. Separate imputation models were fit to the data from each treatment arm; variables used in the model included study site,

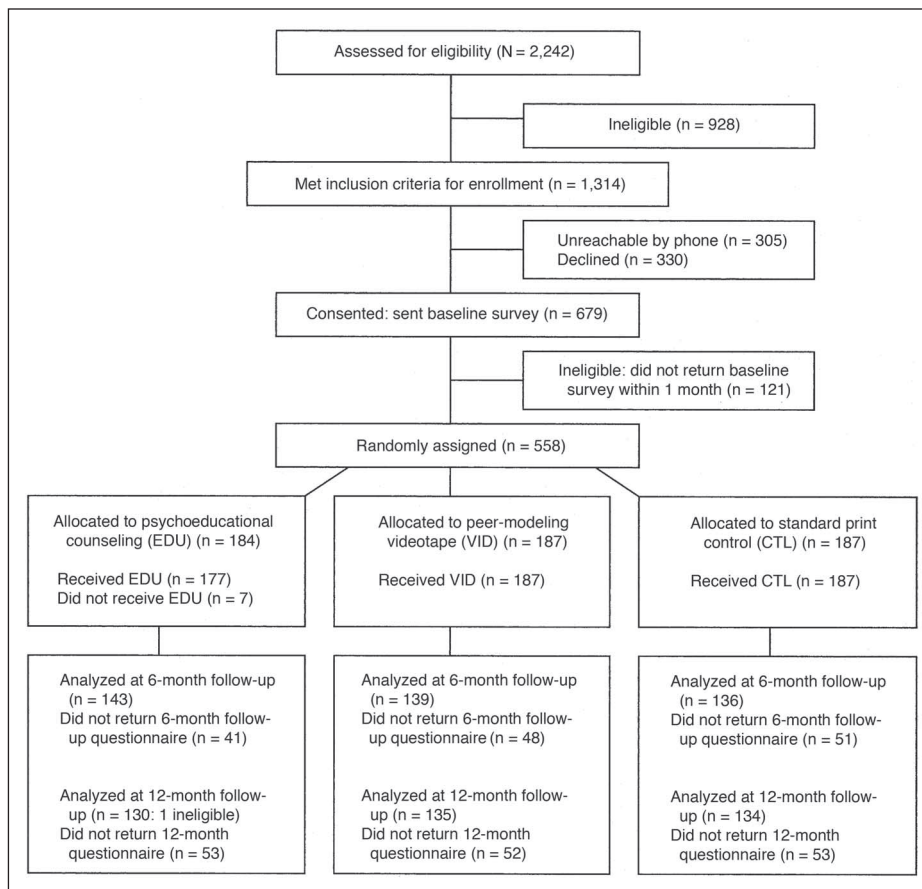


Fig 1. Moving Beyond Cancer trial accrual and retention.

baseline CES-D, treatment group, preparedness, and treatment-preparedness. Statistical analyses were conducted using SAS version 8.02 (SAS Institute). All statistical tests were two sided.

RESULTS

Trial Retention

As shown in Fig 1, of eligible patients, 756 (58%) either actively or passively refused participation, and 558 (42%) participated through random assignment. SF-36 scores did not differ in participants and nonparticipants, although women who were younger, white, married, and better educated were more likely to agree to random assignment.⁵³ In total, 558 women were randomly assigned (n = 187 CTL, n = 187 VID, n = 184 EDU). The arms did not differ with regard to completion rates for the assessments, χ^2_6 (n = 558) = 6.12 (P = .41), with 67% (n = 375) of the total sample completing baseline, 6-month, and 12-month assessments; 12% (n = 66) completing the baseline and one follow-up point; and 21% (n = 117) completing only the baseline assessment.

Analyses assessed whether women who completed the 6- and 12-month assessments differed significantly from those who did not on demographic, treatment-related, or outcome variables. Compared with those who did not complete the assessment at 6 months (n = 140), those who completed the 6-month assessment (n = 418) were significantly older (mean age, 58.1 v 53.6 years; P < .001), more likely to be employed (66% v 53%; P = .009), more likely to be taking tamoxifen (58% v 45%; P = .009), and less likely to report cancer-specific distress on the log(IES-R + 1; mean, 0.42 v 0.51; P = .002) or depressive symptoms on the CES-D (mean, 9.90 v 12.29; P = .005) at baseline. Analyses on those who completed (n = 399) versus those who did not complete the assessment (n = 158) at 12 months revealed nearly identical findings. No significant differences emerged on other demographic (ie, race, marital status, education), treatment-related (ie, receipt of radiation, chemotherapy, reconstruction, type of surgery), or other (ie, preparedness, SF-36, PTGI) variables.

Because the September 11, 2001, terrorist attacks on the United States occurred during the trial and might have affected assessment completion rates, particularly in the DC area, we examined whether completion of follow-up assessments varied as a function of whether they were scheduled before or after that date. Completion rates at 6 and 12 months did not differ in LA and KS. However, completion rates varied for the participants in DC, such that 40% of women did not complete the 6-month assessments who received them after September 11, whereas 22% of women who did not complete the assessment before that date, χ^2_1 (n = 151) = 5.59 (P = .018). At the 12-month assessment, 26% of women did not complete the assessment after Sep-

tember 11, and 3% of women did not complete the assessment before that date, χ^2_1 (n = 126) = 8.36 (P = .004).

With regard to participation, 86% of women in VID, 87% in the EDU, and 1.6% of women in CTL reported at 2 months that they had obtained information from the study videotape. Seven of 151 women assigned to EDU did not participate in the intervention (n = 2, unable to be contacted; n = 3, schedule conflict; n = 2, other) but still completed follow-up assessments. Their data were included in analyses. Thus, we carried out analyses on all available data from 418 participants at 6 months (n = 136, CTL; n = 139, VID; n = 143, EDU) and 399 participants at 12 months (n = 134, CTL; n = 135, VID; n = 130, EDU; one woman became ineligible at 12 months because she began additional chemotherapy).

Sample Characteristics and Success of Random Assignment

Of the 418 participants who completed both the baseline and 6-month assessments, 55% were recruited from LA, 25% from DC, and 20% from KS. Sample characteristics are listed in Table 1. On average, participants were 58.1 years old at baseline (SD, 11.2; range, 26 to 86 years). The majority were white, married, employed, and had at least a college degree. With regard to medical treatment, most had breast-conserving surgery and radiation, and nearly half had chemotherapy. On average, women at baseline had breast surgery almost 6 months earlier. At baseline, 28% had participated in psychotherapy and/or a support group since diagnosis. (An additional 22 women had sought either psychotherapy or a support group by the 6-month follow-up and 20 women did so by the 12-month follow-up. The number seeking psychological support did not differ significantly as a function of intervention arm at either assessment point.) Demographic and treatment variables did not vary significantly as a function of intervention arm.

With regard to psychological variables (Table 1), analyses of variance revealed that the intervention arms differed at baseline on SF-36 Vitality, SF-36 MCS, and CES-D, with the CTL group reporting significantly greater vitality and psychological well-being and fewer depressive symptoms than the two intervention groups (these significant differences also emerged in the total sample of 558 women at baseline). To develop an analytic strategy to handle this limitation and because the group difference was most pronounced on the CES-D, we conducted analyses on baseline scores again, controlling for baseline CES-D. This resulted in the previously significant group differences (SF-36 Vitality and MCS) becoming nonsignificant. Hence, we used baseline CES-D scores as a covariate to serve as a control for initial between-group differences.

Table 1. Sample Characteristics and Descriptive Statistics on Major Variables at Baseline (n = 418)

Variable	Standard Print Control (n = 136)			Videotape (n = 139)			Educational Sessions (n = 143)			P (χ^2)
	%	Mean	SD	%	Mean	SD	%	Mean	SD	
Age at baseline (years)		59.4	11.8		56.9	11.4		57.9	10.3	.18*
Race										
White	88.2			87.7			85.9			.98
African American	5.2			5.8			6.3			
Other	6.6			6.5			7.8			
Marital status										
Married	70.6			68.3			68.5			.96
Divorced	11.0			11.5			12.6			
Widowed	11.8			10.1			11.2			
Single	6.6			10.1			7.7			
Employment										
Part/full time	46.3			59.0			53.9			.77
Unemployed	53.7			41.0			46.2			
Annual household income										
< \$60,000	64.9			57.5			60.9			.46
≥ \$60,000	35.1			42.5			39.1			
Education										
Postcollege	36.0			31.2			40.6			.72
College degree	26.5			26.1			25.2			
Some college	25.0			26.8			23.8			
High school or less	12.5			15.9			10.5			
Surgery/chemotherapy treatment										
Mastectomy only	12.5			15.9			12.6			.69
Lumpectomy only	39.0			35.5			40.6			
Mastectomy and chemotherapy	16.9			22.5			16.1			
Lumpectomy and chemotherapy	31.6			26.1			30.8			
Had breast reconstruction	12.6			16.7			15.5			.62
Had radiation	69.2			66.7			71.8			.65
Currently receiving tamoxifen	56.6			63.3			53.2			.27
Months since surgery		5.5	2.5		5.7	3.0		5.5	2.7	.77*
Psychosocial variables										
Perceived preparedness		2.9	1.1		2.7	1.4		2.8	1.3	.52*
SF-36 Vitality		56.0 _a	19.9		50.2 _b	21.8		50.1 _b	24.0	.04*
Log(IES-R + 1)		0.40	0.27		0.42	0.30		0.43	0.29	.69*
SF-36 PCS		45.9	9.4		45.0	10.9		45.3	9.4	.78*
SF-36 MCS		51.0 _a	9.4		49.2 _{ab}	9.8		47.9 _b	11.0	.04*
CES-D		8.4 _b	7.7		10.2 _{ab}	8.2		11.1 _a	9.1	.02*
PTGI		50.5	25.9		49.3	25.2		49.9	25.5	.94*

NOTE. Means with different subscripts differ significantly at $P \leq .05$. Means with subscript "a" are significantly greater than means with a subscript "b," and subscript "ab" indicates that the mean falls between those indicated by a and b, but does not differ significantly from either mean.

Abbreviations: SD, standard deviation; IES-R, Impact of Events Scale-Revised; PCS, Physical Component Summary; MCS, Mental Component Summary; CES-D, Center for Epidemiological Studies-Depression Scale; PTGI, Posttraumatic Growth Inventory.

* P for analysis of variance.

Treatment Fidelity

Of the audiotapes rated by both raters ($n = 10$), there was 100% agreement that the educators met all 14-item criteria for conducting sessions with adequate fidelity and competence. Of the 42 tapes rated by one researcher (B.E.M.), only three tapes (7%) had any item that did not meet its criterion (two of 14 items for two sessions and one item for one session). For all items, the median and modal ratings all were in the highest two categories on the four- or five-category response options, indicating that the EDU intervention was delivered with high fidelity.

Effects of the Interventions

Primary outcomes. Analyses performed on SF-36 Vitality change scores at 6-month follow-up, controlling for study site and baseline CES-D, revealed a significant VID versus CTL comparison, $t_{1,405} = 2.36$ ($P = .018$), indicating that the VID intervention produced a significantly greater improvement in the Vitality subscale score during 6 months than did the CTL condition (Table 2). Analyses conforming to the original analytic plan to detect main effects of the interactions on the unadjusted mean change scores at 6 months yielded a significant effect for VID versus CTL

Table 2. Adjusted Mean \pm SE Change Scores on Dependent Variables at 6- and 12-Month Follow-Up

Variable	Standard Print Control (n = 136)		VID (n = 139)		Educational Sessions (n = 143)	
	Mean	SE	Mean	SE	Mean	SE
SF-36 Vitality						
6 months*	3.84	1.58	9.06	1.54	5.00	1.54
12 months	6.06	1.53	9.38	1.51	7.36	1.56
Log(IES-R + 1)						
6 months†	-0.09	0.02	-0.08	0.02	-0.06	0.02
12 months	-0.13	0.02	-0.10	0.02	-0.11	0.02
CES-D						
6 months	-0.94	0.62	-1.25	0.61	0.02	0.61
12 months	-1.79	0.57	-1.32	0.56	-0.68	0.58
PTGI						
6 months	0.75	1.46	2.65	1.43	3.32	1.41
12 months	2.43	1.58	3.00	1.56	5.44	1.60

NOTE. Means are adjusted for baseline CES-D scores, study site, and slightly unequal group sizes. Abbreviations: VID, videotape; EDU, educational sessions; IES-R, Impact of Events Scale-Revised; CES-D, Center for Epidemiological Studies-Depression Scale; PTGI, Posttraumatic Growth Inventory. *Analysis yielded significant VID ($P = .0185$) and VID-perceived preparedness effects ($P = .049$). †Analysis yielded significant EDU-perceived preparation effect ($P = .037$).

($P = .008$) on SF-36 Vitality, and nonsignificant differences for EDU versus CTL and VID versus EDU. Mean change scores for SF-36 Vitality were 3.35 (SD, 18.09) for CTL, 9.17 (SD, 18.12) for VID, and 5.62 (SD, 19.54) for EDU, with higher scores reflecting greater improvement. For log(IES-R + 1) change scores, for which negative scores denote improvement, we found the mean to be -0.08 (SD, 0.25) for CTL, -0.08 (SD, 0.25) for VID, and -0.07 (SD, 0.24) for EDU. None of the comparisons was significant for the IES-R.

The main effect for perceived preparedness also was significant ($\beta = 3.73$; 95% CI, 0.95 to 6.52; $t_{1,405} = 2.64$; $P = .009$), such that women who reported being more prepared for re-entry evidenced a greater increase in Vitality subscale score during 6 months than did less prepared women. These main effects were qualified by a significant perceived preparedness-VID interaction ($\beta = -3.55$; 95% CI, -7.09 to -0.01 ; $t_{1,405} = -1.97$; $P = .049$). Follow-up analysis of the interaction revealed that the videotape was more effective for less prepared women (ie, those with preparedness scores at least one SD below mean preparedness; Fig 2A). As hypothesized, women who felt unprepared benefited from the VID intervention, evidencing an increase of greater than 8 points in the Vitality subscale score; in contrast, unprepared women in the CTL condition evidenced a decline in the Vitality subscale of approximately 2 points during 6 months. Conversely, women who reported being well prepared (ie, those at least one SD above mean preparedness) for the re-entry transition evidenced an improvement in the Vitality subscale score of greater than 8 points in both the VID and CTL conditions during 6 months. Effect sizes for the less-prepared, average-prepared (ie, between one SD above and

below mean preparedness), and well-prepared women were 0.51, 0.29, and 0.07, respectively, suggesting a moderate benefit from the VID intervention versus the CTL for the less prepared women, a smaller benefit for women of average preparedness, and limited benefit for well prepared women.

Analyses performed on the log(IES-R + 1) change scores at 6 months, controlling for study site and baseline CES-D scores, revealed no significant main effects (Table 2). However, the perceived preparedness-EDU interaction was significant ($\beta = -0.05$; 95% CI, -0.098 to -0.004); $t_{1,405} = -2.09$; $P = .037$). As shown in Fig 2B, findings ran counter to hypothesis, in that participants who reported being unprepared for re-entry benefited less from the EDU intervention than did prepared women, who evidenced greater improvement relative to CTLs. Effect sizes for the less-prepared, average-prepared, and well-prepared women were 0.38, 0.12, and -0.15 , respectively, suggesting that the EDU intervention was somewhat detrimental for less-prepared women and of some benefit for well-prepared women relative to the CTL condition (note that all groups declined in cancer-related distress, on average).

At 12-month follow-up, no significant effects of the intervention, perceived preparedness, or their interaction emerged on the IES-R or SF-36 Vitality scales. As listed in Table 2, after controlling for study site and baseline CES-D, participants in all conditions on average evidenced an increase in the Vitality subscale score and a decrease in log(IES-R + 1) scores from baseline to 12 months.

Secondary outcomes. Controlling for study site and baseline CES-D, no significant effects for intervention, perceived preparedness, or their interaction emerged on the

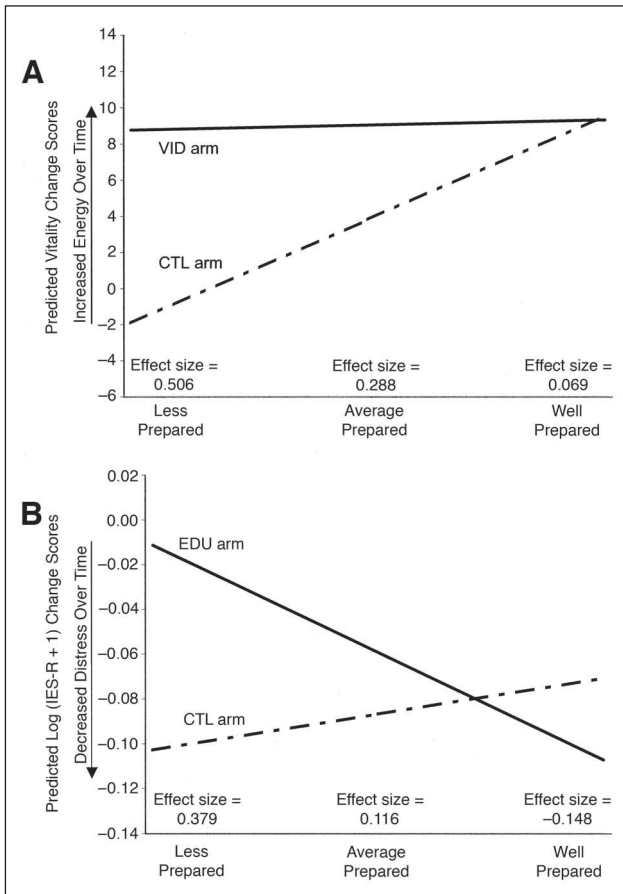


Fig 2. Predicted change scores from baseline to 6-month assessment controlling for study site and baseline Center for Epidemiological Studies-Depression scale (CES-D) stratified by study condition. Well prepared = perceived preparedness scores > 1 standard deviation (SD) above mean; less prepared = > 1 SD below mean; average prepared = within 1 SD above or below mean. (A) Predicted Short Form-36 Vitality subscale change scores for standard print control (CTL) v videotape (VID). (B) Predicted log(Impact of Events Scale-Revised [IES-R] + 1) change scores for CTL v education (EDU).

CES-D or PTGI at either follow-up assessment (Table 2 for adjusted means).

Analysis with imputation of missing values. Findings from multiple imputation analyses were identical to those conducted on complete data (in terms of statistical significance), except for the preparedness-VID interaction on the Vitality subscale score at 6 months, where the point estimates were in the same direction but the imputed-data finding was borderline significant ($\beta = -3.01$; $P = .065$) rather than significant ($\beta = -3.55$; $P = .049$).

DISCUSSION

In the MBC trial to test effects of two psychoeducational interventions to promote adaptive functioning during re-entry, the VID produced an increase in vitality (ie, increased

energy and decreased fatigue) relative to the CTL condition at 6 months. VID offered peer modeling of active coping approaches for fatigue, which was one of the first topics addressed on the videotape and several minutes were devoted to it. On average, women in the VID condition evidenced a 9-point increase on the SF-36 Vitality subscale score, representing an increase from baseline of nearly half an SD. This change in the Vitality subscale score is comparable to or greater than that reported in other trials of effective psychoeducational interventions for cancer patients during medical treatment.^{49,68} The VID condition specifically was effective for women who at baseline felt less prepared for re-entry, with the associated effect size of 0.51, suggesting that the mean outcome in the VID group is at approximately the 69th percentile of the distribution of outcomes in the control group. VID participants continued to demonstrate the most positive change at 12 months, although group differences were not statistically significant.

Thus, exposure to the videotape accelerated the recovery of vitality, particularly among women who felt least prepared for re-entry. The value of these findings is highlighted by evidence that fatigue is the most common adverse effect of cancer treatment and causes significant impairment in emotional, social, and occupational function⁶⁹; facilitating recovery of energy is an important outcome for women who have completed treatment and are ready to resume their lives. This effect was achieved with a relatively minimal intervention that is easily delivered.

Findings on the other end points were rather disappointing. With regard to cancer-specific distress, EDU was effective in decreasing distress at 6 months relative to the CTL, but only among women with greater perceived preparedness for re-entry. Perhaps prepared women had greater psychological readiness for the intervention. In contrast, it is possible that asking unprepared women to identify a re-entry concern and create an action plan was premature and distracted from the impact of the videotape, which they received after the first educational session. Unprepared women may have reaped greater benefit from EDU if they had been exposed to the preparatory videotape and print materials before the first EDU session, or they may have benefited from a more intensive intervention. Since the initiation of the MBC trial, at least three other interventions targeted at the re-entry phase have been reported.^{38,70,71} In each of these, more total time and/or a greater number of sessions devoted to the intervention, as well as distinct intervention contents, have produced more favorable findings.

Three additional observations are relevant to the lack of robust effects on outcomes other than SF-36 Vitality: scores on two psychological outcomes (ie, IES-R, CES-D) were relatively low at baseline and women with higher scores were more likely to be lost to follow-up; similar to other intervention research,⁷² mean scores on all dependent

variables improved for all intervention groups across time; and more than one fourth of the sample had attended psychotherapy or a support group since diagnosis. These factors might have precluded strong intervention effects. A recommendation is to target interventions to those cancer patients most in need at re-entry; for example, those with high cancer-related distress or depressive symptoms.

Several study limitations deserve mention. First, randomization failed to equalize the groups on some psychological variables at baseline. Statistical control was instituted to compensate for this limitation, but different effects might have emerged had the randomly assigned groups been equivalent. Second, participation among the 1,314 eligible women was 42% (although the 23% of eligible women who were unreachable by phone were counted as declining participation), and more than 20% of randomly assigned women were lost to follow-up. Although multiple attempts were made to contact women, it is possible that the relatively minimal nature of the interventions resulted in participants being less committed to the study. Furthermore, the September 11, 2001, terrorist attacks significantly influenced completion of assessments at the DC site. Third, generalizability of findings is limited to relatively educated women with early-stage breast cancer, and intervention effectiveness for diverse groups requires study. Further-

more, because they received distinct breast cancer treatments, women entered the trial at variable points after diagnosis. However, analyses revealed that diagnosis duration and medical treatment received did not influence findings (data not shown). Finally, the measure of perceived preparedness was constructed for this trial, and its reliability and validity are not established.

Notwithstanding these limitations, the MBC trial yielded an easily transportable videotape intervention that can be used in medical practices to prepare breast cancer patients for the re-entry phase, with demonstrated efficacy for accelerating the recovery of vitality after medical treatments. In the future, delivery of intervention to those most likely to experience problematic re-entry and tailoring of intervention approaches to meet the needs of patients with particular attributes may promote a foundation for adaptive survivorship.

Acknowledgment

We thank Susan Love, MD, and Antronette Yancey, MD, whose work aided in the videotape content.

Authors' Disclosures of Potential Conflicts of Interest

The authors indicated no potential conflicts of interest.

REFERENCES

- Ries LAG, Eisner MP, Kosary CL, et al (eds): SEER Cancer Statistics Review, 1975-2000. Bethesda, MD, National Cancer Institute, 2003. http://seer.cancer.gov/csr/1975_2000
- Mullan F: Re-entry: The educational needs of the cancer survivor. *Health Educ Q* 10:88-94, 1984 (suppl)
- Mullan F: Seasons of survival: Reflections of a physician with cancer. *N Engl J Med* 313:270-273, 1985
- Beisecker AE, Cook MR, Ashworth J, et al: Side effects of adjuvant chemotherapy: Perceptions of node-negative breast cancer patients. *Psychooncology* 6:85-93, 1997
- Broeckel JA, Jacobsen PB, Balducci L, et al: Quality of life after adjuvant chemotherapy for breast cancer. *Breast Cancer Res Treat* 62:141-150, 2000
- Ward SE, Viergutz G, Tormey D, et al: Patients' reactions to completion of adjuvant breast cancer therapy. *Nurs Res* 41:362-366, 1992
- Wilson SE, Andersen MR, Meischke H: Meeting the needs of rural breast cancer survivors: What still needs to be done. *J Womens Health Gend Based Med* 9:667-677, 2000
- McKinley ED: Under toad days: Surviving the uncertainty of cancer recurrence. *Ann Intern Med* 133:479-480, 2000
- Schnipper HH: Life after breast cancer. *J Clin Oncol* 19:3581-3584, 2001
- Auchincloss SS: Psychosocial issues in gynecologic cancer survivorship. *Cancer* 76:2117-2124, 1995 (suppl)
- Hoffman RS: The psycho-oncologist in a multidisciplinary breast treatment center, in Cooper CL (ed): *Stress and Breast Cancer*. New York, NY, John Wiley & Sons, 1988, pp 171-193
- Tross S, Holland JC: Psychological sequelae in cancer survivors, in Holland JC, Rowland JH (eds): *Handbook of Psychooncology: Psychological Care of the Patient with Cancer*. New York, NY, Oxford University Press, 1989, pp 101-116
- Breaden K: Cancer and beyond: The question of survivorship. *J Adv Nurs* 26:978-984, 1997
- Maher EL: Anomic aspects of recovery from cancer. *Soc Sci Med* 16:907-912, 1982
- Lethborg CE, Kissane D, Burns WI, et al: "Cast adrift": The experience of completing treatment among women with early stage breast cancer. *J Psychosoc Oncol* 18:73-90, 2000
- Lethborg CE, Kissane D, Burns WI: 'It's not the easy part': the experience of significant others of women with early stage breast cancer, at treatment completion. *Soc Work Health Care* 37:63-85, 2003
- Arnold EM: The cessation of cancer treatment as a crisis. *Soc Work Health Care* 29:21-38, 1999
- Degner LF, Kristjanson LJ, Bowman D, et al: Information needs and decisional preferences in women with breast cancer. *JAMA* 277:1485-1492, 1997
- Girgis A, Boyes A, Sanson-Fisher RW, et al: Information needs of women diagnosed with breast cancer: Rural versus urban location. *Aust N Z J Public Health* 24:166-173, 2000
- Spencer SM, Lehman JM, Wynings C, et al: Concerns about breast cancer and relations to psychosocial well-being in a multiethnic sample of early-stage patients. *Health Psychol* 18:159-168, 1999
- Vickberg SMJ: Fears about breast cancer recurrence: Interviews with a diverse sample. *Cancer Practice* 9:237-243, 2001
- Vickberg SM: The Concerns About Recurrence Scale (CARS): A systematic measure of women's fears about the possibility of breast cancer recurrence. *Ann Behav Med* 25:16-24, 2003
- Bosompra K, Takamaru A, O'Brien PJ, et al: Knowledge about preventing and managing lymphedema: A survey of recently diagnosed and treated breast cancer patients. *Patient Educ Couns* 47:155-163, 2002
- Burstein HJ, Winer EP: Primary care for survivors of breast cancer. *N Engl J Med* 343:1086-1094, 2000
- Michael YL, Kawachi I, Berkman LF, et al: The persistent impact of breast carcinoma on functional health status: Prospective evidence from the Nurses' Health Study. *Cancer* 89:2176-2186, 2000
- Luker KA, Beaver K, Leinster SJ, et al: Information needs and sources of information for women with breast cancer: A follow-up study. *J Adv Nurs* 23:487-495, 1996
- Andersen BL: Psychological interventions for cancer patients to enhance quality of life. *J Consult Clin Psychol* 60:552-568, 1992
- Andersen BL: Biobehavioral outcomes following psychological interventions for cancer patients. *J Consult Clin Psychol* 70:590-610, 2002

29. Meyer TJ, Mark MM: Effects of psychosocial interventions with adult cancer patients: A meta-analysis of randomized experiments. *Health Psychol* 14:101-108, 1995
30. Dorval M, Maunsell E, Deschenes L, et al: Long-term quality of life after breast cancer: Comparison of 8-year survivors with population controls. *J Clin Oncol* 16:487-494, 1998
31. Ganz PA, Desmond KA, Leedham B, et al: Quality of life in long-term, disease-free survivors of breast cancer: A follow-up study. *J Natl Cancer Inst* 94:39-49, 2002
32. Shimozuma K, Ganz PA, Petersen L, et al: Quality of life in the first year after breast cancer surgery: Rehabilitation needs and patterns of recovery. *Breast Cancer Res Treat* 56:45-57, 1999
33. Carver CS, Pozo C, Harris SD, et al: How coping mediates the effect of optimism on distress: A study of women with early stage breast cancer. *J Pers Soc Psychol* 65:375-390, 1993
34. Carver CS, Scheier MF, Weintraub JK: Assessing coping strategies: A theoretically based approach. *J Pers Soc Psychol* 56:267-283, 1989
35. Lazarus R, Folkman S: *Stress, Appraisal, and Coping*. New York, NY, Springer, 1984
36. Stanton AL, Snider PR: Coping with a breast cancer diagnosis: A prospective study. *Health Psychol* 12:16-23, 1993
37. Stanton AL, Danoff-Burg S, Cameron CL, et al: Emotionally expressive coping predicts psychological and physical adjustment to breast cancer. *J Consult Clin Psychol* 68:875-882, 2000
38. Stanton AL, Danoff-Burg S, Sworowski LA, et al: Randomized, controlled trial of written emotional expression and benefit-finding in breast cancer patients. *J Clin Oncol* 20:4160-4168, 2002
39. Carver CS, Scheier MF: Origins and functions of positive and negative affect: A control process view. *Psychol Rev* 97:19-35, 1990
40. Carver CS, Scheier MF: *On the Self-Regulation of Behavior*. New York, NY, Cambridge University Press, 1998
41. Bandura A: Self-efficacy: Toward a unifying theory of behavior change. *Psychol Rev* 84:191-215, 1977
42. Rotter JB: *Social Learning and Clinical Psychology*. New York, NY, Prentice Hall, 1954
43. Polivy J, Herman CP: The false-hope syndrome: Unfulfilled expectations of self-change. *Curr Dir Psychol Sci* 9:128-131, 2000
44. Sears SR, Stanton AL: Expectancy-value constructs and expectancy violation as predictors of exercise adherence in previously sedentary women. *Health Psychol* 20:326-333, 2001
45. Stanton AL, Estes MA, Estes NC, et al: Treatment decision making and adjustment to breast cancer: A longitudinal study. *J Consult Clin Psychol* 66:313-322, 1998
46. Chen CC, David A, Thompson K, et al: Coping strategies and psychiatric morbidity in women attending breast assessment clinics. *J Psychosom Res* 40:265-270, 1996
47. Helgeson VS, Cohen S: Social support and adjustment to cancer: Reconciling descriptive, correlational, and intervention research. *Health Psychol* 15:135-148, 1996
48. Antoni MH, Lehman JM, Kilbourn KM, et al: Cognitive-behavioral stress management intervention decreases the prevalence of depression and enhances benefit finding among women under treatment for early-stage breast cancer. *Health Psychol* 20:20-32, 2001
49. Jacobsen PB, Meade CD, Stein KD, et al: Efficacy and costs of two forms of stress management training for cancer patients undergoing chemotherapy. *J Clin Oncol* 20:2851-2862, 2002
50. Sears SR, Stanton AL, Danoff-Burg S: The Yellow Brick Road and the Emerald City: Benefit-finding, positive reappraisal coping, and posttraumatic growth in women with early-stage breast cancer. *Health Psychol* 22:487-497, 2003
51. Tedeschi RG, Calhoun LG: The posttraumatic growth inventory: Measuring the positive legacy of trauma. *J Trauma Stress* 9:455-471, 1996
52. Ganz PA, Kwan L, Stanton AL, et al: Quality of life at the end of primary treatment of breast cancer: First results from the Moving Beyond Cancer randomized trial. *J Natl Cancer Inst* 96:376-387, 2004
53. Sears SR, Stanton AL, Kwan L, et al: Recruitment and retention challenges in breast cancer survivorship research: Results from a multi-site, randomized intervention trial in women with early-stage breast cancer. *Cancer Epidemiol Biomarkers Prev* 12:1087-1090, 2003
54. National Cancer Institute: *Facing Forward: A Guide for Cancer Survivors*. Bethesda, MD, National Institutes of Health, NIH publication 94-2424, 1994
55. Ware JE Jr, Sherbourne CD: The MOS 36-item short-form health survey (SF-36): I. Conceptual framework and item selection. *Med Care* 30:473-483, 1992
56. Ware JE: *SF-36 Health Survey: Manual and Interpretation Guide*. Boston, MA, New England Medical Center, 1993
57. Ware JE: *SF-36 Physical and Mental Health Summary Scales: A User's Manual*. Boston, MA, New England Medical Center, 1994
58. Weiss DS, Marmar CR: *The Impact of Event Scale-Revised*. In Wilson JP, Keane TM (eds): *Assessing Psychological Trauma and PTSD*. New York, NY, Guilford Press, 1997, pp 399-411
59. Horowitz M, Wilner N, Alvarez W: Impact of Event Scale: A measure of subjective stress. *Psychosom Med* 41:209-218, 1979
60. Radloff LS: The CES-D Scale: A self-report depression scale for research in the general population. *Appl Psychol Measure* 1:385-401, 1977
61. Roberts RE, Vernon SW: The Center for Epidemiologic Studies Depression Scale: Its use in a community sample. *Am J Psychiatry* 140:41-46, 1983
62. Myers JK, Weissman MM: Use of a self-report symptom scale to detect depression in a community sample. *Am J Psychiatry* 137:1081-1084, 1980
63. Day R, Ganz PA, Costantino JP, et al: Health-related quality of life and tamoxifen in breast cancer prevention: A report from the National Surgical Adjuvant Breast and Bowel Project P-1 Study. *J Clin Oncol* 17:2659-2669, 1999
64. Ganz PA, Rowland JH, Desmond K, et al: Life after breast cancer: Understanding women's health-related quality of life and sexual functioning. *J Clin Oncol* 16:501-514, 1998
65. Cordova MJ, Cunningham LLC, Carlson CR, et al: Posttraumatic growth following breast cancer: A controlled comparison study. *Health Psychol* 20:176-185, 2001
66. Baider L, Uzieli B, De-Nour AK: Progressive muscle relaxation and guided imagery in cancer patients. *Gen Hosp Psychiatry* 16:340-347, 1994
67. Aiken LS, West SG: *Multiple Regression: Testing and Interpreting Interactions*. Newbury Park, CA, Sage, 1991
68. Helgeson VS, Cohen S, Schulz R, et al: Long-term effects of educational and peer discussion group interventions on adjustment to breast cancer. *Health Psychol* 20:387-392, 2001
69. Wagner LI, Cella D: Fatigue and cancer: Causes, prevalence and treatment approaches. *Br J Cancer* 91:822-828, 2004
70. Garrett KM, Marcus AC, Cella D, et al: Can a telephone counseling intervention reduce distress, depression and sexual dysfunction among early stage breast cancer patients post-treatment? Paper presented at 6th World Congress of Psycho-oncology, Banff, Canada, April 23-27, 2003
71. Scheier MF, Helgeson VS, Schulz R, et al: Interventions to enhance physical and psychological functioning among younger women who are ending nonhormonal adjuvant treatment for early-stage breast cancer. *J Clin Oncol* 23:4298-4311, 2005
72. Sandgren AK, McCaul KD: Short-term effects of telephone therapy for breast cancer patients. *Health Psychol* 22:310-315, 2003