# Quality of life pilot intervention for breast cancer patients: Use of social cognitive theory

KRISTI D. GRAVES, Ph.d., CINDY L. CARTER, Ph.d., EILEEN S. ANDERSON, Ed.d., AND RICHARD A. WINETT, Ph.d.  $^1$ 

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#### ABSTRACT

*Objective:* The purpose of this article is to evaluate an 8-week pilot intervention based on Social Cognitive Theory to improve quality of life for women with breast cancer.

*Methods:* A total of 32 breast cancer patients were randomized to either the intervention or standard care. Outcome variables included quality of life, mood, self-efficacy, outcome expectations, and self-regulation.

*Results:* Effect sizes were calculated to examine the impact of the intervention, with moderate to large effect sizes found for several subscales of the outcome expectations variable: learning about cancer and treatment (d=0.85), having a positive attitude (d=0.54), talking about cancer (d=1.02), engaging in relaxation (d=0.62), and setting goals (d=1.58).

Significance of results: A nonparametric sign test was conducted, indicating that women in the intervention condition either improved more or showed less decline than the women in standard care, p=.034, two-tailed. Implications and suggestions for the content and delivery of future psychosocial interventions with cancer patients are reviewed.

**KEYWORDS:** Quality of life, Breast cancer, Intervention, Social cognitive theory

#### INTRODUCTION

Improvement in the quality of life of breast cancer survivors may lessen the physical and psychological costs caused by this disease. Psychosocial interventions have been shown to have positive effects for cancer survivors in terms of emotional and functional adjustment as indicated by several reviews (Andersen, 1992; Meyer & Mark, 1995; Owen et al., 2001; Graves, 2003). One critical area benefited by these interventions is quality of life (Telch & Telch, 1986; Greer et al., 1992; Cella et al., 1993). Quality of life (QOL) has been defined as years of healthy

Corresponding author: Kristi D. Graves, Department of Behavioral Science, University of Kentucky, College of Medicine Office Building, Lexington, KY 40536-0086. E-mail: kdgrave@uky.edu.

life (Department of Health and Human Services [DHHS], 1991); Cella and Cherin (1988, p. 70) describe QOL as the "... patients' appraisal of and satisfaction with their current level of functioning compared to what they perceive to be possible or ideal." Therefore, QOL is both a functional and affective variable related to the individual's overall well-being and is conceptualized as a subjective and multidimensional construct (Cella, 1992).

The mechanisms for the beneficial effects of such interventions are not clearly understood. Meyer and Mark (1995) and Redd (1995) encouraged researchers to investigate potential mechanisms for change in QOL through theoretically driven, well-designed experimental studies. Owen et al. (2001) reviewed psychosocial interventions with cancer patients within a three-tiered model defined as global health outcomes, dimensions of health-related QOL, and

<sup>&</sup>lt;sup>1</sup>Center for Research in Health Behavior, Virginia Polytechnic Institute and State University, Blacksburg, Virginia

<sup>&</sup>lt;sup>2</sup>Hollings Cancer Center, Medical University of South Carolina, Charlestown, South Carolina

mechanisms of action. Owen et al. (2001) suggested that as a field, we should examine psychooncology intervention strategies within a theoretical framework to augment our understanding of the mechanisms of action. Social Cognitive Theory (SCT; Bandura, 1997), through its components of perceived coping self-efficacy, outcome expectations, and self-regulation, may account for the mechanisms of action stemming from psychosocial interventions and offer an overarching theoretical model of improvements in QOL and possible reductions in disease progression or recurrence (Bandura, 1986, 1997; Graves, 2003).

# **Social Cognitive Theory**

SCT has been used to promote health behavior and enhance adjustment to chronic illness (see Bandura, 1997, ch. 7). Lev (1997) provides a nice overview of the application of self-efficacy to oncology, noting that increasing self-efficacy can promote better adjustment to cancer. In addition to self-efficacy, two other elements of SCT may impact cancer patients' QOL and adjustment, outcome expectations and self-regulation.

# Self-Efficacy

Self-efficacy, or "beliefs in one's capabilities to organize and execute the course of action required to produce given attainments" (Bandura, 1997, p. 3) may play a critical role in QOL and adjustment for cancer patients (Lev, 1997; Lev & Owen, 2000). Interventions to improve QOL in cancer survivors have included instruction for coping with the disease by providing information and assessing affective reactions. One's belief in his/her coping abilities has been shown to predict more adaptive psychological and physiological functioning (Bandura, 1997), which would then indicate higher QOL. According to Bandura (1997, p. 302):

... perceived capability to exercise control, whether illusory or real but unexercised, decreases emotional distress over aversive events. Thus, belief in one's personal efficacy can, in itself, produce benefits. Additionally, positive cognitive reappraisals that focus on the aspects of one's life that are personally controllable can raise perceived efficacy, which activates many adaptive processes extending well beyond the particular coping skills taught in an intervention.

Controlling for the effects of metastatic disease, moderate and high levels of self-efficacy significantly predicted higher rates of survival after

6 years for women with breast cancer and after 3 years for a sample of individuals with mixed cancer diagnoses (Merluzzi & Nairn, 1999). Further, higher levels of self-efficacy for communicating emotions, remaining focused in the present moment, and confronting issues of death and dying were related to lower levels of trauma symptoms in a sample of breast cancer survivors (Giese-Davis et al., 1999). Likewise, higher efficacy scores were associated with lower mood disturbance after a 3-month intervention with breast cancer survivors (Giese-Davis et al., 1999). In a prospective study with breast cancer patients, self-efficacy for using strategies to promote their health and QOL were found to decrease over time. Women's confidence in their ability to care for themselves was related to overall adjustment to their disease (Lev et al., 1999).

To improve self-efficacy for specific situations, one must have realistic and achievable goals. For example, if an individual's belief in his or her ability to cope with cancer is commensurate with his/ her coping skills (such as clear communication, seeking appropriate social support, praying, etc.), more positive outcomes will occur. As a mutable characteristic, self-efficacy changes with experience. Successful experiences, achieved after setting appropriate goals and engaging in identified behaviors, will become mastery experiences. Mastery experiences allow an individual to see what works and what does not work for achievement of a specific goal (i.e., feedback). A mastery experience occurs when an individual is able to learn from his/ her behavior and internalize that knowledge so that it can be applied during similar situations in the future. One such example might be when a patient brings written questions with her into the exam room. After reading the questions and getting the information, this woman recognizes that writing down her questions before her appointment helps her to have all of her questions answered. She will then bring written questions with her to her next medical appointment. Another part of this process of change is one's expectations about the behavior and its consequences. If the woman in the above example expected her physician to treat her in a brusque manner when responding to questions, she may not be as likely to engage in the behavior of bringing questions to this physician. Expectations like this are described below.

## Outcome Expectations

Outcome expectations are described as the "subjective probability that a particular behavior, if performed by someone at a given level of competence, will be followed by a particular outcome" (Kirsch,

1995, p. 333). Outcome expectations are categorized as the physical, social, and self-evaluative expectations one holds for the outcome of one's behaviors. For example, if a patient expects to experience extreme fatigue immediately after his chemotherapy treatment, he may turn down an invitation to visit with friends. In this example, the patient's negative expectations about the effects of chemotherapy influenced his behavior.

When cognitions/expectations are appropriately realistic and stated positively, cancer patients experience less distress. Specifically, interventions to improve QOL frequently aim to teach cancer patients how to recognize and restructure negative expectations about their illness and the future (Moorey & Greer, 1989; Nezu et al., 1998). Psychologists or other health professionals help patients change unrealistic and pessimistic outcome expectations through restructuring negative selfstatements. In addition, interventions that help cancer patients form realistic goals associated with their illness or treatment result in improved functioning (Telch & Telch, 1986; Moorey & Greer, 1989). Often, outcome expectations are shaped though the process of learning and adaptation (i.e., selfregulation). For example, if a person believes something harmful or unpleasant will result from a specific behavior, his or her behavior is influenced by that belief. The process of self-regulation may therefore influence the expectations of certain outcomes, as well as one's perceived ability to engage in the behavior.

## Self-Regulation

Self-regulation refers to the process of planning, monitoring, and changing one's behaviors and cognitions to correspond with abilities, the environment, and desired outcomes. Self-regulation includes influencing direct control over behavior and selecting or altering environmental conditions which, in turn, influences behavior. Personal standards are adopted for behavior; people can then appraise their behavior against such standards. Employment of self-regulation allows for personal growth and adaptation to changing environments and personal goals (Maddux & Lewis, 1995). For example, a selfmanagement program to augment self-regulatory skills in patients with chronic arthritis led to lower levels of physical and psychological morbidity (Holman & Lorig, 1992). Effective self-regulation may contribute to positive adjustment for cancer patients, as avoidant coping styles have been shown to predict poorer outcomes (Stanton & Snider, 1993). The continual progression of this type of adaptive process, and the agency behind it, contribute to functional behavior, or active participation in daily living along with the absence of distress.

These components of SCT provide a theoretical framework for evaluation of past and current efforts to improve functioning for people with cancer. Several studies have aimed to enhance self-efficacy; however, no studies with cancer patients have evaluated the effects of a manual-based group SCT intervention. Further, previous research has not measured outcome expectations and self-regulation. Identifying key components of successful QOL interventions is important to structure current efforts in psycho-oncology.

#### Psychosocial Interventions to Improve QOL

A skill-building group for cancer survivors was more effective in improving cancer survivors' adjustment to disease and QOL than supportive group therapy and standard care (Telch & Telch, 1986). Cancer survivors in the coping skills group had significantly higher levels of self-efficacy as measured by a researcher-designed instrument that consisted of six subscales: coping with medical procedures; communication with physicians, friends, and family; participation in vocational, social, and physical activities; personal management; affective management; and self-satisfaction (Telch & Telch, 1986). Moreover, compared to the other two groups, the coping skills intervention participants had significantly lower scores on the negative subscales of the Profile of Mood States (POMS) and significantly lower ratings on the Cancer Inventory of Problem Situations (CIPS), a scale that assesses problems frequently encountered by cancer patients. Effect sizes based on the comparison of the coping skills group to the support group were quite high for self-efficacy (0.75) and overall mood (0.76); these effect sizes were even more robust for coping skills versus standard care (1.55 for self-efficacy and 2.11 for overall mood). Similarly, an intervention designed to enhance self-efficacy improved QOL as measured by the Functional Assessment of Cancer Therapy, as well as lowered symptom distress, at 4 and 8 months post intervention (Lev et al., 2001). This intervention was delivered individually to each breast cancer survivor once a month for 5 months and was supplemented by a video designed to augment self-efficacy. Finally, improved mood states were evident in a 6-week skill-building intervention. Cancer patients randomized to the skillbuilding group reported significantly better mood states than those in the supportive discussion group at 3-month follow-up (Cunningham & Tocco, 1989).

A recent study (Antoni et al., 2001) compared a 10-week cognitive-behavioral stress management

intervention to a 1-day educational seminar. Antoni et al. were able to make significant changes in distress, optimism, emotional processing, and benefit finding for women in their treatment group, especially for those women who had high distress and low optimism at baseline. The intervention strategies used by this research team, described as cognitive-behavioral stress management, are similar to those delineated in SCT. These strategies include the practice of specific skills, modeling, and challenging negative expectations. The authors indicate that the specific processes by which the intervention had an influence were not explicable through the variables they measured (Antoni et al., 2001). For example, the improvements in benefit finding could not be explained by changes in mood or optimism. Evaluation of change mechanisms is challenging, and a process variable such as selfregulation may be instructive for understanding change after an intervention.

Most of the empirical research related to psychosocial interventions for cancer survivors involve group or individual treatments structured to teach and practice skills, provide information (i.e., those programs that do not have participants practice new skills), or enhance support through a nondirective, discussion-oriented group. Both skill-building and education-only interventions have been contrasted with nondirective, discussion-oriented support groups (Telch & Telch, 1986; Helgeson et al., 1999), as well as with standard-care or no-treatment control groups (Telch & Telch, 1986; Helgeson et al., 1999; Lev et al., 2001).

# Education versus Support

Attempts have been made to explain potential mechanisms of change for improved functioning in psychosocial interventions with cancer survivors (Helgeson et al., 1999, 2000). The strategy of Helgeson et al. was to examine the differences between education-based and peer discussion-based interventions for cancer survivors. Women in the education-only condition showed improved physical and psychological outcomes at posttest and 6-month follow-up, whereas women in the peer-discussion and education plus peer-discussion conditions did not improve. Effect sizes for the education versus peer-discussion and no-treatment control conditions demonstrated small to moderate effects for positive affect (0.16 and 0.17) and self-reported physical functioning (0.36 and 0.25). Pathways of improved adjustment were examined; women in the education intervention had improved self-esteem and body image, less uncertainty about their illness, and greater likelihood of discussing their illness with friends and family than women not in the education group. These participants also had fewer intrusive thoughts about their illness, greater personal control, and less vicarious (i.e., other) control. Women in the peer-discussion intervention showed more negative social network interactions and downward comparisons as well as more intrusive and avoidant thoughts than women in the other groups (Helgeson et al., 1999, 2000).

#### Potential Mechanisms of Change in QOL

Successful psychosocial interventions for improving the QOL in breast cancer survivors appear to have elements that augment participants' coping self-efficacy, increase positive outcome expectations, and teach appropriate self-regulatory skills. A recent meta-analysis of psychosocial interventions for adult cancer survivors indicated that those studies with SCT-based components had significantly larger effect sizes for all QOL outcomes combined than studies without SCT-based components, Z = 3.72, p < .01 (Graves, 2003). Moreover, measures of affective, social, and physical functioning, as well as specific QOL outcomes, were significantly larger for interventions including SCT-based components. Thus, implementing an SCT-based intervention with adult cancer survivors may provide maximum improvement of QOL outcomes.

The aims of the current project were to enhance QOL through a SCT-based pilot intervention focusing on augmenting self-efficacy, outcome expectations, and self-regulatory skills for women with breast cancer. The hypotheses were that effect sizes would indicate (1) women assigned to the experimental SCT-based skill-building intervention would have higher scores on the FACT-B at posttest, reflecting higher QOL, than women assigned to the standard-care group and (2) the SCT components of self-efficacy, outcome expectations, and self-regulation would be higher for women assigned to the experimental SCT-based skill-building intervention at posttest.

# **METHOD**

# **Participant Recruitment**

Participants recruited for this study consisted of women diagnosed with breast cancer (any stage of disease) within the past 5 years. Several recruitment strategies were attempted to obtain the proposed 60 participants: presentations to oncology physicians and staff, face-to-face contact with potential participants, posters and brochures, letters

mailed from the oncology social worker to 989 women meeting eligibility criteria, and attendance of the study investigator at breast care case conferences at a cancer center. Use of human subjects was approved by the Institutional Review Boards at Virginia Tech and Carilion Health System.

# Response to Recruitment

Of the 989 letters that were mailed out, 26 women called to ask for more information about the study and 22 enrolled. Women who enrolled in the study from other recruitment methods included one who responded to a poster at her physician's office, seven through face-to-face contact, and two who were referred by health care workers.

#### Design

This pilot project was designed as a randomized, two-group design with attention toward balance of treatment status (on versus off primary treatment). The two-group design with the individual as the unit of randomization was determined to provide the most power and allow for evaluation of the influence of the essential components of SCT self-efficacy, outcome expectations, and selfregulation—on QOL outcomes. The treatment condition, skill-building based on SCT, was compared with a standard-care control group. The components included in the skill-building condition follow the recommendations set forth in previous literature by Bandura and others for design of an intervention based on SCT (Maddux & Lewis, 1995; Bandura, 1997).

#### **Description of Treatment Conditions**

Skill-Building Intervention Based on Social Cognitive Theory

The experimental SCT-based skill-building intervention was conducted as an interactive and supportive group program with emphasis on information, skill building, practice, feedback, and enlistment of social supports. The facilitator helped group members enhance their coping self-efficacy by teaching skills related to cognitive restructuring, relaxation, and assertive communication and then practicing these skills within a supportive environment.<sup>1</sup> A summary of each session is pro-

vided in Table 1. Group members were taught how to recognize and change negative outcome expectations into more positive expectations through cognitive restructuring techniques and discussion and setting of realistic goals. Self-regulation was encouraged by providing information for implementation of these skills outside of the group. Once women related their attempts of these skills, feedback was provided so that the participants could further improve the skills. The 8-week intervention was conducted once a week for  $1\frac{1}{2}$  hours each session. New goals were set each week in accordance with the topic being discussed. Sessions included information tailored to individual group participants and their current level of functioning. The investigator, a doctoral candidate in clinical psychology, facilitated one 8-week course of the SCT-based skill-building program, while a trained clinical psychology intern facilitated another 8-week course. The same 8-week course was offered at the conclusion of the study for women in the standard-care control group.

# Standard-Care Control Group

Women assigned to this control group received standard care from the medical community. In addition, these women were provided with brochures printed by the National Institutes of Health, with information related to cancer, treatment options and treatment side effects, and healthy eating. Women assigned to the standard-care group were invited to participate in the skill-building intervention after completion of posttest assessment instruments.

# **Procedures**

Women who completed the baseline assessment were randomized to either the skill-building intervention or standard-care control group. Randomization was conducted after 18 women had returned completed baseline measures, stratified for current or past treatment status. Recruitment continued during implementation of the program. All participants were reassessed after 8 weeks.

Women assigned to the intervention (n=15) attended the program in small groups. Eight women were assigned to the first intervention group and 4 women completed the 8-week program and posttest assessment. In the second intervention group, 7 women were assigned and 3 completed the group program and posttest assessment. Thus, 7 out of 16 women assigned to the intervention completed both the 8-week program and the posttest measures. Posttest measures were provided to the women in

 $<sup>^{1}</sup>$ Copies of the treatment manual are available from the investigator.

**Table 1.** Description of the intervention components

Session number	Session name	Description
1	Introduction	Program goals and topics explained. Women introduced to concept of goal setting. Asked to complete assignment about expectations of health, family environment, occupational functioning, and ability to cope with breast cancer treatment.
2 & 3	Notions and Emotions	Women taught how to restructure negative thoughts about themselves, coping abilities, and the future. Examples solicited for practice with identifying and restructuring negative thoughts. Self-monitoring forms explained.
3 & 4	Communication Skills	Women instructed in appropriate communication skills and conflict resolution; taught how to engage in assertive behavior. Used role playing to practice communication skills and to help women eliminate negative outcome expectations.
5	Dealing with Daily Hassles	Relaxation strategies taught each session. Women assisted with identification of stressors and learned different cognitive and behavioral techniques for managing stress. Asked to self-monitor stressful or anxiety-provoking situations and note physiological, affective, and intellectual responses to these situations.
6	Activity and Independence Concerns	Discussed women's ability to perform specific daily functions and associated feelings of dependence/independence. Issues related to return to work and/or job security addressed.
7	Changing Images and Sex Appeal	Discussed women's fears and expectations about changes in their bodies and feelings of sexuality due to cancer and its treatment. Women taught how to talk with a partner about intimacy and sexuality.
8	Future Directions and Expectations	Issues related to overall impact of cancer on the women's lives reviewed. Suggestions for long-term goals for each participant discussed. Women encouraged to share what they had learned about themselves and each other.

the intervention group at the end of the final session. Women were asked to take the measures home, complete them within 1 week, and mail them back to the investigator in the provided stamped envelope. Women in the standard-care condition (n=17) were mailed the posttest measures, asked to complete and return the measures, and indicate on a brief form whether they were interested in attending the skill-building program in the future. When the posttest measures were not received within 1 week, the investigator called the participants and asked them to complete the measures. Seven of the 17 women assigned to the standard-care condition completed posttest measures.

#### Measures

 ${\it Clinical\ and\ demographic\ information}$ 

Information related to women's age, marital status, educational status, income, stage of disease, time since diagnosis, treatment type(s), and side effects from treatment was obtained during an individual interview with the participant prior to randomization to treatment group.

# QOL

QOL was assessed by the Functional Assessment of Cancer Therapy—Breast (FACT-B, Brady et al., 1997).

The FACT-B is a 44-item self-report instrument designed to measure multidimensional QOL in patients with breast cancer through five subscales. This scale has been shown to have adequate reliability, validity, and sensitivity to change. The subscales, with corresponding Cronbach's alphas based on previous research (Brady et al., 1997), are: physical well-being (.81), social well-being (.69), emotional well-being (.69), functional well-being (.86), and the breast cancer subscale (.63). The overall alpha for the FACT-B is .90. Higher scores indicate better QOL for the total scale and all subscales. The FACT-B takes approximately 10 minutes to complete and is written at a sixth-grade reading level (Brady et al., 1997).

#### Mood

Mood was measured by the Profile of Mood States (POMS; McNair et al., 1971). The POMS consists of 65 adjectives, each rated on a 5-point scale and categorized into six mood states: depression-dejection, tension-anxiety, anger-hostility, vigor, fatigue, and confusion; a total mood disturbance score is calculated. Internal consistency for the total scale is alpha = .95, with test-retest correlations between .65 and .74, concordant for the purpose of measuring fluctuating mood states (McNair et al., 1971). Lower scores indicate less mood disturbance.

#### Self-Efficacy

The Cancer Behavior Inventory (CBI; Merluzzi & Martinez Sanchez, 1997) was administered to assess breast cancer survivors' self-efficacy in coping with cancer. The 33-item CBI has six factors: Maintenance of Activity and Independence, Coping With Treatment-Related Side Effects, Accepting Cancer/ Maintaining a Positive Attitude, Seeking and Understanding Medical Information, Affective Regulation, and Seeking Support. Merluzzi and Martinez Sanchez (1997) reported a Cronbach's alpha of .96 for the total scale; construct validity was established with significant correlations between the CBI and several validated scales (i.e., Sickness of Impact Profile, Psychosocial Adjustment to Illness Scale). Higher scores indicate greater levels of self-efficacy.

# Outcome Expectations and Self-Regulation

These variables were assessed by measures developed by the investigator from guidelines set by Bandura (1986, 1997). The outcome expectations measure consisted of 69 items. Specific situations and behaviors assessed with this measure were determined after focus groups and individual interviews were conducted with breast cancer survivors.

Five domains were developed and consisted of outcome expectations for learning about cancer and its treatment (e.g., If I learned about my cancer and its treatment, I would not worry about the physical changes in my body); having a positive attitude (e.g., If I looked at the positive side of having cancer, I would be giving myself false hope); talking about cancer (e.g., If I talked with my partner/ spouse about my fears, I would make my partner/ spouse afraid as well); engaging in relaxation (e.g., If I relaxed, I would not feel as tired all of the time); and setting goals (e.g., If I set goals related to my illness, I would feel more independent). Items were constructed as Likert scales ranging from 1 to 5, with 1 representing "strongly disagree" and 5 representing "strongly agree." Based on the present sample, the overall scale had an alpha of .74, with alphas ranging from .55 to .93 for the five domains. Negatively worded items were reversed-scored; higher scores indicate more positive outcome expectations.

Self-regulation was measured with another investigator-constructed scale. This 22-item measure included items assessing the participant's level of skills related to planning and adaptation such as communicating assertively, using relaxation, and recognizing and restructuring negative thoughts. For example, women were asked about their planning behavior, goal setting, self-care activities, and problem solving (e.g., "How well does this statement describe you: I know how to recognize when I have a negative thought about something"). A total score is calculated for this measure; it had a coefficient alpha of .88 for the present sample. Again, items for this measure were answered on a 5-point Likert scale, with 1 representing "never" and 5 representing "always." Higher scores indicate better self-regulative abilities.

#### **Data Analysis**

To evaluate whether participants randomized to each group were different at baseline on the demographic, clinical, and SCT variables, t tests were conducted. Effect sizes and a nonparametric sign test were computed to evaluate overall treatment effects on the outcome measures. Analyses included: t tests for independent samples, a nonparametric sign test, and computation of effect sizes for each of the dependent variables.

#### RESULTS

#### **Baseline Sample**

A total of 32 women completed the baseline measures, with 16 in each treatment condition. Demo-

graphic information for this sample is presented in Table 2; women ranged in age from 35 to 81 years (M=55.66, SD=10.75), and were, on average, 2.5 years out from their diagnosis of breast cancer. Despite randomization, significant differences were evident between the intervention and standard-care groups on three variables: outcome expecta-

**Table 2.** Demographic characteristics of initial sample (N = 32)

	n	Percent
$Age\_M = 55.66, SD = 10.75$		
35–40	4	12.5
40–50	2	6.25
50–60	15	46.88
60–70	8	25
70–81	3	9.37
Stage		
0	8	25
1	10	31.3
2	10	31.3
3	4	12.5
Average yearly income— $M = $46,000$		
Less than \$9,999	2	6.3
\$10,000-\$19,999	4	12.5
\$20,000-\$29,999	2	6.3
\$30,000-\$39,999	3	9.4
\$40,000-\$49,999	$^2$	6.3
\$50,000-\$99,999	14	43.8
Over \$100,000	4	12.5
Partner status		
Has partner	23	71.9
Does not have partner	9	28.1
Education level		2011
Completed HS/GED	5	15.6
Some college	16	50.0
Completed 2-year degree	4	12.5
Completed 2-year degree Completed 4-year degree	1	3.1
Some graduate work	5	15.6
Completed graduate degree	1	3.1
	1	5.1
Ethnicity	30	02.0
Caucasian	30 2	93.8
African American	2	6.3
Treatment status		
Had chemotherapy	21	65.5
Had radiation	23	71.9
Taking Tamoxifen	20	62.5
Had lumpectomy	18	56.3
Had mastectomy	13	40.6
Had breast reconstruction	4	12.5
Time since diagnosis— $M = 30$ months		
0–6 months	2	6.25
6–12 months	11	34.38
12–24 months	5	15.62
24–48 months	7	21.88
48–56 months	$\frac{2}{2}$	6.3
56 months or longer	5	15.62

tion for learning about cancer and its treatment, t=2.42, p=.022, vigor scale of the POMS, t=-2.05, p=.05, and the Functional Well-Being Scale Score of the Fact-B, t=2.91, p=.007, with women in the standard-care control group scoring higher. No differences between the intervention and standard care groups were evident for the remainder of study variables: demographic and clinical, four outcome expectation subscales, four subscales and total mood disturbance on the POMS, four subscales of the Fact-B, all six of the self-efficacy subscales, and self-regulation. Correlations among the variables at baseline are presented in Table 3.

# **Posttest Sample**

Seven women from each condition completed posttest measures (n = 14). These 14 women did not differ from the 18 women who did not complete the study on any demographic or clinical characteristics. For women assigned to the intervention group, noncompleters tended to drop out of the study before attending one intervention session, citing conflict with busy schedules. On average, women who completed the intervention attended five sessions. Further, women who completed the intervention appeared to be more distressed at baseline than women who dropped out of the study. Specifically, women who completed the program reported worse functioning at baseline than women who did not complete the program on the following variables: self-efficacy for coping with cancer (7 of 7 subscales), outcome expectations (5 of 5 subscales), self-regulation, performance of positive coping strategies, mood (all 6 subscales and total score on the Profile of Mood States), and quality of life (all 5 subscales and total score on the Functional Assessment of Cancer Therapy-Breast). Completers reported lower self-efficacy for coping with treatment-related side effects, t = 2.68, p = .012. In addition, a nonparametric binomial sign test was conducted due to power constraints with the small sample. Results indicate that the total number of differences between intervention completers and noncompleters was significant, p > .002.

#### **Intervention Effects**

A nonparametric sign test was conducted to evaluate whether the intervention group changed significantly more than the control group in the hypothesized direction. For 17 of 23 outcome variables, the women in the intervention condition either improved more or showed less decline than the women in the standard care condition, p=.034, two-tailed.

**Table 3.** Correlation matrix with means, standard deviations, and coefficient alphas for study variables at baseline

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
1. FACT-B: Quality of Life: $\overline{X}=110.89, SD=23.24$	$1.0 \\ \alpha = .91$														
2. SE: Maintaining Activity/Independ.: $\overline{X}=38.40,SD=6.84$	.62**	$1.0$ $\alpha = .81$													
3. SE: Seeking/Understanding Med. Info.: $\overline{X}2=39.37,SD=5.77$	.26	.23	$\begin{array}{c} 1.0 \\ \alpha = .77 \end{array}$												
4. SE: Stress Mgmt. for Medical Appts.: $\overline{X} = 32.55, SD = 9.17$	.50**	.71**	.36	$\begin{array}{c} 1.0 \\ \alpha = .73 \end{array}$											
5. SE: Coping w/Tx- Related Side Effects: $\overline{X} = 32.35, SD = 9.44$	.46**	.73**	.39*	.84**	$\begin{array}{c} 1.0 \\ \alpha = .79 \end{array}$										
6. SE: Accepting Cancer/Maint. Pos. Att.: $\overline{X}=37.84, SD=8.42$	.77**	.83**	.25	.72**	.71**	$1.0 \\ \alpha = .93$									
7. SE: Affective regulation: $\overline{X} = 29.93, SD = 7.43$	.39*	.48**	.36	.53**	.59**	.47**	$1.0$ $\alpha = .53$								
8. SE: Seeking support: $\overline{X} = 21.53, SD = 4.99$	.67**	.53**	.50**	.50**	.52**	.68**	.53**	$1.0$ $\alpha = .70$							
9. OE: Learning about cancer & tx: $\overline{X} = 45.90$ , SD = 6.49	.57**	.47*	.33	.57**	.56**	.62**	.26	.47**	$\begin{array}{c} 1.0 \\ \alpha = .70 \end{array}$						
10. OE: Positive Attitude: $\overline{X} = 41.94, SD = 8.00$	.42*	.45*	.30	.46*	.48**	.63**	.22	.52**	.46**	$1.0$ $\alpha = .93$					
11. OE: Talking about cancer: $\overline{X} = 54.31, SD = 11.35$	33	19	50*	25	26	18	42*	39*	30	11	$1.0 \\ \alpha = .80$				
12. OE: Relaxation: $\overline{X} = 48.37, SD = 9.50$	.43*	.23	.31	.43*	.43*	.45*	.09	.46**	.58**	.60**	34	$1.0$ $\alpha = .91$			
13. OE: Goals: — X = 22.87, SD? = 3.82	.16	.25	.16	.54*	.41*	.29	.06	.11	.59**	.41*	01	.69**	$1.0$ $\alpha = .55$		
14. Self-regulation: $\overline{X} = 84.72$ , $SD = 12.35$	.59**	.60**	.41*	.52*	.62**	.61**	.49**	.56**	.40*	.40*	26	.42*	.15	$1.0 \\ \alpha = .88$	
15. POMS: TMDS: $\overline{X} = 14.66,^{\text{a}} SD = 39.70$	72**	63**	.02	34	37*	67**	18	38*	28	30	.13	26	01	44*	$1.0^{\rm b}$

Notes: N ranges from 25 to 32. aRange of POMS TMDS was -39 to 140. bReliability not calculated. \*Alpha  $\leq$  .05, \*\*Alpha  $\leq$  .01.

#### **Effect Sizes**

Using an equation based on pre-post change scores (Carlson & Schmidt, 1999), effect sizes were calculated for all of the outcome variables. Of note were the effect sizes for outcome expectations: learning about cancer and treatment (d=0.85), having a positive attitude (d=0.54), talking about cancer (d=1.02), engaging in relaxation (d=0.62), and setting goals (d=1.58). Using guidelines suggested by Cohen (1992), effect sizes ranging from 0.80 and above are large, 0.50 to 0.80 are medium and 0.20 and below are small. Means, standard deviations, and effect sizes for the outcome variables are shown in Table 4.

# **DISCUSSION**

The purpose of this study was to evaluate the results of a pilot QOL intervention for women with breast cancer. As evidenced by effect size calculation, women in the intervention condition had higher outcome expectations than women in the standard care condition. The hypothesis that participation in the intervention would result in higher QOL scores was not supported, as the effect size for differences in QOL scores was small (d = 0.02 using intent to treat model, d = 0.14 using data from completers only).

On follow-up surveys, women in the intervention condition indicated that they enjoyed the program and found it very useful. Clinical observations during the group sessions suggested that women gained mastery over skills such as changing negative thoughts, communicating clearly and more assertively, using relaxation techniques, and setting goals. Women completed the homework associated with each session and discussed the progress and/or difficulties they were experiencing in terms of reaching the goals they had set at the beginning of the program.

Baseline differences between women who completed the program and those who did not complete the program were evident across all variables. One variable, self-efficacy for coping with treatment and related side effects, was significantly lower at baseline in women who completed the program than women who dropped out of the program. Interpretations of the data are premature given the low power associated with small sample sizes (Lipsey, 1990); however, the consistent finding that all of the baseline scores were lower for completers is intriguing. Perhaps women who were more in need of services (i.e., those experiencing more distress) were the participants who completed the program. When change scores were examined for differences

**Table 4.** Effect sizes based on pre-post change scores

			n			Pooled				
Variable	Pre-Tx	Pre-SC	Post-Tx	Post-SC	Pre-Tx	Pre-SC	Post-Tx	Post-SC	SD	d
SE: Maintaining act/independ.	15	17	7	7	36.93	39.82	33.86	37.57	6.72	-0.12
SE: Seek/understand. med info	15	17	7	7	39.00	39.71	38.57	38.14	5.85	0.19
SE: Managing stress	14	17	7	7	30.36	34.35	28.86	33.71	8.83	-0.10
SE: Coping w/ Tx side effects	15	17	7	7	30.20	34.35	27.14	31.86	9.20	-0.06
SE: Accepting cancer/pos att.	15	17	7	7	35.93	39.47	34.00	37.43	8.22	0.01
SE: Regulating affect	14	17	7	7	27.57	32.88	29.57	31.86	7.31	0.41
SE: Seeking support	15	17	7	7	21.73	21.71	22.71	21.14	5.00	0.31
OE: Learning about Ca/Tx	15	16	7	7	3.60	4.03	3.79	3.79	0.50	0.85
OE: Having a positive attitude	15	17	7	7	4.22	4.17	4.10	3.61	0.81	0.54
OE: Talking about cancer	15	17	7	7	2.55	2.62	2.85	2.35	0.55	1.02
OE: Engaging in relaxation	15	15	7	7	3.87	4.19	3.89	3.72	0.78	0.62
OE: Setting goals	14	17	7	7	3.59	3.99	4.09	3.52	0.62	1.58
Self-regulation	15	17	7	7	3.68	4.01	3.76	4.06	0.55	0.15
POMS Total Mood dist. score	15	17	7	7	23.87	6.53	32.20	11.67	39.08	0.19
FACT-B Physical WB	15	17	7	7	21.87	22.88	21.85	24.57	4.87	-0.35
FACT-B Social WB	15	17	7	7	22.07	22.76	21.14	20.42	5.94	0.24
FACT-B Emotional WB	15	17	7	7	18.27	20.94	17.00	20.00	4.12	-0.08
FACT-B Functional WB	15	17	7	7	20.13	24.12	20.00	23.86	3.86	0.03
FACT-B Additional Concerns	15	17	7	7	22.80	26.00	22.42	24.71	6.82	0.13
FACT-B (intent-to-treat)	15	17	7	7	105.10	116.70	102.40	113.60	19.99	0.02
FACT-B (program completers)	7	7	7	7	99.28	116.90	102.40	113.60	19.40	0.14

 $\it Note:$  Tx: treatment group, SC: standard care group,  $\it SD:$  standard deviation,  $\it d:$  Cohen's  $\it d.$ 

between the intervention and standard-care groups, trends emerged that supported the potential efficacy of the intervention. Specifically, women in the intervention group showed more improvement in self-efficacy scores at posttest than women in the control condition, although this finding was not statistically significant. The same findings emerged for QOL; women in the intervention group showed more change in their QOL scores than women in the control condition. Therefore, careful evaluation of the results of this study and its methodological limitations may provide some tentative guidelines and help inform future research.

#### **Efficacy versus Effectiveness**

Once a program has documented positive effects, we must then begin to explore how to apply it in the field in terms of acceptable delivery. Suggestions for delivery are delineated below. Physician referrals, as well as program length, appear very important. For the present study, both the lack of physician referral and the necessity of attending a program once a week for 8 weeks likely contributed to the small sample size. In addition to the self-report data employed in this study, future efficacy research should continue to include physiological measures and monitor service utilization to objectively record improvements in immune functioning and overall functional status (see Antoni et al., 2001, and Stanton et al., 2002). Armed with this information, behavioral medicine specialists may be more likely to convince medical stakeholders to support the widespread implementation of psychosocial interventions. Further, progressive health insurance agencies are beginning to invest in preventive efforts, and thus may reimburse preventive psychological support programs in the future (Sobel, 1995). Expanding these preventive efforts to improve the psychological functioning of cancer patients who report more distress on initial screening measures may alleviate future psychological and physical morbidity, hence lowering costs to the medical community.

In 1994, the National Cancer Institute's 27 Comprehensive Cancer Centers were surveyed by the Center for Advancement of Health. At that time, 24% of the Centers provided some form of coordinated psychosocial services to their patients (Gruman & Convissor, 1998). Survey responses also indicated that the "Centers are disturbingly unaware of the level of utilization of services, the services provided at affiliated institutions, the staffing patterns, and any psychosocial research conducted within their own institutions" (Gruman & Convissor, 1998, p. 1175). A logical extension of the Centers' own lack of awareness of psychological

support services is underutilization (or unavailability) of those services. Of a sample of 731 breast cancer patients, 34% indicated that they would have used a professional supportive care service, but were unable to do so because the desired service was not provided by their medical center. Further, women who were most likely to utilize existing services were younger, more affluent, employed, had private insurance, and received chemotherapy (Gray et al., 2000). Thus, women with fewer resources (no insurance or underinsured, low socioeconomic status), may not seek out or be provided with referrals for support services.

Two issues become evident when evaluating service and delivery of psychosocial programs and support—access and content. As Gray et al. (2000) illustrate, patients seeking specific services may not be able to partake of these services because they are not offered in their medical center. Although the number of psychosocial oncology units in cancer centers is increasing, the field continues to be confronted with the realities of economicsdriven medicine. Thus, for some medical centers, attending to the psychological sequelae of cancer is considered a luxury (Holland, 1998). When services are provided, their content and delivery influence whether cancer patients use them. Most often, the cancer patients who attend support or educational programs are those with the most resources in terms of time and personal motivation (Gray et al., 2000; Coyne et al., 2001). Regarding content, structured and content-limited psychological services, whether delivered individually or in a group, appear to be the most cost effective in terms of benefit to the cancer patient (Spira, 1998). However, the open-ended and less structured groups may have more practical appeal to patients, as they can decide when they need the support and information provided by these programs.

Efforts are being made to remedy the lack of appropriate services and the underutilization of those services. Practice guidelines have been presented by the National Comprehensive Cancer Network (NCCN), the organization that certifies comprehensive cancer centers, for inclusion of routine screening of distress in all cancer patients (National Comprehensive Cancer Network, 1999). These guidelines correspond with the NCCN requirements for designation as a comprehensive cancer center; such centers must employ full-time mental health professionals to address cancer patients' psychosocial needs. In addition to psychological support, such needs include patients' interest in obtaining more information about their disease and treatment options. As not all patients need or desire psychosocial services, screening can also pro-

vide an avenue for tracking which cancer patients are interested in obtaining medical information. Incorporating front-line medical staff in this effort will help raise awareness about the psychological impact of a cancer diagnosis, and will allow behavioral medicine specialists to provide services to those most distressed and in need of psychological support (Gruman & Convissor, 1998; Roter & Fallowfield, 1998; Gray et al., 2000).

### Limitations of the Study

In addition to the small number, the sample in the current study was almost completely Caucasian; future efforts should incorporate strategies to recruit women with diverse ethnic backgrounds. Moreover, the sample mainly consisted of women who were motivated to participate, as 78% responded to letters or posters about the program. Additionally, at the time of randomization, all participants had nonmetastatic disease, thus further limiting the generalization of these results. Lack of follow-up with the study outcomes beyond immediate posttest is another limitation of this study. As enhancement of the SCT variables occur across time and as a continual process, perhaps the assessment conducted immediately at posttest does not capture the change in QOL that may have been evident several months after the intervention. Further study with this intervention will benefit from follow-ups across time. Another limitation to this study was the inclusion of three investigator-developed measures. Although the coefficient alphas for these scales were moderately high, complete validation of the measures necessitate much larger sample sizes.

Not addressed by the present study was the question of benefit finding in the experience of cancer. Do individuals at different stages of disease report the same level of benefit finding in their experience? How do family members of cancer patients report meaning in the experience, if at all? Antoni et al. (2001) and Stanton et al. (2002) indicated that benefit finding can be changed with intervention. Can all cancer patients "benefit" from benefit finding? Do patients with more advanced disease find more or less benefit in the experience of cancer? Conducting empirically based research to answer these questions will help psychosocial oncology researchers improve the survivorship experiences of cancer patients.

# **Summary and Implications** for Future Research

The large effect sizes for outcome expectations and the significant findings from the nonparametric

sign test suggest that an intervention based on SCT to improve the QOL of cancer patients may be effective. In addition to continued measurement of self-efficacy, measurement of outcome expectations and self-regulation in future studies may yield additional information on mechanisms of change in psychosocial interventions. The challenges to successfully executing the present study are not unique, as other psychosocial oncology researchers face similar difficulties. The strong, positive correlations among the social cognitive variables and QOL encourage further investigation of this theory. Future research requires attainment of larger sample sizes; marketing strategies will need to be supported by the medical community stakeholders, thus involving referrals from physicians and other medical staff members.

Psychological adjustment of cancer patients at different stages of the disease needs to be further investigated. Perhaps interventions such as the one in the present study will only benefit women who are healthy enough to consistently attend sessions and practice the targeted coping skills. In addition, better understanding of the processes involved in cancer patients' self-regulation in terms of coping will further inform researchers' development and implementation of psychosocial interventions.

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