

Brief Behavioral Activation and Problem-Solving Therapy for Depressed Breast Cancer Patients: Randomized Trial

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Objective: Major depression is the most common psychiatric disorder among breast cancer patients and is associated with substantial impairment. Although some research has explored the utility of psychotherapy with breast cancer patients, only 2 small trials have investigated the potential benefits of behavior therapy among patients with well-diagnosed depression. **Method:** In a primarily Caucasian, well-educated sample of women (age = 55.4 years, $SD = 11.9$) diagnosed with breast cancer and major depression ($n = 80$), this study was a randomized clinical trial testing the efficacy of 8 sessions of behavioral activation treatment for depression (BATD) compared to problem-solving therapy. Primary outcome measures assessed depression, environmental reward, anxiety, quality of life, social support, and medical outcomes. **Results:** Across both treatments, results revealed strong treatment integrity, excellent patient satisfaction with treatment protocols, and low patient attrition (19%). Intent-to-treat analyses suggested both treatments were efficacious, with both evidencing significant pre–post treatment gains across all outcome measures. Across both treatments, gains were associated with strong effect sizes, and based on response and remission criteria, a reliable change index, and numbers-needed-to-treat analyses, approximately $\frac{3}{4}$ of patients exhibited clinically significant improvement. No significant group differences were found at posttreatment. Treatment gains were maintained at 12-month follow-up, with some support for stronger maintenance of gains in the BATD group. **Conclusions:** BATD and problem-solving interventions represent practical interventions that may improve psychological outcomes and quality of life among depressed breast cancer patients. Study limitations and future research directions are discussed.

Keywords: behavioral activation, problem-solving therapy, depression, cancer, randomized trial

Among cancer patients, major depression is the most common psychiatric disorder, with prevalence rates ranging from 10% to 50% (Croyle & Rowland, 2003; Fann et al., 2008; Massie, 2004). Together with patients who have pancreatic, lung, and oropharyngeal cancer, breast cancer patients are at highest risk for developing depression (10%–25%; Fann et al., 2008; Massie, 2004), particularly in the first year following their cancer diagnosis (Bur-

gess et al., 2005; Rowland, 1999). Functional impairment in depressed breast cancer patients is extensive, including exacerbation of medical illness and poorer physical health, increased anxiety and substance use, and poorer quality of life in the areas of recreational activities, relationships, self-care skills, physical activities, sexual functioning, and sleep (Baum & Andersen, 2001; Burgess et al., 2005; Ciaramella & Poli, 2001; Evans et al., 2005; Fortner, Stepanski, Wang, Kasprovicz, & Durrence, 2002; Lev et al., 2001; Lundberg & Passik, 1997; Williamson, 2000). Although research is inconclusive at this stage, some findings suggest depressed cancer patients may experience decreased immune system functioning, more rapid progression of cancer, more pain, and possibly increased mortality relative to nondepressed patients (Ciaramella & Poli, 2001; Miaskowski & Dibble, 1995; Reddick, Nanda, Campbell, Ryman, & Gaston-Johansson, 2006; Spiegel & Giese-Davis, 2003). Economic issues also are consequential in that depression in cancer patients involves increased physician time, more frequent hospital and primary care visits, and higher health care costs (Carlson & Butz, 2004; Chirikos, Russell-Jacobs, & Jacobsen, 2002; Hewitt & Rowland, 2002). Given the impact of depression, the importance of developing and evaluating psycho-

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social interventions for depressed breast cancer patients has been highlighted as a pressing need (Fann et al., 2008; Spiegel & Giese-Davis, 2003).

A number of meta-analyses have examined the efficacy of psychotherapy in treating depression in breast cancer patients (Fann et al., 2008; Lepore & Coyne, 2006; Meyer & Mark, 1995; Newell, Sanson-Fisher, & Savolainen, 2002; Sheard & Maguire, 1999; Williams & Dale, 2006). Among the interventions evaluated in these reviews are psychoeducation, supportive therapy, cognitive behavior therapy (CBT), relaxation training, problem-solving and social skills training, biofeedback, and hypnosis (Andersen, 1992; Baum & Andersen, 2001; Evans et al., 2005; Fann et al., 2008; Williams & Dale, 2006). To summarize findings, many studies have found interventions effective in reducing symptoms of depression, anxiety, and pain in breast cancer patients (Antoni et al., 2001; Fann et al., 2008; Goodwin et al., 2001; Kissane & Yuelin, 2008; Moorey, Greer, Bliss, & Law, 1998; Williams & Dale, 2006). However, there also are studies where psychosocial interventions have had only minimal effects in reducing depression (e.g., Cunningham et al., 1998; Edelman, Bell, & Kidman, 1999; Fukui et al., 2000). At present, the general consensus is that although no intervention is highly recommended for reducing depression in breast cancer patients, some data support group therapy, psychoeducation, structured counseling, CBT, communication skills training, and self-esteem building approaches (Fann et al., 2008; Newell et al., 2002; Williams & Dale, 2006).

In the past 3 decades, important progress has been made toward developing and exploring the efficacy of psychosocial interventions with depressed breast cancer patients. A number of significant methodological and practical limitations characterize most studies, however, and highlight the need for further scientific inquiry (Fann et al., 2008; Newell et al., 2002). Perhaps most strikingly, all psychosocial treatment outcome studies for depressed breast cancer patients have been criticized as using subsyndromal and unsystematically diagnosed samples (Fann et al., 2008; Hopko, Colman, & Carvalho, 2008; Newell et al., 2002; Sheard & Maguire, 1999; Williams & Dale, 2006). In none of the outcome studies referenced herein did researchers target breast cancer patients with well-diagnosed major depression (i.e., through empirically valid structured interviews; Akechi, Okuyama, Onishi, Morita, & Furukawa, 2009; Fann et al., 2008). As such, the extent to which positive effects of interventions extend beyond nonclinical samples to clinically depressed patients is unclear, the latter population being more difficult to treat (Cuijpers et al., 2010; Williams et al., 2000). Accordingly, it is unclear whether empirically validated treatments for depression (Chambless & Hollon, 1998; DeRubeis & Crits-Christoph, 1998; Hollon & Ponniah, 2010; Hollon, Thase, & Markowitz, 2002; Westen & Morrison, 2001) generalize to breast cancer patients with major depression. As a second limitation, outcome measures primarily have been limited to symptoms of depression and occasionally the assessment of anxiety. Only infrequently have functional status (e.g., quality of life, medical outcomes, social support) and patient satisfaction outcomes been assessed. Third, although short-term benefits of treating breast cancer patients with depression have been reported, long-term follow-up data generally have not been presented. Finally, several depression interventions studied in traditional efficacy studies may not be particularly optimal in medical

care settings given such factors as the expertise and number of sessions required for administration (Coyne & Kagee, 2001).

As a potentially practical solution, CBTs that emphasize behavior activation (Hopko & Lejuez, 2007; Lejuez, Hopko, & Hopko, 2001; Martell, Addis, & Jacobson, 2001) may be useful for medical care settings and breast cancer patients. Behavioral activation treatment for depression (BATD) emphasizes structured attempts to increase overt behaviors that are likely to increase reinforcing environmental contingencies and corresponding improvements in thoughts, mood, and quality of life (Hopko, Lejuez, Ruggiero, & Eifert, 2003). Behavioral activation therapy is time limited and less complicated than many other depression interventions and engenders healthy nondepressed behavior by way of guided behavioral scheduling and avoidance reduction strategies. Particularly relevant to cancer patients, considering limitations in overt behavior and increased problems and daily hassles often reported by cancer patients (Ciaramella & Poli, 2001; Nezu, Nezu, Houts, Friedman, & Faddis, 1999), this intervention may be optimal in eliciting behavior change and corresponding reductions in depressive affect. Behavioral activation also involves increasing control over one's life (and overt behavior), an attribute that may be useful in reversing the loss of control often experienced by cancer patients (Sandoval, Brown, Sullivan, & Green, 2006). Indeed, behavioral activation addresses essential components of cancer treatment that include enhancement of social support, emotional expression, re-ordering of life priorities, stress management, avoidance reduction, and issues of symptom control and health education (Fawzy, Fawzy, & Canada, 2001). For example, through structured activation approaches, the quality of social support is assessed on an ideographic basis as it pertains to intimate, peer, and familial relationships. Graduated exposure to social situations, development of social skills, and anxiety reduction strategies may be used to increase response-contingent positive (social) reinforcement and decrease negative affect. Through incorporating behavioral activation strategies that include mindfulness exercises and relaxation practice (Hopko & Lejuez, 2007), cancer-related symptoms including pain and nausea also can be addressed (Newell et al., 2002).

Behavioral activation interventions largely have been used to treat depressive disorders and symptoms, with three meta-analyses supporting their efficacy such that behavioral activation is now considered an empirically validated treatment for depression (Cuijpers, van Straten, & Warmerdam, 2007; Ekers, Richards, & Gilbody, 2008; Mazzucchelli, Kane, & Rees, 2009; Sturme, 2009). In one of the more compelling studies, behavioral activation was comparable to antidepressant medication and superior to cognitive therapy in treating severe depression (Dimidjian et al., 2006), results that were maintained at 2-year follow-up (Dobson et al., 2008). Behavioral activation also has been effectively used with depressed patients in a variety of settings and among samples with divergent medical and psychiatric problems (Daughters et al., 2008; Ekers, Richards, McMillan, Bland, & Gilbody, 2011; Gawrysiak, Nicholas, & Hopko, 2009; Hopko, Lejuez, LePage, Hopko, & McNeil, 2003; Jacobson et al., 1996; Jakupcak et al., 2006; MacPherson et al., 2010; Pagoto et al., 2008). Perhaps most relevant to the current study are two preliminary studies on the efficacy of eight sessions of behavioral activation with depressed cancer patients in a medical care setting. In the first study, significant treatment gains were evident on measures of depression,

quality of life, and medical functioning, although somatic anxiety symptoms did not improve at posttreatment (Hopko, Bell, Armento, Hunt, & Lejuez, 2005). In a second study, the number of treatment sessions remained the same, and behavioral activation was administered in its usual format (Hopko, Bell, et al., 2008). However, brief cognitive therapy, direct exposure, problem-solving, and sleep skills training also were administered. Results revealed strong treatment integrity, good patient compliance, excellent satisfaction with treatment, and significant treatment gains across outcome measures assessing depression, somatic anxiety, quality of life, and medical outcomes (Hopko, Bell, et al., 2008). These gains also were associated with strong effect sizes and were maintained at 3-month follow-up.

Given significant methodological limitations of treatment outcome research in depressed breast cancer patients (Akechi et al., 2009; Fann et al., 2008; Williams & Dale, 2006) coupled with limited sample sizes and lack of a randomized trial in our preliminary work, a more rigorous trial was conducted to explore the efficacy of psychosocial treatments in breast cancer patients with major depression. Specifically, the primary aim of the study was to conduct a randomized trial using BATD, comparing it to problem-solving therapy (PST) for depressed breast cancer patients. PST was chosen as a treatment arm due to its documented efficacy within medical care settings and its status as the gold standard of treatment within this context (Wolf & Hopko, 2008). Given the coexistent medical and psychiatric problems experienced by patients in this study, a comprehensive battery of primary outcome measures was assessed. These included clinical (depression, anxiety, environmental reward), functional (quality of life, social support, medical outcomes), and patient satisfaction measures. Given preliminary data on the efficacy of behavioral activation and its theoretical appeal as a treatment for depressed breast cancer patients, the primary hypotheses were as follows: (a) At posttreatment, depressed breast cancer patients in the BATD condition would exhibit significantly greater reductions in depression and anxiety and significantly greater increases in environmental reward, social support, quality of life, and medical outcomes; (b) patients in the BATD condition would demonstrate superior maintenance of treatment gains through 1-year follow-up.

Method

Participants

In other outcome studies for depression, effect sizes documenting posttreatment response of patients in behavior therapy compared to other interventions have been moderate to large ($f = .20-.80$, based on the Beck Depression Inventory and Hamilton Rating Scale for Depression [HRSD] measures; Cuijpers et al., 2007; DeRubeis & Crits-Christoph, 1998). Therefore, a small-to-moderate effect size ($f = .30$) was deemed appropriate for identifying statistically and clinically significant effects at posttreatment in this trial. When this effect size was considered in conjunction with an alpha level of .05 and a power of .85, 64 patients (32 per group) were needed. To allow for a 20%–25% attrition rate at posttreatment (consistent with CBT outcome research for depression; Cuijpers et al., 2007; DeRubeis, Gelfand, Tang, & Simons, 1999; Dimidjian et al., 2006; Hollon et al., 2002), 80 patients (40 per group) were recruited.

Participants included 80 adults with a principal diagnosis of major depression who were treated at the University of Tennessee Medical Center's Cancer Institute (Knoxville, TN). All participants provided informed consent prior to study enrollment. Patients were recruited through clinic screening ($n = 16$; 20%), clinic brochures ($n = 9$; 11%), and oncologist referral ($n = 55$; 69%). As indicated on the CONSORT diagram (see Figure 1), during check-in at the Cancer Institute, patients were approached by clinical psychology doctoral students and given the opportunity to complete the Harvard National Depression Screening scale (HANDS; Baer et al., 2000), a 10-item measure assessing core symptoms of major depression (*Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. [DSM-IV]; American Psychiatric Association, 1994). The HANDS has been used with cancer patients (Hopko, Bell, et al., 2008) and other samples of depressed medical patients (Farabaugh et al., 2009; Gonzalez et al., 2007). The HANDS has a score range of 0–30, with a cutpoint of 9 or greater having diagnostic sensitivity of 95% (Baer et al., 2000). Patients who had breast cancer and met this criterion were asked to participate in the comprehensive pretreatment diagnostic assessment. Other patients who were referred through oncologist referral first communicated with the principal investigator (Derek R. Hopko) or the project director by telephone. Those individuals endorsing symptoms of depression also were asked to schedule a comprehensive assessment. This assessment included administration of the Anxiety Disorders Interview Schedule-IV¹ (ADIS-IV; Brown, Di Nardo, & Barlow, 1994), HRSD (Hamilton, 1960), and self-report instruments outlined below. Note that the ADIS-IV is based on diagnostic criteria of the *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)*; American Psychiatric Association, 1994) and provides a valid diagnosis of major depressive disorder (Brown et al., 1994). Advanced doctoral students conducted psychological assessments and were supervised by the principal investigator (Derek R. Hopko) in the context of audiotape review and discussion, resulting in a consensus diagnosis. Inclusion criteria included the following: greater than 18 years of age, diagnosed with breast cancer, and a principal (and primary) consensus diagnosis of major depression of moderate severity, that is, a 4 on a 0 (*no depressive symptoms*) to 8 (*very severe symptoms*) scale. For purposes of generalizability, antidepressant and anti-anxiety medication usage was not exclusionary. Participants were included if not taking antidepressant or anti-anxiety medication ($n = 38$; 48%) or if they were taking such medications and had been stabilized at a consistent dosage for 8 weeks prior to study assessment ($n = 38$; 48%). Due to ethical considerations with regard to withholding treatment, patients also were included who had initiated taking medication but were not stabilized ($n = 4$; 4%). Individuals were excluded if they had bipolar disorder, psychosis, mental retardation, current alcohol or drug dependence, or a principal diagnosis other than major depression ($n = 0$).

Clinic screening occurred over 27 months (June 2008–September 2010) during which 87 screened individuals agreed to complete the comprehensive assessment. Of these patients, 80 were included and randomized to receive eight sessions of BATD

¹ Note that the ADIS-IV comprehensively assesses for all anxiety and mood disorders and also includes screens for substance abuse and psychotic disorders.

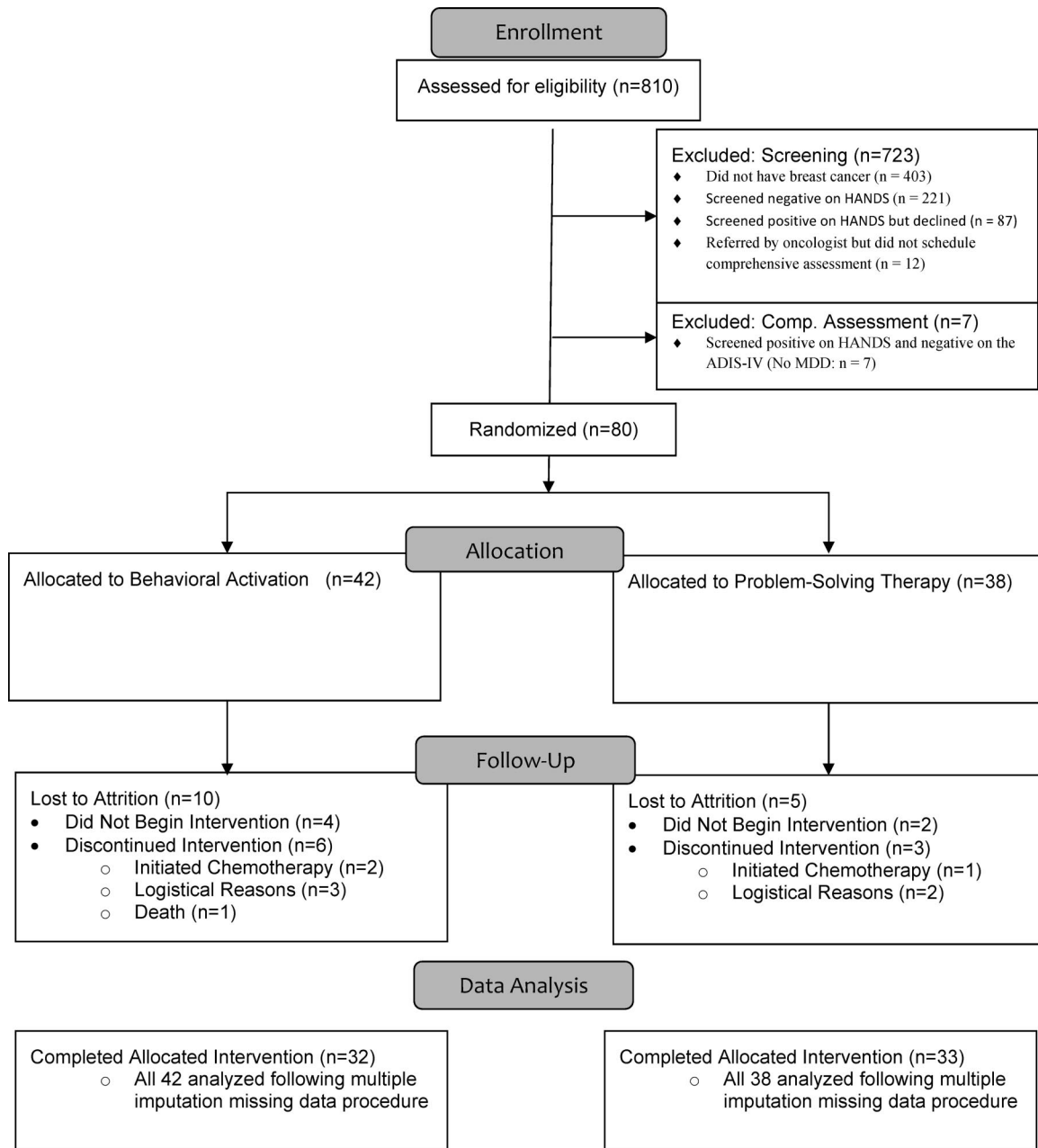


Figure 1. CONSORT flow diagram. ADIS-IV = Anxiety Disorders Interview Schedule-IV; Comp. = comprehensive; HANDS = Harvard National Depression Screening scale; MDD = major depressive disorder.

or PST. All seven excluded patients had breast cancer but did not meet ADIS-IV diagnostic criteria for major depression. As illustrated in the CONSORT diagram, of the 80 patients randomized to receive treatment, 65 patients completed their respective treatment, resulting in an overall attrition rate of 19%.² Of the 15 patients who did not complete treatment, six discontinued prior to initiating treatment and nine discontinued during treatment due to logistical problems, onset of chemotherapy treatment, or death (range = 1–7 completed sessions). Patient attrition did not differ as a function of treatment condition, $\chi^2(1) = 1.48$, $p = .26$. Additionally, as indicated by a series of Fisher's exact tests due to small or empty

cells, the timing of attrition did not differ as a function of treatment condition.

The overwhelming majority of patients were Caucasian (93%; 7% African American; mean age = 55.4 years, $SD = 11.9$). Patients had an average education of 14.8 years ($SD = 2.3$).

² Note that the attrition rate is relatively equivalent to or in many cases less than that reported for other cognitive-behavioral interventions for depression (Cuijpers et al., 2007; DeRubeis et al., 1999; Hollon et al., 2002).

Marital status was as follows: married (56%), single (29%), divorced (11%), and separated (4%). Approximately 42% of the sample was employed either full or part time, and the remaining patients were unemployed (28%) or retired (30%). The average time since breast cancer diagnosis was 3.2 years ($SD = 3.9$), and average tumor size was 2.49 cm ($SD = 1.8$). Patients of all cancer stages were included: Stage 0 (lobular carcinoma in situ, ductal carcinoma in situ: 26%), Stage 1 (28%), Stage 2 (32%), Stage 3 (11%), and Stage 4 (3%). In terms of cancer treatment, 94% of patients had surgery (i.e., lumpectomy, mastectomy), 74% had chemotherapy, 60% had radiation treatment, and 1% had hormonal therapy. Seventy-six percent of patients tested positive for estrogen receptor status, and 65% tested positive for progesterone receptor status. Only 15% of patients tested positive for the HER-2/NEU gene, a gene known to facilitate abnormal cell growth and worsen prognosis. All cancer data were collected from pathology reports at the University of Tennessee Cancer Institute. In terms of treatment history, 43% of patients had a history of psychotherapy, and 11% had received inpatient treatment for depression in the past. During the study, no patient participated in adjunctive psychotherapy. Mean level of ADIS-IV clinician-rated severity of major depression was 5.3 ($SD = 1.1$), suggesting moderate clinical depression. Coexistent diagnoses included generalized anxiety disorder ($n = 35$; 44%), social phobia ($n = 9$; 11%), posttraumatic stress disorder (PTSD; $n = 5$; 6%), specific phobia ($n = 3$; 4%), panic disorder ($n = 2$; 3%), and anxiety disorder not otherwise specified ($n = 1$; 1%). Patient characteristics by treatment condition are presented in Table 1. On the basis of a series of analyses of variance for continuous variables and chi-square analyses for categorical variables, treatment groups did not statistically differ on any demographic, cancer-related, or psychological variables.

Outcome Measures

The HRSD (Hamilton, 1960) is a 24-item semistructured interview designed to measure symptom severity in patients with depression. The instrument is the most widely used outcome measure for evaluating depression and is the standard outcome measure in clinical trials (Kobak & Reynolds, 1999; Wolf & Hopko, 2008; $\alpha = .82$, range = 8–36, $M = 19.7$, $SD = 6.5$, for the present study).

The Beck Depression Inventory–II (BDI-II; Beck, Steer, & Brown, 1996) consists of 21 items rated on a 4-point Likert-type scale. The instrument has excellent reliability and validity data with depressed younger and older adults (Beck et al., 1996; Dozois, Dobson, & Ahnberg, 1998). The psychometric properties of the BDI-II also have been studied in cancer patients and a diverse primary care sample, with the instrument having strong predictive validity as it pertains to a diagnosis of clinical depression, strong internal consistency ($\alpha = .94$), and adequate item–total correlations ($R = .54$ – $.74$; Arnau, Meagher, Norris, & Bramson, 2001; Katz, Kopek, Waldron, Devins, & Thomlinson, 2004; $\alpha = .84$, range = 14–60, $M = 27.0$, $SD = 8.5$, for the present study).

The Environmental Reward Observation Scale (EROS; Armento & Hopko, 2007) is a 10-item measure that assesses exposure to environmental rewards deemed essential for increasing response-contingent positive reinforcement (RCPR; Lewinsohn, 1974). RCPR is defined as positive or pleasurable outcomes or rewards that follow behaviors (i.e., extrinsic [e.g., social, mone-

tary] or intrinsic [e.g., physiological, feeling of achievement]) and increase the likelihood of those behaviors occurring in the future. Decreased RCPR is a central predictor of increased depression and is a product of (a) a decreased availability of potential reinforcers in the environment, (b) inability to experience rewarding contingencies due to inadequate instrumental behaviors such as social skills, and (c) increased distressing or unpleasant events (Lewinsohn, 1974; Lewinsohn & Graf, 1973; Lewinsohn, Sullivan, & Grosscup, 1980). Higher scores on the EROS suggest increased environmental reward. Sample items include “The activities I engage in usually have positive consequences” and “Lots of activities in my life are pleasurable.” On the basis of psychometric research with three independent college samples, the EROS has strong internal consistency ($\alpha = .85$ – $.86$) and excellent test–retest reliability ($r = .85$) and correlates strongly with other psychometrically sound measures of depression ($r = -.63$ to $-.69$) and anxiety (Armento & Hopko, 2007). In this study, internal consistency was adequate ($\alpha = .78$, $M = 22.7$, $SD = 4.6$).

The Beck Anxiety Inventory (BAI; Beck & Steer, 1993) is a 21-item measure designed to distinguish cognitive and somatic symptoms of anxiety from those of depression. Good psychometric properties have been demonstrated among community, medical, and psychiatric outpatient samples (Morin et al., 1999; Wetherell & Areán, 1997; $\alpha = .88$, $M = 16.8$, $SD = 9.5$).

The Quality of Life Inventory (QOLI; Frisch, 1994) is a 16-item self-report measure of life satisfaction. The instrument provides a global measure (ranging from -6 to 6) based on the average of satisfaction ratings across a range of life domains. The scale is a valid and reliable measure of life satisfaction (Frisch, 1999; $\alpha = .83$, $M = 0.39$, $SD = 1.8$).

The Medical Outcomes Study Short Form (SF-36; Ware & Sherbourne, 1992) assesses health and functional status and includes eight subscales: physical functioning, role disability–physical problems, bodily pain, health perceptions, vitality, social functioning, role disability–emotional problems, and mental health. Higher scores indicate more optimal functioning. The SF-36 has a stable factor structure and adequate psychometric properties (Dexter, Stump, Tierney, & Wolinsky, 1996; Ware & Sherbourne, 1992; $\alpha = .80$ for this study). Factor structure, strong internal consistency, and good discriminant validity were demonstrated in a sample of patients with laryngeal cancer (Mosconi, Cifani, Crispino, Fossati, & Apolone, 2000).

The Multidimensional Scale of Perceived Social Support (MSPSS; Zimet, Dahlem, Zimet, & Farley, 1988) is a 12-item scale that assesses adequacy of social support from family, friends, and significant others, with higher scores indicating poorer social support. The instrument has adequate psychometric properties in clinical and nonclinical samples of adults (Stanley, Beck, & Zebb, 1998; Zimet et al., 1988; $\alpha = .87$, $M = 32.9$, $SD = 17.8$). The measure was included to assess whether activation strategies designed to increase social reinforcement translated into patients perceiving stronger social support systems at posttreatment.

Satisfaction with both interventions was assessed with the Client Satisfaction Questionnaire (CSQ; Larsen, Attkisson, Hargreaves, & Nguyen, 1979). The scale is an eight-item measure (scored from 0 to 32), with higher scores indicating greater treatment satisfaction ($\alpha = .81$, $M = 30.6$, $SD = 2.1$).

Table 1
Patient Characteristics Across Treatment Condition

Characteristic	Behavioral activation (<i>n</i> = 42)	Problem-solving therapy (<i>n</i> = 38)
Age	56.4 years (<i>SD</i> = 11.1)	54.3 years (<i>SD</i> = 11.2)
Education	15.1 years (<i>SD</i> = 2.1)	14.5 years (<i>SD</i> = 2.4)
Marital status		
Married	24 (57%)	21 (55%)
Single	11 (26%)	12 (32%)
Divorced	6 (14%)	3 (8%)
Separated	1 (3%)	2 (5%)
Ethnicity		
Caucasian	38 (90%)	36 (95%)
African American	4 (10%)	2 (5%)
Occupational status		
Employed (full time)	7 (17%)	10 (26%)
Employed (part time)	9 (21%)	8 (21%)
Unemployed	11 (26%)	11 (29%)
Retired	15 (36%)	9 (24%)
Time since cancer diagnosis	3.5 years (<i>SD</i> = 4.0)	2.8 years (<i>SD</i> = 3.9)
Cancer stage		
Stage 0 (LCIS, DCIS)	11 (26%)	10 (26%)
Stage 1	15 (36%)	8 (21%)
Stage 2	10 (24%)	16 (42%)
Stage 3	5 (12%)	3 (8%)
Stage 4	1 (2%)	1 (3%)
Cancer tumor size	2.65 cm (<i>SD</i> = 1.8)	2.33 cm (<i>SD</i> = 1.7)
Cancer treatment received		
Surgery	40 (95%)	35 (92%)
Chemotherapy	31 (74%)	28 (74%)
Radiation	26 (62%)	22 (58%)
Hormone therapy	0 (0%)	1 (3%)
Estrogen receptor status		
Positive	34 (81%)	27 (71%)
Negative	8 (19%)	11 (29%)
Progesterone receptor status		
Positive	30 (71%)	22 (58%)
Negative	12 (29%)	16 (42%)
HER-2/NEU gene		
Positive	4 (10%)	8 (21%)
Negative	38 (90%)	30 (79%)
ADIS-IV depression severity	5.3 (<i>SD</i> = 1.2)	5.2 (<i>SD</i> = 1.1)
Current antidepressant use		
Yes	24 (57%)	18 (47%)
No	18 (43%)	20 (53%)
Stabilized on antidepressant medication		
Yes	21 (88%)	17 (94%)
No	3 (12%)	1 (6%)
Previous hospitalization for depression		
Yes	5 (12%)	4 (11%)
No	37 (88%)	34 (89%)
History of psychotherapy for depression		
Yes	16 (38%)	18 (47%)
No	26 (62%)	20 (53%)
Coexistent diagnoses		
Generalized anxiety disorder	21 (50%)	14 (37%)
Social phobia	4 (10%)	5 (13%)
Posttraumatic stress disorder	2 (5%)	3 (8%)
Panic disorder	2 (5%)	0 (0%)
Specific phobia	2 (5%)	1 (3%)
Anxiety disorder NOS	1 (3%)	0 (0%)

Note. ADIS-IV = Anxiety Disorders Interview Schedule-IV; DCIS = ductal carcinoma in situ; LCIS = lobular carcinoma in situ; NOS = not otherwise specified.

Behavioral Activation Therapy for Depression (BATD)

On the basis of behavioral theory, depression persists because (a) reinforcement for nondepressed (healthy) behavior is low, (b) depressed behavior is reinforced, (c) exposure to aversive or unpleasant life experiences is significant, or (d) some combination of these factors (Lewinsohn, 1974). BATD focuses on increasing overt behaviors to bring patients into contact with reinforcing environmental contingencies and corresponding improvements in thoughts, mood, and quality of life (Hopko, Lejuez, Ruggiero, & Eifert, 2003). Within the BATD model (Hopko & Lejuez, 2007; Lejuez, Hopko, Acierno, Daughters, & Pagoto, 2011; Lejuez et al., 2001), the process of increasing response-contingent reinforcement follows the basic principles of extinction, shaping, fading, and in vivo exposure (Hopko, Lejuez, Ruggiero, & Eifert, 2003). Initial sessions involve assessing the function of depressed behavior, establishing patient rapport, motivational exercises focused on the pros and cons of behavioral change, depression psychoeducation and understanding the relationship between depression and breast cancer, and introduction of the treatment rationale.

Within the BATD model, systematically increased activity is a necessary precursor to the reduction of overt and covert depressed behavior. Patients began by engaging in a self-monitoring (or daily diary) exercise to examine already occurring daily activities and to provide a baseline measurement and ideas with regard to identifying activities to target during treatment. Patients were asked to keep a daily diary during 4 days of the week and to monitor their primary overt behaviors at half-hour intervals (from 8:00 a.m. to 2:00 a.m.). For each behavior, they also were asked to indicate their level of reward or pleasure on a 4-point Likert-type scale. This monitoring allowed for an overall assessment of patient activity and an understanding of particular behaviors that were rewarding or unpleasant. Following monitoring, emphasis shifted to identifying values and goals within life areas that included family, social, and intimate relationships, education, employment/career, hobbies/recreation, volunteer work/charity, physical/health issues, spirituality, and anxiety-eliciting situations (Hayes, Strosahl, & Wilson, 1999). An activity hierarchy was then constructed in which 15 activities were rated ranging from *easiest* to *most difficult* to accomplish. Using a master activity log and behavioral checkout to monitor progress, patients progressively moved through the hierarchy, from easier behaviors to the more difficult (beginning in Session 3). For each activity, the therapist and patient collaboratively determined the final goal in terms of the frequency and duration of activity per week. These goals were recorded on a master activity log kept in the possession of the therapist. Weekly goals were recorded on a behavioral checkout form that the patient returned to therapy each week. At the start of each session, the behavioral checkout form was examined and discussed, with the following weekly goals being established as a function of patient success or difficulty.

Toward understanding how BATD was used to address coexistent anxiety problems, in addition to increasing environmental reward, a focus of treatment was on reducing aversive experiences. Accordingly, a number of anxiety reduction strategies are easily implemented into the hierarchy (Hopko, Robertson, & Lejuez, 2006), including muscle relaxation, assertiveness training, and graduated exposure to anxiety-eliciting stimuli. For example, patients with social phobia might have assertiveness skills and

graded exposure to social situations incorporated into their behavioral hierarchies. In the case of a patient presenting with PTSD and unresolved grief issues surrounding the recent death of her mother, activities were structured to confront this experience, decreasing avoidance and fostering acceptance (e.g., journaling, visiting gravesite, arranging photographs). Important to acknowledge because being diagnosed and living with breast cancer ultimately creates some level of anxiety in most patients and a PTSD syndrome in others (Andrykowski, Cordova, Studts, & Miller, 1998), all patients engaged in exposure exercises surrounding this issue. More specifically, behavioral exposure involved three written exercises (integrated into Sessions 3, 4, and 5) designed to expose cancer patients to the experience of being diagnosed and living with cancer. Patients were encouraged to write about situational details and emotional (physical, cognitive, and behavioral) experiences involved with being diagnosed and living with cancer and then to process these experiences in session with their clinician. In total, BATD treatment involved eight sessions of approximately 1 hr in duration.

Problem-Solving Therapy

Depressed breast cancer patients randomized to the PST condition were treated with an adapted version of the PST for anxiety and depression manual (Mynors-Wallis, 2005). As with the BATD intervention, initial sessions involved development of patient rapport, motivational exercises focusing on the pros and cons of behavioral change, depression psychoeducation, understanding the relationship between depression and breast cancer, and introduction to the PST treatment rationale. The specific goals of PST were to (a) increase patients' understanding of the connection between current depression and anxiety symptoms with everyday problems, (b) increase the ability to clearly and accurately define current problems, (c) teach patients a specific problem-solving method to allow for a more structured skill set to address life problems, and (d) create more positive experiences through patients' improved abilities to solve problems (Mynors-Wallis, 2005). The basic premise of the treatment was that as patients learned to identify and resolve problems, they would gain an increased sense of self-efficacy, control, and confidence while becoming more active in eliciting reward from their environment, characteristics critical to improving mental health in depressed cancer patients (Fawzy et al., 2001; Sandoval et al., 2006). According to problem-solving and behavioral theories, such changes theoretically would serve to attenuate symptoms of depression and anxiety.

Similar to the BATD intervention, an acceptance versus change model (Hayes et al., 1999) was incorporated throughout treatment. This model involves the rationale that some experiences in life are more controllable and changeable, whereas other experiences are not as readily changed and thus must be met with acceptance (e.g., being diagnosed and treated with cancer or experiencing periodic negative emotional states). According to this model, to improve affect and emotional well-being, behavioral change focuses on life experiences and events that are more apt to be controlled and modified, namely, overt behavior. To facilitate this process, patients in the PST condition also received eight weekly psychotherapy sessions (of 1 hr in duration). Problem-solving treatment was divided into seven stages: (a) understanding the PST treatment and its rationale; (b) identification, definition, and breaking down of

the problem; (c) establishing achievable goals for problem resolution; (d) generating possible solutions; (e) evaluating and choosing the solution; (f) implementing the chosen solution; and (g) evaluating the outcome (Mynors-Wallis, 2005). There are variations of the PST approach when applied to cancer patients, including targeting of specific cancer symptoms (e.g., pain, fatigue, nausea, insomnia) and a systematic approach to patient-symptom matching (Nezu, Nezu, Felgoise, McClure, & Houts, 2003; Nezu, Nezu, Friedman, Faddis, & Houts, 1998; Nezu et al., 1999). Given the medical care setting in which this study was completed, however, the Mynors-Wallis (2005) approach was used given its documented efficacy in this context (Wolf & Hopko, 2008).

Stage 1 was accomplished during the first session, along with establishing a comprehensive list of current problems in each patient's life and education regarding the relationship of depression and breast cancer. Among the different potential problem areas addressed in this session were relationship with partner or spouse; relationships with children, parents, siblings, and other family members; relationships with friends; participation in potentially enjoyable behaviors, activities, or hobbies; spirituality; work; finances; housing; health problems; and legal issues. During each subsequent session of treatment, the patient and therapist collaborated on solving a different problem of the patient's choosing using Stages 2 through 7 (Stage 6 was assigned as homework, and Stage 7 was carried out at the beginning of the subsequent session). The patient chose each problem from the problem list generated in Session 1. During the course of treatment, patients were encouraged to continue to modify this problem list as new problems arose or as other problems not initially identified were recalled. Gradually throughout treatment, patients took a more prominent role in performing the problem-solving stages, requiring less input and guidance from the therapist as they became more skilled at implementing the stages. Similar to the BATD condition, patients completed written exposure exercises on the situational details and emotional (physical, cognitive, and behavioral) experiences of being diagnosed and living with cancer and then processed these experiences in session with their clinician.

Therapists and Treatment Fidelity

Six advanced clinical psychology (doctoral) students served as therapists in this study. Two manuals were created for this study, one for each treatment condition.³ All therapists were skilled in the administration of both the BATD and PST interventions and were trained by the principal investigator (Derek R. Hopko) to administer these treatments. On the basis of randomization procedures, therapists treated patients in both the BATD and PST conditions. To ensure competent provision of both interventions, all sessions were audio-taped, and all therapists met for weekly individual supervision sessions with the principal investigator (Derek R. Hopko). Including patients completing their respective intervention and those discontinuing treatment, 549 therapy sessions were conducted across treatment conditions. Fifteen percent of these tapes ($n = 82$) were selected randomly for ratings of therapist competence and adherence by an independent evaluator with expertise in CBT (Sandra Denise Hopko, master's degree). Ratings were made on 0 (*no adherence/competence*) to 8 (*complete adherence/competence*) Likert-type scales on a session-by-session basis, with ratings based on adherence and ability in completing session objectives highlighted in the respective treat-

ment manuals. Ratings indicated high therapist adherence (BATD: $M = 7.3$, $SD = 0.7$; PST: $M = 7.1$, $SD = 0.8$) and competence (BATD: $M = 6.8$, $SD = 0.9$; PST: $M = 6.7$, $SD = 0.9$) in administering both protocols, with no significant differences in adherence, $F(1, 81) = 0.55$, $p = .46$, or competence, $F(1, 81) = 0.20$, $p = .65$, as a function of intervention.

Response and remission criteria. Consistent with methods highlighted in previous trials of behavioral activation (Dimidjian et al., 2006), response represented significant symptomatic improvement, whereas remission represented improvement to the point of being asymptomatic within normal range. On the HRSD and BDI-II, response was defined as at least 50% reduction from baseline. Remission was defined as scores ≤ 7 on the HRSD and ≤ 10 on the BDI-II.

Procedure

Following recruitment and screening procedures described above, eligible participants were administered the ADIS-IV and all self-report measures. All psychological assessments and treatment sessions were conducted at the Cancer Institute. Advanced doctoral students in clinical psychology conducted the comprehensive assessments. At the time of these assessments, examiners were unaware of the potential treatment condition of the patient if included in the study. If included following the comprehensive assessment, based on a preestablished randomization chart (Random Allocation Software, Version 1.0; Saghaei, 2004), patients were randomized to either BATD or PST. Patients subsequently engaged in their 8-week (one-on-one) treatment. When convenient, therapy sessions were scheduled to coincide with medical appointments. Two assessment and therapy rooms were reserved for study personnel, and ongoing communication was maintained among the principal investigator, director of the Cancer Institute (John L. Bell), medical oncologists, and staff. Accordingly, obstacles impeding data collection were quite limited. Posttreatment assessments were conducted following completion of treatment and at 3-, 6-, 9-, and 12-month follow-up. To promote continuity of care, therapists who had treated patients primarily conducted posttreatment assessments. Patients were paid \$25.00 for each assessment.

Results

Treatment Outcome Data

All clinical variables were initially examined with mixed-model analyses of variance (between subjects: treatment condition; within subjects [time]: pretreatment, posttreatment).⁴ The clinical significance of pre-post differences was assessed using Cohen's d statistic (using the pooled standard deviation), where effect sizes of .2, .5, and .8 are considered small, medium, and large, respectively. On the basis of general guidelines (Hollis & Campbell, 1999), data

³ Both treatment manuals are available from Derek R. Hopko on request.

⁴ A statistical (e.g., Bonferroni) correction was not used given concerns regarding its use with conceptually divergent outcome variables (e.g., depression, social, medical outcomes), experimenter reluctance to increase Type II error, and other concerns associated with statistical adjustment procedures (Perneger, 1998).

on all patients randomly assigned to receive BATD or PST were analyzed on an intention-to-treat basis (ITT). For the 80 patients in the study, available data were as follows: posttreatment ($n = 65$; i.e., 15 patients lost to attrition), 3-month follow-up ($n = 57$), 6-month follow-up ($n = 50$), 9-month follow-up ($n = 45$), and 12-month follow-up ($n = 41$). Fisher exact tests indicated that frequency of follow-up data at all assessment intervals did not differ as a function of treatment group (range: $p = .08-.35$). Given missing values, data were first subjected to a missing values analysis using SPSS Version 17.0. Data are considered missing completely at random (MCAR) when the probability that an observation (X_i) is missing is unrelated to the value of X_i or to the value of any other variables. The null hypothesis for Little's statistical test is that data are MCAR, and in this study, the missing value analysis suggested missing data points were in fact MCAR, $\chi^2(393) = 309.31, p = .99$. Accordingly, multiple imputation (MI) strategies were implemented to replace missing values. The basic strategy of MI is to progress through a series of data estimation steps resulting in multiple complete data sets whose coefficients vary from set to set (Allison, 2002; Little & Rubin, 1987). Analyses are then pooled according to Rubin's (1987) rules for combining estimates and standard errors from multiple data sets, and a final complete database is generated based on all available data.

To control for clinical and cancer-related variables that might potentially confound any between-group differences on primary outcome measures, data were collected at 3-, 6-, 9-, and 12-month follow-up to assess for any continued psychotherapy, antidepressant use, and whether patients underwent cancer-related treatment (i.e., breast surgery, chemotherapy, radiation therapy). For continued psychotherapy following the randomized controlled trial, at 3-month follow-up, 10 patients (18%) continued to receive psychotherapy based on referrals provided at posttreatment, BATD: 5; PST: 5; $\chi^2(1) = 0.10, p = .75$. At 6-month follow-up, nine patients (20%) were involved in continued psychotherapy, BATD: 5; PST: 4; $\chi^2(1) = 0.56, p = .45$. At 9-month follow-up, seven patients (18%) were involved in continued psychotherapy, BATD: 4; PST: 3; $\chi^2(1) = 1.21, p = .55$. Finally, at 12-month follow-up, six patients (19%) were involved in continued psychotherapy, BATD: 3; PST: 3; $\chi^2(1) = 0.25, p = .62$. For antidepressant and/or antianxiety medication, at 3-month follow-up, 27 patients reported being on medication, BATD: 13; PST: 14; $\chi^2(1) = 0.20, p = .66$. Of these patients, 22 were stabilized on medication at pretreatment and adhered to their original prescription, while five initiated pharmacotherapy, BATD: 3; PST: 2; $\chi^2(1) = 0.20, p = .65$. Three patients had switched antidepressant medications, and three had changed dosages of their original medication at pretreatment (two increased, one decreased). At 6-month follow-up, 30 patients reported being on medication, BATD: 14; PST: 16; $\chi^2(1) = 0.18, p = .67$. Of these patients, 25 maintained prescriptions reported at 3-month follow-up, while five initiated pharmacotherapy, BATD: 3; PST: 2; $\chi^2(1) = 0.20, p = .56$. At 9-month follow-up, 28 patients reported being on medication, BATD: 13; PST: 15; $\chi^2(1) = 0.01, p = .96$. Of these patients, 23 maintained prescriptions reported at 6-month follow-up, while five initiated pharmacotherapy, BATD: 2; PST: 3; $\chi^2(1) = 0.02, p = .95$. Finally, at 12-month follow-up, 21 patients reported being on medication, BATD: 10; PST: 11; $\chi^2(1) = 0.64, p = .42$. Of these patients, all 21 maintained prescriptions reported at 9-month follow-up. In terms of breast surgery, chemotherapy, and radiation therapy, the

frequency of these procedures at each follow-up interval was as follows: 3-month follow-up: breast surgery = 2 (4%), chemotherapy = 6 (12%), and radiation therapy = 8 (16%); 6-month follow-up: breast surgery = 3 (7%), chemotherapy = 1 (2%), and radiation therapy = 2 (4%); 9-month follow-up: breast surgery = 1 (3%), chemotherapy = 3 (8%), and radiation therapy = 1 (3%); 12-month follow-up: breast surgery = 4 (13%), chemotherapy = 1 (3%), and radiation therapy = 1 (3%). For all these assessment intervals, chi-square analyses revealed no significant differences in cancer treatment between BATD and PST patients.

Finding no significant between-group differences on these clinical and cancer-related variables, we conducted ITT analyses. As reported in Table 2, there were no significant Group \times Time interactions across any outcome measure. However, main effects of time were evident across all outcome measures, range, $F(1, 78) = 10.37$ (SF-36 bodily pain: $p < .01$) to 318.82 (HRSD: $p < .001$). Significant pre-post treatment improvement was observed on measures of self-reported (BDI-II) and clinician-rated depression (HRSD), environmental reward (EROS), somatic anxiety (BAI), quality of life (QOLI), social functioning (MSPSS), and all eight indices of medical outcomes (SF-36). Patients also reported strong treatment satisfaction with the BATD and PST protocols (CSQ). Also of high relevance, treatment improvements were clinically significant as indicated by moderate to large effect sizes on all depression, anxiety, and quality of life outcomes (range = 0.54–2.28). Effect sizes were also meaningful but somewhat less robust on indices of social support (MSPSS: range = 0.29–0.49) and medical outcomes (SF-36: range = 0.33–1.24). Important to note, based on a series of analyses of covariance that controlled for baseline symptoms, there were no significant differences in outcomes at posttreatment as a function of whether patients were medicated or nonmedicated with antidepressant or antianxiety medications.

Follow-up hierarchical linear modeling analyses. Following examination of treatment effects, growth curve analyses with hierarchical linear modeling (HLM, Version 6.08; Bryk, Raudenbush, & Congdon, 2004) were used to examine the extent to which treatment effects were maintained over the 12-month posttreatment follow-up. Specifically, we fit the following Level 1 model to each outcome, where time was defined as month since the end of treatment:

$$Y_{it}(\text{Outcome}) = \pi_{0i} + \pi_{1i}(\text{Time}) + e_i.$$

Accordingly, Y_{it} is the outcome for individual i at Time t , π_{0i} is the level of the outcome immediately after treatment for individual i , π_{1i} is the per-month change in the outcome for individual i , and e_i is the variation in the outcome for individual i that is not due to time. This model can be understood as a within-person regression in which each outcome is regressed onto time and in which the nonindependence of individuals' repeated assessment is controlled in the second level of the model. This second level of the model also examined treatment differences as a function of time, where between-person differences in each parameter estimated in the Level 1 model were regressed onto treatment group in the second level of the model. Treatment group was differentially dummy-coded in separate analyses to obtain change estimates for each group.

Results of these analyses are presented in the last column of Table 2. As indicated, in no analysis for either treatment group did

Table 2
Treatment Outcome as a Function of Intervention Group: Intent-to-Treat Analyses

Measure and intervention group	Pretreatment <i>M (SD)</i>	Posttreatment <i>M (SD)</i>	Group × Time interaction, <i>F</i> (1, 78)	Follow-up				Treatment effect size (<i>d</i>)	Follow-up effect (π)
				3-month <i>M (SD)</i>	6-month <i>M (SD)</i>	9-month <i>M (SD)</i>	12-month <i>M (SD)</i>		
BDI-II			0.04						
BATD	27.2 (9.5) _a	9.9 (6.8) _b		9.6 (5.4)	9.0 (5.6)	11.6 (9.6)	7.0 (4.8)	1.55	-0.13 _c
PST	26.7 (7.4) _a	8.9 (7.4) _b		9.1 (6.9)	9.7 (7.4)	10.4 (7.3)	7.7 (6.4)	1.75	-0.04 _c
HRSD			0.04						
BATD	19.2 (7.0) _a	6.0 (4.7) _b		6.1 (4.4)	5.7 (3.2)	6.1 (4.8)	4.5 (3.6)	1.91	-0.11 _c
PST	20.1 (5.9) _a	6.7 (4.0) _b		6.4 (4.4)	6.3 (4.7)	5.9 (4.7)	4.8 (4.4)	2.28	-0.14 _c
EROS			0.01						
BATD	23.0 (5.3) _a	28.2 (3.8) _b		28.8 (4.0)	28.3 (3.5)	29.1 (4.7)	31.0 (3.3)	0.93	-0.19 _c
PST	22.4 (3.7) _a	27.6 (5.2) _b		28.5 (5.5)	28.3 (4.8)	28.2 (4.9)	29.6 (4.7)	0.95	-0.13 _c
BAI			0.41						
BATD	17.1 (9.0) _a	10.7 (7.8) _b		9.5 (7.8)	9.0 (5.5)	10.0 (6.6)	7.5 (5.2)	0.73	-0.19 _c
PST	16.3 (10.1) _a	11.2 (8.2) _b		9.8 (7.0)	10.7 (7.1)	10.7 (6.8)	9.2 (7.2)	0.54	-0.10 _c
QOLI			0.71						
BATD	0.3 (1.9) _a	2.1 (1.6) _b		2.1 (1.3)	2.6 (1.0)	2.6 (1.7)	2.1 (1.4)	1.02	0.02 _c
PST	0.5 (1.8) _a	1.9 (1.8) _b		2.2 (1.8)	2.2 (1.5)	2.2 (1.7)	2.2 (1.5)	0.77	0.02 _c
MSPSS			0.88						
BATD	33.5 (18.8) _a	26.4 (12.9) _b		29.1 (12.6)	29.6 (12.3)	26.5 (12.1)	25.5 (8.5)	0.49	-0.14 _c
PST	32.3 (16.8) _a	28.2 (13.7) _b		29.4 (15.3)	26.9 (11.1)	31.3 (13.4)	29.4 (13.5)	0.29	0.14 _c
SF-36 PF			0.12						
BATD	49.3 (30.1) _a	58.3 (24.5) _b		61.7 (25.0)	62.2 (23.3)	65.8 (19.4)	63.9 (17.9)	0.42	0.51 _c
PST	53.7 (24.8) _a	64.3 (20.8) _b		61.4 (23.9)	59.5 (20.9)	62.0 (20.3)	61.7 (20.9)	0.59	-0.15 _c
SF-36 RF			0.15						
BATD	22.0 (34.1) _a	42.4 (32.1) _b		55.9 (31.8)	51.0 (30.4)	53.2 (29.4)	61.9 (24.8)	0.53	1.22 _c
PST	27.0 (37.8) _a	43.6 (41.3) _b		38.2 (35.4)	53.5 (30.7)	48.4 (31.7)	52.8 (34.2)	0.36	0.95 _c
SF-36 SF			0.01						
BATD	32.4 (22.8) _a	62.1 (22.3) _b		66.0 (26.8)	70.9 (20.7)	68.1 (21.4)	72.9 (17.7)	1.21	0.79 _c
PST	40.8 (24.6) _a	69.9 (20.8) _b		65.8 (26.9)	65.6 (22.1)	67.6 (20.1)	69.4 (21.6)	1.18	0.02 _c
SF-36 MH			0.02						
BATD	48.1 (17.9) _a	70.8 (13.5) _b		71.5 (13.9)	69.8 (13.0)	67.7 (17.6)	72.9 (12.1)	1.24	0.01 _c
PST	46.2 (16.8) _a	69.6 (18.9) _b		69.1 (19.2)	66.3 (17.7)	65.7 (17.5)	69.8 (18.0)	1.12	-0.37 _c
SF-36 RE			0.60						
BATD	19.0 (32.2) _a	58.1 (30.7) _b		58.1 (34.5)	60.5 (34.1)	53.4 (29.2)	67.1 (23.9)	0.98	0.45 _c
PST	15.0 (27.6) _a	61.2 (39.7) _b		60.6 (38.1)	57.6 (31.7)	47.2 (34.7)	59.4 (39.7)	1.08	-0.57 _c
SF-36 V			3.71						
BATD	27.6 (19.6) _a	39.1 (19.7) _b		46.3 (19.7)	45.3 (18.6)	48.5 (15.8)	51.8 (15.5)	0.44	0.92 _c
PST	23.6 (14.6) _a	45.8 (20.8) _b		44.1 (23.6)	42.6 (19.1)	43.9 (19.3)	46.8 (18.0)	0.94	0.06 _d
SF-36 GH			0.02						
BATD	43.2 (19.1) _a	50.9 (22.5) _b		57.9 (21.1)	60.5 (16.6)	64.0 (17.7)	62.7 (16.1)	0.47	0.99 _c
PST	51.3 (21.6) _a	58.5 (17.3) _b		60.0 (20.2)	61.9 (20.6)	62.3 (18.1)	67.0 (17.2)	0.37	0.64 _c
SF-36 BP			0.11						
BATD	46.4 (26.6) _a	55.5 (22.7) _b		60.5 (20.7)	65.1 (17.0)	63.3 (16.4)	65.0 (15.3)	0.33	0.73 _c
PST	51.4 (26.7) _a	62.6 (22.1) _b		56.7 (23.4)	55.9 (25.6)	60.0 (24.2)	54.6 (19.8)	0.41	-0.42 _d
CSQ									
BATD	—	30.7 (2.2)		30.3 (2.4)	30.9 (2.4)	30.4 (2.9)	30.5 (2.7)	—	-0.12
PST	—	30.6 (2.1)		30.5 (1.9)	30.2 (2.5)	30.7 (2.3)	30.6 (2.4)	—	-0.08

Note. Dashes indicate that data were not collected. Subscripts _a and _b represent statistically significant values, and subscripts _c and _d represent statistically significant values. π = raw change in dependent variable every month as estimated across the 12 follow-up months; BDI-II = Beck Depression Inventory-II; HRSD = Hamilton Rating Scale for Depression; EROS = Environmental Reward Observation Scale; BAI = Beck Anxiety Inventory; QOLI = Quality of Life Inventory; MSPSS = Multidimensional Scale of Perceived Social Support; SF-36 PF = Medical Outcomes Physical Functioning; SF-36 RF = Medical Outcomes Role Functioning; SF-36 SF = Medical Outcomes Social Functioning; SF-36 MH = Medical Outcomes Mental Health; SF-36 RE = Medical Outcomes Role Emotional; SF-36 V = Medical Outcomes Vitality; SF-36 GH = Medical Outcomes General Health; SF-36 BP = Medical Outcomes Bodily Pain; CSQ = Client Satisfaction Questionnaire; BATD = behavioral activation treatment for depression; PST = problem-solving therapy.

* $p < .05$. ** $p < .01$. *** $p < .001$.

an outcome change in the direction of pretreatment levels. Indeed, in several cases, patients in each group demonstrated continued improvement throughout the follow-up interval. Notably, patients in the BATD group demonstrated continued posttreatment improvement on a greater number of outcomes (seven out of 14) than

patients in the PST group (two out of 14). In fact, for SF-36V vitality and SF-36 bodily pain, patients in the BATD group demonstrated significantly more posttreatment improvement than patients in the PST group. In summary, treatment effects experienced by both groups either persisted or increased in magnitude over the

12-month follow-up, and such improvements were particularly likely within the BATD group.

Reliable change index. To assess the significance of patient change on a more ideographic level, we utilized the reliable change index (RCI), a very rigorous statistic used to assess the clinical significance of pre–post changes for each individual patient (Jacobson & Truax, 1991). An RCI critical score is formulated based on descriptive data from the pretreatment (mean and standard deviation) and posttreatment assessment (mean), as well as the reliability of the measure being analyzed. For this study, critical values were formulated for the two primary depression outcome measures: HRSD (7.61) and BDI-II (10.02). For the HRSD, an ITT RCI analysis was conducted on the entire sample. Results revealed that 62 patients (78%; BATD = 30, PST = 32) were considered to have clinically significant reductions in clinician-rated depression symptoms. These RCI responders did not differ as a function of treatment condition, $\chi^2(1) = 1.87, p = .19$. For the BDI-II, the ITT RCI analysis indicated that 63 patients (79%; BATD = 31, PST = 32) had clinically significant reductions in self-reported depression, and responders did not differ as a function of treatment, $\chi^2(1) = 1.29, p = .29$.

Response and remission. ITT categorical response and remission rates for the BATD and PST groups at posttreatment also were calculated. As presented in Figure 2, overall combined rates of response and remission based on the BDI-II were 70% ($n = 29$) in BATD and 81% ($n = 31$) in PST. There was no significant difference across treatment groups in either response, $\chi^2(1) = 2.29, p = .20$, or remission rates, $\chi^2(1) = 0.68, p = .49$. Furthermore, both response, $\chi^2(1) = 1.01, p = .45$, and remission, $\chi^2(1) = 0.68, p = .49$, were unrelated to whether patients were unmedicated or stabilized on medications at the time of the study. As presented in Figure 3, overall combined rates of response and

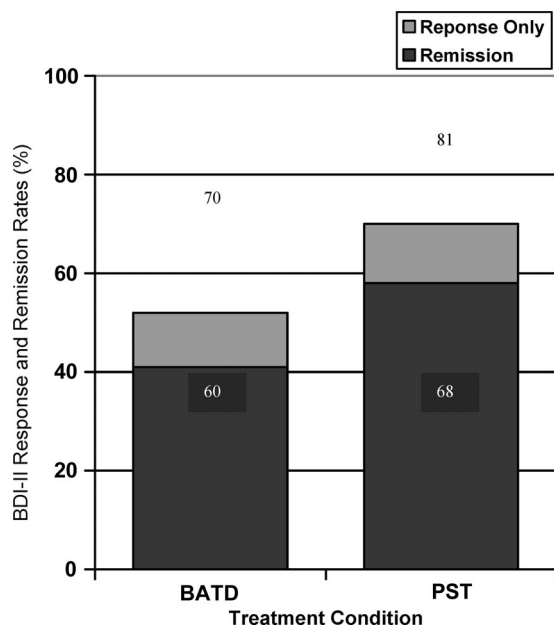


Figure 2. Response and remission rates at posttreatment based on the Beck Depression Inventory–II (BDI-II). BATD = behavioral activation treatment for depression; PST = problem-solving therapy.

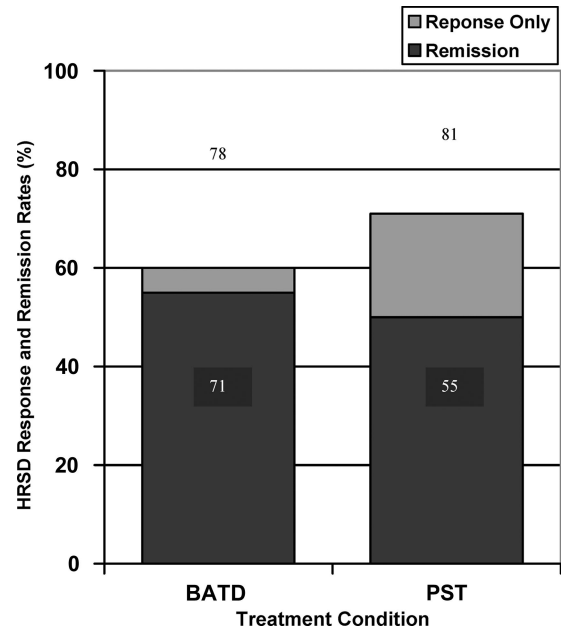


Figure 3. Response and remission rates at posttreatment based on the Hamilton Rating Scale for Depression (HRSD). BATD = behavioral activation treatment for depression; PST = problem-solving therapy.

remission based on the HRSD were 78% ($n = 33$) in BATD and 81% ($n = 31$) in PST. There was no significant difference across treatment groups in either response, $\chi^2(1) = 0.35, p = .60$, or remission rates, $\chi^2(1) = 2.26, p = .17$. Consistent with BDI-II data, both response, $\chi^2(1) = 1.30, p = .29$, and remission, $\chi^2(1) = 0.68, p = .49$, were unrelated to whether patients were unmedicated or stabilized on medications at the time of the study.

Number needed to treat. The number needed to treat (NNT) is calculated to determine the number of patients who would need to be treated to prevent one additional bad outcome (i.e., the number of patients who need to be treated for a single patient to benefit when provided one intervention relative to another in a clinical trial; Laupacis, Sackett, & Roberts, 1988). In comparing BATD and PST, for example, the NNT is calculated as the reciprocal of the difference in the response rates between the interventions (Herbert, 2000). For treatment response to significantly differ across interventions, absolute risk reduction must not be associated with a confidence interval (CI) that crosses zero. On the basis of the total response and remission rates as defined by the BDI-II, the PST and BATD groups were not significantly different: 31 PST (81%) versus 29 BATD patients (70%), absolute risk reduction = 12.53%, 95% CI [−6.1, 31.2]. This corresponded to an NNT of eight, 95% CI [3.2, 14.0]. On the basis of the total response and remission rates as defined by the HRSD, the PST and BATD groups also did not experience differential treatment outcome: 31 PST (81%) versus 33 BATD patients (78%), absolute risk reduction = 0.38%, 95% CI [−17.6, 18.3]. This corresponded to an NNT of 266, 95% CI [5.5, ∞].

Discussion

Major depression is highly prevalent in breast cancer patients and is associated with significant life impairment (Massie, 2004),

yet meta-analytic research has yielded minimal convincing support for treating depression in this population (Fann et al., 2008; Lepore & Coyne, 2006; Newell et al., 2002). This study aimed to assess the efficacy of BATD, which is a practical and uncomplicated form of behavior therapy for treating depressed breast cancer patients, as compared to the gold-standard treatment PST. This study represents the third largest randomized trial of behavioral activation to date (following Dimidjian et al., 2006; Jacobson et al., 1996), is the largest and most rigorous trial of the BATD protocol (Hopko & Lejuez, 2007; Lejuez et al., 2001), and is the first randomized trial of behavioral activation with depressed cancer patients. In a stringent examination of BATD relative to the empirically validated PST, this longitudinal investigation provided compelling support for both treatments. Among the major findings, BATD and PST were both effective in decreasing depression and anxiety symptoms, as well as increasing environmental reward, quality of life, social support, and medical outcomes. Treatment gains were associated with strong effect sizes, and the reliable change, response and remission, and NNT criteria suggested that approximately two thirds of patients exhibited clinically significant improvement. These data are persuasive in that both BATD and PST produced response rates similar to the behavioral activation condition and superior to medication and cognitive therapy in what has been the defining trial of behavioral activation (Dimidjian et al., 2006). Strong therapist treatment integrity and excellent patient satisfaction also were evident with both treatment protocols. Robust treatment gains across outcome measures were maintained at 12-month follow-up, suggesting that both BATD and PST may elicit enduring treatment effects. Further research would be helpful to replicate the finding that BATD was associated with a greater likelihood of posttreatment improvement on several outcomes, particularly increased vitality and decreased bodily pain. Pertaining to potential additive benefits of medication, it is noteworthy that treatment gains at posttreatment and follow-up intervals were not associated with antidepressant and anti-anxiety medication usage, suggesting no significant synergistic benefit of a multimodal approach in this sample. Finally and perhaps somewhat surprisingly given sample characteristics that included a diagnosis of major depression and a major medical diagnosis, patient attrition (19%) was equivalent to or in some cases lower than that reported in prior treatment outcome research, suggesting good patient tolerability (Cuijpers et al., 2007; DeRubeis et al., 1999; Hollon et al., 2002).

These results build upon the two preliminary studies supporting BATD among depressed cancer patients in medical care settings (Hopko et al., 2005; Hopko, Bell, et al., 2008). The stronger research design, increased breadth of outcome measures, experimental control of cancer-related variables and medication usage, and year-long follow-up interval address many limitations associated with previous works. In addition, the favorable outcomes of patients in the PST treatment condition add to a growing literature supporting the efficacy of this intervention for depressed cancer patients (Allen et al., 2002; Meyer & Mark, 1995; Nezu et al., 2003). To be certain, there are fundamental differences in the way BATD and PST are administered. In BATD, depression is treated through self-monitoring, contingency management, a value assessment, and structured activity scheduling. In contrast, PST largely is based on learning a problem-solving algorithm that allows for increased coping skills and emotion regulation, decreased impul-

sivity, enhanced logic, and subsequent depression management. Applied to cancer patients, BATD has perhaps been more focused on anxiety-related exposure (Hopko & Lejuez, 2007), and PST more focused on cancer-symptom management (Nezu et al., 1998). Despite these distinctions and addressing the finding of no differences between BATD and PST at posttreatment, there are functional similarities between treatments. Perhaps most importantly, the interventions employ different strategies to achieve a common purpose, namely, behavior modification to increase RCPR. For that matter, it could be argued that both interventions also decrease aversive environmental contingencies, a maintaining factor of depression (Lewinsohn, 1974). Consistent with unified theories of emotional disorders (Barlow, Allen, & Choate, 2004), decreasing avoidance behavior through both BATD and PST may potentially be the critical (and similar) component of change.

Although study findings are promising, several limitations remain evident. First, primarily due to population characteristics in the geographical region of study, the sample was predominantly Caucasian, raising some concerns about generalizability. Accordingly, to complement behavior activation research with Latina samples (Kanter, Santiago-Rivera, Rusch, Busch, & West, 2010), a more concerted effort is needed to examine the efficacy of BATD and PST among minorities as well as whether minority-specific protocol modifications are essential to improving treatment outcome. Second, although results support BATD and PST for attenuating depression, only the BAI was used to assess anxiety, and there was no assessment of anxiety disorder remission at assessment intervals. In the two earlier randomized trials, anxiety also was not examined systematically (Dimidjian et al., 2006; Jacobson et al., 1996). This situation is problematic given the comorbidity between depression and anxiety (Barlow, 2002; Mineka, Watson, & Clark, 1998). Indeed, when clearly distinguishing behavior activation from exposure-based therapy (Hopko et al., 2006), research on the efficacy of behavior activation for anxiety is minimal (Jakupcak et al., 2006; Mulick & Naugle, 2004). Accordingly, there is a pressing need to assess whether behavior activation therapies can stand alone or whether these approaches require supplementation of specific anxiety interventions to adequately treat coexistent anxiety disorders (DeRubeis & Crits-Christoph, 1998). Third, related to this issue, at this stage it is unclear whether a more systematic BATD treatment-patient matching procedure would increase positive treatment outcome (e.g., an extra module for patients with a coexistent anxiety disorder). Fourth, although there was some support for continued improvement in the BATD group at 12-month follow-up, any incremental benefits of BATD must be weighed against potential costs. For example, it may be argued that BATD is somewhat more complex due to the inclusion of behavioral interventions that might not be easily transportable to medical settings (e.g., progressive muscle relaxation, anxiety-related exposure). Fifth, the study design could have been strengthened via inclusion of an additional group receiving no treatment. This not only would have allowed for strengthened conclusions on treatment effects but also would have allowed for assessment of mortality as a function of psychotherapy, an area of research yielding equivocal findings in cancer patients (Coyne, Stefanek, & Palmer, 2007; Spiegel & Giese-Davis, 2003). Sixth, although the ADIS-IV has good psychometric properties and likely yielded valid diagnostic data, it is conceivable that a more comprehensive protocol such as the Structured Clinical

Interview for *DSM-IV* (First, Spitzer, Gibbon, & Williams, 1996) would have allowed for a more complete diagnostic picture. Indeed, the ADIS-IV was chosen to abbreviate an already very time-intensive assessment procedure. Relatedly, readministering the ADIS-IV at posttreatment and follow-up to determine whether patients met criteria for major depression could have solidified outcome data. Seventh, although all outcome measures have strong psychometric properties, with the exception of the BDI-II, substantially more empirical work is necessary to demonstrate their utility among cancer patients. For example, it is conceivable that the BAI, which is not well studied among cancer patients, may include somatic symptoms that overlap too greatly with physical symptoms of cancer and associated interventions so as to decrease the likelihood of finding significant and meaningful treatment effects. Finally, as suggested earlier, a more extensive and heterogeneous patient sample will be necessary to replicate findings and assess external validity.

Despite these limitations, this study addressed methodological limitations highlighted in previous works and a largely cynical and controversial perspective of the merits of psychotherapy with cancer patients (Lepore & Coyne, 2006; Newell et al., 2002). Although more data are required, the study supports the efficacy of BATD and PST as viable treatments for depressed breast cancer patients. These data are especially important given inadequate attention to recognizing and treating depression in breast cancer patients and the substantial psychosocial and medical impairment that depressed cancer patients often experience. Further programmatic research in the form of carefully designed randomized trials will help to discern the practicality and efficacy of BATD and PST in reducing depression in breast cancer patients and other medical samples, as well as whether activation-based treatments may ultimately help to improve quality of care and longevity of life. From the practical perspective of working toward developing uncomplicated interventions that could be of value in medical care settings where time, expertise, and cost-effectiveness are at a premium, the potential utility of these approaches also is appealing. Being able to provide these services within medical oncology settings may increase treatment access and adherence as well as decrease stress in breast cancer patients who may already be overwhelmed by numerous medical appointments. Finally, as demonstrated with brief problem-solving interventions administered in medical care settings (Arean, Hegel, Vannoy, Fan, & Unutzer, 2008; Hegel, Barrett, Cornell, & Oxman, 2002; Mynors-Wallis, Davies, Gray, Barbour, & Gath, 1997; Mynors-Wallis, Gath, Day, & Baker, 2000; Mynors-Wallis, Gath, Lloyd-Thomas, & Thomlinson, 1995; Wolf & Hopko, 2008), it also might be reasonable to effectively train behavioral activation treatment providers who might include oncologists, nurses, nurse practitioners, depression health specialists, and/or physician extenders.

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