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A randomized trial of a cognitive-behavioral therapy and hypnosis intervention on positive and negative affect during breast cancer radiotherapy

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Abstract

Breast cancer radiotherapy can be an emotionally difficult experience. Despite this, few studies have examined the effectiveness of psychological interventions to reduce negative affect, and none to date have explicitly examined interventions to improve positive affect among breast cancer radiotherapy patients. The present study examined the effectiveness of a multimodal psychotherapeutic approach, combining cognitive-behavioral therapy and hypnosis (CBTH), to reduce negative affect and increase positive affect in 40 women undergoing breast cancer radiotherapy. Participants were randomly assigned to receive either CBTH or standard care. Participants completed weekly self-report measures of positive and negative affect. Repeated and univariate analyses of variance revealed that the CBTH approach reduced levels of negative affect [F (1, 38) = 13.49; p = .0007], and increased levels of positive affect [F (1, 38) = 9.67; p = .0035, ω^2 = .48], during the course of radiotherapy. Additionally, relative to control group, the CBTH group demonstrated significantly more intense positive affect [F (1,38) = 7.09; p = .0113, d = .71] and significantly less intense negative affect [F (1,38) = 10.30; p = .0027, d = .90] during radiotherapy. The CBTH group also had a significantly higher frequency of days where positive affect was greater than negative affect (85% of days assessed for the CBTH group versus 43% of the Control group) [F (1,38) = 18.16; p = .0001, d = 1.16]. Therefore, the CBTH intervention has the potential to improve the affective experience of women undergoing breast cancer radiotherapy.

Keywords

breast cancer; radiotherapy; cognitive-behavioral therapy; hypnosis; positive affect; negative affect

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It is estimated that over 182,000 women will be diagnosed with breast cancer in the United States this year (American Cancer Society, 2008). One of the key approaches to prolonging survival, improving localized tumor control, and reducing mortality in these women is radiotherapy (Vinh-Hung & Verschraegen, 2004). However, despite its medical benefits, the radiotherapy process can be emotionally difficult (Hickok, Morrow, Roscoe, Mustian, & Okunieff, 2005; Knobf & Sun, 2005). At the commencement of breast cancer radiotherapy, it has been found that 31% of patients experienced moderate to severe levels of negative affect (Söllner, Maislinger, Konig, Devries, & Lukas, 2004); that 40% – 48.7% of patients were anxious about upcoming radiotherapy and 54% – 69.1% were anxious about potential side effects (Mose et al., 2001; Rahn et al., 1998); and that 40.5% were worried in particular about negative radiotherapy effects on the appearance of their breast (Mose et al., 2001). Furthermore, when asked to reflect back on their treatment, 33% of breast cancer patients reported that they had felt powerless when alone in the linear accelerator room as radiation began, 22.7% had found the linear accelerator room threatening, and 40.5% had felt psychologically distressed by the radiotherapy treatment (Mose et al., 2001). Overall, the experience of negative affect associated with radiotherapy is quite common.

Not surprisingly then, psychotherapeutic interventions are desired by a substantial number of breast cancer radiotherapy patients. Alder and Bitzer (2003) queried patients after radiotherapy treatment and found that up to 45% of a sample of breast cancer patients wished that they had received some psychotherapeutic intervention during treatment. Söllner and colleagues (2004) found that prior to radiotherapy, 42% of their sample of breast cancer radiotherapy patients reported that they would be interested in receiving psychotherapeutic intervention. Additionally, Söllner et al. found that desire for psychological services was unrelated to level of negative affect, suggesting a broad interest in psychological services among breast cancer radiotherapy patients, a desire not solely restricted to those women experiencing the most severe levels of negative affect.

Thus, the literature indicates that breast cancer radiotherapy patients have both a need and a desire for psychological interventions aimed at helping them to manage negative affect. Narrative reviews suggest that cognitive-behavioral therapy is helpful for reducing negative affect in cancer patients (Redd, Montgomery, & DuHamel, 2001). Meta-analyses further indicate that individual-format cognitive behavioral therapy (CBT) with a variety of adult cancer patients is effective in reducing negative affect, with effect sizes ranging from medium (d = .48) to large (d = 1.44 – 2.41) (Osborn, Demoncada, & Feuerstein, 2006; Tatrow & Montgomery, 2006). Consistent with this literature, the few studies that have examined CBT techniques in the radiotherapy setting in particular (Bridge, Benson, Pietroni, & Priest, 1988; Decker, Gallagher, & Cline-Elsen, 1992; Kolcaba & Fox, 1999) have demonstrated the effectiveness of such techniques in reducing negative affect.

Meta-analyses have further indicated that although CBT is effective on its own, the combination of CBT and hypnosis can yield even larger clinical effect sizes (Kirsch, Montgomery, & Sapirstein, 1995). To date, this multimodal approach has not been tested with radiotherapy patients. There has been one study which tested hypnosis on its own; a randomized trial on the use of hypnosis with adult radiotherapy patients (Stalpers et al., 2005). In that study, the hypnosis intervention was found to have no effect on anxiety, but the authors reported that a significantly greater proportion of hypnosis group participants reported improvements in mental well-being as a result of participating in the study than control group participants (Stalpers et al., 2005). The mixed results of this trial may be due to the use of hypnosis alone, rather than pairing it with CBT. Therefore, it is possible that an intervention package combining hypnosis and CBT could be especially effective (Kirsch et al., 1995) in reducing negative affect in breast cancer radiotherapy patients.

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The present study was designed to investigate the effectiveness of a multimodal CBTH (cognitive-behavior therapy plus hypnosis) intervention package for reducing negative affect in a sample of women undergoing breast cancer radiotherapy. However, consistent with the positive psychology principles of nurturing and enhancing positive well-being (Seligman & Csikszentmihalyi, 2000), we recognize that it is insufficient to focus exclusively on reducing individuals' negative affect without also taking into consideration their level of *positive* affect (Gable & Haidt, 2005; Seligman et al., 2000). Therefore, we intended to assess the effectiveness of our CBTH intervention through its effect on measures of both positive *and* negative affect. Both components of the intervention package were designed to both improve positive as well as reduce negative affective experience: hypnosis via direct suggestions for reduced negative affect and increased positive affect; and CBT via changing negative maladaptive cognitions and behaviors to promote more adaptive, positive cognitions and behaviors. To date, only one study in the breast cancer radiotherapy setting has explicitly examined both negative *and* positive affect (Buick et al., 2000), and this was done within a longitudinal design, without an intervention. The aim of the present study was to extend this dual focus by examining the effects of a CBTH intervention on both negative and positive affect over the course of radiation treatment for breast cancer.

Method

Background and Participants

A total of 40 women (*age range:* 30–80 years; *race*: 62.5% White, 20% Black/African-American, 10% Black/West Indian or Caribbean, 7.5% Asian; *ethnicity:* 22.5% Latina) participated in the current study: 20 in the CBTH group and 20 in the Standard Care Control group. The study was approved by the Institutional Review Board, and written informed consent was obtained from all participants.

Eligibility criteria for the present study included being: scheduled for breast cancer radiotherapy; able to speak and read English (as the CBTH intervention and all questionnaires were in English); over age 18; willing to be randomized to study intervention group; and having Stage 0, I, II or III breast cancer. Exclusion criteria were uncontrolled mental illness or medical illness (as determined by medical chart review) and metastatic disease. Participants were recruited from the radiation oncology practice of a large urban teaching hospital), and data were collected from participants at their regularly scheduled radiation oncology appointments, in the radiation oncology clinic.

Measures

Outcome Variable—The primary outcome variable was the 9 item mood report form developed by Diener and Emmons (1984), which was administered to each participant on a weekly basis during the course of radiotherapy (on days 7, 14, 21, 28, and 35) to assess positive affect (items are: happy, pleased, joyful, enjoyment/fun) and negative affect (items are: unhappy, depressed/blue, frustrated, angry/hostile, worried, anxious and fearful). Each item on the mood report describes a mood state. Participants were asked to rate the degree to which they experienced each item on a 0–6 scale, where 0 = not at all, and 6 = extremely much. Each form yields a *positive affect score (PA)* and a *negative affect score (NA)*. Weekly PA and NA scores were collected for each participant (i.e., scores on day 7, day 14, day 21, day 28, day 35). The measure also yields a *frequency score*. The frequency score is calculated by "… adding up the instances when the … positive affect score exceeded the … negative affect score, and dividing this number by the number of days sampled. Therefore, the 'frequency' dimension refers … to the frequency of predominantly 'happy' days. It is a percentage that can vary from 0 (most unhappy persons) to 100 (most happy persons)" (Diener, Larsen, Levine, & Emmons, 1985, p. 1256). Additionally, the measure yields

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positive and negative intensity scores, which represent "the strength with which subjects experienced their dominant affect" (Diener et al., 1985, p. 1256). The positive intensity score assesses how strongly positive affect was felt when it was the dominant emotion (i.e., the mean positive affect score on days when positive affect was greater than negative affect), and the negative intensity score assesses how strongly negative affect was felt when it was the dominant emotion (i.e., the mean negative affect score on days when negative affect was greater than positive affect) (Diener et al., 1984). This scale has shown good reliability (*Cronbach's alpha*: positive affect=.89, negative affect=.84) (Diener et al., 1984; Emmons & Diener, 1985), and has been used previously in women with breast cancer (Manne et al., 1994). In the current research sample, the average Cronbach's alpha for the positive affect scale was .94 and for the negative affect scale was .92.

Personality traits may also play an important role in determining affect (Benotsch, Lutgendorf, Watson, Fick, & Lang, 2000; Raikkonen, Matthews, Flory, Owens, & Gump, 1999; Zautra, Affleck, Tennen, Reich, & Davis, 2005). In the present study, we investigated the trait variables of neuroticism and trait anxiety. *The NEO-Five Factor Inventory* Neuroticism Subscale (NEO-N) (Costa & McCrae 1985; 1992) was used (short form, from the NEO-FFI) to assess neuroticism. The shortened form of the NEO-N (Costa & McCrae, 1992) is a widely used, well-validated, self-report questionnaire which contains 12 items, and has good internal consistency (α =.86). Cronbach's alpha for the current sample was .86. *The State-Trait Anxiety Inventory* (STAI) (Spielberger, Gorsuch, & Lushene, 1970) is a classic measure assessing acute and chronic levels of anxiety (Spielberger, 1983). The 20 item trait subscale was used to assess characterological levels of anxiety. Cronbach's alpha for the current sample was .89. As a check on randomization, we also screened participants for their pre-intervention levels of negative affect, specifically anxiety. Anxiety was measured using the tension-anxiety subscale of the short version of the Profile of Mood States (SV-POMS) (DiLorenzo, Bovbjerg, Montgomery, Jacobsen, & Valdimarsdottir, 1999). This measure has been used previously to assess anticipatory distress in women with breast cancer (Montgomery et al., 2003), and Cronbach's alpha in the current sample was .95.

Self-reported demographic information was also collected from participants. Relevant medical history variables, abstracted from participants' medical charts, included their cancer stage, chemotherapy history, and Karnofsky Performance Status (Karnofsky & Burchenal, 1949) rating upon beginning radiotherapy, where 0% = death and 100% = normal functioning.

Procedure

Radiotherapy Procedure—Consistent with standard clinical practice at our institution, all patients were informed before treatment of possible radiotherapy-related side effects. Before beginning treatment, patients participate in two treatment planning sessions – a *simulation* session and a *verification* session. Following verification, patients begin radiotherapy, which takes place five weekdays per week until the total dose is received. Radiation was delivered via Varian linear accelerators.

Study Procedure—Patients scheduled for radiotherapy for primary breast cancer were referred by their radiation oncologist, and those expressing interest were contacted by study personnel who described the study and obtained written informed consent. After providing written informed consent, participants were randomly assigned to either a CBTH or a Standard Care Control Group, using computer-generated random positive integers (SAS) (SAS Institute, 2002). Randomization assignments were generated by GM, who informed the interventionist of the participant group assignment on the morning of the intervention.

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The sequence and assignments were unknown to the research assistants, who enrolled participants and collected all outcome data. As participants were active in the intervention, it was impossible to blind them to group assignment. Similarly, interventionists (n=2) were necessarily not blind to group assignment, as they had to conduct the intervention. Interventionists were blind to all outcome data.

Consenting participants completed the demographics questionnaire, the NEO-N, the STAI-T, and the SV-POMS on the simulation day, prior to receiving the hypnosis component of the intervention. Once radiotherapy began, participants were asked to complete assessments of positive and negative affect on a weekly basis for the first five consecutive weeks of treatment. Research assistants and medical staff were blind to participants' intervention group assignment.

Intervention Procedures—All intervention sessions were conducted by a licensed clinical psychologist. The CBTH procedure was based on a manual specifically developed by our group for this population. The CBTH training procedures took place prior to the commencement of radiation, consistent with literature suggesting that negative affect related to breast cancer radiotherapy is at its worst pre-treatment (Buick et al., 2000). Additionally, an individual psychotherapy format was selected based on meta-analytic results suggesting the superiority of individual CBT over group CBT for distress in women with breast cancer (Tatrow et al., 2006). Both the CBTH and the Standard Care procedures are described below.

CBTH - Hypnosis Procedures—On the day of their simulation appointment, prior to the simulation, the interventionist met with each patient in a private room in the radiation oncology clinic to conduct a brief (15 minute) hypnosis session which consisted of: 1) addressing common misconceptions about hypnosis; 2) a hypnotic induction including suggestions for mental and physical relaxation (adapted from Rhue, Lynn, & Kirsch, 1993 specifically for breast cancer radiotherapy patients); 3) guided imagery of a peaceful and safe place; 4) a deepening component with suggestions for increased hypnotic depth; 5) and symptom-focused suggestions for decreased negative affect, increased positive affect, increased comfort with the radiotherapy room/setting, and reduced radiotherapy-side effects. Following these suggestions, participants were given a cue word, which they were instructed they could use to enter hypnosis whenever they liked. The interventionist then ended the hypnosis session, and gave participants a CD player and a pre-recorded hypnosis CD of the intervention to listen to at home.

CBTH - Cognitive-Behavioral Therapy Procedures—On participants' verification day, prior to the verification, the interventionist met with each participant individually in a private room in the radiation oncology clinic for 30 minutes to educate them regarding: how to identify negative, unhelpful beliefs regarding the radiotherapy experience (e.g., catastrophizing/awfulizing); the emotional, behavioral, and physical consequences of those beliefs; methods for disputing such beliefs and replacing them with more helpful (i.e., rational) alternatives (Ellis, 1994); and behavioral strategies to manage treatment-related stress. To support this didactic training, all participants were given a CBT workbook developed by our group for breast cancer radiotherapy patients, were taught to complete a thought record worksheet, and were asked to complete two of these worksheets per week (during the course of their radiotherapy) as homework. The interventionist subsequently met with each participant twice per week (in the radiation oncology clinic, just prior to medical appointments) to go over these homework sheets. Each homework check lasted approximately 5–15 minutes. No adverse or side effects of the CBTH intervention were observed.

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Standard Care Control Group Procedures—Participants randomly assigned to the Standard Care Control group had no contact at all with the interventionist. Their involvement in the study consisted solely of regularly completing questionnaire packets. Control group participants were informed that if they were interested in the intervention subsequent to the conclusion of the study, they were eligible to receive (at no cost to themselves) an intervention session. They were also given a CD player, in order to ensure that this compensation did not differ between groups.

Objectives and Hypotheses—The objective was to determine whether the CBTH intervention would improve participants' affective experience relative to standard care. The specific hypotheses were that, relative to a standard care control group, the CBTH group would: 1) report higher levels of positive affect; 2) report lower levels of negative affect; 3) demonstrate increased frequency of positive affect; 4) demonstrate decreased intensity of negative affect; and 5) demonstrate increased intensity of positive affect. The primary outcome with respect to intervention efficacy for the present study was the Diener and Emmons (1984) mood report form.

Data analytic approach—Skewness and kurtosis values were calculated for all outcome variables to check for deviations from normality. These values were acceptable for all outcomes (between -3 and 3), with the exception of negative affect on days seven and 35 where kurtosis values were 3.60 and 3.36 respectively. We log transformed these variables which reduced kurtosis to acceptable levels. The pattern of results using transformed and non-transformed data was identical, so for ease of interpretation we report the results for the non-transformed data below.

For primary outcomes, data were analyzed using repeated measures analysis of variance (R-ANOVA). Additionally, chi-square procedures and analysis of variance (ANOVA) procedures were used to test between-group differences in background demographic and medical variables. All analyses were performed using SAS 9.1 (SAS Institute, 2002).

Effect sizes were calculated for between-groups effect using generalized omega-squared (ω^2) (Olejnik & Algina, 2003) for repeated measures effects, and *d* for one-way analyses of variance effects. Both ω^2 and *d* can be evaluated on the same metric, with .2 representing a small effect, .5 a moderate effect, and .8 a large effect (Cohen, 1988). An effect size greater than .2 has been considered as a benchmark for clinically meaningful effects (Revicki et al., 2006).

Determinations of sample size were based on considerations of statistical power (143) as applied to our primary outcome. Based on an anticipated medium to large effect size (Schnur et al. 2008, Schnur, Kafer, Marcus, & Montgomery, 2008; Tatrow & Montgomery, 2006), power set at .80, two-tailed alpha set at .05, using a repeated measures design with 5 assessment points, and two groups, minimum total sample size was calculated at 40 participants (Faul, Erdfelder, Lang, & Buchner, 2007).

Results

Prior to conducting the primary analyses, ANOVA and chi-square analyses were conducted to determine the success of the randomization procedures. We found no significant between-group differences on any of the demographic (age, education, race, ethnicity, marital status), medical history (surgery type, prior chemotherapy, cancer stage, KPS score), or trait (trait anxiety, neuroticism) variables (all *ps* > .10). Additionally, the groups did not differ significantly on their pre-intervention levels of SV-POMS tension-anxiety ($p = .27$), nor did they differ based on interventionist ($p > .2$).

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See Figure 1 for a diagram showing the flow of participants through the study. Recruitment took place from June 2005 through June 2007.

To test the impact of the CBTH intervention on positive and negative affect across the course of radiotherapy, we conducted two R-ANOVAs. Both were two-factor designs with one between subjects factor (Treatment, 2 levels: CBTH n=20, Control n=20) and one within subjects factor (Time, 5 levels: Weeks 1–5). In the first analysis, the outcome was negative affect, and in the second, the outcome was positive affect. Both R-ANOVAs showed a significant main effect of Treatment group [*negative affect*: F (1, 38) = 13.49; p = .0007, ω^2 = .56; *positive affect*: F (1, 38) = 9.67; p = .0035, ω^2 = .48]. There was also a main effect of Time for negative affect [F (4, 152) = 3.31; p = .0124] but not for positive affect [F (4, 152) = .25; p = .9063]. Polynomial trend analyses indicated that the Time effect for negative affect was consistent with a quadratic function [F (1, 38) = 12.25; p = .0012]. There was no significant Group by Time interaction [*negative affect*: F (4, 152) = 1.15; p = .3372; *positive affect*: F (4, 152) = .65; p = .6278].

Between-groups planned comparisons revealed (see Figure 2 and Figure 3) that the CBTH group reported significantly lower levels of negative affect than the Control group in each week (all *ps* < .03). The CBTH group also reported significantly higher levels of positive affect than the Control group in weeks 1, 2, 3, and 5 (all *ps* < .03 except week 4 when p = .07). At each week, positive and negative affect were significantly (p < .001) and negatively correlated (Week 1, r = −.63; Week 2, r = −.70; Week 3, r = −.61; Week 4, r = −.67; Week 5, r = −.57).

To test the effect of the CBTH intervention on intensity and frequency of affect, we conducted three additional ANOVAs. Results revealed that relative to the control group (n=20), the CBTH group (n=20) demonstrated significantly higher levels of positive affect intensity [F (1,38) = 7.09; p = .0113, d = .71] and significantly lower levels of negative affect intensity [F (1,38) = 10.30; p = .0027, d = .90]. Additionally, the average frequency value was significantly greater for the CBTH group than for the Control group. The CBTH group had a significantly higher frequency of predominantly positive affect days (85% of days assessed for the CBTH group versus 43% of the Control group) [F (1, 38) = 18.16; p = .0001, d = 1.16].

As trait neuroticism and trait anxiety have been related to affect (Benotschet al., 2000; Raikkonen, Matthews, Flory, Owens, & Gump, 1999; Zautra, Affleck, Tennen, Reich, & Davis, 2005), post-hoc analyses were performed to explore these traits as covariates of treatment effects. Analyses revealed that the overall group effects remained, even after accounting for both neuroticism and trait anxiety (see Table 2).

Using intent-to-treat guidelines (DeMets, 2004), analyses were repeated and no differences in the pattern of results were found compared to the results presented above.

Discussion

The present study was the first to examine whether a treatment combining cognitive-behavioral therapy and hypnosis (CBTH) would improve positive and negative affect over the course of radiotherapy in a sample of women with breast cancer. Results indicate that relative to a standard care control group, the CBTH group participants demonstrated: 1) significantly lower levels of negative affect each week; 2) significantly higher levels of positive affect in weeks 1, 2, 3, and 5 of the radiotherapy regimen; 3) increased frequency of days where positive affect was greater than negative affect; 4) less intense negative affect; and 5) more intense positive affect. In other words, the CBTH intervention not only reduced negative affect, but also increased positive affect during breast cancer radiotherapy.

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Computation of effect sizes indicated that the effects seen here are not only statistically significant, but clinically meaningful as well (Revicki et al., 2006). All between-group effect sizes were in the moderate to large range (Cohen, 1988).

The present results are consistent with prior literature demonstrating beneficial effects of cognitive-behavioral therapy on the affective experience of individuals with cancer (e.g., Bridge, Benson, Pietroni, & Priest, 1988; Decker, Gallagher, & Cline-Elsen, 1992; Kolcaba & Fox, 1999; Osborn, Demoncada, & Feuerstein, 2006; Redd, Montgomery, & DuHamel, 2001; Tatrow & Montgomery, 2006). The results are also consistent with meta-analytic findings suggesting that combining CBT with hypnosis adds to clinical benefit (Kirsch et al., 1995). Indeed, the strong effects produced by the multimodal approach used here, in contrast with the lack of effect on anxiety found for the hypnosis-alone approach used by Stalpers and colleagues (2005), suggest that a combined, CBT plus hypnosis intervention may be more effective than hypnosis alone for women undergoing breast cancer radiotherapy. This increased effectiveness may be explained as follows. CBT teaches clients to identify and dispute negative, irrational beliefs, and to replace them with more helpful, rational alternatives. Specifically, our CBT intervention focused on reducing demandingness, awfulizing/catastrophizing, frustration intolerance, and self-downing, other-downing, and life-downing, which are all related to dysfunctional negative affect (David, Schnur, & Birk, 2004). Hypnosis helps clients feel more relaxed and comfortable, works in part through changing expectations for nonvolitional outcomes such as distress (Kirsch, 1990; Montgomery, Weltz, Seltz, & Bovbjerg, 2002), and is often focused on symptom control. Together, CBT and hypnosis address a broader range of factors during radiotherapy than either technique alone, and give individuals a wider range of tools to improve their affective experience. To empirically test this speculation, future research may want to consider an experimental analysis of treatment components (CBT and hypnosis) to better understand their relative and potentially additive contributions to clinical effects.

The present study also extends the literature in that, to our knowledge, only one prior study has explicitly examined positive affect in breast cancer radiotherapy patients, and that was in the context of a longitudinal study design (Buick et al., 2000). With the advent of the positive psychology movement, there has been a notable shift towards recognizing that it is insufficient to exclusively focus on the investigation and amelioration of negative affect without also studying and enhancing positive affect (Seligman et al., 2000). The present results, demonstrating that a brief CBTH intervention can not only reduce negative affect, but also increase positive affect in women undergoing breast cancer radiotherapy, is heartening in its suggestion that psychological interventions hold the potential to help people have a more positive affective experience during the trying course of a radiotherapy regimen. It is important to note that we do not intend to suggest that the CBTH participants became unrealistically happy about having cancer or having to undergo radiotherapy, but rather, that individuals can be taught skills to promote better emotional well-being during this difficult time.

Like any study, this one has limitations. First, we did not have an attention control condition to control for non-specific effects, including professional time and attention. Thus, we cannot be certain that the beneficial effects demonstrated for positive and negative affect were a direct result of the specific intervention techniques used. However, we felt that it was important in this initial study to first establish an intervention effect, before delving into the possible mechanisms underlying that effect. Professional attention as a potential mechanism needs to be investigated in future research, as should other potential mechanisms including changes in negative/irrational beliefs and changes in expectations for positive and negative affect. On a related note, our results indicate that negative and positive affect are significantly and negatively correlated at each time point. Although the positive and

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negative affect scores are derived from entirely different items (i.e., there is no item overlap between the scales), this finding raises the possibility that a change in one type of affect might mediate a change in the other. For example, a decline in negative affect may be mediated by an increase in positive affect. Although the present study was underpowered to test these mediational hypotheses, future research with larger sample sizes should pursue the study of these mechanism questions. Second, our study concluded 5 weeks into participants' radiotherapy treatment. Future research should investigate whether a CBTH intervention during treatment has more long-term benefits for negative and positive affect in survivors (e.g., up to one year post-treatment). Finally, this sample was restricted to women undergoing breast cancer radiotherapy. Future research should determine the generalizability of this intervention to other populations of external beam radiotherapy patients (e.g., prostate cancer), as well as to more demographically diverse samples.

In conclusion, the present study supports the use of CBTH with women undergoing breast cancer radiotherapy to reduce negative affect and to increase positive affect during the radiotherapy treatment regimen. As a result, the CBTH intervention has the potential to make the difficult experience of breast cancer radiotherapy easier for women to bear.

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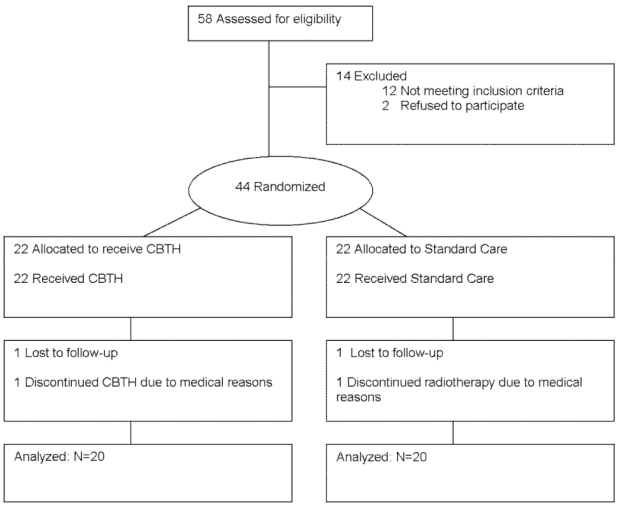

Figure 1.
CONSORT Flow Diagram
Note: CBTH = Cognitive behavior therapy plus hypnosis.

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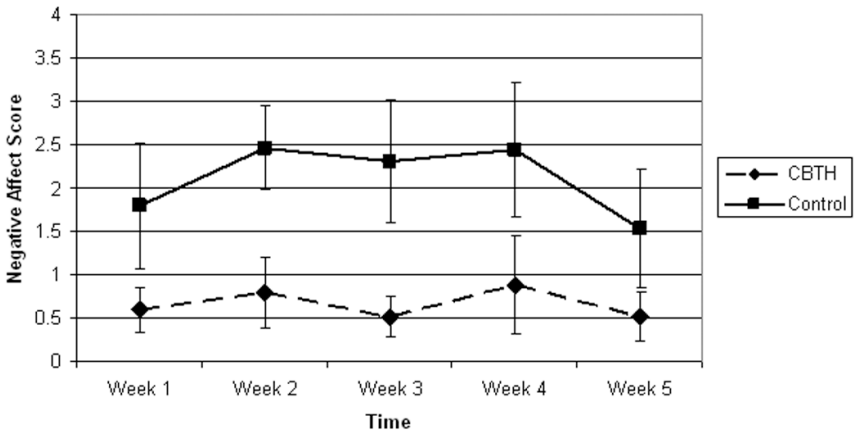

Figure 2.
Mean Nagative Affect During Radiotherapy
Note: Error bars indicate 95% Confidence Intervals.

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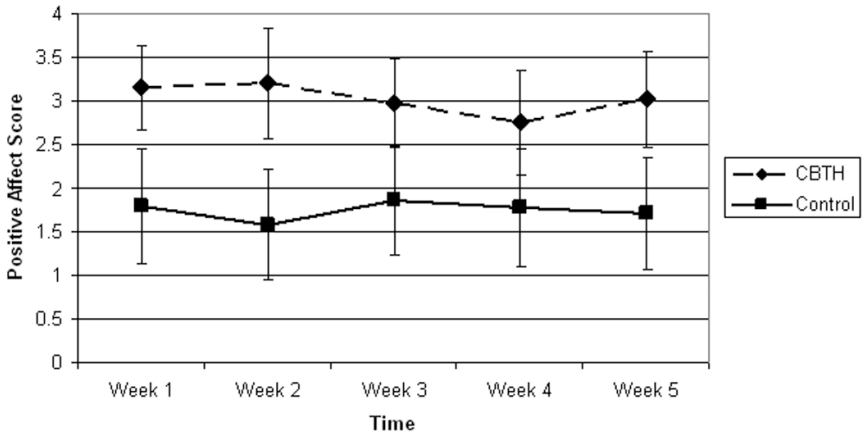

Figure 3.
Mean Positive Affect During Radiotherpy
Note: Error bars indicate 95% Confidence Intervals.

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Table 1

Post-hoc analyses of group effects with neuroticism and trait anxiety as covariates

Outcome	Predictor	*F (df)*	*p*
Negative Affect	Neuroticism	.01 (1,36)	.9265
	Trait Anxiety	6.32 (1,36)	.0165
	Intervention Group	15.59 (1,36)	.0004
Positive Affect	Neuroticism	.02 (1,36)	.8858
	Trait Anxiety	4.43 (1,36)	.0424
	Intervention Group	10.77 (1,36)	.0023
Positive Intensity	Neuroticism	.00 (1,36)	.9993
	Trait Anxiety	2.90 (1,36)	.0970
	Intervention Group	7.26 (1,36)	.0106
Negative Intensity	Neuroticism	.76 (1,36)	.3906
	Trait Anxiety	1.47 (1,36)	.2335
	Intervention Group	11.47 (1,36)	.0017
Frequency	Neuroticism	.32 (1,36)	.5776
	Trait Anxiety	2.08 (1,36)	.1574
	Intervention Group	19.79 (1,36)	.0001