

**EFFECTS OF ART THERAPY ON EMOTIONAL DISTRESS IN
FEMALE CANCER PATIENTS:
A RANDOMIZED CONTROLLED TRIAL**

Donna Radl, PhD Principal Investigator, Drexel University (Philadelphia)

Joke Bradt, PhD Co-Investigator, Drexel University (Philadelphia)

Maureen Vita, Key Personnel, Drexel University College of Medicine (DUCOM) (Philadelphia)

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Final Research Report

Effects of Art Therapy on Emotional Distress in Female Cancer Patients: A Randomized Controlled Trial

Donna Radl, PhD Principal Investigator, Drexel University (Philadelphia)

Joke Bradt, PhD Co-Investigator, Drexel University (Philadelphia)

Maureen Vita, Key Personnel, Drexel University College of Medicine (DUCOM) (Philadelphia)

I. Abstract

Purpose: The aim of this study was to evaluate the effects of the Self-Book[®] art therapy intervention on emotional distress and psychological well-being in female cancer patients. **Background:** According to the National Cancer Institute, emotional distress ranks as the highest of unmet needs for female cancer patients in the United States. These unmet needs impelled the National Comprehensive Cancer Network to launch governmental efforts to provide better emotional support in all oncology clinics and hospitals by the year 2015. **Method:** A repeated measures randomized controlled trial design was employed. Sixty participants were randomly assigned to either the six-session Self-Book[®] art therapy group or the standard care control group. Data on emotional distress and psychological well-being were collected using standardized instruments at four time points: baseline, week 3, week 6 and 1-to-2 months post-intervention. **Results:** Forty participants completed the study and were included in the final analysis. Findings suggest that Self-Book[®] art therapy may help decrease emotional distress and enhance spiritual well-being in female cancer patients during active oncology treatment.

II. Executive Summary

Assessing and treating patients' unmet emotional needs is a national focus in oncology care. The purpose of this study was to evaluate the effects of the Self-Book[®] art therapy intervention on emotional distress and psychological well-being in female cancer patients during active oncology treatment. The intervention provided oncology patients with an opportunity to portray their feelings and identify coping skills artistically through an art making process. The human mind tends to experience intrusive and avoidant stress response symptoms when faced with adverse events, such as a life-threatening illness. Art therapy is based on the theory that the creative expression can help patients confront adversity by reintegrating their sense of self and strengthen personal attributes.

A repeated measures randomized controlled trial design was employed. Sixty consenting women from Hahnemann University Hospital were enrolled and randomly assigned to either the six-session Self-Book[®] art therapy group ($n = 30$) or the standard care control group ($n = 30$). Data were collected at four time points: baseline, week 3, week 6, and 1-to-2 months post-intervention. Forty participants completed the study. The results suggest that Self-Book[®] art therapy may help decrease emotional distress and enhance spiritual well-being in female cancer patients during active oncology treatment. Positive trends in the data were present, but there were no statistically significant group by time interaction effect for emotional distress ($F[2.29, 87.25] = 1.37, p = 0.26$). However, 30% of art therapy participants reported post-intervention emotional distress scores that were below the clinical range for emotional distress, compared with only 5% of standard care control participants, suggesting that Self-Book[®] art therapy has clinical significance. There were also positive trends in the data but no group by time interaction effect for psychological well-being ($F[2.37, 90.10] = 2.47, p = 0.12$). One subscale measure revealed statistically significant greater improvements in Self-Book[®] art therapy participants' spiritual well-being compared to the standard care control participants ($F[1, 38] = 5.88, p = 0.02$). Analysis of limited narrative data from exit interviews support the positive trends in emotional distress, suggesting that emotional needs were met for the majority of Self-Book[®] art therapy participants.

III. Full Research Report

The purpose of this study was to examine the effects of Self-Book[®] art therapy on the emotional distress and psychological well-being of female oncology patients during active treatment (radiation and chemotherapy). Self-Book[®] is an art therapy intervention that invites participants to create a visual book with magazine images and words to portray their feelings artistically, and to help each participant identify and develop coping skills.

Research Importance

A cancer diagnosis is frequently correlated with a high prevalence of cancer-related emotional distress in women during treatment. According to the American Cancer Society (ACS) (2012), over 38% of women in the United States are estimated to develop cancer during their lifetimes. Research literature indicates that up to 43% of those women experience emotional distress as a result of their cancer diagnoses and treatments (Bar-Sela, Atid, Danos, Gabay, & Epelbaum, 2007; Egberg Thyme et al., 2009; McWilliam, Brown, & Stewart, 2000; Nainis, 2008; Puig, Lee, Goodwin, & Sherrard, 2006; Siedentopf et al., 2010). The impact of cancer indeed precipitates secondary psychological, social, and spiritual needs. The most common psychological symptom of cancer patients includes high levels of emotional distress from feelings of helplessness and uncertainty, and a fear of death (Elkit & Blum, 2010). In addition, the development of spiritual and personal meaning appears to be a singular factor for successfully addressing unmet emotional needs (Anagnostopoulos, Slater, & Fitzsimmons, 2010).

The treatment focus in cancer care has begun to shift from a predominantly biomedical approach to one that is more biopsychosocial (Singh, 2011). In the past, treatment focused on the profound physical aspects of the cancer effects, while the emotional and mental components were not as much an apparent concern (Collie, Bottorff, & Long, 2006). Today researchers are increasingly focusing on mind-body connections. This is evident, for example, by the increase of published studies aimed at exploring the impact of mindfulness interventions on the psychosocial and emotional needs of cancer patients (Johnson, 2009; Kendall-Tackett, 2009; Monti et al., 2006). Unfortunately, a higher percentage of research studies on psychosocial and emotional interventions focus on post-treatment cancer survivors, and not as many on patients during active treatment.

Early intervention is a priority because the effects of prolonged emotional distress on the human body and mind, which causes sustained cortisol release and compromises the immune system (Melzack, 2005). Researchers emphasize that early detection of emotional distress is critical to cancer recovery; distress symptoms at six weeks after cancer diagnosis strongly predict a high risk for the delayed onset of severe clinical levels of psychiatric distress (Elklit & Blum, 2010). Medical art therapy is identified as a promising solution to help with the reduction of stress in cancer patients, but the evidence for this claim is insufficient (Monti et al., 2006; Wood et al., 2011).

Additionally there is the lack of research justifying the use of art as a legitimate therapy for reducing emotional distress in cancer patients. Only six randomized controlled trials (RCTs) were found on the efficacy of medical art therapy interventions for addressing the psychosocial and emotional needs of cancer patients during active cancer treatment. The RCTs found were mostly on group interventions and not individual interventions (Bar-Sela et al., 2007; Monti et al., 2006), and were exclusively for breast cancer patients. The literature discusses a concern with the disproportionate amount of cancer research specifically focused on breast cancer: The needs of females with other cancers are not being studied equally, and their specific needs are therefore less likely to be met (Öster, Svensk, Magnusson, & Thyme, 2006; Puig et al., 2006; Svensk, 2009; Thyme et al., 2009).

The impact of emotional distress on the cancer patient's oncology treatments is significant. Approximately 50% of women experiencing cancer-related emotional distress delay receiving help for their psychosocial and emotional issues due to numerous reasons, including a lack of accessibility to services (Siedentopf et al., 2010). In 2008, Mao and colleagues recommended that psychosocial interventions be accessible to all female cancer patients. Other investigators have expressed a need for interventions that give women in active oncology treatment an opportunity for self-expression related to the distressing cancer experience (Bultz & Carlson, 2006; Grassi, Nanni, & Caruso, 2010; Jacobsen, 2012; Mertz et al., 2012). The justification for selecting art therapy over other creative and nonverbal interventions such as music therapy was based on the predominate use of common imagery in the Self-Book[®] process. Imagery of everyday people and things contain symbols and metaphor that help the patient nonverbally articulate complicated or difficult emotions (Gorelick, 1989).

Medical art therapy seems to fulfill the unmet emotional needs of female cancer patients. However, even if medical art therapy is increasingly being requested by patients and or staff, it continues to lack the evidence of efficacy required by hospital administrators and healthcare providers (Carlson & Bultz, 2008; Collie et al., 2006; Egberg Thyme et al., 2009; Elkis-Abuhoff, Gaydos, Goldblatt, Chen, & Rose, 2009; Geue

et al., 2010; Nainis, 2008; Öster, Åström, Lindh, & Magnusson, 2009; Puig et al., 2006; Visser & Op 't Hoog, 2008; Weitz, Fisher, & Lachman, 2012). This lack of rigorous evidence is preventing medical art therapy from becoming an established discipline in oncology care nationwide. Few RCT art therapy research studies have been conducted with patients during active oncology treatment (Wood et al., 2011; Nainis et al., 2006). Despite evidence-based practice demands for randomized controlled trials, there are an unbalanced number of qualitative research studies, especially with breast cancer patients, that support the successful use of medical art therapy with cancer patients (Collie & Kante, 2011; Öster et al., 2009; Sabo & Thibeault, 2011; Singh, 2011; Wood et al., 2011).

In summary, this study was important to pursue for two reasons: 1) Rigorous quantitative research was needed to study the efficacy of a medical art therapy intervention for addressing the emotional needs of cancer patients during active oncology treatment; and 2) Self-Book[®] art therapy had been pilot tested but needed further scientific validation.

Literature Review

Up to 43% of women receiving oncological treatments are newly diagnosed with various stress disorders (American Psychiatric & American Psychiatric Association, 2000; Alfano & Rowland, 2006; Anton et al., 2011; Banou, Hobfoll, & Trochelman, 2009; Bergouignan et al., 2011; Chan, Ho, Tedeschi, & Leung, 2011; Cordova et al., 2007; Elklit & Blum, 2010; Hakamata et al., 2007; Hara et al., 2008; Mehnert & Koch, 2007; Shelby, Golden-Kreutz, & Andersen, 2008), including post-traumatic stress disorder (PTSD) (Shelby et al., 2008). It is apparent in the literature that these women have limited opportunity to articulate their emotions about their cancer experiences, and that the issue of emotional distress is becoming a significant concern in oncology (Bultz & Carlson, 2006; Grassi, Nanni, & Caruso, 2010; Jacobsen, 2012; Mertz et al., 2012). According to the National Cancer Institute (NCI) (National Institute of Health, 2013), emotional distress ranks as the highest of unmet needs for female cancer patients in the United States. Based on these facts, it seems appropriate to focus research on an art therapy intervention for addressing emotional distress in this population so that a valid, evidence-based model can be developed.

The National Comprehensive Cancer Network (NCCN) (2012) reported on worldwide governmental efforts (such as new guidelines and mandates in the United States, Europe, Canada, and Australia) to provide better emotional support in oncology clinics and hospitals by the year 2015. This movement appeared to be an opportunity for the integration of psychological services such as art therapy into a more holistic approach to oncology care. No randomized controlled trials have been conducted on individual art therapy with people with cancer during active oncology treatment (Geue et al., 2010; Grassi et al., 2010; Monti et al., 2006; Wood et al., 2011). Although several publications have focused on the use of medical art therapy with cancer patients during the past two decades, most of the reports were anecdotal and lacked efficacy data to support a claim of therapeutic benefit. In 2006, Monti and colleagues piloted one of the first fully powered RCTs to evaluate a group art therapy intervention called mindfulness-based art therapy (MBAT) with patients in active oncology treatment. Four years later, Geue and colleagues (2010) conducted a systematic review of art therapy research articles published between 1987 and March 2009 and reported that more research was needed to support the efficacy of art therapy interventions with oncology patients. The following year, Wood and colleagues (2011) concurred that art therapy research with cancer patients was “still in its infancy,” with only a few RCTs being published to date.

Theory

The theoretical principles supporting Self-Book[®] art therapy are grounded in positive psychology that focus on personal strengths and virtues (Seligman & Csikszentmihalyi, 2000), and incorporate the essential and nonverbal healing components from art therapy (Naumburg, 1966). One critical mechanism in art therapy is based on the concept that the human mind tends to suppress adverse events, such as a life-threatening illness. The process for creating art can help patients become more self-aware and make sense of the adversity in a safe manner (Gantt & Tinnin, 2008). Naumburg (1966) theorized that the creative and expressive process is important because the suppressed feelings may otherwise manifest into psychosomatic symptoms. However, empirical data verifying these assumptions are inadequate (Wood, Molassiotis, & Payne, 2011; Geue, Goetze, Buttstaedt, Kleinert, & Richter, 2010). Self-Book[®] integrates medical art therapy with positive psychology for emotional strength-building and to help transform the patient's negative sense of self to a more positive one.

Research shows that interventions targeting positive actions and cognitions decrease emotional distress and enhance well-being (Morris & Shakespeare-Finch, 2011).

Medical art therapy for oncology patients is theorized to help “adults with cancer to manage a spectrum of treatment-related symptoms and facilitate the process of psychological readjustment to the loss, change, and uncertainty characteristic of cancer survivorship” (Wood et al., 2011, p. 135). According to the American Cancer Society (2013), art therapy is reported to help cancer patients:

Manage physical and emotional problems by using creative activities to express emotions. It provides a way for people to come to terms with emotional conflicts, increase self-awareness, and express unspoken and often unconscious concerns about their illness and their lives. ‘Expressive arts therapy’ or ‘creative arts therapy’ may also include the use of dance and movement, drama, poetry, and phototherapy, as well as more traditional art methods. Art therapy is based on the idea that the creative act can be healing. According to practitioners, called art therapists, it helps people express hidden emotions; reduces stress, fear, and anxiety; and provides a sense of freedom. (p. 5)

Rubin (1987) stated that creating art offers patients a gentle way to express a narrative without retraumatization. Malchiodi (1999) elaborated by sharing that medical art therapy as a visual narrative is particularly critical for patients after a traumatic cancer diagnosis and/or turbulent treatment, because the imagery in art therapy helps patients reflect upon their lives and re-create their lives anew through art-making. Medical art therapy helps to address five major psychological areas (Malchiodi, 1999):

- Alleviation of or reduction in emotional distress, anxiety, and stress reactions.
- Increased positive emotions, improved quality of life, and enhanced well-being.
- A strengthened self-concept, a sense of control, and improved self-perception for things such as body image and chronic pain.
- Reduced levels of fatigue and other depressive symptomologies such as anger.
- Increased meaning-making and stimulation of cognitive functioning and insight.

Different art therapy approaches are required for diverse patient populations (Nainis, 2006). For example, Nainis (2006) stated that cancer patients tend to be physically fragile and often are contending with pain management issues. She reported that severe physical concerns often precipitate emotional problems such as anger, anxiety, and depression. Therefore, Self-Book[®] art therapy focuses primarily on the positive attributes of the patient’s inner strengths and virtues and not as much on pathology (Donald, 2012). Also, due to time constraints, medical art therapy directives tend to be success-oriented in order to provide the patient with an immediate sense of satisfaction and productivity. In both traditional art therapy and medical art therapy, the key elements that remain constant over time are the therapeutic presence of the art therapist and the patient’s relationship with the artwork. In both approaches, the art therapist uses the artwork to help the patient process emotions by discussing the patient’s experience and personal meaning of the images in the artwork (Donald, 2012).

According to Malchiodi (1999), medical art therapy is used to help a range of physically ill children and adult patients who struggle emotionally with dealing with a traumatizing medical procedure or chronic pain. Medical art therapy is used similarly with patients adapting to a terminal condition or chronic illness such as cancer. The physical suffering differentiates patients of medical art therapy from traditional art therapy patients. The physical dimension dictates a different approach to treatment that may involve common themes relevant to cancer-related issues, such as mortality, death, and dying; pain or physical limitations; and side effects from biomedical treatments (Malchiodi, 1999).

Intervention

Self-Book[®] is a six-session art therapy intervention administered by a board-certified art therapist using magazine collage to create a visual book. One section of the book is created each week during a 50-minute, private session. During the first five sessions, the art therapist gives the participant an art therapy directive that addresses one of five self-related themes as seen in table 1. During the sixth session, the participant is instructed to assemble and decorate the outside cover of the book. The final Self-Book[®] is a ten-page book with an outside cover. The Self-Book[®] provides a participant with an opportunity to reconstitute a sense of self and to identify and reestablish coping skills.

Table 1. Self-Book[®] Art Therapy Intervention Six-Session Curriculum

Session	Self-Book [®] Directives	Self-Book [®] Therapeutic Objectives
1	Using precut, categorized magazine images, “create a safe place” on the inside spread of the Self-Book [®] blank segment. (Blank segment, scissors, magazine images, and a glue stick are provided at each session.)	<ul style="list-style-type: none"> • Become acquainted with the art materials. • Identify with a personal sense of safety. • Begin to establish a trusting relationship. • Experience privacy.
2	“Identify your supports” on the inside of the second blank segment.	<ul style="list-style-type: none"> • Identify and value supports. • Connections with others.
3	“Identify your strengths and virtues” on the inside of the third blank segment spread. (A list of the 26 strengths and virtues from positive psychology are offered to patients to select 6 to 7 that the patient identifies as belonging to them.)	<ul style="list-style-type: none"> • Learn about positive psychology. • Identify personal strengths and virtues. • Explore self-awareness. • Encourage reintegration of self. • Initiate awareness of inner coping skills.
4	“Make a wish for people close to you and or loved ones” on the inside of the fourth blank segment spread.	<ul style="list-style-type: none"> • Express positive well-being for those close to self. • Explore personal connection(s).
5	“Make a wish for yourself” on the inside of the fifth blank segment spread.	<ul style="list-style-type: none"> • Increase awareness of self-care. • Sponsor ownership and gifting to self. • Acknowledge self-empowerment and autonomy. • Engender hope of survival and personal growth.
6	“Assemble and decorate your Self-Book [®] . Glue the five segments together to form a book. Use colorful stickers, jewels, and anything that can adhere to the pages to decorate your Self-Book [®] .”	<ul style="list-style-type: none"> • Make meaning of personal choices. • Celebrate progress. • Create a transitional object. • Engage in a verbal response.

Research Design

This study was a repeated measures randomized controlled trial (RCT) that employed a two-arm parallel-group design. Sixty adult women in active cancer treatment were randomly assigned to either the six-week Self-Book[®] art therapy intervention group or the standard care control group. This research design tested the following two hypotheses:

- Female oncology patients who use the Self-Book[®] art therapy intervention during active oncology treatment will report emotional distress scores that are significantly different from those of female oncology patients in the standard care control group.
- Female oncology patients who use the Self-Book[®] art therapy intervention during active oncology treatment will report psychological well-being scores that are significantly different from those of female oncology patients in the standard care control group.

The primary outcome in this study was emotional distress. Emotional distress was defined as a complex experience involving unpleasant emotional and physical symptoms affecting the self psychologically, cognitively, behaviorally, socially, and spiritually (NCCN, 2013). The secondary outcome was psychological well-being. Well-being was defined as an overall subjective assessment of the general quality of daily living (Monti et al., 2006; Visser & Hoog, 2008).

Instruments

Data were collected using a demographic questionnaire and four standardized instruments: 1) the Distress Thermometer (DT) to screen for emotional distress; 2) the Perceived Emotional Distress Inventory (PEDI) Scale to measure ongoing symptoms of emotional distress; 3) the Patient-Reported Outcomes Measurement Information System (PROMIS) Brief Psychological Well-Being test to measure weekly well-being; and 4) the Functional Assessment of Chronic Illness Therapy—Spiritual Well-Being (FACIT-Sp) Scale to measure overall well-being. Data on nausea, fatigue, physical pain, and treatment adherence were retrieved from the participants' medical chart.

The Distress Thermometer (DT) is a screening tool widely used in oncology treatment facilities. The DT was used in this study to screen all participants and to measure ongoing emotional distress before and after art therapy sessions. The DT was developed by the NCCN for quickly ascertaining a symbolic representation of a patient's emotional distress level during active oncology treatment. The patient circles a number on the scale to answer the question "How distressed have you been during the past week, on a scale of 0 to 10?" Zero means no stress and 10 means extreme stress (NCCN, 2007). The National Cancer Institute (NCI) states that various cutoff scores have been used in clinical trials. The most frequently used cutoff scores are 4 and 5. Approximately 40% of cancer patients report scores above this cutoff. Furthermore, women have been observed to be more likely to produce a score ≥ 4 on the DT, compared to men (NCI, 2013).

The Perceived Emotional Distress Inventory (PEDI) (Moscoso, McCreary, Goldenfarb, Knapp, & Rohr, 1999; Moscoso, McCreary, Goldenfarb, Knapp, & Reheiser, 2000) is a 15-item self-report questionnaire designed to measure the perceived and present state of emotional distress in cancer patients. The score for the inventory ranges from 0–45 points, with lower scores corresponding to lower levels of perceived emotional distress. This questionnaire measures general mood; social isolation; and subjective feelings such as sadness, uncertainty, confusion, worry, anxiety, anger, depression, and hopelessness. The PEDI was specifically developed for cancer patients in active treatment and has been tested exclusively with this population. The instrument has been found to be reliable ($\alpha = 0.91$). To date, the PEDI has been used only by the developer in several large-scale cancer trials (Moscoso et al., 1999; Moscoso et al., 2000; Moscoso & Reheiser, 2010; Moscoso, 2012). Other research studies are currently using the tool, but results are yet to be published (Moscoso, personal communication, June 24, 2013). The PEDI has no cutoff score for clinical emotional distress, because it was not developed to serve as a diagnostic tool. The PEDI was specifically designed to compare scores between subjects.

The Patient-Reported Outcomes Measurement Information System (PROMIS) Brief Psychological Well-Being Test was used to measure weekly psychological well-being. This brief questionnaire has seven items that ask about general well-being, and it is an abbreviated version of the more extensive, original tool. The justification for shortening the original instrument was to create a brief form that obtains a quick read for psychological well-being. The score values for this instrument range from 7–35, with higher scores indicating a healthier level of psychological well-being. It takes approximately two minutes to complete. The original PROMIS was developed and calibrated by the National Institutes of Health (NIH) as an initiative to improve standardized measurement of self-reported health outcomes. The reliability coefficient of the original PROMIS instrument ranges between 0.85 (Irwin et al., 2010) and 0.95 (Pilkonis et al., 2011). The NIH reports an alpha reliability of 0.97 (NIH, 2012).

The Functional Assessment of Chronic Illness Therapy—Spiritual Well-Being (FACIT-Sp) Scale (Cella et al., 1998) was used as a second measurement tool to measure participants' well-being. It is a 40-item, multidimensional outcome measurement tool aimed at assessing a sense of meaning and peace in illness. The FACIT-Sp total range is 0–156. The higher the score, the better the quality of life (QOL) and/or spiritual well-being. The FACIT-Sp is a psychometrically sound measure that contains many items that directly refer to well-being (Brady, Peterman, Fitchett, Mo, & Cella, 1999; Peterman, Fitchett, Brady, Hernandez, & Cella, 2002). Five quality-of-life domains are covered: physical well-being, social/family well-being, emotional well-being, functional well-being, and spiritual well-being. The FACIT-Sp demonstrates good reliability (0.85–0.88), validity, and sensitivity to change (Canada, Murphy, Fitchett, Peterman, & Schover, 2008; Murphy et al., 2010). Participants require 4 to 5 minutes to fill out the FACIT-Sp. This scale was developed for individuals with chronic illness and has been tested on cancer patients (Canada et al., 2008; Oeki et al., 2012).

Data Analysis

Descriptive frequency analysis was performed for cases with missing data to look for potential patterns related to the missing data. For missing data, the scoring guidelines for each instrument were followed. Descriptive statistics were used to create a demographic profile of the treatment and control groups. Given the relatively small sample size, baseline equivalence between the two groups was examined by use of Chi-square and independent group t-test. In addition, the distribution of the data was explored, and in cases that data were not normally distributed, a nonparametric statistical test was employed.

Since data met the criteria for inferential statistics, a repeated measures, mixed methods ANOVA was used to compare the two groups for changes in emotional distress and psychological well-being over time. Post-hoc analyses were employed to determine the location of between-group differences. Repeated measures analysis of covariance (ANCOVA) was used to examine group differences after adjusting for baseline differences when baseline differences were present. ANCOVA was intended for use in examining group differences concerning oncology side effects such as the psychological, physical, and behavioral outcomes extracted weekly from each participant's medical chart. However, the data was not obtained consistently hospital-wide, and therefore this analysis could not be carried out. Additionally, an examination of covariates would have been outside of the stated hypotheses. Future exploratory analyses should be considered.

Additionally, a repeated measures ANOVA was applied to examine the within-group differences for the treatment group for emotional distress and well-being over time (weekly measurements). All statistical computations were performed on the Statistical Package for the Social Sciences (SPSS) and Microsoft Excel StatPlus. All charts and graphs were created in SPSS and Microsoft Excel by a statistical consultant.

Findings

Results suggest that Self-Book[®] art therapy may help decrease emotional distress and enhance spiritual well-being in female cancer patients during active oncology treatment. Positive trends in the data were present, but there were no statistically significant differences between the groups for the two main variables: emotional distress and psychological well-being. Table 2 shows the positive trends but no significant group by time interaction effect for emotional distress ($F[2.29, 87.25] = 1.37, p = 0.26$). Lower scores indicate less stress.

Table 2. Emotional distress mean scores and standard deviations (SDs) at T1, T2, T3, and T4.

	T1	T2	T3	T4
Self-Book [®] art therapy	15.45±9.30	14.20±9.84	10.40±6.60	10.55±8.65
Standard care control	12.95±8.51	13.40±9.05	12.00±8.04	11.80±10.20

No group by time interaction effect for psychological well-being was found ($F[2.37, 90.10] = 2.47, p = 0.12$). Higher scores indicate enhanced psychological well-being (Table 3).

Table 3. Well-being mean scores and SDs at T1, T2, T3, and T4.

	T1	T2	T3	T4
Self-Book [®] art therapy	98.28±25.10	93.82±27.59	105.80±24.72	109.22±24.08
Standard care control	100.16±25.35	101.71±28.51	101.88±25.78	102.76±31.79

Table 4 shows the means and SDs for one subscale measure. There was a statistically significant greater improvement in Self-Book[®] art therapy participants' spiritual well-being compared to the standard care control participants ($F[1, 38] = 5.88, p = 0.02$). Higher scores indicate enhanced spiritual well-being.

Table 4. Spiritual well-being mean scores and SDs at T1, T2, T3, and T4.

	T1	T2	T3	T4
Self-Book [®] art therapy	33.80±9.45	32.80±0.14	36.55±9.76	37.05±9.93
Standard care control	35.40±9.44	35.20±11.47	34.15±10.03	34.20±11.39

Additionally, 30% of art therapy participants reported post-intervention emotional distress scores that were below the clinical range for emotional distress, compared with only 5% of standard care control participants, suggesting that Self-Book[®] art therapy has clinical significance. Analysis of limited narrative data from exit interviews supported the positive trends in emotional distress, suggesting that emotional needs were met for the majority of Self-Book[®] art therapy participants.

Conclusion

In summary, the statistical results of this study suggest that Self-Book[®] art therapy may help enhance spiritual well-being in female cancer patients during active oncology treatment. Positive trends in the data were present, but at this time there were no statistically significant differences between the treatment group and control group for the two main variables. Only small treatment effects were found for Self-Book[®] art therapy on participants' psychological well-being. In contrast, one subscale measure revealed that Self-Book[®] art therapy resulted in statistically significant greater improvements in spiritual well-being compared to the control group. This result is important because to date, no other controlled art therapy study has demonstrated a significant change in spiritual well-being. Findings from participant open-ended interviews indicate that almost all of the art therapy participants viewed the intervention as beneficial during their active cancer treatments.

Although the small sample size was the most significant limitation of this study, the participants in the Self-Book[®] art therapy group were clearly affected by the intervention according to the qualitative data. Self-Book[®] revealed a small to moderate effect size reducing emotional distress and enhancing psychological well-being. Following the intervention, 30% of Self-Book[®] art therapy participants reported distress scores below the clinical range of emotional distress compared with only 5% of standard care control participants, indicating that Self-Book[®] art therapy treatment was able to affect meaningful change in emotional distress. This finding is supported by the content analysis of the exit interviews, which suggests that a high percentage of art therapy participants experienced a reduction in emotional distress.

Thus, this project accomplished six primary objectives: 1) To date, this research is the first study ever to provide evidence that art therapy can statistically significantly improve spiritual well-being in female cancer patients during active oncology treatment; 2) The results make the connect between art-making and spirituality, demonstrating the body-mind-spirit connection; 3) The results show that art therapy can reduce emotional distress while enhancing psychological well-being; 4) The results provide evidence that art therapy has clinical significance; 5) The project makes a contribution to best practice standards in oncology care for complementary medicine using evidence-based art therapy; and 6) The project contributes to the field of art therapy with a randomized controlled trial that tested an innovative art therapy intervention.

Technical Notes of the Methodology

A randomized controlled trial was selected to address the research question and gaps. A major limitation of this study was the small sample size, which resulted in inadequate statistical power. Initially, 72 women were targeted to ensure statistical power but that was not achieved due to recruitment challenges and a greater than estimated attrition rate. Besides the issues of study power, the Self-Book[®] art therapy treatment effects were not as large as anticipated. The art therapy treatment had a small to medium effect on emotional distress and psychological well-being.

The results are not generalizable to other populations for several reasons. First, this study was limited to adult female cancer patients. Second, the study lacked diversity: 80% of the participants were African American, a medically underserved population (Davis et al., 2009). These limitations prevent the findings from being generalized to all oncology patients. Lastly, the intervention was administered to participants by one art

therapist with no evaluation of treatment fidelity. Future studies should consider using a mixed methods intervention research design with a more significant qualitative study component embedded within an RCT. Such design may be better suited for exploring the impact of the Self-Book[®] art therapy intervention on women with cancer as it would allow for a better, more in-depth exploration of participants' perspectives.

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