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# Sexual Functioning and Body Image in Younger Breast Cancer Survivors

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Sexual Functioning and Body Image in Younger Breast Cancer Survivors

by

Carly L. Paterson

A dissertation submitted in partial fulfillment  
of the requirements for the degree of  
Doctor of Philosophy  
College of Nursing  
University of South Florida

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## **Abstract**

Younger breast cancer survivors often report problems related to sexuality following surgical and adjuvant treatment that often lead to sexual distress and body image distress. This research was conducted as an exploratory study within a larger R01 trial with the purpose to evaluate sexual distress and body image related-distress in younger women with breast cancer and to examine the extent to which the Mindfulness-Based Stress Reduction-Breast Cancer (MBSR(BC)) was efficacious in improving distress related to sexuality, i.e. sexual distress and body image related-distress. The aims of this study were to: 1) evaluate the efficacy of the MBSR(BC) program in improving the psychological symptoms of sexual distress and body image related distress; and 2) evaluate whether positive effects achieved from the MBSR(BC) program are modified by specific patient characteristics measured at baseline.

Ninety-one participants were randomized to either the MBSR(BC) intervention or Usual Care (UC) and assessments were conducted at baseline, 6-week and 12-week follow-up for sexual distress, body image related distress, demographic data as well as clinical history. For aim 1, analysis of covariance (ANCOVA) and linear mixed model (LMM) analysis were the methods used to evaluate the efficacy of the MBSR(BC) program. For aim 2, ANCOVA and stepwise multiple linear regression were used to evaluate the patient characteristics at baseline that modified the effects achieved from the MBSR(BC) program.

Results showed the mean age of the sample was 57 years and 74% were White, non-Hispanic. Chi square analyses found that there were no significant differences between the MBSR(BC) and UC groups on baseline demographic or clinical characteristics. For Aim 1,

results of the ANCOVA analyses found that there was no significant difference between the MBSR(BC) and UC groups at the 6-week follow-up on sexual distress or body image related distress (both  $p > .05$ ). However, ANCOVA analyses found that there was a significant relationship between baseline scores and scores at the 6-week follow-up for both sexual distress ( $p < .0001$ ) and body image related distress ( $p < .0001$ ). Further ANCOVA analyses for Aim 1 found that there was a trend towards a statistical significance for the difference between the MBSR(BC) group and UC groups at the 12-week follow-up for both sexual distress ( $p = .09$ ) and body image related distress ( $p = .06$ ). Results of the Linear Mixed Model (LMM) analyses, implemented to assess sexual distress over time, showed a significant main effect (ME) of time ( $p < .000$ ) and a trend towards significance for the time by assignment interaction ( $p = .104$ ). The LMM analyses for body image disturbance resulted in a significant ME of ( $p < .000$ ) and an interaction that approached significance ( $p = .071$ ). For aim 2, ANCOVA results found that age at baseline was a significant predictor of change at 6 weeks in levels of body image related distress ( $p = .007$ ), but no relationship was observed for sexual distress. Further, analysis using a stepwise multiple linear regression analysis found age at baseline to be the only significant predictor of both baseline sexual distress ( $p = .004$ ) and baseline body image related distress ( $p = .008$ ).

Although the MBSR(BC) program was not tailored for integrating sexuality content, results of this stress reducing program (MBSR(BC)) program, adapted for breast cancer survivors, appeared to benefit these young women. The findings of this study identify that there is a need for stress reducing interventions addressing problems related to sexual distress and body image related distress. In addition, these results identified that clinically, BCS should be

assessed for sexual distress and body image disturbance post-treatment, and interventions to assist with this distress should be incorporated into their plan of care.

## **Chapter One**

### **Introduction**

#### **Background**

**Breast Cancer in the United States.** Breast cancer is a major health problem in the United States, comprising the largest population of cancer survivors, estimated at 2.7 million women and 22% of all survivors (National Cancer Institute 2011b, 2012). Future trends estimate world cancer rates will double by 2050, increasing the number of persons living with cancer from 1.6 million in 2000 to near 3 million in 2050 (Hayat, Howlader, Reichman, & Edwards, 2007). In women, breast cancer continues to be the most common site of cancer among all ethnicities from 1999 through 2010 (U.S. Cancer Statistics Working Group, 2013). While mortality rates have decreased, the incidence rate remains high and is increasing, with 15,480 new breast cancer cases estimated in Florida for 2014, and 232,670 cases nationwide, thereby making breast cancer a major health problem (American Cancer Society, 2014).

Breast cancer is the most common cancer diagnosis among young women ages 15-39 (Bleyer et al., 2008). According to the National Cancer Institute (2011) Surveillance, Epidemiology, and End Results (SEER) statistics, the incidence rate for breast cancer in women between 21 and 54 years of age was 33.6% of all breast cancer cases (National Cancer Institute 2014a). Concurrent with this, for women ages 25 to 39 years old diagnosed with breast cancer, there has been an increase in the incidence of distant disease in all races and ethnicities equivalent to approximately 2% per year from 1975 to 2009, while older age groups did not

experience this trend (Johnson, Chien, & Bleyer, 2013). Mortality in women with breast cancer ages 15 to 54 is 20.8% of all deaths from breast cancer between 2006-2010, being the highest mortality of any cancer in this age group (National Cancer Institute 2014a). Women diagnosed at younger age with more advanced disease often undergo extensive surgery and adjuvant treatment as a result of this diagnosis, with the potential for long-lasting deleterious physical and psychological effects.

There has also been a notable increase in survival rates of breast cancer patients over the past decade, with over 89% of women treated for breast cancer surviving at least five years after treatment (Ganz, Greendale, Petersen, Kahn, & Bower, 2003; National Cancer Institute, 2011a). The National Comprehensive Cancer Network (NCCN) 2014 Survivorship Guidelines outline a detailed description of screening and follow-up recommendations for survivorship care for the chronic physical and psychological effects of cancer treatment (National Comprehensive Cancer Network, 2014). Although these guidelines related to sexuality are considered standards of care for cancer survivors, there remains a significant lack of assessment and intervention in this area of survivorship among breast cancer survivors. With the vast majority of women treated for breast cancer transitioning into survivorship after treatment, it is important to understand that there are a number of unresolved issues affecting the quality of life of breast cancer survivors (BCS) following their treatment. A cancer diagnosis, as well as the subsequent treatment for this disease, can be exceptionally distressing to survivors of breast cancer.

**Physical and Psychological Symptoms and Quality of Life in Younger Women After Breast Cancer.** The specific symptoms of distress that occur in younger women with breast cancer are both physical and psychological. According to the American Cancer Society, most individuals will experience symptoms of anxiety, fear and depression to some extent when

cancer becomes a part of their lives (American Cancer Society, 2013). Survivors of breast cancer report continued psychological stress, anxiety, depression, fear of recurrence, and impaired cognitive functioning along with physical symptoms of pain, fatigue and sleep disturbances, which can negatively impact their quality of life after treatment (Ganz et al., 2002; Ganz et al., 2003).

Younger age is a predictor of poor breast cancer prognosis, with younger women being more likely to be diagnosed with cancer in later stages, requiring more aggressive treatments (Walsh, 2005). These more aggressive treatments often require more radical surgeries as well as adjuvant treatments such as chemotherapy and radiation, resulting in the younger age group being particularly vulnerable to distressing symptoms after breast cancer treatment (Johnson et al., 2013; Katz, 2011; Shields et al., 2010; Wong-Kim & Bloom, 2005), with particularly high anxiety levels having been found in the younger age group (Hopwood et al., 2010; Mehnert & Koch, 2008) as well as higher levels of depression (Marcus et al., 2010), increased levels of distress (Hoffman, McCarthy, Recklitis, & Ng, 2009; Sherman, Heard, & Cavanagh, 2010), and more difficulty adapting to their lives after diagnosis and the adjustments that have to be made (Katz, 2011).

Moreover, a greater percent of survivors are younger and in the workforce, and the ability to reduce symptoms would be expected to result in fewer office visits, increased productivity, and a proactive approach to managing health and improved outcomes. A study of recommendations from young survivors of breast cancer identified that the women needed more comprehensive assistance regarding information about insurance coverage and financial assistance as they underwent treatment and transitioned into survivorship (Easley & Miedema, 2012). As treatment for cancer ends and survivors are left with the lasting physical and

psychological effects of their treatment, there is a necessity to address this vulnerable time among the population.

**Sexual Distress in Younger Women after Treatment for Breast Cancer.** For younger women diagnosed with breast cancer, problems related to sexuality are also common and often follow surgical and adjuvant treatment, leading to sexual distress (Avis, Crawford, & Manuel, 2005; Katz, 2011; Kingsberg, 2010; Rowland et al., 2009). Studies have shown that difficulties related to sexuality occur most often immediately following surgical and adjuvant treatment, and particularly so in younger age cohorts (Fobair et al., 2006; Jun et al., 2011; Katz, 2011). Young survivors after breast cancer identify sexuality counseling as one of the five top rehabilitation areas they would like to have included in their survivorship care (Easley & Miedema, 2012). Addressing these problems is imperative to improve the quality of life among young women with breast cancer (Fobair et al., 2006).

A recent report noted that 85% of breast cancer patients disclosed that cancer had affected their sexual well-being and relationships, but that 65% of these women had never discussed these concerns with their healthcare providers (Ussher, Perz, & Gilbert, 2013). Survivors asked about improvements needed in survivorship care after treatment recommend that healthcare providers be more proactive in their recommendation of rehabilitative services after treatment and that communication about potential issues be a greater priority (Easley & Miedema, 2012). The National Cancer Institute acknowledges that further research related to interventions for sexuality and body image are necessary, and one study noted that while satisfaction with discussions about sexual well-being with healthcare providers was low, breast care nurses scored the highest at almost 60% satisfaction (National Cancer Institute, 2014b; Ussher et al., 2013).

## **Body Image Related Distress in Younger Women after Treatment for Breast**

**Cancer.** Body image is a complex concept with several elements, especially for the younger breast cancer survivor. In terms of those with a cancer diagnosis, women with better body image scores have been found to cope better with cancer (Han, Grothuesmann, Neises, Hille, & Hillemanns, 2010). In contrast, a study published in 2011 reported that women found to be less satisfied with their body image after breast cancer diagnosis were 2.5 times more likely to experience sexual functioning issues, which establishes the importance of addressing both of these topics concurrently (Panjari, Bell, & Davis, 2011). Further, younger women have been reported to experience a lesser quality of life and reported more negative changes in body image after operations than older women (Axelrod et al., 2008). The various treatments for cancer can also cause distressing physical symptoms for those afflicted. Treatment with chemotherapy can result in hair loss, weight gain, and abrupt onset of menopausal symptoms, particularly distressing to younger women (Axelrod et al., 2008; Frith, Harcourt, & Fussell, 2007; Hansen, 2007; Kingsberg, 2010). Those younger women with breast cancer receiving mastectomy and reconstruction as treatment for breast cancer, a more prevalent treatment in the younger population, also report a more negative body image than those receiving breast conserving surgery immediately following treatment (Collins et al., 2011; Rasmussen, Hansen, & Elverdam, 2010).

Studies done in this area have further found that breast cancer survivors with poorer body image also reported greater mental distress (Falk Dahl, Reinertsen, Nesvold, Fossa, & Dahl, 2010). This identifies an impending need to investigate interventions that have the potential to improve the quality of life among this population.



**Interventions to Improve Sexual Distress and Body Image Related Distress.** There have been a limited number of interventions implemented to address various aspects of recovery after breast cancer, including body image and sexual distress concerns (Benton, Schlairet, & Gibson, 2013; Decker, Pais, Miller, Goulet, & Fifea, 2012; Jun et al., 2011; Kalaitzi et al., 2007; Speck et al., 2010). Two studies have utilized an exercise intervention program (Benton et al., 2013; Speck et al., 2010), another study utilized an intervention for psychosexual morbidity for breast cancer patients and their partners (Decker et al., 2012), another employed a sexual life reframing program intervention (Jun et al., 2011), and the final utilized a combination of a brief couples and sex therapy intervention (Kalaitzi et al., 2007). While one intervention did last 12 months (Speck et al., 2010), the majority of the interventions lasted approximately six weeks and ranged from three to six sessions each. One of the studies that employed an exercise intervention was the only one to report a statistically significant improvement in body image for younger women compared to older women ( $p = .001$ ) (Benton et al., 2013), while the other exercise intervention study found that the intervention participants experienced greater improvement in body image at follow-up than controls ( $p < .0001$ ), with no effect found based on age of participants (Speck et al., 2010). In the remaining studies, body image was assessed as part of the outcomes assessed but no statistically significant differences were found between the control and intervention groups over time (Decker et al., 2012; Jun et al., 2011; Kalaitzi et al., 2007). In the study by Decker et al. (2012), sexual functioning was maintained at the same level in the intervention groups throughout the study, whereas those in the comparison group declined at the second follow-up and then returned to baseline at the long-term follow-up (Decker et al., 2012). In the study by Jun and colleagues, there was an improvement in sexual satisfaction in the intervention group ( $p < .001$ ) (Jun et al., 2011), and in the study by Kalaitzi et al. (2007), the

intervention group had statistically significant improvements in depression ( $p < .001$ ); state anxiety ( $p = .006$ ); intercourse frequency ( $p = .021$ ); orgasm frequency ( $p = .042$ ); initiative for sex ( $p = .035$ ); and satisfaction with relationship ( $p < .001$ ).

These results show that although there are aspects of each of these interventions that assisted with improvement in one or more of the aspects of either body image related distress or sexual distress, there is a lack of consistent evidence regarding interventions that have been shown to improve body image related distress and sexual distress, particularly among younger women.

There is limited research that explored the use of mindfulness and meditation to help improve sexual functioning, but the potential usefulness of mindfulness to address issues related to sexuality after breast cancer has been considered in the literature (Johnston, 2012; Krychman & Katz, 2012). Though not specific to breast cancer, research on couples has found mindfulness to enhance intimate relationships (Carson et al., 2004). Furthermore, new research implementing components of mindfulness to assist with issues related to sexual dysfunction in survivors of cervical and endometrial cancer has had promising results (Brotto et al., 2012; Brotto et al., 2008). Multimodal interventions that address self-identity issues, including body image and sexuality, have the potential for significant effects in regard to sexual outcomes. Mindfulness Based Stress Reduction (MBSR), a standardized program with meditation and yoga components, has been evaluated as a promising intervention to reduce psychological distress and increase quality of life among BCS while also decreasing fears of recurrence by self-regulating arousal to stressful circumstances or symptoms (Lengacher et al., 2009). The potential for mindfulness practice to be beneficial for both individuals and couples in cancer care has been discussed in the literature, and this may offer a useful approach for addressing sexuality issues,

including self-identity and body image, but this research has not yet been performed with BCSs (Johnston, 2012).

### **Statement of the Problem**

After treatment for breast cancer, survivors often experience distressing symptoms that occur for many years after treatment. The National Comprehensive Cancer Network (NCCN) 2014 Survivorship Guidelines defines the period of survivorship for any individual with cancer as starting from the time of diagnosis through the balance of his or her life; family members, friends and caregivers also being affected (National Comprehensive Cancer Network, 2014). The NCCN definition of survivorship focuses on the areas of survivorship that have the potential for consistent interference in the life of a cancer survivor, including potential impacts on health and health behaviors, physical and mental well-being, identities (professional and personal), sexuality, and financial standing (National Comprehensive Cancer Network, 2014). Specific assessment and follow-up for the psychological symptoms of anxiety, depression and cognitive dysfunction and physical symptoms of pain, fatigue, sexual function, and sleep disorders are identified as standards of care for cancer survivorship (National Comprehensive Cancer Network, 2014). Problems related to sexuality in younger BCS are prevalent and often reported following surgical and adjuvant treatment leading to sexual distress and body image related-distress in this population.

There are limited data examining the potential impact of problems related to sexuality and body image that also may affect the quality of life of breast cancer survivors. There is the potential for these problems to have the greatest impact on younger women (Avis, Crawford, & Manuel, 2005; Collins et al., 2011; Howard-Anderson, Ganz, Bower, & Stanton, 2012; Rasmussen et al., 2010), a group that is an increasingly greater proportion of the long-term

cancer survivor population (Bloom, Stewart, Chang, & Banks, 2004). Younger women are often treated for more aggressive cancers, requiring more radical surgeries as well as adjuvant treatments such as chemotherapy and radiation (Johnson et al., 2013). As the number of BCS continue to increase, it is becoming important to investigate the survivorship issues of sexual distress, body image related-distress and the interventions that may improve these symptoms in the BCS population.

### **Statement of the Purpose**

The purpose of this study was to formally evaluate sexual distress and body image related-distress in younger women with breast cancer and examine the extent to which the Mindfulness-Based Stress Reduction-Breast Cancer (MBSR(BC)) as a stress reducing program is efficacious in improving distress related to sexuality, i.e. sexual distress and body image related-distress. In addition, this study also evaluated whether younger breast cancer survivors derive more benefit from MBSR(BC) compared to older breast cancer survivors. This study was conducted within the *R01 MBSR Symptom Cluster Trial for Breast Cancer Survivors/1R01CA131080*.

### **Research Aims and Hypotheses**

For this study, the following aims and hypotheses were tested:

***Aim 1:*** To evaluate the efficacy of the MBSR(BC) program in improving the psychological symptoms of sexual distress and body image related distress.

***Hypothesis 1:*** Compared to the usual care regimen, patients randomly assigned to the MBSR(BC) program will experience greater improvements at 6 weeks and sustained improvements at 12 weeks in sexual distress and body image related distress.

**Aim 2:** To evaluate whether positive effects achieved from the MBSR(BC) program are modified by specific patient characteristics measured at baseline.

*Hypothesis 1:* It is hypothesized that efficacy of the MBSR(BC) program will be greatest among patients with specific distress profiles of high sexual distress and low body image as well as demographic characteristics including younger age, race and ethnicity, stage of disease, and treatment type.

### **Definitions of Relevant Terms**

For the purpose of this study, the following terms and definitions were used.

1. *Sexual distress* is a term used to discuss sexually related personal distress in women (Derogatis, Rosen, Leiblum, Burnett, & Heiman, 2002).
2. *Body image* has been defined as the mental image of one's body, attitude about appearance and state of health, and sexual functioning (Han et al., 2010).
3. *Mindfulness-based stress reduction for breast cancer (MBSR(BC))* is a clinical program adapted from Dr. Jon Kabat-Zinn's MBSR program that provides systematic training to promote stress reduction by self-regulating arousal to stressful circumstances or symptoms (Kabat-Zinn, 1990). MBSR(BC) gives careful consideration to the breast cancer survivors' health status and symptom management for specific emotional/psychological symptoms (anxiety, depression and fear of recurrence) and physical symptoms such as pain and sleep (Lengacher et al., 2009).
4. *Usual care* refers to the comparison group for this study. These participants continued to participate in standard post-treatment medical and nursing clinic visits that were not modified by study participation; however, UC participants were asked not to initiate a mindfulness program during the study period. Participants randomized to this condition were offered the MBSR(BC) intervention within 6 months of completing the 12-week follow-up for the study.

## **Delimitations**

The sample included women with breast cancer and consisted of the following inclusion criteria:

1. Women age 21 or older
2. Diagnosed with Stage 0, I, II, or III breast cancer
3. Treated with a lumpectomy and/or mastectomy and are at least 2 weeks from end of treatment with adjuvant radiation and/or chemotherapy or are a maximum of 2 years out from completion of such treatment. Exclusion criteria include patients who have advanced stage breast cancer (stage IV), a severe current psychiatric diagnosis (e.g. bipolar disorder) or recurrent treatment for prior breast cancer.

## **Limitations**

The study is the first step in examining the MBSR(BC) intervention as a potentially appropriate intervention for alleviating post-treatment sexual distress and body image related distress in younger breast cancer survivors. Limitations of the study include those generally experienced with intervention research:

1. This study included an ethnically and racially diverse group of women, but was otherwise homogenous; generalizations to other socioeconomic groups and men are limited.
2. The study participants were concentrated in the southeast region of the United States, which may have unique influential characteristics based on geographic location, potentially limiting generalization of findings to other geographic locations.
3. The potentially sensitive nature of the questionnaires could have aroused anxiety in participants and subsequently influenced their responses to such questions.
4. There is always a possibility that study participants' replied in a less truthful but more

socially desirable manner.

5. Dissemination of the treatment condition could have occurred between the experimental and control group participants as both received care at the same NCI-designated cancer center.

6. Subjects in the intervention group were exposed to the intervention; those in the control group, now aware of the existence of such an intervention, may have attempted to increase their self-care prior to study completion.

7. The MBSR(BC) intervention was not designed or implemented with change (improvement) in sexual distress and body image related distress as primary outcomes.

### **Significance of the Study**

There is limited research and a lack of well-established interventions to minimize sexual distress and body image disturbance symptoms among younger breast cancer survivors. This study is warranted due to the a lack of empirical knowledge regarding the extent of sexual distress and body image related distress in younger breast cancer survivors, the lack of knowledge regarding the impact of these symptoms in this younger group of survivors, and the lack of knowledge of the impact that the MBSR(BC) program will have related to these symptoms. Although this study was not adapted for sexuality, and body image distress, the MBSR(BC) program was adapted for symptoms related to breast cancer and these patients may have benefited from the related knowledge obtained in the adapted program. This study provides a greater understanding of sexual distress and body image related distress and a research foundation to identify strategies aimed at decreasing morbidity in women experiencing sexual distress and body image related distress as a result of their breast cancer treatment. It is anticipated that the findings of this study will provide evidence supporting an intervention

appropriate for improved symptom management, support, and education for women in this population.



## **Chapter Two**

### **Literature Review**

#### **Introduction**

This chapter presents the hypothesized research model, an empirical review of the literature and a summary of findings. The empirical review of literature focuses on symptoms experienced by younger women after breast cancer treatment, sexual distress in younger women, body image related distress in younger breast cancer survivors, interventions and their impact on the symptoms of sexual distress and body image related distress in younger women, and mindfulness-based stress reduction.

#### **Theoretical Framework**

The logic model developed by Evans (1992), a model which is based upon the Psychosocial Nursing Research Model, guided this research (Evans, 1992). The logic model was used to test the effect of the MBSR(BC) intervention on symptoms of sexual distress and body image related distress after treatment for breast cancer. This theoretical logic model postulates that participation in this behavioral intervention, the MBSR(BC) program, will improve the psychological outcomes of sexual distress and body image related distress.

#### **Hypothesized Research Model**

The theoretical logic model (Figure 1) is an adaptation of the logic model developed by Evans (1992) and is based upon the Psychosocial Nursing Research Model as a heuristic device for research (Evans, 1992). Therefore, additional pathways not depicted may be plausible.

Specific to this study, the dependent variables being assessed are the psychological symptoms of sexual distress and body image related distress experienced by breast cancer survivors after treatment and the impact of a mindfulness based stress reduction for breast cancer (MBSR(BC)) program on improvement of these symptoms post-treatment.

The logic model postulates the MBSR(BC) program improves the psychological outcomes related to sexual distress and body image related distress in breast cancer survivors. Additionally, the positive effects achieved from the MBSR(BC) program were evaluated to determine if these are modified by specific patient characteristics measured at baseline, including specific distress profiles of high sexual distress and body image disturbance. It is hypothesized based on an empirical review of the literature that prior to undergoing the MBSR program (or corresponding usual care regimen), younger women would present with overall greater levels of psychological distress, including sexual distress and body image related distress, compared to older women. This research provides further insight into the understanding of the mechanism behind how the meditative practices of MBSR work, and identifies if certain patient characteristics, including age, baseline sexual distress levels, and baseline body image related distress levels influence the improvement of sexual distress and body image related distress post-intervention.

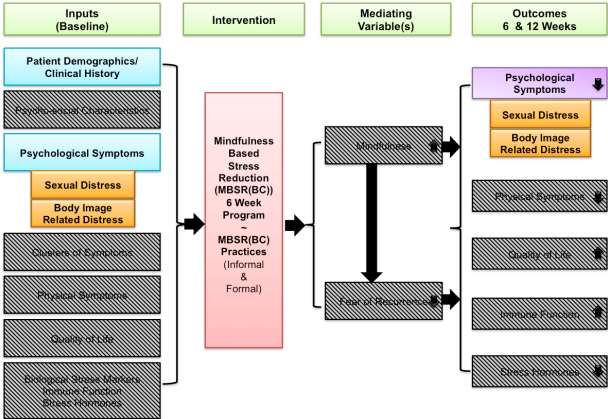


Figure 1. Hypothesized Research Model

## **Review of Empirical Literature**

This review of empirical literature focuses on the variables being examined in this study. First a review of research on symptoms experienced by younger women after breast cancer treatment is presented, followed by sexual distress in younger women, body image related distress in younger women, interventions and their impact on the symptoms of sexual distress and body image related distress in younger women, and finally a review of research on mindfulness-based stress reduction and cancer.

**Post-Treatment Symptoms in Younger Breast Cancer Survivors.** Breast cancer survivors are at risk for distress related to the diagnosis and subsequent treatment they undergo. Research has shown that younger women treated for breast cancer often have higher levels of physical and psychological distress than older women after treatment (Avis et al., 2005; Befort & Klemp, 2011; Hartl et al., 2010; Kenny et al., 2000; Miller, Schnur, Weinberger-Litman, & Montgomery, 2013; Rosenberg et al., 2013; Shields et al., 2010; Speck et al., 2010; Wang et al., 2013; Wong-Kim & Bloom, 2005), with particularly high anxiety levels having been found in the younger age group (Hopwood et al., 2010; Mehnert & Koch, 2008) and increased levels of distress (K. E. Hoffman et al., 2009).

A cross-sectional study by Kenny et al. (2000) investigated quality of life outcomes of early stage breast cancer treatment among 291 Australian women one year after initial surgical treatment. Quality of life outcomes were assessed using the European Organization for the Research and Treatment of Cancer QOL Questionnaire- Cancer (EORTC QLQ-C30) and the investigators found that younger women had poorer emotional functioning ( $p = .0004$ ), social functioning ( $p = .01$ ) and global health status ( $p = .05$ ) when compared to older women (Kenny et al., 2000).

The 2010 longitudinal study by Hartl and colleagues aimed to assess long-term quality of life among survivors of breast cancer in Europe. A total of 236 women with a primary diagnosis of breast cancer or Ductal Carcinoma in Situ (DCIS) completed the European Organization for the Research and Treatment of Cancer QOL Questionnaire-Breast Cancer (EORTC QLQ-BR23) questionnaire after surgical treatment, and again at 6 months and 12 months post-surgery. Results found that younger patients (less than 60 years of age vs. 60 and older) showed significantly greater impairment in both emotional and social functioning after surgical treatment ( $p < .00$  for both) and that the impairment in emotional functioning was still present at 12 months post-surgery ( $p = .036$ ) (Hartl et al., 2010). Younger patients had higher scores for anxiety after primary surgical treatment ( $p = .016$ ) than older patients, and the younger patients scores maintained at the same level at the one-year follow-up, while older women anxiety scores went down ( $p < .000$ ) (Hartl et al., 2010).

In a cross-sectional study of women ages 25-50 treated for stage I-III breast cancer, the investigators aimed to describe the QOL of younger women after breast cancer diagnosis and to identify factors associated with impaired QOL. A total of 202 breast cancer survivors 4-42 months post-diagnosis answered items from the psychosocial subscale of the Cancer Rehabilitation Evaluation System (CARES) and results showed that poorer body image was significantly associated with emotional well-being ( $p < .01$ ), breast cancer-specific concerns, ( $p < .0001$ ), and health related quality of life ( $p < .01$ ) (Avis et al., 2005).

In the study by Miller et al. (2013) the intent was to assess the relationship between age, body image, and emotional distress in women scheduled for breast cancer surgery. This cross-sectional design assessed 80 women, 40 older ( $\geq 65$ ) vs. 40 younger ( $< 65$ ) matched on race/ethnicity, marital status, and surgery type using items from the Additional Concerns section

of the Functional Assessment of Cancer Therapy – Breast (FACT-B). Older women were found to report less pre-surgical emotional distress than younger women ( $p < .01$ ) Age moderated the relationship between body image and emotional distress, but not significantly ( $p < .06$ ) (Miller et al., 2013).

In a randomized controlled trial of 44 women ages 45 and younger diagnosed with Stages I-III breast cancer, investigators sought to determine the impact of a communication coaching intervention encouraging BC patients to discuss their fears of recurrence, anxiety and depression with their oncology providers on these symptoms (Shields et al., 2010). Participants were between three and 8 years post-diagnosis and treated with chemotherapy, with assessments taking place 1 week prior to their physician visit, at the physician visit, and follow-ups at 1 week and 2 months after the physician visit. The researchers assessed anxiety using the State Trait Anxiety Inventory (STAI) state subscale, a researcher developed self-efficacy scale to assess self-efficacy, the Center for Epidemiologic Studies Depression scale (CES-D) to assess depression, and the Concerns about Recurrence (CARS) to assess fear of recurrence (Shields et al., 2010). Results found that change in self efficacy was a predictor of depression one week after the physician visit ( $p < .05$ ), was a strong predictor of anxiety one week after the physician visit ( $p < .0001$ ), was a predictor of womanhood worries ( $p < .05$ ), and was a marginal predictor of role worries ( $p < .10$ ) two months after the physician visit. Self-efficacy two months after the physician visit was significantly different between the two groups ( $p = .04$ ), with the intervention group experiencing greater self-efficacy post-intervention after adjusting for baseline self-efficacy (Shields et al., 2010).

In a cross-sectional study by Wong-Kim and Bloom (2005) researchers examined depressive symptoms among 331 women 50 and younger newly diagnosed with breast cancer.

The focus of the study was to determine the relative importance of biological, psychological and social variables as correlates of depression levels among younger women with breast cancer (Wong-Kim & Bloom, 2005). Depression was assessed using the Center for Epidemiologic Studies Depression scale (CES-D). Results found that four variables were statistically significant for predicting depressive symptoms and these included positive associations with amount of bodily pain as a treatment side effect ( $p < .02$ ), self-esteem ( $p < .0005$ ), and emotional support ( $p < .0005$ ) and a negative association with age ( $p < .035$ ), the adjusted  $R^2$  for this model being 0.47 (Wong-Kim & Bloom, 2005).

Hopwood et al. (2010) conducted a prospective study on the course of anxiety and depression and their determinants in women with early breast cancer. Assessments took place before adjuvant radiotherapy (RT) and over 5 years of follow-up among 2208 breast cancer survivors using the Hospital Anxiety and Depression Scale (HADS) (Hopwood et al., 2010). Results relevant to age found that younger age predicted worse anxiety among these women (Hopwood et al., 2010).

In the study published by Mehnert and Koch (2008), a cross-sectional assessment of 1,083 breast cancer survivors an average of 47 months post-diagnosis were assessed for anxiety and depression using the Hospital Anxiety and Depression Scale (HADS) (Mehnert & Koch, 2008). Results indicated that disease progress, detrimental interactions, less social support, a lower educational level, and younger age were predictors of psychological comorbidity ( $p < .004$ ) (Mehnert & Koch, 2008).

Hoffman and colleagues (2009) examined results of a National Health Survey to compare 4,636 survivors of adult onset cancer of 5 years or more, including breast cancer, and 122,220 individuals never diagnosed as having cancer (Hoffman et al., 2009). Individuals had completed

the K6 scale as part of the survey, which is a validated and reliable screening scale designed to assess for nonspecific psychological distress. Results found that survivors were significantly more likely to experience serious psychological distress when controlling for other clinical and sociodemographic variables (OR 1.4; 95% CI 1.2-1.7) than those that had never been diagnosed with cancer and that long-term survivors of a younger age were more likely to experience serious psychological distress (Hoffman et al., 2009).

In terms of physical symptoms, Rosenberg et al., conducted a cross-sectional study to assess body image concerns among 419 young women after diagnosis with Stages 0-III breast cancer at age 40 or younger using three items from the psychosocial subscale of the Cancer Rehabilitation Evaluation System (CARES). Results found greater issues in younger women related to musculoskeletal pain ( $p < .0001$ ), and the physical changes of weight gain ( $p = .01$ ) and weight loss ( $p = .02$ ) (Rosenberg et al., 2013). In addition, at baseline (T1) and one year (T2), younger patients had more arm complaints ( $p = .002$  T1 and  $p = .038$  T2) and breast complaints ( $p = .014$  T1 and  $p = .001$  T2) (Rosenberg et al., 2013).

Another study aimed to examine the physical and psychosocial effects of breast cancer experienced by rural survivors at the time of treatment and the differences between younger and older rural survivors based on menopausal status at diagnosis (Befort & Klemp, 2011). This study included 770 breast cancer patients treated within 6 years of the on-study date and used the Breast Cancer Prevention Trial Symptom Checklist to assess symptoms. Results reported that younger women had decreased physical strength compared to older women ( $p < .001$ ) (Befort & Klemp, 2011).

In a randomized controlled trial to evaluate the impact of a twice-weekly strength training program intervention on perceptions of body image among 234 breast cancer survivors,

participants were randomized to either a 1-year weightlifting intervention or a waitlist control. The women enrolled in the study were treated for non-metastatic breast cancer at least one year prior to study enrollment and were cancer-free with BMI  $\leq 50$  kg/m<sup>2</sup> at the time of enrollment. Baseline and 12 month follow-up assessments were conducted using the Body Image and Relationships Scale (BIRS) and the results found that older women experienced greater improvement in strength and health than younger women ( $p = .03$ ) (Speck et al., 2010).

In a qualitative study, interviews were conducted with 20 breast cancer survivors. The researchers aimed to evaluate changes to sexual well being following breast cancer. Women in the study were pre-menopausal at time of treatment for breast cancer and they identified that menopausal symptoms including vaginal dryness, irritability, mood swings, and loss of tissue elasticity were also found to be a common complaint (Wang et al., 2013).

In summary, younger women are at-risk for greater distress as a result of their diagnosis and treatment for breast cancer. Specifically, compared to older women, younger women experience greater levels of anxiety, emotional and role functioning concerns, musculoskeletal pain and menopausal symptoms, and these symptoms have been found to persist as long as a year after treatment. Furthermore, younger age has been found to be a predictor of higher levels of depression and anxiety after breast cancer treatment.

**Sexual Distress.** For younger women diagnosed with breast cancer, problems related to sexuality are common and often follow surgical and adjuvant treatment leading to sexual distress and body image issues among this cohort, and particular issues of sexual functioning that cause distress for younger women vary by each individual (Alder et al., 2008; Andrzejczak, Markocka-Maczka, & Lewandowski, 2013; Avis et al., 2005; Bakht, 2010; Befort & Klemp, 2011; Burwell, Case, Kaelin, & Avis, 2006; Chung, Cimprich, Janz, & Mills-Wisneski, 2009;



Fallbjork, Rasmussen, Karlsson, & Salander, 2013; Fobair et al., 2006; Garrusi, 2008; Kenny et al., 2000; Wang et al., 2013; Zee, 2008).

In the cross-sectional study conducted by Avis and colleagues (2005) the purpose of which was to describe the QOL of younger women after breast cancer diagnosis, 202 women diagnosed with Stage I-III breast cancer ages 25-50 completed the psychosocial and sexual subscales of the Cancer Rehabilitation Evaluation System (CARES). Results found that in younger women, body image, sexual dysfunction, and early menopausal symptoms including hot flashes, vaginal dryness, atrophic vaginitis and decreased libido are particular concerns more prevalent in this age group (Avis et al., 2005).

In another study, Wang and colleagues (2013) conducted a cross-sectional investigation to evaluate changes to sexual well being following breast cancer treatment. The team enrolled 180 Chinese breast cancer survivors ages 30-60 diagnosed and treated for breast cancer from 2007-2012 and that were married women living with their spouses. Answers to a structured questionnaire developed by the research team found that 88.9% of participants experienced long-term sexual issues after breast cancer treatment and 92% reported a desire for professional consultation on sexual issues following treatment (Wang et al., 2013).

Another cross-sectional study aimed to explore aspects of body image in women post-mastectomy. Participants were 76 women two years post-treatment and they were assessed using the Life after Mastectomy Scale (LAM). Findings showed that women after breast cancer felt significantly less sexually attractive ( $p = .012$ ) and less comfortable during sexual intimacy ( $p < .001$ ) (Fallbjork et al., 2013).

In the study by Zee and colleagues (2008), the researchers examined characteristics associated with sexuality in breast cancer patients in Hong Kong. A total of 162 breast cancer

survivors completed the European Organization for the Research and Treatment of Cancer QOL Questionnaire- Cancer (EORTC QLQ-C30) and results showed that changes in body image were found to significantly increase the influence of cancer treatment on sexual functioning and to increase the influence of sexual problems on QOL ( $p < 0.01$ ) (Zee, 2008).

In a study conducted by Andrzejczak and colleagues (2013) with the purpose to assess the impact of undergoing a mastectomy without reconstructive surgery on a patient's psychological state, 60 European breast cancer survivors married or in a relationship completed the Marital Happiness Questionnaire (MHQ). Results showed that 80% of women in the youngest group (34-49) reported covering up their body for aesthetic reasons during intimate relations, while 73% in the middle age group (50-65) and 58% in the oldest ( $> 65$ ) reported the same behavior (Andrzejczak et al., 2013).

The cross-sectional study by Kenny et al. (2000) investigated the quality of life outcomes of early stage breast cancer treatment among 291 Australian women one year after initial surgical treatment. Quality of life outcomes were assessed using the European Organization for the Research and Treatment of Cancer QOL Questionnaire- Cancer (EORTC QLQ-C30) and the investigators found that younger women placed a greater importance on their breasts in sexuality and femininity ( $p = .009$ ) (Kenny et al., 2000).

The cross-sectional study by Fobair and colleagues (2006), the purpose of which was to determine the frequency of body image and sexual problems in younger women with breast cancer after treatment, 546 women ages 50 or younger in a stable relationship completed 3 items from the Body Image Scale (BIS) and four items from the MOS SF-36 assessing sexuality problems, and results found that experiencing sexual problems was associated with poorer body image ( $p < .05$ ) (Fobair et al., 2006).

A comparison study conducted by Bakht and Najafi (2010) among women ages 50 and younger with breast cancer compared to healthy age-matched controls investigated the impact of breast cancer on patients. Twenty women completed the Multidimensional Body Self-Relations Questionnaire (MBSRQ) at a single time point. Findings included a significant differences in sexual desire ( $p < .01$ ), sexual arousal ( $p < .01$ ), and sexual satisfaction ( $p < .01$ ) among the breast cancer survivors vs. healthy controls (Bakht, 2010).

In a study by Befort and Klemp (2011), investigators examined the physical and psychosocial effects of breast cancer experienced by rural survivors at the time of treatment and differences in these effects between younger and older rural survivors based on menopausal status. Participants included 770 women treated for breast cancer within 6 years of the on-study date completed the Breast Cancer Prevention Trial Symptom Checklist (BCPT). Findings showed that women premenopausal at diagnosis were significantly more likely to experience symptoms during treatment including hot flashes, vaginal dryness, loss of sexual desire, sleeplessness, and weight gain ( $p < .001$ ) (Befort & Klemp, 2011).

Alder and colleagues (2008) measured levels of androgen activity in breast cancer patients to investigate predictors of sexual dysfunction after breast cancer. There were 29 participants, all with a premenopausal diagnosis of stage I-II breast cancer that had completed treatment within 6 months to 5 years of the time of enrollment. Participants completed the European Organization for the Research and Treatment of Cancer QOL Questionnaire-Cancer (EORTC QLQ-C30). Results showed that women without a history of chemotherapy had preserved sexual function compared to those who had received chemotherapy ( $p < .001$ ) (Alder et al., 2008).

A study of women ages 50 and younger conducted by Burwell and colleagues (2006) examined sexual problems in younger women diagnosed with breast cancer during the first year after surgery. Assessments were conducted at baseline (within 24 weeks of surgery), and again at 6 weeks and 6 months post-enrollment. The participants included 323 women ages 50 and younger that were between 4-26 weeks post-surgery, and the Body Image Index (BII) was used at all four time points. Findings showed that vaginal dryness, body image, and feeling sexually attractive were all significantly related to sexual function in women ages 50 and younger with breast cancer, but the significance levels were not reported in the published article (Burwell et al., 2006).

In the study by Garrusi et al. (2008), the aim was to identify sexual dysfunction and related factors in Iranian women after a diagnosis of breast cancer. Participants were an average of 2.5 years since treatment and 82 women completed the measure designed by the research team to assess body image perceptions. Findings reported that body image perception was significantly related to sexual satisfaction, but the level of significance for these reported findings was not reported (Garrusi, 2008).

Finally, in a qualitative study of African American women intending to determine the utility and cultural relevance of the taking CHARGE breast cancer survivorship program for African American women, 13 women ages 25 and older that self-identified as African-American and completed primary treatment 2 to 12 months earlier answered a series of focus group questions. The results of these focused questions identified that the breast cancer survivors expressed needs for positive body image valuations in survivorship programs as well as additional need for information about age-specific concerns related to body image and sexuality for younger women (Chung et al., 2009).

In summary, sexual functioning continues to be an unmet need in breast cancer survivorship care. It has implications for body image perceptions, the partnered relationship, and survivors of younger age are at particular risk for issues related to sexual functioning after breast cancer treatment.

**Body Image.** Cancer is generally viewed as a disease of aging, and the diagnosis of breast cancer can be devastating to a young woman (Shields et al., 2010). As a result, younger women are at particular risk for psychological symptoms during and after treatment, including body image issues (Alder et al., 2008; Avis, Crawford, & Manuel, 2004; Avis et al., 2005; Bakht, 2010; Befort & Klemp, 2011; Biglia et al., 2010; Burwell et al., 2006; Decker et al., 2012; Elmir, Jackson, Beale, & Schmied, 2010; Fobair et al., 2006; Lee et al., 2013; Mahapatro & Parkar, 2005; Rosenberg et al., 2013; Sayakhot, Vincent, & Teede, 2012; Wang et al., 2013).

One study compared younger women (ages 50 and younger) to healthy controls, a comparison of women ages 50 and younger with breast cancer to healthy age-matched controls, Bakht and Najafi (2010) aimed to study the disease of breast cancer and its consequences. Twenty women completed the Multidimensional Body Self-Relations Questionnaire (MBSRQ) at a single time point finding that there were significantly worse total body image scores among the younger breast cancer survivors ( $p < .01$ ) (Bakht & Najafi, 2010).

In another study that evaluated the frequency of body image and sexual problems in younger women with breast cancer after treatment, 546 women ages 50 or younger in a stable relationship completed 3 items from the Body Image Scale (BIS). Results found that greater body image problems among women who are sexually active are associated with type of surgery, concerns about weight fluctuations, hair loss due to chemotherapy, partner inability to understand the feelings of the patient, and lower scores in mental health as well as self-esteem.

Furthermore, chemotherapy treatment was also found to have a negative impact on body image among younger women ( $p < .05$ ) (Fobair et al., 2006).

Other studies comparing younger women treated for breast cancer to older women treated for breast cancer found that the younger women in the study had worse body image compared to older women (Andrzejczak et al., 2013; Begovic-Juhant, Chmielewski, Iwuagwu, & Chapman, 2012; Elmir et al., 2010; Hartl et al., 2010; Hopwood et al., 2007; Moreira & Canavarro, 2010; Przewdziecki et al., 2013).

In the study conducted to assess the impact of undergoing a mastectomy without reconstructive surgery on a patient's psychological state, 60 European breast cancer survivors married or in a relationship completed the Marital Happiness Questionnaire (MHQ) (Andrzejczak et al., 2013). Eighty percent of women in the youngest group (34-49) reported covering up their body for aesthetic reasons during intimate relations, while 73% in the middle age group (50-65) and 58% in the oldest (> 65) reported the same behavior (Andrzejczak et al., 2013).

In the study by Begovic-Juhant et al. (2012), the researchers assessed body image, physical attractiveness, and femininity and the effect of these variables on QOL in breast cancer survivors. There were 70 women that participated by completing the European Organization for the Research and Treatment of Cancer QOL Questionnaire-Breast Cancer (EORTC QLQ-BR23) at a single time point (Begovic-Juhant et al., 2012). Results showed age was negatively associated with body image, attractiveness, femininity, aversion to nakedness and dissatisfaction with one's body, with younger women experiencing greater body image disturbances (all  $p < .01$ ) (Begovic-Juhant et al., 2012). Overall, 30% of the study participants were "very

dissatisfied” with their body image and 47% were either a little or quite a bit dissatisfied with their body image (Begovic-Juhant et al., 2012).

A qualitative study among four breast cancer survivors ages 50 and younger explored younger women’s experiences of recovery from breast cancer-related breast surgery (Elmir et al., 2010). Women diagnosed with breast cancer that resulted in breast surgery participated in the study and answered focus group questions. During the interviews, women talked about their body image with respect to femininity and sexuality as a result of surgery, including one participant that expressed issues of body disfigurement because of breast surgery and another talking about her inability to feel desirable towards her husband as a result of breast surgery (Elmir et al., 2010).

Another study by Hartl and colleagues (2010) assessed long-term QOL and other factors in 236 survivors of breast cancer with a primary diagnosis of breast cancer or ductal carcinoma in-situ (Hartl et al., 2010). Participants completed questionnaires after surgical treatment, and again 6 months and 12 months post-surgery using the European Organization for the Research and Treatment of Cancer QOL Questionnaire-Breast Cancer (EORTC QLQ-BR23). In comparing younger (less than 60 years old) vs. older (60 and older) women, older patients reported better body image after the operation ( $p = .006$ ) (Hartl et al., 2010).

Hopwood and colleagues (2007) investigated the effects on QOL of age, time since surgery, type of breast surgery, chemotherapy and endocrine therapy among 2208 breast cancer survivors. Body image was assessed using the Body Image Scale (BIS) (Hopwood et al., 2007). Results showed that age had significant effects on quality of life, with women younger than 50 having worse quality of life in respect to body image ( $p < .001$ ) than older women (Hopwood et al., 2007).

In another study conducted to examine the evolution of body image dimensions from the period of surgery to 6 months after treatment ending among breast cancer patients (Moreira & Canavarro, 2010). Fifty-six breast cancer survivors completed the Derriford Appearance Scale (DAS) at surgery and 6 months after treatment, and there was a significant increase in body shame over time ( $p = .002$ ) (Moreira & Canavarro, 2010). Significant associations were also found between age and self-consciousness of appearance ( $p = .03$ ); surgery type and body shame ( $p = .01$ ) and surgery and appearance satisfaction ( $p = .01$ ) (Moreira & Canavarro, 2010).

Przedziecki and colleagues conducted a study to test the hypothesis that self-compassion mediates the relationship between body image and distress among 279 Australian breast cancer survivors (Przedziecki et al., 2013). Participants completed the Body Image Scale (BIS) and findings included that body image was significantly associated with age ( $p = .01$ ) with younger women reporting more body image disturbance (Przedziecki et al., 2013). Furthermore, body image disturbance was found to exert an indirect effect on distress and for anxiety and stress, only self-compassion uniquely contributed to the effect (Przedziecki et al., 2013).

However, two studies comparing younger women treated for breast cancer to older women treated for breast cancer did not find a significant difference in body image by age (Miller et al., 2013; Speck et al., 2010). In the study by Miller et al. (2013) the intent was to assess the relationship between age, body image, and emotional distress in women scheduled for breast cancer surgery. This cross-sectional design assessed 80 women, 40 older ( $\geq 65$ ) vs. 40 younger ( $< 65$ ) matched on race/ethnicity, marital status, and surgery type using items from the Additional Concerns section of the Functional Assessment of Cancer Therapy – Breast (FACT-B) (Miller et al., 2013). However, body image did not differ significantly by age in this study ( $p > .999$ ) (Miller et al., 2013).



In the study by Speck and colleagues (2010) the purpose was to determine the impact of a twice-weekly strength training program intervention on perceptions of body image for non-metastatic breast cancer patients. Participants were currently cancer-free with a body mass index of 50 or less 50 (Speck et al., 2010). In this randomized controlled trial, 234 women were randomized to either a one-year weightlifting intervention or a waitlist control. The Body Image and Relationships Scale (BIRS) assessed body image at baseline and the 12-month follow-up (Speck et al., 2010). While the main effect of age was not significant, the interaction between age and treatment allocation was significant, with older women experiencing greater improvement in strength and health ( $p = 0.03$ ) (Speck et al., 2010).

Two other studies found that younger women treated for breast cancer actually had a better body image perception than older women treated for breast cancer (Benton et al., 2013; Pikler & Winterowd, 2003). In the nonrandomized intervention trial by Benton and colleagues (2013) researchers sought to evaluate the effect of age on QOL in breast cancer survivors following resistance training. Twenty women were assigned to two groups and stratified by age (younger: 40-59 years vs. older: 60-80 years) to the intervention group, consisting of 3 sets of 8 exercises twice a week for 8 weeks versus a control group (Benton et al., 2013). Participants completed the Body Image and Relationships Scale (BIRS). Results found that younger women reported greater improvements than older women in the BIRS total score ( $p = .001$ ) (Benton et al., 2013).

In the study conducted by Pikler et al. (2003), the researchers explored racial and body image differences in coping and self-efficacy in coping as well as racial differences in body image perceptions among breast cancer patients. Ninety-two breast cancer survivors completed the Measure of Body Apperception (MBA) and findings showed that the average age for lower

(worse) body image was 59.91 and average age for higher (better) body image was 56.02, indicating younger women had a better body image perception (Pikler et al., 2003).

In summary, results are mixed as to whether there exists greater body image disturbance among younger versus older women after breast cancer treatment. Nonetheless, it is clear that this is a particularly important issue for younger women in the majority of the research findings available. This unmet need is one that must be addressed in order to decrease symptom burden and improve quality of life after breast cancer treatment.

**Interventions and their Impact on Sexual Distress and Body Image Related Distress in Younger Breast Cancer Survivors.** There have been numerous studies that employed an intervention targeting various aspects of recovery after breast cancer, including sexual distress and body image concerns (Benton et al., 2013; Decker et al., 2012; Jun et al., 2011; Kalaitzi et al., 2007; Marcus et al., 2010; Schover et al., 2006; Speck et al., 2010). These include counseling programs and exercise programs of varying lengths and delivery format, with none of the intervention studies being limited to only younger women after breast cancer treatment.

In two studies examining the effect of different counseling programs on sexual functioning, none examined sexual distress as a specific entity, but rather sexual functioning and distress were examined separately (Marcus et al., 2010; Schover et al., 2006). In the study by Schover et al. (2006) women participated in a 3-session peer counseling program. The researchers measured sexual function and emotional distress at baseline, post-intervention, and a 3-month follow-up. Participants improved in emotional distress ( $p = .0047$ ) and sexually dysfunctional women were found to be less distressed post-intervention ( $p = .0047$ ) (Schover et al., 2006).

The randomized trial conducted by Marcus and colleagues (2010) tested the effect of a telephone-counseling program on distress and sexual dysfunction among early stage breast cancer survivors. The counseling program was a one-year, 16 session counseling program supplemented with print materials and assessments were performed at baseline, 12, and 18 months post-enrollment, while the control group received a breast cancer resource directory. The sexual dysfunction instrument used in the study was researcher developed, and the Impact of Events Scale was used to measure distress. The results showed a significant improvement in the intervention group on sexual dysfunction at 12 months ( $p = 0.03$ ) and a significant improvement in both groups for distress at both the 12 and 18-month follow-ups ( $p = 0.003$ ) (Marcus et al., 2010).

Two studies examined the effects of an exercise intervention program on sexuality and body image (Benton et al., 2013; Speck et al., 2010). In the study by Benton et al. (2013) conducted a resistance training intervention study among 20 women, grouped by age (40-59 years vs. 60-80 years). Participants completed 3 sets of 8 exercises two times a week for 8 weeks and the Body Image and Relationships Scale (BIRS) was used to assess body image at baseline and post-intervention. This study was the only to report a statistically significant improvement in body image for younger women compared to older women, with a statistically significant higher score on the BIRS among younger women ( $p < .001$ ) (Benton et al., 2013).

In another resistance training intervention study, participants were stratified by lymphedema status and randomized to a 12-month weightlifting group or a waitlist control (Speck et al., 2010). The Body Image and Relationships Scale (BIRS) was used to measure body image and sexual function at baseline and 12 month time points. Results of the study found that the intervention participants experienced greater improvement in body image at follow-up than

controls ( $p < .0001$ ), but no effect was reported based on age of participants (Speck et al., 2010).

Two studies that investigated sexual functioning and body image after breast cancer implemented interventions that focused on the couple as a dyad. In a dyadic study of female breast cancer survivor couples, the three intervention sessions took place two to three weeks apart and focused on communication, intimacy and sexual well-being, and dyadic coping and effective coping strategies (Decker et al., 2012). Sexual functioning was measured using the Watts Sexual Functioning scale and body image was measured using the Body Image Scale, with assessments taking place at baseline, post-intervention, and 6 months post-intervention (Decker et al., 2012). Results from this study found no statistically significant differences between the control and intervention groups over time for body image or sexual functioning.

In the study by Kalaitzi and colleagues (2007), the researchers used a combination of a brief couples and sex therapy intervention for breast cancer survivors who had undergone a mastectomy and their partners vs. a control group (Kalaitzi et al., 2007). Assessments were completed at baseline (2 days before mastectomy) and follow-up (3 months post-mastectomy). The intervention consisted of 6 therapeutic sessions, the first one taking place while the patient was still in the hospital and then on a biweekly basis focusing on communication, body imagery, and sensate focus. Results found that the intervention group improved in orgasm frequency ( $p = .042$ ) intercourse frequency ( $p = .021$ ), and initiative for sex ( $p = .035$ ) from baseline to follow-up. However, the control group also showed improvements in intercourse frequency ( $p < .001$ ) and initiative for sex ( $p < .001$ ) as well as in satisfaction with body image when naked ( $p < .001$ ) and satisfaction with body image when dressed ( $p = .005$ ) from baseline to follow-up.

In another intervention focused on the physical, psychological, and relational aspects of sexual health elements in marriages using discussion, counseling, role-play, and films about the

marital relationship for 2 hours per week over a 6-week period (Jun et al., 2011). Body image was measured using the body image subscale from the Cancer Rehabilitation Evaluation System questionnaire (CARES) and sexual functioning was measured using the sexual dysfunction subscale of CARES. The participants in the study reported poor body image and sexual function, and although there were no statistically significant differences in body image, sexual interest, or sexual dysfunction post-intervention, a trend towards improvement in the intervention group was found (Jun et al., 2011).

In summary, a number of interventions, including aspects of counseling and exercise, have been implemented among breast cancer survivors to assist in managing symptoms after cancer treatment, including sexual distress and body image. Although some of these were effective in reducing sexual distress and body image disturbance, the evidence is not consistent nor has the research been repeated on a larger scale and furthermore, no study exclusively examined the unique population of younger women after breast cancer.

**Mindfulness-Based Stress Reduction (MBSR) for Breast Cancer.** Mindfulness-based stress reduction is an intervention that has a strong foundation of research evidence supporting the positive effect this mindfulness training can have on both psychological and physical symptoms after treatment for breast cancer. In previous randomized controlled trials (RCTs) that included breast cancer patients, MBSR improved sleep (Andersen et al., 2013; Shapiro, Bootzin, Figueredo, Lopez, & Schwartz, 2003), reduced fatigue (Carlson & Garland, 2005), distress (anxiety, depression, anger and confusion) (Henderson et al., 2012; Hoffman, Ersser, Hopkinson, et al., 2012; Lengacher et al., 2009; Lengacher et al., 2014; Lerman, Jarski, Rea, Gellish, & Vicini, 2012; Wurtzen, 2013), mood disturbance (Hoffman, Ersser, Hopkinson, et al., 2012), perceived stress (Lengacher et al., 2014; Speca, Carlson, Goodey, & Angen, 2000), fear of

recurrence (Lengacher et al., 2009; Lengacher et al., 2014), and physical functioning (Lengacher et al., 2009; Lengacher et al., 2014), and improved quality of life (Henderson et al., 2012; Henderson et al., 2013; Hoffman, Ersser, Hopkinson, et al., 2012; Lerman et al., 2012). In non-randomized comparison studies with cancer patients, MBSR has been identified to significantly improve symptoms of sleep disturbance, fatigue, mood disturbance, stress, depression and anxiety (Brown & Ryan, 2003; Garland, Carlson, Cook, Lansdell, & Speca, 2007; Labelle, 2010) and decrease rumination (Campbell, Labelle, Bacon, Faris, & Carlson, 2012; Labelle, 2010). In single group studies of MBSR in cancer patients, improvements in mood disturbance (Altschuler, Rosenbaum, Gordon, Canales, & Avins, 2012; Birnie, Garland, & Carlson, 2010; Brown & Ryan, 2003; Carlson & Garland, 2005; Garland, Tamagawa, Todd, Speca, & Carlson, 2013), stress (Brown & Ryan, 2003; Carlson & Garland, 2005; Carlson, Speca, Patel, & Goodey, 2003; Dobkin, 2008; Garland et al., 2013; Hoffman, Ersser, & Hopkinson, 2012; Lengacher, Kip, et al., 2012; Matousek & Dobkin, 2010; Matousek, Pruessner, & Dobkin, 2011), sleep disturbance (Carlson & Garland, 2005), fatigue (Carlson & Garland, 2005), fear of recurrence (Lengacher et al., 2011), anxiety (Lengacher et al., 2011; Lengacher, Kip, et al., 2012; Tacon, 2004), depression (Kieviet-Stijnen, Visser, Garssen, & Hudig, 2008; Matousek & Dobkin, 2010; Matousek et al., 2011), and quality of life (Altschuler et al., 2012; Carlson et al., 2003; Kieviet-Stijnen et al., 2008; Lengacher et al., 2011).

Henderson et al. (2012) conducted a 3-arm randomized controlled trial study among 163 early stage breast cancer patients using an 8 week MBSR program compared to a nutrition education program or usual care (Henderson et al., 2012). The MBSR program in this study consisted of 2.5 to 3.5 hour weekly sessions as well as a 7.5 hour weekend retreat. The researchers conducted assessments at baseline and at post-intervention timepoints of 4 months, 1 year and 2

years (Henderson et al., 2012). The team measured outcomes of depression using the Beck Depression Inventory, anxiety using the State Trait Anxiety Inventory, general distress using the Symptom Checklist 90 (revised), self-esteem using the Rosenberg Self-Esteem scale, social support using the UCLA Loneliness scale, resilience using the Sense of Coherence scale, degree of emotional control using the Courtald Emotional Control scale, and cancer-specific coping using the Mental adjustment to Cancer scale (Henderson et al., 2012). Quality of life was measured using the Functional Assessment of Cancer Therapy breast cancer version. The researchers hypothesized that quality of life and coping skills would be higher in the MBSR group than the two comparison conditions in the study. Results found that the mean age was 49.8, and at the 4 month post-intervention assessment, MBSR participants improved significantly in spirituality subscale of the FACT-B ( $p < .05$ ) as well as improvement in depression and unhappiness compared to the nutrition program arm ( $p < .05$ ), and decreased hostility and anxiety as well as increased emotional control and meaningfulness when compared to both comparison conditions ( $p < .05$ ) (Henderson et al., 2012).

Lengacher and colleagues (2011) published results of a feasibility study of MBSR among 19 women post-treatment for early stage breast cancer (Lengacher et al., 2011). The MBSR program was an 8-week MBSR program conducted by a licensed psychologist trained in the program. Outcome measures assessed at baseline and post-intervention included measures of psychological status, including fear of recurrence (concerns about recurrence scale), perceived stress (perceived stress scale), anxiety (state trait anxiety inventory), and depression (center for epidemiologic studies – depression) as well as optimism (life orientation test), social support (medical outcomes social support survey), spirituality (2 items assessing the concept), physical symptoms (memorial symptom assessment scale) and quality of life (medical outcomes studies

short-form general health survey) (Lengacher et al., 2011). Results found a significant reduction in fear of recurrence post-intervention ( $p = .01$ ) and decreased trait anxiety ( $p = .01$ ), depression ( $p = .009$ ), and perceived stress ( $p = .01$ ) (Lengacher et al., 2011). There was a significant improvement in aspects of quality of life, including emotional well-being ( $p = .003$ ) and general health ( $p = .03$ ) (Lengacher et al., 2011).

In the study conducted by Lengacher and colleagues (2009), 84 female breast cancer survivors were randomized to either an MBSR program consisting of 6 weekly 2-hr sessions or a waitlist control group. Participants were assessed for the outcomes of depression (CES-D), anxiety (STAI), perceived stress (PSS), fear of recurrence (Concerns about Recurrence Scale), optimism (Life Orientation Test), social support (Medical Outcomes Social Support Survey), and psychological and physical subscales of quality of life using the MOS SF-36 (Lengacher et al., 2009). Assessments were conducted at baseline and 6 week follow-up. Results found that the MBSR participants had significantly lower levels of depression, anxiety, and fear of recurrence along with higher energy levels, physical functioning, and physical role functioning at the 6 week follow-up compared to the usual care participants (all  $p < .05$ ) (Lengacher et al., 2009). Furthermore, the findings indicated that those most compliant with MBSR training experienced the greatest amount of improvement in energy and physical functioning (Lengacher et al., 2009). In the same trial, Lengacher and colleagues also measured patient symptoms using the M.D. Anderson Symptom Inventory (MDASI) to investigate the severity of symptoms experienced and symptom clustering (Lengacher, Reich, et al., 2012). Results found that the MBSR group showed significant reduction in fatigue and disturbed sleep ( $p < .01$ ) compared to the usual care group (Lengacher, Reich, et al., 2012). Furthermore, both the control and MBSR groups saw



statistically significant decreases in symptom cluster scores, but the MBSR group did see lower symptom cluster scores in all three clusters evaluated (Lengacher, Reich, et al., 2012).

Lerman et al. (2012) conducted a randomized study of MBSR vs. waitlist control among 68 female cancer survivors, of whom 70.6% were breast cancer survivors (Lerman et al., 2012). The MBSR program consisted of an 8 week program, with 8 weekly 2 hour sessions and one 4 hour weekend retreat. The researchers assessed using the Symptoms Checklist to evaluate symptom patterns, the European Organization for Research and Treatment of Cancer Quality of Life to assess quality of life, and the Symptoms of Stress Inventory to evaluate the physical, psychological and behavioral responses to stress (Lerman et al., 2012). In addition, the breast cancer survivors in the study also completed the EORTC breast specific quality of life measure (Lerman et al., 2012). Assessments were performed at baseline and post-intervention. Results found that the intervention group improved significantly on the EORTC quality of life measure ( $p = .005$ ), six of eight scales of the symptoms of stress inventory ( $p < .049$ ), and on both scales of the symptom checklist ( $p \leq .023$ ) and the control group did not improve on any measures pre to post intervention (Lerman et al., 2012).

In the study conducted by Speca and colleagues (2000) the Profile of Mood States (POMS) and the Symptoms of Stress Inventory (SOSI) were implemented pre and post intervention among 90 male and female cancer outpatients (Speca et al., 2000). Participants were randomly assigned to either the MBSR program or a waitlist control group. The MBSR intervention in this study entailed seven weekly 1.5 hour sessions (Speca et al., 2000). The intervention group saw a significantly greater decrease in the POMS subscales of anxiety ( $p < .001$ ), depression ( $p < .01$ ), anger ( $p < .01$ ), vigor ( $p < .01$ ), confusion ( $p < .01$ ) and also on total mood disturbance ( $p < .001$ ) than those in the control group (Speca et al., 2000). Furthermore,

the intervention group total mood disturbance scores decreased by 65% post-intervention vs. only 12% in the control group (Speca et al., 2000). Greater decreases in stress were also seen in the treatment group for emotional irritability ( $p < .05$ ) and total stress scores ( $p < .01$ ) and there was an overall reduction of 30.7% of total stress symptoms in the intervention group vs. 11.1% in the control group (Speca et al., 2000).

In a nonrandomized waitlist control study by Campbell et al. (2012), 70 female post-treatment cancer patients participated in either an 8-week MBSR program or waitlist control group (Campbell et al., 2012). The MBSR program in this study consisted of weekly 60-90 minute sessions and one 6 hour retreat and was delivered by a clinical psychologist experienced in delivering the MBSR intervention. Mindfulness was measured using the Mindful Awareness Attention Scale (MAAS), rumination was measured using the Rumination Reflection Questionnaire rumination subscale (RRQ-Rum), with assessments taking place prior to beginning the intervention and then post-intervention (Campbell et al., 2012). An objective measure of blood pressure was also taken by each participant on the morning of the first and last day of the MBSR program. Results found that the MBSR participants had a significant reduction in rumination ( $p = .01$ ) and a significant increase in mindfulness ( $p = .01$ ) when compared to controls (Campbell et al., 2012). Furthermore, in the MBSR group, reductions in rumination were associated with decreased resting systolic blood pressure ( $p = .03$ ) (Campbell et al., 2012). For participants in the MBSR group with higher systolic blood pressure at baseline, there was a lower systolic blood pressure at the follow-up compared to the control group ( $p = .04$ ) (Campbell et al., 2012).

Garland and colleagues (2007) conducted a study among 104 cancer outpatients self-selected into an 8-week MBSR program or a healing through creative arts program. The MBSR

intervention included eight 1.5 hour weekly sessions and one three hour retreat (Garland et al., 2007). The healing through creative arts comparison group consisted of six weekly 2-hour sessions and was designed to provide cancer patients the opportunity for self-discovery and empowerment through creativity (Garland et al., 2007). The study utilized the Post-Traumatic Growth Inventory-Revised (PTGI-R), the Functional Assessment of Chronic Illness Therapy – Spiritual Well-Being (FACIT-Sp), the Symptoms of Stress Inventory (SOSI), and the Profile of Mood States (POMS) and assessments were conducted at baseline and again post-intervention (Garland et al., 2007). Results found the MBSR group had a greater increase in spiritual well-being compared to the healing arts program participants ( $p = .029$ ) (Garland et al., 2007). The MBSR group also significantly reduced in stress were significantly related to reductions in mood disturbance ( $p < .000$ ) (Garland et al., 2007). Increased post-traumatic growth was positively related to increased spirituality ( $p = .028$ ) in the MBSR program, but not the healing arts program (Garland et al., 2007).

In the study conducted by Labelle and colleagues (2010) 77 female cancer patients participated in an 8 week MBSR program consisting of eight weekly 90-minute sessions and a 6-hour retreat (Labelle, 2010). The researchers in the study intended to test for mediators of MBSR in a cancer population. Depression was measured using the Center for Epidemiologic Studies Depression scale (CESD-10), mindfulness was measured using the Mindful Awareness Attention Scale (MAAS), and rumination was measured using the Rumination Reflection Questionnaire (RRQ) (Labelle, 2010). Assessments were conducted pre- and post-intervention. Results found that MBSR participants had lower CES-D scores than the control group ( $p < .05$ ), higher MAAS scores ( $p < .01$ ), and lower rumination scores than the control group ( $p < .01$ ) (Labelle, 2010). Mediation analyses found that mindfulness did not mediate the effect of MBSR on depressive

symptoms but that rumination change mediated the impact of MBSR on depression ( $p < .01$ ) (Labelle, 2010).

Altschuler et al. (2011) conducted a single-group study among 20 oncology patients during which participants completed a 12-week home program that consisted of listening to MBSR tapes and meditating 5 times per week for 12 weeks (Altschuler et al., 2012). Potential participants had to score greater than or equal to an 8 on the Hospital Anxiety and Depression Scale (HADS) during initial screening (Altschuler et al., 2012). Assessments took place at baseline and post-intervention and included the HADS, Profile of Mood States (POMS), and the Functional Assessment of Chronic Illness Therapy-Spirituality scale (FACIT-Sp) (Altschuler et al., 2012). Reported results were limited to the HADS, for which participant scores dropped from an average of 18.3 or “severe” to 12.2 or “moderate” (Altschuler et al., 2012).

Birnie et al. (2010) conducted a study of 21 cancer patients and their partners in a single group format using an MBSR intervention. The MBSR intervention in this study consisted of an 8-week program with 1.5 hour weekly sessions and one 3-hour silent retreat (Birnie et al., 2010). Measures included the Calgary Symptoms of Stress Inventory (SOSI), the Profile of Mood States (POMS) and the Mindful Attention and Awareness Scale (MAAS). Results showed that both patients and partners saw improved scores for mood disturbance ( $p < .05$ ), tension and anxiety ( $p < .01$ ), and fatigue ( $p < .05$ ) (Birnie et al., 2010). Both the patient and partner also had significant increases in mindfulness ( $p < .05$ ) (Birnie et al., 2010). After the intervention, patients that had more symptoms of stress and lower levels of mindfulness had partners with significantly greater mood disturbance ( $p < .05$ ) (Birnie et al., 2010).

In two publications encompassing one single group study, Carlson and colleagues investigated physical and psychological symptoms as well as biological markers among early

stage breast and prostate cancer patients and the impact of MBSR on these symptoms (Carlson et al., 2003; Carlson, Speca, Patel, & Goodey, 2004). The MBSR program in this study consisted of an 8-week program with 1.5 hour weekly sessions and one 3 hour retreat. Assessments took place pre- and post-intervention and included immune measures CD4, CD8, IFN- $\gamma$  T, TNF, IL-4, salivary cortisol, dehydroepiandrosterone sulfate (DHEAS) and melatonin as well as the Symptoms of Stress Inventory (SOSI), the Profile of Mood States (POMS), and the European Organization for Research and Treatment measure of quality of life (Carlson et al., 2003, 2004). While no significant association was found between the self-report and immune measures in the study, the findings did show an increase in the IL-4 cytokine, typically having antiinflammatory effects ( $p < .001$ ) (Carlson et al., 2003). There was a significant reduction in SOSI scores among participants ( $p < .01$ ) post-intervention (Carlson et al., 2003). Quality of life also improved post-intervention ( $p < .05$ ) but no significant improvement was seen for mood scores in this study (Carlson et al., 2003). Furthermore, no significant changes were seen for cortisol, DHEAS or melatonin, but DHEAS did shift in a direction towards a profile of healthy adults (Carlson et al., 2004).

Carlson and Garland (2005) conducted a single group MBSR study among 63 cancer outpatients of any stage or prognosis (Carlson & Garland, 2005). There was an 8-week MBSR program that consisted of 1.5 hour weekly sessions with one 3-hour silent retreat. Assessments were completed pre and post-intervention and included the Pittsburgh Sleep Quality Index (PSQI), the Symptoms of Stress Inventory (SOSI), and the Profile of Mood States (POMS) (Carlson & Garland, 2005). There was a significant change in sleep quality pre to post-intervention ( $p < .001$ ) as well as a significant reduction in symptoms of stress ( $p < .001$ ) and mood disturbance ( $p < .001$ ) (Carlson & Garland, 2005). Furthermore, a significant correlation

between reduction in stress symptoms and improved sleep quality was seen ( $p < .005$ ) (Carlson & Garland, 2005). Fatigue was measured by a subscale of the POMS, and a significant relationship between fatigue and sleep was found at pre ( $p < .05$ ) and post-intervention ( $p < .001$ ) but no significant relationship between improvements in sleep and fatigue was found (Carlson & Garland, 2005).

Dobkin (2008) conducted a small single group study to investigate the processes that may influence improvement after participation in an MBSR program among 13 breast cancer patients that had completed treatment (Dobkin, 2008). The details of the MBSR program delivered in this study was not outlined in the article, but assessments were conducted pre- and post-intervention. Measures included the Center for Epidemiologic Studies – Depression scale (CES-D), the Medical Symptom Checklist (MSCL), the Perceived Stress Scale (PSS), the Coping with Health Injuries and Problems measure (CHIP), the Orientation to Life Questionnaire (OLQ), and the Mindful Attention Awareness Scale (MAAS) (Dobkin, 2008). Participants experienced a significant reduction in perceived stress ( $p = .008$ ) and an increase in mindfulness ( $p = .028$ ) (Dobkin, 2008). A qualitative component of the study found that women used mindfulness in their everyday lives and felt better able to respond to stressors post-intervention (Dobkin, 2008).

Kieviet-Stijnen and colleagues (2008) implemented an MBSR program among 77 cancer patients and their caregivers with assessments pre and post intervention as well as a 1-year follow-up. The MBSR program in this single group study consisted of 8 weekly 2.5 hour sessions and one 8-hour retreat (Kieviet-Stijnen et al., 2008). Quality of life was measured with a visual analog scale, physical symptoms were measured by seven items from the Rotterdam Symptom Checklist, mood disturbance was measured by the Profile of Mood States (POMS), joy in life was measured by a subscale of the Health and Disease Inventory, experienced meaning in

life by four questions, social desirability by the Marlowe Crown Social Desirability Scale, and satisfaction with training by the Client Satisfaction Questionnaire (CSQ) (Kieviet-Stijnen et al., 2008). Significant improvements in all measures were found except the anger subscale of the POMS and the meaning in life questions (Kieviet-Stijnen et al., 2008). Participants were also found to be very satisfied with their training and the amount of assistance they perceived the program to have provided them in handling life problems (Kieviet-Stijnen et al., 2008).

Matousek et al. (2011) conducted an assessment of women after treatment of breast cancer and the impact of an MBSR program on self-report and cortisol outcomes. Cortisol measures and questionnaires were completed 3 days prior to beginning the MBSR training and 3 days post MBSR training (Matousek et al., 2011). The MBSR program consisted of an 8-week program with weekly 2.5-hour sessions and one 6-hour silent retreat. Measures included the biological stress measure cortisol, the Perceived Stress Scale (PSS) to measure perceived stress, the Center for Epidemiologic Studies Depression scale (CES-D) to measure depression, and the Medical Symptoms Checklist (MSCL) to measure medical symptoms (Matousek et al., 2011). There was a significant reduction in depression ( $p < .0001$ ), perceived stress ( $p < .0001$ ), and medical symptoms ( $p < .0001$ ) (Matousek et al., 2011). There was also a significant increase in cortisol post-MBSR cortisol ( $p < .05$ ), but interpretation of this finding was limited by mixed results and interpretations in the existing literature (Matousek et al., 2011). There was an association between the medical symptoms checklist difference scores (pre and post MBSR) and the cortisol awakening response, with lower cortisol awakening response before MBSR being associated with less improvement in medical symptoms pre to post MBSR ( $p < .002$ ).

Matousek and Dobkin (2010) delivered an MBSR intervention to 59 post-treatment breast cancer patients in a single group study. The MBSR program consisted of an 8-week

program with weekly 2.5-hour sessions (Matousek & Dobkin, 2010). Measures included stress using the Perceived Stress Scale (PSS), depression using the Center for Epidemiologic Studies – Depression scale (CES-D), medical symptoms using the Medical Symptoms Checklist (MSCL), sense of coherence using the Sense of Coherence questionnaire (SOC), and mindfulness using the Mindful Attention Awareness Scale (MAAS) (Matousek & Dobkin, 2010). Questionnaires were completed pre and post MBSR intervention. There was a significant decrease in depressive symptoms, perceived stress and medical symptoms (all  $p < .0001$ ) and an increase in mindfulness, meaningfulness and sense of coherence (all  $p < .0001$ ) (Matousek & Dobkin, 2010). Increased mindfulness was associated with decreased stress and depression and increased sense of coherence (all  $p < .0001$ ) (Matousek & Dobkin, 2010).

Tacon and colleagues (2004) conducted a single group MBSR study of 27 breast cancer patients. The team implemented an 8-week MBSR program with 1.5-hour weekly sessions (Tacon, 2004). Measures were taken pre- and post-intervention and at a 3-month follow-up and included assessment of stress using a single, Likert-type question, anxiety using the State Trait Anxiety Inventory (STAI), psychological adjustment using the Mental Adjustment to Cancer Scale (MAC), and locus of control in health using the Mental Health Locus of Control Scale (MHLC) (Tacon, 2004). Results found a significant reduction in stress ( $p < .001$ ), state anxiety ( $p < .001$ ), helplessness-hopelessness ( $p < .01$ ), anxious preoccupation ( $p < .01$ ) post-intervention (Tacon, 2004). Furthermore, participants reported post-intervention that their most favored MBSR components included Yoga (50.6%) and body scan (42%) and these remained the most favored techniques at the 3-month follow-up (Tacon, 2004).

In summary, there is an extensive body of literature supporting the use of MBSR to reduce a number of psychological (anxiety, depression, perceived stress, mood disturbance) and



physical (fatigue, sleep quality) symptoms after breast cancer treatment. Evidence that objective measures such as blood pressure were also positively impacted after participation in an MBSR intervention was also found in the literature. Potential mediators of these effects, suggested in the literature as being through increased mindfulness and decreased rumination, warrant further studies for investigation. Ultimately, no study has examined the impact of an MBSR program on sexuality or body image after treatment for breast cancer, and no study focused on the unique needs of younger women after treatment.

**MBSR for Sexuality after Cancer.** There have been two studies conducted that assessed the impact of a mindfulness-based program on sexuality after treatment for cancer. Brotto and colleagues (2008) conducted a pilot study of a brief, three-session psychoeducational program, which included mindfulness and was delivered monthly to 22 women diagnosed with gynecological cancer (Brotto et al., 2008). The intervention was made up of three one-hour sessions that combined components of behavioral treatment for women with orgasmic disorders, information on marriage and making it work, progressive relaxation and mindfulness training. Sexual functioning was assessed using the Female Sexual Functioning Inventory (FSFI) and the Female Sexual Distress Scale (FSDS). Results found that the mean FSDS score was found to fall within the range of significant levels of sexual distress, and higher depression scores were significantly associated with higher levels of sexual distress ( $p = 0.004$ ) (Brotto et al., 2008). Furthermore, sexual distress was significantly decreased post-intervention ( $p < .001$ ) (Brotto et al., 2008). Qualitative results from this study also found that women identified the mindfulness aspect of this intervention as the most helpful (Brotto et al., 2008).

In another study by Brotto et al. (2012), 31 women treated for cervical or endometrial cancers were randomized to either a mindfulness-based cognitive behavioral intervention or

waitlist control (Brotto et al., 2012). The intervention, which was the same content and structure of the 2008 study by Brotto and colleagues, consisted of three 90-minute sessions, which took place monthly with a psychologist or sex therapist. Female sexual distress was assessed using the FSDS at baseline, one month post-intervention and 6 months post-intervention (Brotto et al., 2012). Results found that both the intervention and control groups had clinically significant levels of sexual distress, and sexual distress was significantly decreased in the intervention group at the one-month follow-up ( $p = .008$ ) but was not significantly decreased from the one-month follow-up to the 6-month follow-up (Brotto et al., 2012).

Although there is a small body of research that investigates the aspects of mindfulness and meditation and their impact on sexual functioning and distress after gynecological cancer, the potential usefulness of mindfulness to address issues related to sexuality after breast cancer has not been considered in the literature. Multimodal interventions such as MBSR have the potential for significant effects in regard to sexual outcomes, when issues of self-perception, including body image and sexuality are addressed.

## **Summary**

In summary, distress related to sexuality and body image during and after treatment for breast cancer are often unreported concerns for breast cancer survivors, particularly younger women with breast cancer. The National Comprehensive Cancer Network identifies a need for specific assessment and follow-up of sexual function in cancer survivors as a standard of care for cancer survivorship (National Comprehensive Cancer Network, 2014). However, these concerns are not often assessed during treatment or added to the treatment plan as survivors transition off treatment.

Findings from the literature identify that younger women are at-risk higher levels of a number of symptoms, including anxiety, depression, emotional and role functioning concerns, musculoskeletal pain and menopausal symptoms, all of which have been found to persist for years after treatment. Sexual functioning continues to be an unmet need in breast cancer survivorship care. It has implications for body image perceptions, the partnered relationship, and survivors of younger age are at particular risk for issues related to sexual functioning after breast cancer treatment.

Although a limited number of studies have been implemented among breast cancer survivors to assist in managing symptoms of sexual distress and body image, the evidence is not strong and no study has examined the unique population of younger women after breast cancer and interventions to assist with sexual distress and body image disturbance experienced after treatment for breast cancer. There is an extensive body of literature supporting the use of MBSR to reduce a number of psychological and physical symptoms after breast cancer treatment, but no study has examined the impact of an MBSR program on sexuality or body image after treatment for breast cancer, and no study focused on the unique needs of younger women after treatment. This research is particularly warranted in the light of work done by Brotto and colleagues (2008, 2012) showing preliminary evidence that aspects of mindfulness training assisted in improving sexuality outcomes for survivors of cervical and endometrial cancer.

This dissertation research investigates whether MBSR(BC), an adapted MBSR stress reducing program for breast cancer survivors, may affect these symptoms for survivors after treatment along with examining the effect of baseline characteristics, including age, levels of sexual distress, and levels of body image disturbance on this relationship.

## **Chapter Three**

### **Methods**

#### **Introduction**

Chapter three describes the research methods and procedures for this study. This chapter details the design, setting and sample for this dissertation research being conducted within the *R01 MBSR Symptom Cluster Trial for Breast Cancer Survivors/ 1R01CA131080*. In addition, a thorough review of the instruments used to measure the outcome variables is included along with the procedures and data analyses used for the dissertation research.

#### **Research Design**

This pilot study, funded by the National Institute of Nursing Research Predoctoral National Research Service Award (NRSA), Grant #1F31NR013585, was conducted within the *MBSR Symptom Cluster Trial for Breast Cancer Survivors/ 1R01CA131080*. This study used a 2 group randomized design, where interested breast cancer survivors were randomly assigned in a 1:1 ratio to either: (1) the 6-week MBSR(BC) program; or (2) Usual Care (UC) (waitlisted later to the MBSR program). Randomization was stratified by: (1) the type of surgery (lumpectomy vs. mastectomy); (2) BC treatment (chemotherapy with or without radiation vs. radiation alone); and (3) stage of cancer (0-III) and treatment received (radiation  $\pm$  chemotherapy). The current study implemented additional measures of sexual distress and body image to examine the levels of these symptoms in study participants and to determine the impact that the MBSR(BC) program had on these symptoms in BCS.

**Setting.** Participants were recruited from the H. Lee Moffitt Cancer Center and Research Institute as well as the Carol and Frank Morsani Center for Advanced Health Care, both located in Tampa, Florida. The assessments and intervention delivery were implemented at the Survivorship Clinic of the Moffitt Cancer Center and Research Institute.

**Population and Sample.** The primary inclusion criterion for this study were: 1) women age 21 or older; 2) diagnosis of stage 0, I, II, or III breast cancer; 3) completion of lumpectomy and/or mastectomy; 4) between two weeks to two years from end of treatment with adjuvant radiation and/or chemotherapy; 5) read and speak English at the 8th grade level or above; and 6) completion of baseline self-report questionnaires. Exclusion criteria consisted of the following: 1) women who had advanced stage breast cancer (Stage IV); 2) a severe current psychiatric diagnosis e.g. bipolar disorder or schizophrenia; and 3) recurrent treatment for prior breast cancer (Lengacher, 2008). Due to the anticipation of considerable psychological distress among the source population, women with mild yet clinically established depression, anxiety, or other psychiatric conditions were not excluded from the study. Appropriate treatment for these individuals was in place, and referrals for further care were made if any new discoveries with the patient were made during the course of the research. The participants for the research consisted of the remaining 80 participants recruited and enrolled in Dr. Cecile Lengacher's R01 *Symptom Cluster Trial for Breast Cancer Survivors*.

### **Instrumentation**

**Demographic Data.** A demographic questionnaire captured participants' socio-economic demographic data for a description of the sample. Data gathered included age, race/ethnicity, religion, highest level of education completed, marital status, employment status, and income (see Appendix A).

**Clinical History.** A clinical history form captured participants' clinical data for a description of the sample. Data gathered included cancer diagnosis, cancer stage at time of diagnosis, type of breast cancer, length of time since cancer diagnosis, treatment type, and number of weeks on radiation/chemotherapy (see Appendix A).

**Sexual Distress.** Sexual distress was measured by the Female Sexual Distress Scale (FSDS) (Derogatis et al., 2002), designed to measure sexually related personal distress in women. This is a 12-item Likert-type scale with ratings from 0 (never) to 4 (always) (Derogatis et al., 2002) (see Appendix B). Scores range from 0-48 with a higher score correlating with a higher level of sexual distress. This instrument has a Cronbach's alpha coefficient ranging from 0.86-0.92 (Derogatis et al., 2002). Permission was obtained from the author to use this instrument (see Appendix D).

**Body Image Disturbance.** Body image was be measured by the Body Image Scale (Hopwood, Fletcher, Lee, & Al Ghazal, 2001). This tool is designed to measure body image and its distress among cancer patients. This has been previously tested among breast cancer survivors, providing evidence of validity in this population (Hopwood et al., 2001; Marcus et al., 2010). This is a brief, 10-item questionnaire that assesses body image among cancer patients on a Likert-type scale from 0 (not at all) to 3 (very much) (see Appendix C). The items assess affective (i.e. feeling feminine or attractive), behavioral (i.e. difficulty seeing oneself naked, avoiding others due to appearance), and cognitive (i.e. satisfied with appearance) in nature. The final score range is 0-30 with higher scores representing increasing distress. The Cronbach's alpha coefficient for this scale is 0.93 (Hopwood et al., 2001). Permission was obtained from the author to use this instrument (see Appendix D).

## **Procedures**

**Approvals.** This study was approved by the University of South Florida Institutional Review Board (IRB #104708) and the Scientific Review Committee at Moffitt Cancer Center (see Appendix E). All policies for the IRB from Moffitt Cancer Center and Research Institute and the University of South Florida have been and continue to be adhered to. Permission to use the Female Sexual Distress Scale (Derogatis et al., 2002) and the Body Image Scale (Hopwood et al., 2001) was obtained from the developers of each tool (see Appendix D).

**Recruitment.** For consistency in recruitment, a script was developed to describe the study and the recruitment process. Flyers and brochures describing the study were distributed to patients via advertisements within the Moffitt Cancer Center and Research Institute and USF's Carol and Frank Morsani Center for Advanced Healthcare. The distribution of how subjects were contacted and participation rate was tracked. Patients who expressed interest in the study and met the study inclusion criteria were asked to sign a participant interest form prior to enrollment and randomization and were invited to an orientation session.

**Informed Consent.** For women who expressed an interest in the study, the in-person orientation session provided information on the study requirements. All critical elements of the study were reviewed including the informed consent, and the 6-week schedule of the MBSR(BC) program and the questionnaires to be completed at baseline, 6 and 12 weeks. To maximize enrollment and minimize patient dropout, participants were given opportunity, irrespective of the random assignment, to have the opportunity to participate in the MBSR(BC) program (e.g. either initially or following a wait period). If the participants were interested, informed consent was obtained, followed by baseline data collection.

**Data Collection Procedures.** Participants who agreed to participate in the study completed the baseline assessment including collection of demographic data, clinical history forms, the Female Sexual Distress Scale and the Body Image Scale. Data collection intervals for participants included an in-person baseline assessment at the initial orientation, an in-person assessment at the end of the 6-week intervention period, and a follow-up assessment at the study site 12 weeks after baseline enrollment. Data collection occurred for both the intervention and control groups at the baseline orientation session, at the end of the 6-week intervention period, and 12 weeks after baseline enrollment. After baseline data were collected, subjects were randomized to the MBSR(BC) group or UC. If randomized to the MBSR(BC) program, they were scheduled for 6 weekly (2-hour sessions) conducted by a trained professional leader in MBSR(BC). Class sizes consisted of a minimum of 5 to 6 participants. MBSR(BC) participants were instructed to record their meditation, yoga, walking meditation, and body scan practice time in a daily diary during the intervention period as well as during the subsequent 6-week period after the intervention.

**Description of Intervention.** The MBSR(BC) intervention is modeled on the program developed by Jon Kabat-Zinn at the Massachusetts Medical Center (Kabat-Zinn, Lipworth, & Burney, 1985; Kabat-Zinn et al., 1992). The intervention components consist of three processes: 1) educational material related to relaxation, meditation, the mind-body connection and a healthy lifestyle for survivors; 2) practice of meditation techniques in group meetings and homework assignments; and 3) group processes related to barriers to the practice of meditation, application of mindfulness in daily situations (Lengacher et al., 2012). Participants receive training in 4 types of meditation techniques focusing on attention to the breath: 1) sitting meditation; 2) body scan (observing any sensations in the body); and 3) Gentle Hatha Yoga (postures and stretches



that increase awareness and strengthens the musculoskeletal system); and 4) walking meditation, which focuses on attention and awareness with walking activity.

Subjects assigned to the MBSR(BC) group were scheduled for 6 weekly (2-hour sessions) conducted by a trained professional leader in MBSR(BC). Class sizes consisted of a minimum of 5 to 6 participants. MBSR(BC) participants were instructed to record their meditation, yoga, walking meditation, and body scan practice time in a daily diary during the intervention period as well as during the subsequent 6-week period after the intervention.

**Data Management.** The Statistical Package for Social Sciences (SPSS) version 21.0 was utilized for all data entry, data management and data analysis for this pilot study. To maintain patients' confidentiality, data was de-identified and stored in password-protected files secured in the investigator's office. Results were reported using only de-identified data and without patient identifiers.

### **Data Analysis**

Frequency distributions and descriptive statistics were generated for sample characteristics. Although random assignment was expected to balance the two study groups on presenting baseline characteristics, all socio-demographic and clinical variables with a  $p$ -value of less than  $p < .05$  were included as potential covariates for this study.

***Aim # 1: To evaluate the efficacy of the MBSR(BC) program in improving the psychological symptoms of sexual distress and body image related distress.*** The hypothesis being tested was that compared to the usual care regimen, patients randomly assigned to the MBSR(BC) program would experience greater improvements at 6 weeks and sustained improvements at 12 weeks in sexual distress and body related distress. To test this hypothesis, ANCOVA was used to compare adjusted mean outcome scores (sexual distress, body image)

between patients assigned to the MBSR(BC) program versus patients assigned to the Usual Care. The “intent to treat” principle was used, and both outcomes were considered of equal importance. There were two post-MBSR(BC) outcome assessment periods - one at 6 weeks immediately upon completion of the program and one at 12 weeks. This design, coupled with initial baseline assessment, resulted in three separate measures and hence the opportunity for repeated measures analysis. The two post MBSR(BC) outcome assessment periods represented separate questions, thereby warranting separate analyses. First, the efficacy of MBSR(BC) was evaluated using the 6-week assessment period as the outcome period of interest. For this ANCOVA, the baseline value of the outcome variable of interest (i.e. sexual distress and body image disturbance) were included as a covariate, along with all other potential confounding variables not adequately balanced by random assignment. This provided an assessment of the efficacy of MBSR(BC) in improving patient outcome (i.e. sexual distress and body image related distress) in the short-term or immediate and above and beyond improvements that occur simply due to increasing time since treatment completion (as measured in the Usual Care group). In the second analysis, the 12-week assessment period served as the outcome period of interest, again including baseline status of the outcome variable of interest as a covariate along with potential confounding variables. This provided an assessment of the sustainability of MBSR(BC) in improving patient outcomes. Furthermore, linear mixed model analysis was performed to examine change over time of the sexual distress and body image related distress measures based on randomization assignment as well as to examine the interaction of time and randomization assignment for each of the variables.

**Aim # 2: To evaluate whether positive effects achieved from the MBSR(BC) program are modified by specific patient characteristics measured at baseline. It was**

hypothesized that efficacy of the MBSR(BC) program would be greatest among patients with specific distress profiles of high sexual distress and low body image as well as demographic characteristics including younger age, race and ethnicity, stage of disease, and treatment type.. When evaluating whether positive effects achieved from the MBSR(BC) program were modified by specific patient characteristics measured at baseline and that efficacy of the MBSR(BC) program would be greatest among younger patients, several subgroup analyses were conducted to evaluate MBSR(BC) versus Usual Care. The *a priori*-defined subgroups of interest included ages 21-54 and 55 and older. Interaction terms were used to formally test whether the efficacy of MBSR is modified by age. However, a premium was placed on interpreting the results of potential moderating variables based on absolute measures of effect (e.g. adjusted means) rather than statistical significance alone, which is influenced heavily by the number of patients in each subgroup evaluated. Stepwise multiple linear regression was then used to identify the characteristics of participants that were predictors of baseline sexual distress and body image related distress levels.

**Statistical Power.** With a sample size of 80 participants, assuming two-sided type I error rate of 0.05, the study provided 80% power to detect a modest-to-large effect size associated with the MBSR(BC) program (difference in mean levels at 12 weeks between the group and standard deviation) of 0.63. For this study, it was feasible within the R01 Symptom Cluster Trial for Breast Cancer Survivors to collect data from a minimum of 80 participants, an adequate sample size with power to detect medium to large effect size. This was the goal as small effect sizes are not considered clinically meaningful.

**Methodological Issues and Limitations.** Estimates of clinical effectiveness of the MBSR(BC) program may be subject to uncertainty due to assumptions made, as well as the modest sample size of 91 patients.

## **Chapter Four**

### **Results**

#### **Introduction**

This chapter first discusses the descriptive characteristics of the sample, followed by the study findings for Aim 1 and Aim 2 that investigated differences in body image related distress and sexual distress in the MBSR(BC) vs. UC group by randomization assignment. It also summarizes those characteristics identified as predictors of higher levels of sexual distress and body image related distress at baseline, and identified those individuals that received the most benefit from the MBSR(BC) program. These results are presented according to the aims and hypotheses

#### **Participant Characteristics**

The sample consisted of 91 BCS participants out of 322 BCS enrolled in the *R01 Symptoms Cluster Trial for Breast Cancer Survivors/1R01CA131080*. Of these 91 participants, 74 participants were recruited from H. Lee Moffitt Cancer Center and the remaining 17 were recruited from the Carol and Frank Morsani Center for Advanced Healthcare. Participants were enrolled by assigned research staff and a computer-generated random number system was used to randomly assign subjects stratified by stage of cancer (Stage 0 or I versus II or III) and types of treatment (lumpectomy versus mastectomy and radiation with or without chemotherapy) to either the MBSR(BC) or UC group.

Baseline demographic comparisons were completed for all participants. Furthermore, sexual distress and body image related distress data used for analysis was complete for all 91

participants at baseline and the 12-week follow-up. Although at the 6-week follow-up, there were 87 completed assessments for sexual distress and body image related distress and all 91 participants completed the study.

Table 1 illustrates the results related to overall and group comparisons of the demographic characteristics for age and race/ethnicity using the Chi-Square tests to identify any potential differences between groups, not controlled for by randomization. Results include means and standard deviations for age and race/ethnicity by MBSR(BC) vs. UC groups.

*Table 1. Baseline Demographics (Age, Age Categories, and Race/Ethnicity) By Randomization Assignment by Frequency and Percent*

Variable	Total N=91	UC n=41	MBSR(BC) n=50	p value
Mean Age + Standard Deviation (years)	57.46±9.5	56.76±8.3	58.04±10.5	.873
<u>Age Categories</u>				
54≥	34 (37.4)	16 (39.0)	18 (36.0)	.767
55≤	57 (62.6)	25 (61.0)	32 (64.0)	
<u>Race/Ethnicity</u>				
White, Non-Hispanic	67 (73.6)	31 (75.6)	36 (72.0)	.507
White, Hispanic	9 (9.9)	4 (9.8)	5 (10.0)	
Black, Non-Hispanic	11 (12.1)	3 (7.3)	8 (16.0)	
Other	4 (4.4)	3 (7.3)	1 (2.0)	

There were no significant differences between the MBSR(BC) and UC groups on any of the demographic characteristic categories for age and ethnicity. The mean age for the sample was 57.5 years, with the mean age for the MBSR(BC) group being 58 years and 57 years for the UC group. The age group categories for the overall sample included n=34 (37.4%) of the participants being ages 54 and younger, with the MBSR(BC) group having n=18 (36%) ages 54 and younger, and the UC group having n=16 (39%) ages 54 and younger (Table 1). In terms of race and ethnicity, the majority (n=67) of participants were White, non-Hispanic (73.6%), and the

MBSR(BC) group was n=36 (72%) White, non-Hispanic while the Control group included n=31 White, non-Hispanic participants (75.6%).

Table 2 illustrates the overall and comparisons by group (MBSR(BC) and UC) on the demographic characteristics: marital status, educational status, and annual income. Chi-Square tests were implemented to identify any potential differences between groups not controlled for by randomization.

The majority (n=65) of participants in the sample were married (71.4%), and this was similar for both the MBSR(BC) group, with n=35 (70%) of participants being married and for the UC group, with n=30 (73.2%) of participants being married. The education status of the total sample was nearly equally divided between those having some college education or less (n=45, or 49.5%) and those that were a college graduate and above (n=46, or 50.5%). This was consistent with group comparisons, with n=25 of the MBSR(BC) group having some college education or less (50%) and 48.8% of the UC group having some college education or less. The employment status of the sample included n=37 (40.7%) being employed either full or part-time, a category including retired, homemaker, and disabled individuals. The MBSR(BC) group included n=20 (40%) employed and the UC group was made up of n=17 (41.5%) employed participants. Finally, the annual household income was between 0-40,000 for n=39 (42.9%) of the sample, with n=20 (40%) of the MBSR(BC) group participants having an annual household income of 0-40,000 and n=19 (46.3%) of participants in the UC group participants with an annual household income of 0-40,000.

Table 3 presents the results related to stage of disease and type of cancer characteristics of the participants in the total sample, as well as comparisons of the MBSR(BC) and UC group. Patient clinical characteristics were similar by random assignment. The most common type of

breast cancer, ductal carcinoma in situ accounted for n=46 (50.6%) of the sample, followed by invasive ductal, accounting for 25.3% (n=23) of participants. Cancer staging for the sample included Stage 0, n=12 (13.2%); Stage I, n=30 (33%); Stage II, n=30 (33%); Stage III, and n=19 (20.8%).

*Table 2. Baseline Demographics (Marital Status, Education Status, Employment Status, and Annual Household Income of Participants) By Randomization Assignment by Frequency and Percent*

Variable	Total N=91	UC n=41	MBSR(BC) n=50	p value
<u>Marital Status, n (%)</u>				.739
Married	65 (71.4)	30 (73.2)	35 (70.0)	
Unmarried	26 (28.6)	11 (26.8)	15 (30.0)	
<u>Education Status, n (%)</u>				.908
Some College or Less	45 (49.5)	20 (48.8)	25 (50.0)	
College graduate and above	46 (50.5)	21 (51.2)	25 (50.0)	
<u>Employment Status, n (%)</u>				.888
Employed	37 (40.7)	17 (41.5)	20 (40.0)	
Not Employed	54 (59.3)	24 (58.5)	30 (60.0)	
<u>Annual Household Income, n (%)</u>				.644
0-40,000	39 (42.9)	19 (46.3)	20 (40.0)	
40,000-80,000	52 (57.1)	22 (53.7)	30 (60.0)	

*Table 3. Stage of Disease and Type of Breast Cancer of Participants by Randomization Assignment by Frequency and Percent*

Variable	Total N=91	UC n=41	MBSR(BC) n=50	p value
<u>Cancer Stage, n (%)</u>				.490*
0	12 (13.2)	4 (9.8)	8 (16.0)	
1	30 (33.0)	14 (34.1)	16 (32.0)	
2	30 (33.0)	14 (34.1)	16 (32.0)	
3	19 (20.8)	9 (21.0)	10 (20.0)	
<u>Type of Breast Cancer, n (%)</u>				.416
Ductal Carcinoma In Situ	46 (50.6)	17 (41.4)	29 (58.0)	
Invasive lobular	3 (3.3)	2 (4.9)	1 (2.0)	
Invasive ductal	23 (25.3)	12 (29.3)	11 (22.0)	
Not specified	7 (7.7)	5 (12.2)	2 (4.0)	
Unknown	12 (13.2)	5 (12.2)	7 (14.0)	

\*p value for Mantel-Haenszel test for linear trend.



Table 4 presents surgery and post-surgery demographic characteristics including the surgery type, average time since treatment, and treatment type for the sample. The average time since treatment for the total sample was 209 days ( $\pm 163.15$ ). The total participants were nearly evenly split based on surgery type, with  $n=46$  (50.5%) participants having received a lumpectomy and  $n=45$  (49.5%) having received a mastectomy. The treatment type breakdown included  $n=22$  (24.2%) of participants had surgery only,  $n=9$  (9.9%) had received adjuvant treatment with chemotherapy only,  $n=30$  (33%) received radiation only, and  $n=30$  (33%) both chemotherapy and radiation. There were no statistically significant differences between groups (all  $p > .05$ ) for any of the clinical characteristics discussed.

*Table 4. Surgery Type, Treatment Type, and Time Since Treatment for Participants by Randomization Assignment by Frequency and Percent*

Variable	Total n=91	UC n=41	MBSR(BC) n=50	<i>p</i> value
<u>Surgery Type, n (%)</u>				.467
Lumpectomy	46 (50.5)	19 (46.3)	27 (54.0)	
Mastectomy	45 (49.5)	22 (53.7)	23 (46.0)	
<u>Treatment Type, n (%)</u>				.179
Chemotherapy	9 (9.9)	7 (17.1)	2 (4.0)	
Radiation	30 (33.0)	12 (29.3)	18 (36.0)	
Chemotherapy and Radiation	30 (33.0)	14 (34.1)	16 (32.0)	
<i>Table 4 (Continued)</i>				
Surgery only	22 (24.2)	8 (19.5)	14 (28.0)	
<u>Hormonal Therapy Status (%)</u>				.549
Yes	26 (28.6)	13 (31.7)	13 (26.0)	
No	65 (71.4)	28 (68.3)	37 (74.0)	
<u>Time Since Treatment (Days+ Standard Deviation)</u>	209+ 163.15	190+ 142.56	225+ 178.16	.278

In summary, randomization assignment successfully controlled for any potential differences between the two groups in demographic and clinical characteristics. The MBSR(BC) and UC groups were not significantly different for any demographic or treatment factors discussed.

## Research Aim 1

The first aim of this study was to test the efficacy of the MBSR(BC) program in improving the psychological symptoms of sexual distress and body image related distress by use of analysis of covariance (ANCOVA). The hypothesis for this aim was that compared to the UC regimen, patients randomly assigned to the MBSR(BC) program would experience greater improvements at 6 weeks and sustained improvements at 12 weeks in sexual distress and body image related distress.

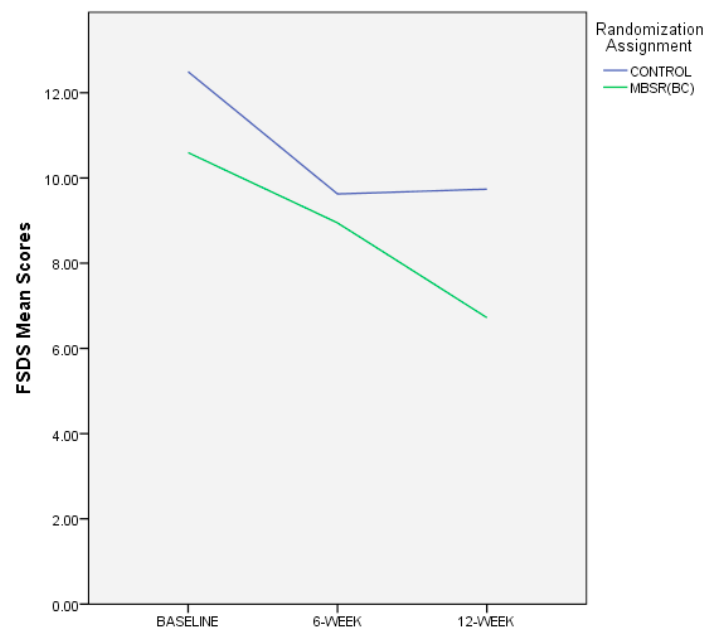
In order to assess the efficacy of the MBSR(BC) program improving symptoms of sexual distress and body image related distress, mean scores and standard deviations for the baseline, 6-week and 12-week assessment time points were calculated and displayed for both the MBSR(BC) and UC groups. Results of the ANCOVA analyses are then presented, first for sexual distress and then for body image related distress. These results compare the MBSR(BC) and UC groups at the 6 and 12-week follow-ups, with baseline scores for each variable entered as a covariate. Finally, results of linear mixed model analyses are presented, evaluating the main effects of randomization assignment and time as well as the potential interaction between randomization assignment and time.

Table 5 presents the number of participants, means and standard deviations for the Female Sexual Distress Scale scores among the MBSR(BC) and UC groups at the baseline, 6 and 12-week assessments. The mean scores at baseline differed between the MBSR(BC) ( $10.79 \pm 9.35$ ) and UC ( $12.50 \pm 10.14$ ) groups for sexual distress (Table 5). The scores decreased steadily in the MBSR(BC) group at both the 6 and 12 week follow-up assessments, with a decrease in the mean score for the MBSR(BC) group to  $8.95 (\pm 10.85)$  at 6 weeks and  $6.18 (\pm 9.01)$  at 12 weeks (Figure 2). For the UC group, the mean score of  $12.50 (\pm 10.14)$  at baseline

is above the cutoff score established by Derogatis and colleagues for Female Sexual Distress (Derogatis et al., 2002). Mean scores in the UC group decreased at 6 weeks to 9.62 ( $\pm 8.83$ ), and then increased minimally at 12 weeks to 9.74 ( $\pm 9.23$ ) (Figure 2). Although the MBSR(BC) and UC groups did not start with the same levels of body image related distress, with the MBSR(BC) group participants having a lower mean score (indicating less disturbance) for this variable when compared to the UC group, these differences were not statistically significant ( $p > .05$ ). Furthermore, the Cohen's  $d$  effect size for change in sexual distress at 6 weeks in the MBSR(BC) and UC groups was  $d = -0.16$  and at 12 weeks was  $d = 0.23$ , indicating small effects.

*Table 5. Means and Standard Deviations for the Female Sexual Distress Scale scores at Baseline, 6 weeks and 12 weeks by Randomization Assignment*

Randomization Assignment	Baseline			6 week follow-up			12 week follow-up		
	<i>N</i>	Mean	Standard Deviation	<i>N</i>	Mean	Standard Deviation	<i>N</i>	Mean	Standard Deviation
MBSR(BC) Group	50	10.79	9.35	46	8.95	10.85	50	6.18	9.01
Control Group	41	12.50	10.14	41	9.62	8.83	41	9.74	9.23



*Figure 2. Mean Female Sexual Distress Scores by Randomization Assignment at Baseline, 6-Week, and 12-Week Follow-Ups.*

Table 6 presents the number of participants, means and standard deviations for the Body Image Scale among the MBSR(BC) and UC groups at the baseline, 6 and 12-week assessments. The mean scores at baseline also differed between the MBSR(BC) ( $7.9 \pm 6.44$ ) and UC ( $8.83 \pm 7.33$ ) groups for body image related distress at baseline (Table 6). The scores for body image related distress decreased steadily in the MBSR(BC) group at both the 6 and 12 week follow-up assessments, with a decrease in the mean score for the MBSR(BC) group to  $5.47 (\pm 6.15)$  at 6 weeks and  $4.46 (\pm 5.50)$  at 12 weeks (Figure 3). For the UC group, the mean score of  $8.83 (\pm 7.73)$  at baseline decreased at 6 weeks to  $6.00$ , and then increased minimally at 12 weeks to  $6.90 (\pm 7.45)$  (Figure 3). This indicates that at the start of the study, the MBSR(BC) and UC groups did not start with the same levels of sexual distress, with the MBSR(BC) group participants having a lower mean score (indicating less distress) for this variable when compared to the UC group, although these differences were not statistically significant ( $p > .05$ ). Furthermore, the Cohen's  $d$  effect size for change in body image related distress at 6 weeks in the MBSR(BC) and UC groups was  $d = -0.14$  and at 12 weeks was  $d = 0.30$ , indicating small effects.

*Table 6. Means and Standard Deviations for the Body Image Scale scores at Baseline, 6 weeks and 12 weeks by Randomization Assignment*

	Baseline			6 week follow-up			12 week follow-up		
	<i>N</i>	Mean	Standard Deviation	<i>N</i>	Mean	Standard Deviation	<i>N</i>	Mean	Standard Deviation
<u>MBSR(BC) Group</u>	50	7.9	6.44	49	5.47	6.15	50	4.46	5.50
<u>Control Group</u>	41	8.83	7.33	41	6.00	6.61	41	6.90	7.45

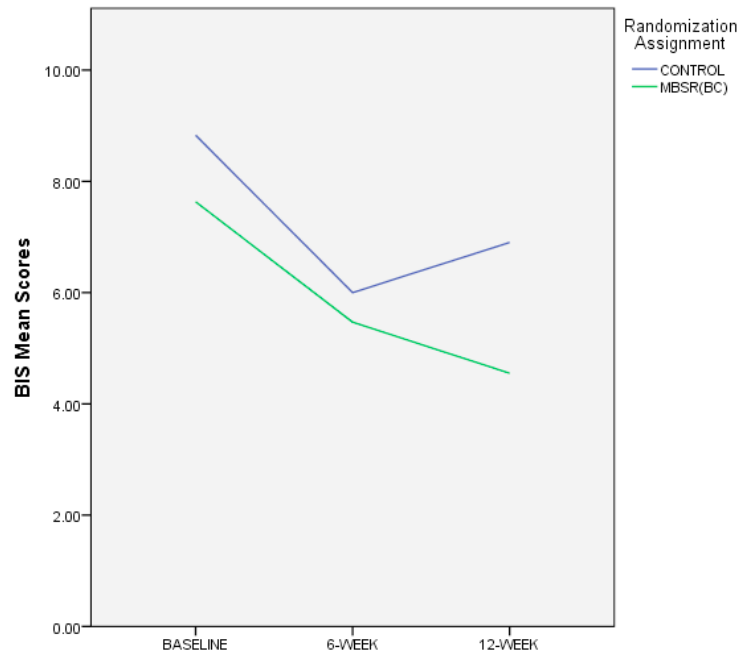


Figure 3. Mean Body Image Scores by Randomization Assignment at Baseline, 6-Week, and 12-Week Follow-Ups.

The ANCOVA results for sexual distress at the 6-week follow-up time point based on randomization assignment and accounting for baseline levels of sexual distress as a covariate in Table 7. There was no significant difference between the MBSR(BC) and control groups at the 6-week follow-up for sexual distress  $F(1, 84) = .200, p > .05$ . There was a significant relationship between baseline female sexual distress scores and scores at the 6-week follow-up  $F(1, 84) = 79.05, p < .0001$ . This indicates that there is no difference based on randomization assignment between baseline and 6-week follow-up for sexual distress but that there is a relationship between baseline and 6-week follow-up scores for sexual distress, particularly considering the adjusted  $R^2$  for the model was .473, meaning that 47% of the variance was explained by this analysis.

Table 8 portrays the ANCOVA results for sexual distress at the 12-week follow-up by randomization assignment with baseline sexual distress scores entered as a covariate. The results

found that there was a trend towards statistical significance for the difference between the MBSR(BC) group and UC group at the 12-week follow-up  $F(1, 88) = 2.88, p = .09$ . In addition, there was a statistically significant relationship between baseline female sexual distress scale scores and the 12-week follow-up scores  $F(1, 88) = 60.08, p < .0001$ . This indicates that the relationship between baseline scores and follow-up scores for sexual distress is still present at the 12-week follow-up, but that the effect of the MBSR(BC) intervention was not statistically significant compared to the UC group for sexual distress at the 12-week follow-up. The adjusted  $R^2$  for the model was .415, meaning that 42% of the variance is explained by this analysis.

*Table 7. ANCOVA Results for Sexual Distress at 6 weeks by Randomization Assignment and Baseline Sexual Distress Scores*

Source	SS	df	MS	F	p value
<u>Baseline FSDS (BFSDS)</u>	4082.96	1	4082.96	79.05*	<.0001
<u>Group</u>	10.35	1	10.35	.200	.656
<u>Error</u>	4338.91	84	51.65		

*Note.*  $R^2 = .485, Adj. R^2 = .473$ .

\*  $p < .0001$

*Table 8. ANCOVA Results for Sexual Distress at 12 weeks by Randomization Assignment and Baseline Sexual Distress Scores*

Source	SS	df	MS	F	p value
<u>Baseline FSDS (BFSDS)</u>	2995.94	1	2995.94	60.08**	<.0001
<u>Group</u>	143.77	1	143.77	2.88*	.09
<u>Error</u>	4388.16	88	49.87		

*Note.*  $R^2 = .428, Adj. R^2 = .415$ .

\*\*  $p < .0001$

\* $p=.09$

Table 9 displays the analysis of covariance (ANCOVA) results comparing adjusted means for body image related distress by randomization at the 6-week follow-up, with baseline body image related distress scores as a covariate. There was no significant effect by randomization group of the MBSR(BC) intervention at 6 weeks on body image related distress  $F$

(1, 87) = 2.00,  $p > .05$ . However, there was a significant relationship between baseline body image related distress and 6-week follow-up levels of body image related distress  $F(1, 87) = 103.24, p < .0001$ . This indicates that baseline body image related distress levels are associated with 6-week follow-up levels of body image related distress, but that there is no difference based on randomization assignment between baseline and 6-week follow-up for body image related distress levels.

*Table 9. ANCOVA Results for Body Image Related Distress at 6 weeks by Randomization Assignment and Baseline Body Image Related Distress Scores*

Source	SS	df	MS	F	$p$ value
<u>Baseline BIS (BBIS)</u>	1932.03	1	1932.03	103.24*	<.0001
<u>Group</u>	2.00	1	2.00	.107	.745
<u>Error</u>	1628.17	87	18.72		

*Note.*  $R^2 = .543, Adj. R^2 = .533$ .

\*  $p < .0001$

Table 10 portrays the ANCOVA results for body image related distress at 12 weeks by randomization assignment, with baseline body image scores as a covariate. Results found that there was a nearly significant difference by randomization assignment at the 12-week follow-up for body image related distress  $F(1, 88) = 3.67, p = .06$ . Furthermore, there was a significant relationship between baseline body image related distress scores and body image related distress scores at the 12-week follow-up  $F(1, 88) = 97.09, p < .0001$ , similar to the findings for the 6-week follow-up. This indicates that the relationship between baseline scores and follow-up scores for body image related distress is still present at the 12-week follow-up. However, although the effect of the intervention was not found to be statistically significant when compared to the UC group for body image related distress at the 12-week follow-up, the trend was in the direction of a positive effect ( $p = .06$ ).

*Table 10. ANCOVA Results for Body Image Related Distress at 12 weeks by Randomization Assignment and Baseline Body Image Related Distress Scores*

Source	SS	df	MS	F	<i>p</i> value
<u>Baseline BIS (BBIS)</u>	1942.95	1	1942.95	97.09**	<.0001
<u>Group</u>	73.38	1	73.38	3.67*	.06
<u>Error</u>	1761.08	88	20.01		

Note.  $R^2 = .541$ ,  $Adj. R^2 = .531$ .

\*\*  $p < .0001$

\* $p = .06$

The results for the Linear Mixed Model analysis of body image related distress by randomization assignment and time are displayed in Table 11. There was a significant main effect of time  $F(2, 85.67) = 15.55, p < .000$ , but the main effect of randomization assignment was not statistically significant  $F(1, 89) = 1.06, p = .307$ . The interaction between time and assignment for this analysis approached significance,  $F(2, 85.67) = 2.73, p = .071$ . This indicates that symptoms of body image related distress improved over time. However, improvement of symptoms was not significantly different based on randomization assignment.

*Table 11. Linear Mixed Model Results for Body Image Related Distress by Randomization Assignment and Time*

Source	df (num, den)	F	<i>p</i> value
<u>Time</u>	(2, 85.67)	15.55	.000
<u>Assignment</u>	(1, 89)	1.06	.307
<u>Time*Assignment</u>	(2, 85.67)	2.73	.071

The results in Table 12 illustrate the findings of the Linear Mixed Model analysis for sexual distress by time and randomization assignment. There was a significant main effect of time  $F(2, 85.96) = 9.53, p < .000$ . The main effect of randomization assignment was not statistically significant  $F(1, 89) = 1.33, p = .252$ . There was a trend towards significance for the time by assignment interaction  $F(1, 85.96) = 2.33, p = .104$ . This indicates that symptoms of



sexual distress improved over time. However, improvement of symptoms was not significantly different based on randomization assignment.

*Table 12. Linear Mixed Model Results for Sexual Distress by Randomization Assignment and Time*

Source	df (num, den)	F	p value
<u>Time</u>	(2, 85.96)	9.53	.000
<u>Assignment</u>	(1, 89)	1.33	.252
<u>Time*Assignment</u>	(2, 85.96)	2.33	.104

In summary, there was a statistically significant relationship between baseline sexual distress and body image related distress scores and both respective 6 and 12-week follow-ups. However, there were no statistically significant differences found between the MBSR(BC) group and the UC group for sexual distress or body image related distress at the 6-week or 12-week follow up time points. Also of interest to note is that there was a significant effect of time for the Linear Mixed Models analysis for both the sexual distress and the body image related distress variables. Furthermore, the interaction term for the Linear Mixed Models analysis of assignment by time for both sexual distress and body image related distress approached significance. However, there was no significant difference based on assignment in the Linear Mixed models analyses for either sexual distress or body image related distress.

## **Research Aim 2**

The second aim of this study was to evaluate whether positive effects achieved from the MBSR(BC) program are modified by specific patient characteristics measured at baseline. It was hypothesized that efficacy of the MBSR(BC) program would be greatest among patients with specific distress profiles of high sexual distress and high body image related distress as well as demographic characteristics including younger age, race and ethnicity, stage of disease, and

treatment type. Although there were no statistically significant effects of the MBSR(BC) intervention compared to UC found, further analyses were conducted to determine the particular characteristics at baseline associated with changes in sexual distress and body image related distress scores as well as the primary predictors of levels of sexual distress and body image related distress at baseline. This was achieved through ANCOVA analyses that accounted for age at baseline as a covariate and stepwise multiple linear regression to identify potential predictors of baseline levels of sexual distress and body image related distress.

Table 13 outlines the ANCOVA results for change in sexual distress at 6 weeks by randomization assignment with age at baseline as a covariate. Results found that age at baseline was not associated with change in sexual distress scores between the baseline and 6-week follow-up  $F(1,83) = 1.659, p = .201$ . There was no statistically significant difference based on randomization assignment for change in sexual distress scores between the baseline and 6-week follow-up  $F(1,83), p = .562$ . Furthermore, the interaction term for age at baseline and randomization assignment was not statistically significant  $F(1,83) = .029, p = .865$ . This indicates that age at baseline was not predictive of change in scores for sexual distress at the 6-week follow-up, and there was no difference based on randomization assignment for changes in 6-week scores for sexual distress.

*Table 13. ANCOVA Interaction Results for Change in Sexual Distress at 6 weeks by Randomization Assignment and Age*

Source	SS	df	MS	F	<i>p</i> value
<u>Age at Baseline</u>	96.807	1	96.807	1.659	.201
<u>Assignment</u>	19.765	1	19.765	.339	.562
<u>Age at Baseline x Assignment</u>	1.699	1	1.699	.029	.865
<u>Error</u>	4484.02	83	58.362		

*Note.*  $R^2 = .026, Adj. R^2 = -.009$ .

The results in Table 14 depict the ANCOVA results for change in body image related distress scores from baseline to 6 weeks by randomization assignment and age at baseline. The results found that age at baseline was associated with change in body image scores from baseline to 6 weeks and age at baseline  $F(1,86) = 7.702, p = .007$ . However, there was no significant effect of group assignment and change in body image related distress scores from baseline to 6-week follow-up  $F(1,83) = .923, p = .339$  and the interaction term for age at baseline and randomization assignment was not statistically significant  $F(1,83) = 2.523, p = .116$ . This indicates that age at baseline was associated with 6-week change scores for body image disturbance, but that there was no difference based on randomization assignment.

*Table 14. ANCOVA Interaction Results for Change in Body Image Related Distress at 6 weeks by Randomization Assignment and Age*

Source	SS	df	MS	F	<i>p</i> value
<u>Age at Baseline</u>	161.175	1	161.175	7.702	.007
<u>Assignment</u>	19.319	1	19.319	.923	.339
<u>Age at Baseline x Assignment</u>	52.804	1	52.804	2.523	.116
<u>Error</u>	1799.58	86	20.925		

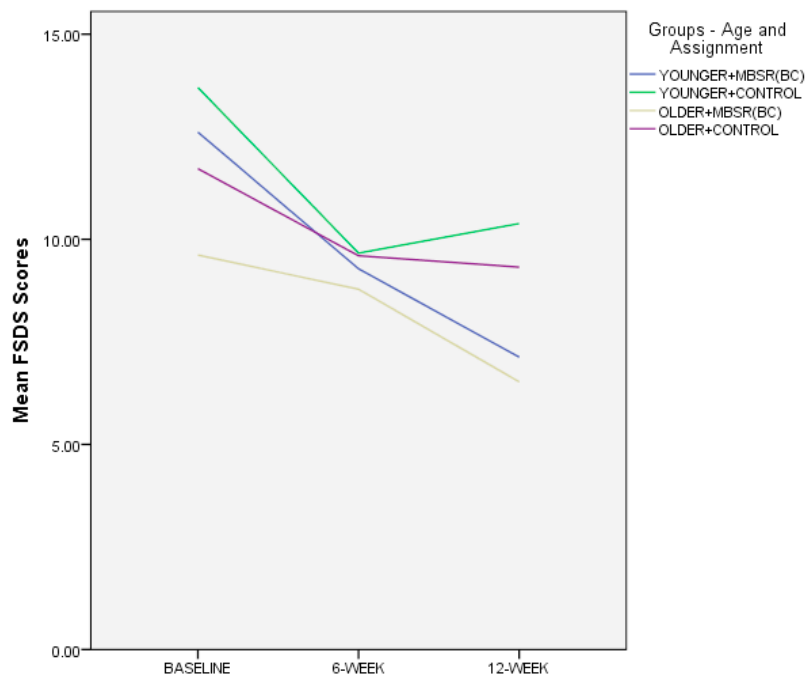
*Note.*  $R^2 = .106, Adj. R^2 = .075$ .

To further investigate the change in levels of sexual distress based on age and randomization assignment in the study, the means and standard deviations as well as sample size at baseline, 6-week and 12-week follow-ups are presented in Table 15 for four subgroups: 1) younger women (ages 54 and younger) in the MBSR(BC) group, 2) older women (ages 55 and older) in the MBSR(BC) group, 3) younger women in the UC group, and finally 4) older women in the UC group. Furthermore, Figure 4 presents the means for each of the four groups at baseline, 6-week and 12-week follow-ups. The findings show that younger women as a whole

started out with higher levels of sexual distress, with the younger MBSR(BC) group showing the most steady decline in symptoms over the 12 weeks. The younger UC group also saw a marked decline in sexual distress at 6 weeks, but then the 12-week follow-up scores indicated an increase. Older women in the MBSR(BC) group started out with lower levels of sexual distress, but also saw a steady decrease in their sexual distress scores over the three time points.

*Table 15. Means and Standard Deviations for the Female Sexual Distress Scale scores at Baseline, 6 weeks and 12 weeks by Age and Assignment*

	Baseline			6 week follow-up			12 week follow-up		
	<i>N</i>	Mean	Standard Deviation	<i>N</i>	Mean	Standard Deviation	<i>N</i>	Mean	Standard Deviation
<u>Younger MBSR(BC) Group</u>	18	13.29	8.98	15	9.28	9.00	18	5.94	8.70
<u>Older MBSR(BC) Group</u>	32	9.39	9.39	31	8.78	11.79	32	6.32	9.32
<u>Younger Control Group</u>	16	13.70	10.85	16	9.66	9.09	16	10.38	9.53
<u>Older Control Group</u>	25	11.72	9.81	25	9.60	8.85	25	9.32	9.20



*Figure 4. Mean Female Sexual Distress Scale Scores Grouped by Randomization Assignment and Age at Baseline, 6-Week, and 12-Week Follow-Ups.*

Similarly, to further investigate the change in levels of body image related distress based on age and randomization assignment in the study, the means and standard deviations as well as sample size at baseline, 6-week and 12-week follow-ups are presented in Table 16 for the same four subgroups: 1) younger women (ages 54 and younger) in the MBSR(BC) group, 2) older women (ages 55 and older) in the MBSR(BC) group, 3) younger women in the UC group, and finally 4) older women in the UC group. Furthermore, Figure 5 presents the means for each of the four groups at baseline, 6-week and 12 –week follow-ups. The findings show that younger women as a whole started out with higher levels of sexual distress, with the younger MBSR(BC) group showing the most steady decline in symptoms over the 12 weeks. The younger UC group also saw a marked decline in body image related distress at 6 weeks, but then the 12-week follow-up scores indicated an increase. The older women in the MBSR(BC) group started with lower levels of body image related distress, but they also reported a steady decline in body image related distress over the 3 time points.

*Table 16. Means and Standard Deviations for the Body Image Scale scores at Baseline, 6 weeks and 12 weeks by Age and Assignment*

	Baseline			6 week follow-up			12 week follow-up		
	<i>N</i>	Mean	Standard Deviation	<i>N</i>	Mean	Standard Deviation	<i>N</i>	Mean	Standard Deviation
<u>Younger MBSR(BC) Group</u>	18	9.28	6.35	17	5.64	5.74	18	4.61	5.20
<u>Older MBSR(BC) Group</u>	32	7.13	6.45	32	5.38	6.44	32	4.38	5.74
<u>Younger Control Group</u>	16	10.75	7.51	16	5.25	5.70	16	7.00	7.73
<u>Older Control Group</u>	25	7.60	7.10	25	6.48	7.20	25	6.84	7.43

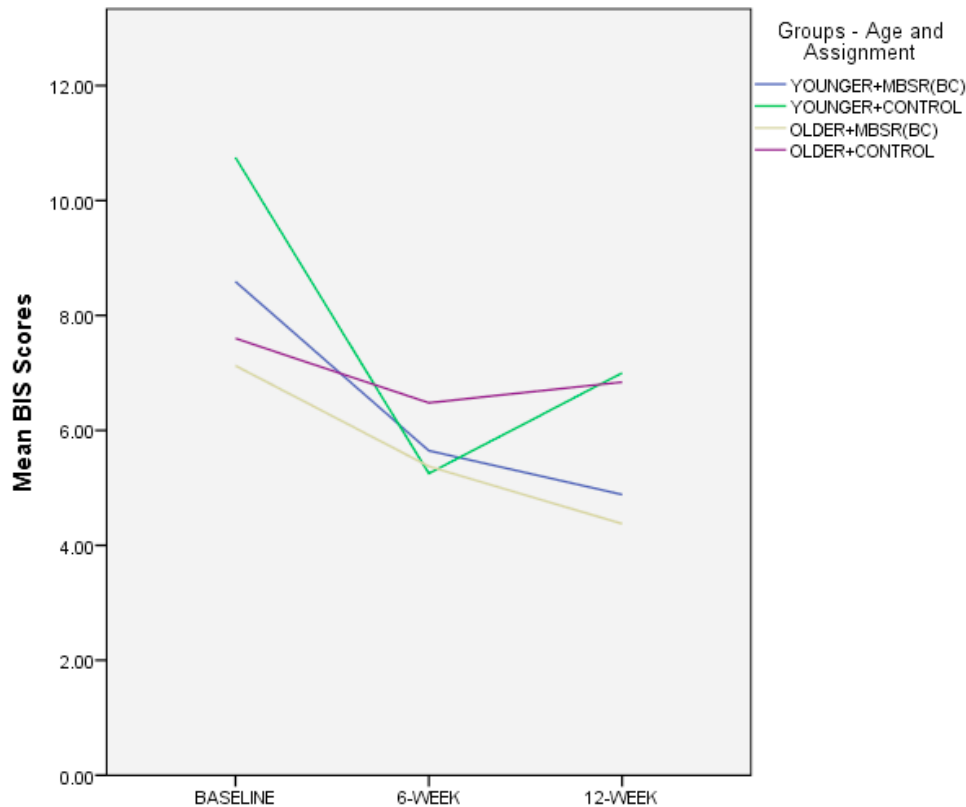


Figure 5. Mean Body Image Scores Grouped by Randomization Assignment and Age at Baseline, 6-Week, and 12-Week Follow-Ups.

Table 17 reports results of the stepwise multiple linear regression analysis to identify which of the clinical and demographic characteristics at baseline predicted the baseline levels of sexual distress. The analysis evaluated age at baseline, treatment regimen, hormone therapy status, and time since treatment and their strength as potential predictors of baseline sexual distress scores. The unstandardized and standardized  $\beta$  coefficients, t-test,  $p$  value, and the adjusted  $R^2$  for the model are displayed in Table 17. Results found that age at baseline was the only statistically significant predictor of baseline sexual distress scores ( $p = .004$ ) of all those in the model. The model explained 7.8% of the variance in baseline sexual distress scores. This indicates that although the majority of predictors examined were not predictive of baseline

sexual distress levels, age at baseline was a significant predictor of baseline sexual distress levels.

*Table 17. Predictors (Stepwise Multiple Linear Regression) of Sexual Distress at Baseline*

Dependent Variable	Primary Predictors	Unstandardized Coefficient		Standardized Coefficients	T	p value
		B	Std. Error	Beta		
<u>Baseline Sexual Distress</u>	<b>Included:</b>					
	Intercept	28.92	6.00		4.82	.000
	Age at Baseline	-.302	.103	-.297	-2.93	.004*
	<b>Excluded:</b>					
	Treatment Regimen				1.20	.232
Hormone Therapy Status				1.16	.251	
Time Since Tx				.676	.501	
Adjusted R squared						.078

\* Predictor is significant at the 0.05 level.

The results of the stepwise multiple linear regression analysis to identify which of the clinical and demographic characteristics at baseline predicted the baseline levels of body image related distress are reported in Table 18. The analysis evaluated age at baseline, treatment regimen, hormone therapy status, and time since treatment and their strength as potential predictors of baseline body image related distress scores. The unstandardized and standardized  $\beta$  coefficients, t-test,  $p$  value, and the adjusted  $R^2$  for the model are displayed in Table 18. Results found that age at baseline was the only statistically significant predictor of baseline body image related distress scores ( $p = .008$ ) of all those in the model. The model explained 6.6% of the variance in baseline body image related distress scores. This indicates that although the majority

of the predictors evaluated were not associated with baseline body image related distress levels, age at baseline was indicative of baseline body image related distress levels.

*Table 18. Predictors (Stepwise Multiple Linear Regression) of Body Image Related Distress at Baseline*

Dependent Variable	Primary Predictors	Unstandardized Coefficient		Standardized Coefficients	T	p value
		B	Std. Error	Beta		
<u>Baseline Body Image Related Distress</u>	<b>Included:</b>					
	Intercept	19.71	4.26		4.63	.000
	Age at Baseline	-.198	.073	-.276	-2.71	.008*
	<b>Excluded:</b>					
	Treatment Regimen				1.14	.260
Hormone Therapy Status				1.05	.296	
Time Since Tx				-.167	.867	
Adjusted R squared						.066

*\*Predictor is significant at the 0.05 level.*

In summary, the results of the aim 2 ANCOVA analyses that examined age at baseline as a covariate with randomization assignment and their impact on the 6-week change scores for sexual distress and body image related distress found a significant relationship between age at baseline and 6-week change scores for body image related distress, but no significant differences for sexual distress. Furthermore, when evaluating predictors, age at baseline was the only statistically significant predictor of sexual distress and body image related distress scores at baseline.

### Summary

The results of this study found that although scores for sexual distress and body image related distress improved over time (both  $p < .001$ ), baseline sexual distress and body image



related distress scores were predictive of both the 6 and 12-week follow-up levels. Although there was no significant effect of the MBSR(BC) program for body image related distress or sexual distress scores at the 6-week follow-up (both  $p > .05$ ), there was a trend based on randomization assignment at the 12-week follow-up, with the MBSR(BC) group experiencing greater improvement in sexual distress ( $p = .09$ ) and body image related distress ( $p = .06$ ). Furthermore, although there were no statistically significant differences between the MBSR(BC) group and the UC group for sexual distress or body image related distress at the 6-week or 12-week follow up time points, results by randomization assignment were in the direction of a positive effect for both sexual distress ( $p = .252$ ) and body image related distress ( $p = .307$ ), with greater symptom reduction in the MBSR(BC) group. There was also a trend towards significance for the interaction between time and randomization assignment for body image related distress ( $p = .07$ ) and sexual distress ( $p = .104$ ), with the MBSR(BC) group experiencing greater reduction in symptoms.

In terms of age, there was a significant relationship between age at baseline and 6-week change scores for body image related distress ( $p = .007$ ) but not sexual distress ( $p = .201$ ). The interaction between age at baseline and randomization assignment was not statistically significant for either sexual distress ( $p = .865$ ) or body image related distress ( $p = .116$ ). Furthermore, age at baseline was a significant predictor for both sexual distress ( $p = .004$ ) and body image related distress ( $p = .008$ ), with younger age being predictive of higher levels of sexual distress and body image related distress at baseline. This indicated that for these symptoms, age may be a predictive characteristic that can be used to identify those that may exhibit higher levels of sexual distress and body image related distress after treatment for breast cancer.

## **Chapter Five**

### **Discussion, Conclusions, and Recommendations**

#### **Introduction**

The final chapter of the dissertation includes a synthesis of the results from the study with discussion of the findings, conclusions, implications for nursing and future research recommendations. The purpose of this study was to formally evaluate sexual distress and body image related-distress in younger women with breast cancer and examine the extent to which the Mindfulness-Based Stress Reduction-Breast Cancer (MBSR(BC)) as a stress reducing program is efficacious in improving distress related to sexuality, i.e. sexual distress and body image related-distress. In addition, this study also evaluated whether younger breast cancer survivors derive more benefit from MBSR(BC) compared to older breast cancer survivors.

#### **Summary of the Study**

This study was conducted within the *R01 MBSR Symptom Cluster Trial for Breast Cancer Survivors*, 1R01CA131080. The sample included 91 women diagnosed with breast cancer (Stages 0, I, II, or III) and had received a lumpectomy or mastectomy and were within 2 weeks to 2 years post-treatment with surgery and any adjuvant chemotherapy and/or radiation treatment. Participants completed a demographic data form as well as the FSIDS and BIS assessments at an orientation session, 6-week follow-up and 12-week follow-up. These assessments were conducted in-person at the Survivorship Clinic located within the Moffitt Cancer Center and Research Institute. Baseline data collection took place prior to randomization

to either the MBSR(BC) intervention or the Usual Care group, and the intervention was delivered to those in the MBSR(BC) group in-person at the Survivorship Clinic at Moffitt Cancer Center and Research Institute, with waitlisted enrollment in the MBSR(BC) classes available after completion of the 12-week follow-up for participants in the Usual Care group.

Descriptive data were also obtained from participants and demographic data was illustrated using means and standard deviations, percentages, and statistical comparisons using Chi Square tests of the MBSR(BC) and Usual Care groups. To explore sexual distress and body image related distress among breast cancer survivors and the impact of the MBSR(BC) intervention on these outcomes, two aims were proposed. For aim 1, analysis of covariance was used to test the between-group differences for the sexual distress and body image related distress variables, controlling for baseline scores of each variable. This was tested for both the 6-week and 12-week follow-ups for each variable. Linear mixed models analysis was used to determine the main effects of time and randomization assignment between the MBSR(BC) and Usual Care groups, as well as to test for interaction of time and treatment group. For aim 2, analysis of covariance was used to test the between-group differences for the sexual distress and body image related distress 6-week change scores, with age at baseline as a covariate. Stepwise multiple linear regression was used to identify the clinical characteristics predictive of baseline levels of sexual distress and body image related distress in the sample.

## **Discussion and Conclusion**

The study yielded four main findings. First, while there was no significant difference between the MBSR(BC) and Usual Care groups for sexual distress or body image related distress at 6 weeks, there were trends towards significant differences at 12 weeks for both variables, with the MBSR(BC) group experiencing greater improvements in sexual distress and body image

related distress. The Cohen's *d* effect sizes for change in body image related distress and sexual distress at 6-week and 12-week follow-ups were in the range of what is considered to be a small effect size. Second, baseline scores for sexual distress and body image related distress, independent of randomization assignment, were a strong predictor of 6 and 12-week follow-up scores for each of the variables, accounting for over 50% of the variance in each case. Third, there was a main effect of time for both body image related distress and sexual distress independent of randomization assignment, with further analysis showing that younger age indicated higher levels of sexual distress and body image related distress at baseline, and younger women in the MBSR(BC) group were found to have the steadiest decrease in symptoms of sexual distress and body image related distress over the three assessment time points. Finally, age at baseline was a significant predictor of the levels of both body image related distress and sexual distress at baseline. The following discussion outlines the demographic and clinical treatment characteristics of the sample followed by the findings according to the two aims of the study and conclusions that can be drawn from the findings. Limitations of the study as well as directions for future research are also presented.

The sample was relatively diverse in terms of race/ethnicity, with only 67 (73.6%) of participants identifying themselves as White, non-Hispanic. There were 9% White, Hispanic and 12% Black, non-Hispanic that participated, identifying a fair level of interest in the study from diverse racial and ethnic backgrounds. The mean age for the overall sample was 57.46 ( $\pm 9.5$ ) and there were 34 participants (37.4%) ages 54 and younger. The majority of the sample was married (71.4%), and approximately half of the sample had completed a college degree (50.5%). Less than half of the participants were employed at the time of the study (40.7%) and annual household income was \$40,000 or higher for more than half of participants (57.1%). In terms of

treatment characteristics, the majority of participants had Stage I-II breast cancer (66%) and the sample had almost equal numbers of those that received a mastectomy (49.5%) and lumpectomy (50.5%). Most participants received adjuvant treatment with radiation or chemotherapy and radiation (66%). There were no significant differences between the two groups for any of the demographic (race/ethnicity, age groups, mean age, education status, marital status, employment status, and annual household income) or clinical (stage, cancer type, average time since treatment, cancer stage, surgery type, and adjuvant treatment) characteristics. These findings are congruent with the findings of a mindfulness intervention study for gynecologic cancers, which found no significant differences based on demographics or clinical characteristics (Brotto et al., 2012). Other intervention studies implemented with breast cancer survivors that aimed to improve symptoms of body image related distress and/or sexual distress also found no statistically significant differences between the intervention and control groups for baseline demographic and clinical characteristics (Jun et al., 2011; Speck et al., 2010)

The first aim was assessed using ANCOVA to determine the between-group differences for body image related distress and sexual distress from baseline to 6-week follow-up and baseline to 12-week follow-up. The baseline scores for each variable were controlled for as a covariate. Results of the ANCOVA analyses found no significant difference in the MBSR(BC) vs. Usual Care groups for body image related distress or sexual distress scores at 6-week follow-up (both  $p > .05$ ). However, the results were in the direction of positive effects and there was also a trend towards significant differences based on randomization assignment for both body image related distress ( $p = .06$ ) and sexual distress ( $p = .09$ ) at the 12-week follow-up, with the MBSR(BC) group experiencing greater improvement in sexual distress and body image related distress. This potentially indicates an effect of the intervention in reducing the symptoms of

sexual distress and body image related distress in the MBSR(BC) group over time. Also important to consider is the significant relationship between baseline body image related distress and sexual distress scores and both the 6-week and 12-week follow-up scores (all  $p < .0001$ ), with younger women experiencing higher levels of sexual distress and body image related distress at baseline.

The MBSR(BC) program is one that gives careful consideration to the breast cancer survivors' health status and symptom management for specific emotional/psychological symptoms (anxiety, depression and fear of recurrence) and physical symptoms such as pain and sleep (Lengacher et al., 2009). Although no significant effect of the MBSR(BC) intervention was found based on randomization assignment in this study, it is important to interpret these results while bearing in mind that this sub-study did not permit adaptation of the MBSR(BC) intervention to include specific information related to sexual distress or body image related distress. The limited existing literature focused on this area of research identifies mindfulness-based stress reduction as a promising intervention to address sexuality issues after treatment for cancer, particularly when the intervention has been tailored to address these areas of survivorship (Brotto et al., 2012; Brotto et al., 2008). Interventions with significant effects in regard to sexual outcomes are effective when issues of self-identity, including body image and sexuality are addressed, and mindfulness practice has been identified as beneficial for both individuals and couples addressing self-identity and body image after treatment for cancer (Johnston, 2012). Furthermore, interventions with an exercise component have been shown to improve body image related distress after treatment for breast cancer (Benton et al., 2013; Speck et al., 2010), with one study also finding that the intervention was particularly effective in younger women (Benton et al., 2013). Although the intervention in this study was tailored to symptom management after

breast cancer, the intervention used in this study was not specifically tailored to include information about issues of self-identity in the context of body image and sexuality in particular may have limited the ability of the program to significantly improve these symptoms.

Further analysis pertinent to aim 1 was conducted using linear mixed model analysis to examine the main effects of time and randomization assignment on the outcomes of sexual distress and body image related distress, and also the potential for interaction between time and randomization assignment for each variable. There was a significant main effect of time for both sexual distress and body image related distress (both  $p < .001$ ), and overall levels of sexual distress and body image related distress decreased over time. The main effect of randomization assignment was not statistically significant for either sexual distress ( $p = .252$ ) or body image related distress ( $p = .307$ ), however the results were in the direction of a positive effect, with greater symptom reduction in the MBSR(BC) group vs. the UC group. There was also a trend towards significance for the interaction between time and randomization assignment for body image related distress ( $p = .07$ ), and although the interaction between time and randomization assignment for sexual distress was not statistically significant ( $p = .104$ ), the results did trend in the direction of positive effects, with the MBSR(BC) group experiencing greater reduction in symptoms of sexual distress and body image related distress.

Although there was improvement in both sexual distress and body image over time in this study independent of group assignment, it is recognized that changes to sexual well-being can be one of the most problematic aspects of life after breast cancer, with the impact lasting for many years after successful treatment, often associated with serious physical and emotional adverse effects (Ussher, Perz, & Gilbert, 2012). Altered physical appearance due to, for example, removal of a breast can affect body image and sexuality (Schover et al., 2006). Studies have

shown that difficulties related to sexuality are common, but also that they occur most often immediately following surgical and adjuvant treatment, and particularly so in younger age cohorts (Fobair et al., 2006; Jun et al., 2011; Katz, 2011).

Analyses for aim 2 included ANCOVA and compared the MBSR(BC) and Usual Care groups for sexual distress and body image related distress 6-week change scores with age at baseline included as a covariate. There were no significant differences based on randomization assignment for the 6-week change scores of either sexual distress ( $p = .562$ ) or body image related distress ( $p = .339$ ). Age at baseline had no significant relationship to 6-week change scores for sexual distress ( $p = .201$ ) but there was a significant relationship between age at baseline and 6-week change scores for body image related distress ( $p = .007$ ). The interaction between age at baseline and randomization assignment was not statistically significant for either sexual distress ( $p = .865$ ) or body image related distress ( $p = .116$ ).

Although the only statistically significant finding was for the relationship between age at baseline and 6-week change scores for body image related distress, further investigation found that the subgroups of younger women in the study experienced higher mean scores for both body image related distress and sexual distress when compared to older women. The scientific literature supports this finding, and younger age had often been associated with higher levels of both sexual distress and body image related distress among breast cancer survivors in previous research (Andrzejczak et al., 2013; Bakht, 2010; Begovic-Juhant et al., 2012; Chung et al., 2009; Elmir et al., 2010; Hartl et al., 2010; Hopwood et al., 2007; Kenny et al., 2000; Moreira & Canavarro, 2010; Przewdziecki et al., 2013). In a study conducted by Andrzejczak and colleagues (2013), 80% of women in the youngest group (34-49) reported covering up their body for aesthetic reasons during intimate relations, while 73% in the middle age group (50-65) and 58%



in the oldest (> 65) reported the same behavior (Andrzejczak et al., 2013). Younger women have also been found to place a greater importance on their breasts in sexuality and femininity ( $p = 0.009$ ) (Kenny et al., 2000). In a qualitative exploration of African American women, the breast cancer survivors expressed needs for positive body image valuations as well as additional need for information about age-specific concerns related to body image and sexuality for younger women (Chung et al., 2009). In a comparison of younger women (ages 50 and younger) to healthy controls, findings included significantly worse total body image scores among the younger breast cancer survivors (Bakht & Najafi, 2010). However, the literature in this area is not entirely conclusive, with two studies found comparing younger women treated for breast cancer to older women treated for breast cancer that did not find a significant difference in body image by age (Miller et al., 2013; Speck et al., 2010) and two other studies found that younger women treated for breast cancer actually had a better body image perception than older women treated for breast cancer (Benton et al., 2013; Pikler & Winterowd, 2003).

Finally, stepwise multiple linear regression was performed to identify potential predictors of levels of sexual distress and body image related distress at baseline. Results found that age at baseline was a significant predictor for both sexual distress ( $p = .004$ ) and body image related distress ( $p = .008$ ), with younger age being predictive of higher levels of sexual distress and body image related distress at baseline. This indicates that for both body image related distress and sexual distress, age is a predictive characteristic that can be used to identify those that may exhibit higher levels of sexual distress and body image related distress after treatment for breast cancer.

Younger age as a predictor of worse body image is consistent with other findings in the literature (Zimmermann, Scott, & Heinrichs, 2010). The existing literature also supports the

finding of a trend towards surgery type predicting levels of body image related distress, with surgery type having an impact on appearance satisfaction being well-documented in previous research (Al-Ghazal, Fallowfield, & Blamey, 2000; Arora et al., 2001; Avis et al., 2004; Fobair et al., 2006; Janz et al., 2005; Mahapatro & Parkar, 2005; Moreira & Canavarro, 2010). A study by King et al. (2000) found that there was a negative impact of mastectomy on body image in married women, particularly younger married women (King, Kenny, Shiell, Hall, & Boyages, 2000). In a qualitative exploration of this topic among breast cancer survivors ages 50 and younger, participants discussed their body image with respect to femininity and sexuality as a result of surgery, including one participant who expressed issues of body disfigurement because of breast surgery and another talking about her inability to feel desirable towards her husband as a result of breast surgery (Elmir et al., 2010). Younger women have been found to be more likely to opt for breast reconstruction (Fallbjork et al., 2013; Lardi et al., 2013), to have better body image than those that did not undergo reconstruction (De Gournay et al., 2010) and also more likely to opt for further plastic surgery to improve cosmetic results even after breast-conserving surgery (Bani et al., 2008).

In summary, although there were no significant main effects supporting a reduction in symptoms for women who received the MBSR(BC) intervention vs. Usual Care in this study, there were a number of results that were in the direction of positive effects in the MBSR(BC) compared to UC group. Furthermore, the lack of significant findings is inconsistent with other existing literature supporting the use of mindfulness meditation to address sexuality and body image issues in women after treatment for cancer. Age at baseline was associated with change scores at 6 week follow-ups, which is consistent with the majority of the existing literature that identifies younger women as at greater risk for body image related distress and sexual distress

issues after treatment. Finally, existing literature supports the findings that age at baseline may be predictive of baseline body image related distress and sexual distress.

**Limitations.** There are limitations to this study that are essential to discuss. There is the possibility that due to a relatively small sample size there may be greater sample variability, and subsequently an underestimation or overestimation of the extent of relationships identified. Furthermore, there were a number of nearly statistically significant trends identified in the results of this study. There may be a relationship in the hypothesized direction for these trends, but the ability of this study to elucidate these relationships may have been limited by sample size constraints. With larger sample sizes, the analyses that identified trends may have been statistically significant. Another limitation of this study is that, even with randomization of participants, the MBSR(BC) and Usual Care groups did not have the same scores at baseline for either sexual distress or body image related distress, with the Usual Care group starting the study with higher scores for both variables. This may have dampened the potential to assess the true impact of the MBSR(BC) intervention, with sizeable differences between the two groups at baseline. Furthermore, setting this study within the larger R01 trial limited the ability to insure that balanced numbers of younger and older women were recruited, and as a result there were less younger women included in the study, which may have limited the extent to which the study could make age comparisons. Also, the nature of this sub-study did not allow for the adaptation of the intervention to include specific applications of the mindfulness program to issues related to sexual distress and body image related distress, potentially limiting the ability of the intervention to have a significant effect on these symptoms.

## **Implications for Nursing**

Although further empirical research is needed in this area, the nurse caring for an individual as they transition into survivorship is in an ideal situation to conduct an assessment of body image and sexuality concerns and to start an open dialogue regarding these topics. This rapport can make it easier for patients to feel comfortable discussing their concerns related to these sensitive topic areas with the nurse, and in turn, the nurse will be able to provide the patient with resources to help patients better understand and address these concerns after cancer treatment. While the National Cancer Institute acknowledges that further research related to interventions for sexuality and body image is necessary, they have resources available to the nurse that can be used to address and discuss these concerns with breast cancer patients (National Cancer Institute, 2013). This is an important issue in treatment and survivorship care, and one that needs to be addressed with patients on a regular basis throughout the cancer continuum.

## **Recommendations for Future Study**

Based on the existing scientific literature in this area and the findings of the current study, the following are future research recommendations for this area of study.

1. To replicate the current study with a larger sample size, with recruitment procedures in place that require matching younger women and older women in a 1:1 ratio.
2. Adapt the current MBSR(BC) intervention to include an explicit focus on the ways that the content can be applied to improvement of symptoms of sexual distress and body image related distress, subsequently pilot-testing the adapted intervention.
3. Initiate a study examining sexual distress and body image related distress starting with initial assessments conducted prior to participants undergoing surgery and

adjuvant treatments and delivery of the intervention earlier in the treatment care plan, with longitudinal follow-ups after treatment is received.

4. A qualitative exploration of the optimal timing of this intervention in the treatment trajectory may provide further insight into the time from diagnosis through treatment and into survivorship that may be best to target for delivery of the MBSR(BC) intervention, as well as the most distressing symptoms that addressing specifically may be most desired by women treated for breast cancer.
5. Establishment of a clinical recommendation for nurses and advanced practice nurses to identify those that may be most at-risk for sexual distress and body image related distress and therefore would derive the most benefit from screening and intervention for these symptoms.

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## **Appendices**





## Appendix A: (Continued)

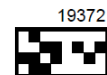
Today's Date:  /  /  Randomization #:  Group #:

What is your income? (choose only one response)

- Less than \$10,000
- \$10,000 to < \$20,000
- \$20,000 to < \$40,000
- \$40,000 to < \$80,000
- \$80,000 to < \$100,000
- \$100,000 or more

Type of employment (choose only one response)

- Forestry, fishing, hunting and agricultural support
- Mining
- Utilities
- Construction
- Manufacturing
- Wholesale trade
- Retail trade
- Transportation and warehousing
- Information
- Finance and Insurance
- Real estate and rental and leasing
- Professional, scientific, and technical services
- Management of companies and enterprises
- Administration, support, waste management, remediation services
- Educational services
- Health care and social assistance
- Arts, entertainment, and recreation
- Accommodation and food services
- Other services



**Appendix A: (Continued)**

Today's Date:  /  /  Randomization #:  Group #:

**Clinical History**

**1. Medical History**

**Current Episode of Breast**  
Please enter the details of this episode here:

1. Type of breast cancer:  Lobular carcinoma in-situ (LCIS)  Invasive lobular  
 Ductal carcinoma in-situ (DCIS)  Invasive ductal  
 Not specified  Unknown  
 Other

Date of diagnosis (mm/dd/yyyy)  
 /  /

Side  
 Left  Right  Both  Unknown

If "Other", please describe:

Treatment  
 Chemotherapy  Radiation therapy  
 Hormone therapy  Surgery

**Personal History of Cancers Other than Breast Cancer:**  Yes  No  Unknown  
If "Yes", please enter the details here:

1.

Year of diagnosis  Treatment (check all that apply)  
 Chemotherapy  Radiation therapy  None  
 Hormone therapy  Surgery  Other

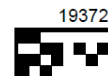
2.

Year of diagnosis  Treatment  
 Chemotherapy  Radiation therapy  None  
 Hormone therapy  Surgery  Other

**Which option below best describes your current level of physical activity WITHIN THE PAST WEEK?**  
Please choose only one response.

Fully active, able to carry on all usual activities without restrictions  
 Restricted in physically strenuous activity, but can walk and is able to carry out light housework  
 Can walk and take care of yourself, but unable to carry out any work activities. Up more than half a day  
 Need some help taking care of yourself, spend more than half a day in bed or a chair  
 Cannot take care of yourself at all, and spend all of time in bed or a chair

**Do you perform Breast self exams:**  No  Weekly  Monthly  Occasionally



Appendix A: (Continued)

Today's Date: [ ]/[ ]/[ ] Randomization #: [ ] Group #: [ ]

Clinical History

2. Medical History (Please answer ALL of the following questions related to your health)

Have you ever had a heart attack? [ ] No [ ] Yes

Have you ever been treated for heart failure? (You may have been short of breath and the doctor may have told you that you had fluid in your lungs or that your heart was not pumping.) [ ] No [ ] Yes

Have you ever had an operation to unclog or bypass the arteries in your arms or legs? [ ] No [ ] Yes

Have you ever had a stroke, cerebrovascular accident, blood clot or bleeding in the brain or transient ischemic attack (TIA)? [ ] No [ ] Yes

If Yes, do you have difficulty moving an arm or leg as a result of a stroke or a cerebrovascular accident? [ ] No [ ] Yes

Do you have asthma, emphysema, chronic bronchitis or chronic obstructive lung disease? [ ] No [ ] Yes

If Yes, take medication for your condition (either on a regular basis or just for flare-ups)? [ ] No [ ] Yes

Do you have stomach ulcers or peptic ulcer disease? [ ] No [ ] Yes

If Yes, was this condition diagnosed by endoscopy (where a doctor looks into your stomach through a scope), or an upper GI or barium swallow study (where you swallow chalky dye and then x-rays are taken)? [ ] No [ ] Yes

Do you have diabetes or high blood sugar? [ ] No [ ] Yes

If Yes, please answer the following questions:
Is it treated by monitoring your diet? [ ] No [ ] Yes
Is it treated by medications taken by mouth? [ ] No [ ] Yes
Is it treated by insulin injections? [ ] No [ ] Yes

Has your diabetes caused problems with your kidneys or problems with your eyes treated by an ophthalmologist? [ ] No [ ] Yes

Have you ever had problems with your kidneys? [ ] No [ ] Yes

If Yes, please answer the following questions:

Have you had poor kidney function with blood tests showing high creatinine levels? [ ] No [ ] Yes

Have you used hemodialysis or peritoneal dialysis? [ ] No [ ] Yes

Have you received a kidney transplant? [ ] No [ ] Yes

Do you have rheumatoid arthritis? [ ] No [ ] Yes

If Yes, do you take medication for your arthritis regularly? [ ] No [ ] Yes

Do you have lupus (systemic lupus erythematosus) or polymyalgia rheumatica? [ ] No [ ] Yes

Do you have Alzheimer's Disease or another form of dementia? [ ] No [ ] Yes

Do you have cirrhosis or severe liver disease? [ ] No [ ] Yes

Do you have leukemia or polycythemia vera? [ ] No [ ] Yes

Do you have lymphoma? [ ] No [ ] Yes

Do you have AIDS (HIV)? This question is optional. [ ] No [ ] Yes

Do you have any other cancer (other than breast cancer, skin cancer, leukemia or lymphoma)? [ ] No [ ] Yes

If Yes, has the cancer spread or metastasized to other parts of your body? [ ] No [ ] Yes

Do you have any other medical problems?

If Yes, please describe the problem(s) here:

[Empty text box for describing medical problems]

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## Appendix A: (Continued)

Today's Date:  /  /  Randomization #:  Group #:

### Clinical History

#### 3. Past Surgical History

<b>Hysterectomy</b> (Removal of the uterus):	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Unknown		
Date of hysterectomy (mm/dd/yyyy):	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Reason for hysterectomy:	<input type="radio"/> Excessive bleeding	<input type="radio"/> Endometriosis			
	<input type="radio"/> Uterine fibroid	<input type="radio"/> Unknown			
	<input type="radio"/> Cancer	<input type="radio"/> Other			
If "Other", please specify:	<input type="text"/>				

<b>Oophorectomy</b> (Removal of an ovary):	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Unknown		
Date of oophorectomy (mm/dd/yyyy):	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Side of oophorectomy:	<input type="radio"/> Left	<input type="radio"/> Right	<input type="radio"/> Bilateral	<input type="radio"/> Unknown	
Reason for oophorectomy:	<input type="radio"/> During hysterectomy	<input type="radio"/> Benign ovarian mass			
	<input type="radio"/> Ovarian cancer	<input type="radio"/> Endometrial cancer			
	<input type="radio"/> Ovarian cyst	<input type="radio"/> Other			
If "Other", please specify:	<input type="text"/>				

#### 4. Diagnostic Studies

<b>Mammograms</b>					
Date of most recent mammogram (mm/dd/yyyy):	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Age at most recent mammogram (years):	<input type="text"/> <input type="text"/> <input type="text"/>				
Location of most recent mammogram (Name of facility):	<input type="text"/>				
Result of most recent mammogram:	<input type="radio"/> Normal	<input type="radio"/> Abnormal	<input type="radio"/> Unknown		
Was this your first mammogram:	<input type="radio"/> Yes	<input type="radio"/> No			

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# Appendix A: (Continued)

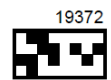
Today's Date:  /  / 
 Randomization #: 
 Group #:

## Clinical History

### 5. Current Medications

Please list any medications you are now taking, including vitamins and non-prescription drugs. If there are more than 10, please write other medications below.

	Medication Name	Date Started	Reason for Use
1.	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 40px; height: 20px; border: 1px solid black;"/>	<input style="width: 95%; height: 20px;" type="text"/>
2.	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 40px; height: 20px; border: 1px solid black;"/>	<input style="width: 95%; height: 20px;" type="text"/>
3.	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 40px; height: 20px; border: 1px solid black;"/>	<input style="width: 95%; height: 20px;" type="text"/>
4.	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 40px; height: 20px; border: 1px solid black;"/>	<input style="width: 95%; height: 20px;" type="text"/>
5.	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 40px; height: 20px; border: 1px solid black;"/>	<input style="width: 95%; height: 20px;" type="text"/>
6.	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 40px; height: 20px; border: 1px solid black;"/>	<input style="width: 95%; height: 20px;" type="text"/>
7.	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 40px; height: 20px; border: 1px solid black;"/>	<input style="width: 95%; height: 20px;" type="text"/>
8.	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 40px; height: 20px; border: 1px solid black;"/>	<input style="width: 95%; height: 20px;" type="text"/>
9.	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 40px; height: 20px; border: 1px solid black;"/>	<input style="width: 95%; height: 20px;" type="text"/>
10.	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 40px; height: 20px; border: 1px solid black;"/>	<input style="width: 95%; height: 20px;" type="text"/>
11.	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 40px; height: 20px; border: 1px solid black;"/>	<input style="width: 95%; height: 20px;" type="text"/>
12.	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 40px; height: 20px; border: 1px solid black;"/>	<input style="width: 95%; height: 20px;" type="text"/>
13.	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 40px; height: 20px; border: 1px solid black;"/>	<input style="width: 95%; height: 20px;" type="text"/>
14.	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 40px; height: 20px; border: 1px solid black;"/>	<input style="width: 95%; height: 20px;" type="text"/>
15.	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 40px; height: 20px; border: 1px solid black;"/>	<input style="width: 95%; height: 20px;" type="text"/>
16.	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 40px; height: 20px; border: 1px solid black;"/>	<input style="width: 95%; height: 20px;" type="text"/>
17.	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 40px; height: 20px; border: 1px solid black;"/>	<input style="width: 95%; height: 20px;" type="text"/>
18.	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 40px; height: 20px; border: 1px solid black;"/>	<input style="width: 95%; height: 20px;" type="text"/>
19.	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 40px; height: 20px; border: 1px solid black;"/>	<input style="width: 95%; height: 20px;" type="text"/>
20.	<input style="width: 95%; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 20px; height: 20px; border: 1px solid black;"/> / <input style="width: 40px; height: 20px; border: 1px solid black;"/>	<input style="width: 95%; height: 20px;" type="text"/>



Appendix A: (Continued)

Today's Date:  /  /  Randomization #:  Group #:

Clinical History

6. Social History

Marital status:  Married  Single  Widowed  Divorced

Where were you born?

Where were you raised?

How many years have you been in Florida?

Current/Former occupation:

Do you smoke cigarettes?  Yes, currently  No, previously  No

If yes, please answer the following:

Total years as a smoker:

Number of cigarettes per week:  (1 pack = 20 cigarettes) Packs per day:

Date started:  /  /

Date stopped:  /  /

Do you drink alcoholic beverages?  Yes  No

Note: If you drink only occasionally, please answer "0":

How many beers do you drink per week:  0  1-2  3-4  Greater than 5

How many glasses of wine do you drink per week:  0  1-2  3-4  Greater than 5

How much hard liquor do you drink per week:  0  1-2  3-4  Greater than 5

Do you drink caffeinated beverages?  Yes  No

How many cups of coffee or tea per day?

How many soft drinks (soda) per day?

What type?

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## Appendix A: (Continued)

Today's Date:  /  /  Randomization #:  Group #:

### Clinical History

#### 6. Social History (Cont.)

Diet:

In the last 5 days, how many fruits per day have you had?

How many vegetables have you had per day?

Exercise:

How many days a week do you exercise?

How many times a day do you exercise?

What type(s) of exercise do you engage in?

Therapy:

1. Do you regularly use a support group to assist you with your recovery?  Yes  No

2. Do you regularly use meditation to assist you with your recovery?  Yes  No

3. Do you regularly use prayer to assist you with your recovery?  Yes  No

4. Do you regularly use guided imagery to assist you with your recovery?  Yes  No

5. Do you regularly use hypnosis to assist you with your recovery?  Yes  No

6. Do you regularly use counseling to assist you with your recovery?  Yes  No

7. Do you regularly use yoga to assist you with your recovery?  Yes  No

8. Do you regularly engage in other stress reducing techniques to assist you with your recovery?  Yes  No





# Appendix A: (Continued)

Today's Date:  /  /  Randomization #:  Group #:

## Clinical History

### 8. Family History (cont.)

**Family history of benign breast conditions:**  Yes  No  Unknown

If "Yes", please enter the details here:

	Family member*	Age at diagnosis
1.	<input type="text"/>	<input type="text"/>
2.	<input type="text"/>	<input type="text"/>
3.	<input type="text"/>	<input type="text"/>
4.	<input type="text"/>	<input type="text"/>
5.	<input type="text"/>	<input type="text"/>

**Family member key**

\* Please use the following key when filling in "Family Member" information. Maternal refers to your mother's side of the family and Paternal refers to your father's side of the family.

1 = Mother	11 = Maternal aunt
2 = Father	12 = Maternal uncle
3 = Sister	13 = Paternal aunt
4 = Brother	14 = Paternal uncle
5 = Daughter	15 = Cousin (maternal or paternal)
6 = Son	
7 = Maternal grandmother	
8 = Maternal grandfather	
9 = Paternal grandmother	
10 = Paternal grandfather	

**Family history of other cancer (including breast cancer):**  Yes  No  Unknown

If "Yes", please enter the details here (\*please use the Family Member key at the top of this page):

	Family member*	Age at diagnosis	Status of family member	Type of cancer	Death due to cancer	Age of death
1.	<input type="text"/>	<input type="text"/>	<input type="radio"/> Alive <input type="radio"/> Dead <input type="radio"/> Unknown	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	<input type="text"/>
2.	<input type="text"/>	<input type="text"/>	<input type="radio"/> Alive <input type="radio"/> Dead <input type="radio"/> Unknown	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	<input type="text"/>
3.	<input type="text"/>	<input type="text"/>	<input type="radio"/> Alive <input type="radio"/> Dead <input type="radio"/> Unknown	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	<input type="text"/>
4.	<input type="text"/>	<input type="text"/>	<input type="radio"/> Alive <input type="radio"/> Dead <input type="radio"/> Unknown	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	<input type="text"/>
5.	<input type="text"/>	<input type="text"/>	<input type="radio"/> Alive <input type="radio"/> Dead <input type="radio"/> Unknown	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	<input type="text"/>
6.	<input type="text"/>	<input type="text"/>	<input type="radio"/> Alive <input type="radio"/> Dead <input type="radio"/> Unknown	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	<input type="text"/>
7.	<input type="text"/>	<input type="text"/>	<input type="radio"/> Alive <input type="radio"/> Dead <input type="radio"/> Unknown	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	<input type="text"/>

19372



## Appendix B: Female Sexual Distress Scale

Today's Date:  /  / 
 Randomization #: 
 Group #: 
 Week:

**(FSDS-R)**  
**FEMALE SEXUAL DISTRESS SCALE**

Below is a list of feelings and problems that women sometimes have concerning their sexuality. **Please read each item carefully, and circle the number that best describes how often that problem has bothered you or caused you distress during the past 30 days including today.**

HOW OFTEN DID YOU FEEL:	Never	Rarely	Occasionally	Frequently	Always
1. Distressed about your sex life	0	1	2	3	4
2. Unhappy about your sexual relationship	0	1	2	3	4
3. Guilty about sexual difficulties	0	1	2	3	4
4. Frustrated by your sexual problems	0	1	2	3	4
5. Stressed about sex	0	1	2	3	4
6. Inferior because of sexual problems	0	1	2	3	4
7. Worried about sex	0	1	2	3	4
8. Sexually inadequate	0	1	2	3	4
9. Regrets about your sexuality	0	1	2	3	4
10. Embarrassed about sexual problems	0	1	2	3	4
11. Dissatisfied with your sex life	0	1	2	3	4
12. Angry about your sex life	0	1	2	3	4
13. Bothered by low sexual desire	0	1	2	3	4

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## Appendix C: Body Image Scale

Today's Date:  /  /   
 Randomization #:  Group #:  Week:

### (BIS) BODY IMAGE SCALE

In this questionnaire you will be asked how you feel about your appearance, and about any changes that may have resulted from your disease or treatment. **Please read each item carefully, and circle the number that best describes the reply that comes closest to the way you have been feeling about yourself, during the past week.**

HOW OFTEN:	Not at all	A little	Quite a bit	Very much
1. Have you been feeling self-conscious about your appearance?	0	1	2	3
2. Have you felt <b>less</b> physically attractive as a result of your disease or treatment?	0	1	2	3
3. Have you been <b>dissatisfied</b> with your appearance when dressed?	0	1	2	3
4. Have you been feeling <b>less</b> feminine as a result of your disease or treatment?	0	1	2	3
5. Did you find it difficult to look at yourself naked?	0	1	2	3
6. Have you been feeling less sexually attractive as a result of your disease/treatment?	0	1	2	3
7. Did you avoid people because of the way you felt about your appearance?	0	1	2	3
8. Have you been feeling the treatment has left your body less whole?	0	1	2	3
9. Have you felt <b>dissatisfied</b> with your body?	0	1	2	3
10. Have you been <b>dissatisfied</b> with the appearance of your scar?	0	1	2	3

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## Appendix D: Permission to Use Instruments

**Subject:** RE: Female Sexual Distress Scale  
**Date:** Wednesday, June 15, 2011 at 12:49:56 PM Eastern Daylight Time  
**From:** Derogatis, Leonard R.  
**To:** 'Paterson, Carly'

Dear Carly:

Please take this e-mail to confirm my permission to use the FSDS-R in your research. I have attached a copy of the instrument and a validation paper for the "R" version of the scale.

Good luck with your research.

Sincerely,

Leonard R. DeRogatis, Ph.D.  
Director, Center For Sexual Medicine  
at Sheppard Pratt, Associate Professor  
of Psychiatry, Johns Hopkins Univ. School of Medicine  
6501 N. Charles St.  
Baltimore, MD 21285  
Phone: (410) 938-4336  
Fax; (410) 938-4340  
*email: Lderogatis@sheppardpratt.org*

---

**From:** Paterson, Carly [mailto:cpaterso@health.usf.edu]  
**Sent:** Wednesday, June 15, 2011 11:37 AM  
**To:** Derogatis, Leonard R.  
**Subject:** Female Sexual Distress Scale

Dear Dr. Derogatis,

My name is Carly Paterson and I am a Doctoral Student of Dr. Cecile Lengacher at the University of South Florida College of Nursing. Currently, I am a Research Associate with Dr. Cecile Lengacher on her "R01 MBSR Symptom Cluster Trial for Breast Cancer Survivors" and I am interested in extending her work by focusing on sexual distress in a subgroup of young women with breast cancer within her study for my dissertation. I am currently writing a Pre-doctoral NRSA (F31) application and I would be honored if you would give me permission to utilize your Female Sexual Distress Scale to measure the sexual distress in this study. Thank you in advance for your time and consideration of this matter.

Carly Paterson, BSN  
BS-PhD Student/Doctoral Student  
Research Associate  
MBSR Symptom Cluster Trial for Breast Cancer Survivors  
University of South Florida  
Office: 813-974-0718  
Fax: 813-974-7903  
Email: [cpaterso@health.usf.edu](mailto:cpaterso@health.usf.edu)

## Appendix D: (Continued)

**Subject:** Re: Body Image Scale  
**Date:** Tuesday, June 21, 2011 at 1:12:09 PM Eastern Daylight Time  
**From:** Penny Hopwood  
**To:** cpaterso@health.usf.edu

Dear Carly

Thank you for your email - apologies for the delay replying but I have been on holiday. Yes you are very welcome to use the Body Image Scale for use in your research.

If you have any queries at any stage please feel free to get in touch again.

Meantime good luck with your study!

Kind regards

Penelope

Dr Penelope Hopwood  
Visiting Professor of Psycho-Oncology  
(University of Salford)  
ICR Clinical Trials & Statistics Unit (ICR-CTSU)  
Section of Clinical Trials  
The Institute of Cancer Research  
Sir Richard Doll Building  
Cotswold Road  
Sutton  
SM2 5NG  
Tel: 02087224171  
[penny.hopwood@icr.ac.uk](mailto:penny.hopwood@icr.ac.uk)

"Paterson, Carly" <[cpaterso@health.usf.edu](mailto:cpaterso@health.usf.edu)> 06/15/11 6:08 PM >>>

Dear Dr. Hopwood,

My name is Carly Paterson and I am a Doctoral Student of Dr. Cecile Lengacher at the University of South Florida College of Nursing. Currently, I am a Research Associate with Dr. Cecile Lengacher on her "R01 MBSR Symptom Cluster Trial for Breast Cancer Survivors" and I am interested in extending her work by focusing on body image and sexual distress in a subgroup of young women with breast cancer within her study for my dissertation. I am currently writing a Pre-doctoral NRSA (F31) application and I would be honored if you would give me permission to utilize your Body Image Scale to measure body image among the young women in this study. Thank you in advance for your time and consideration of this matter.

Carly Paterson, BSN  
BS-PhD Student/Doctoral Student  
Research Associate  
MBSR Symptom Cluster Trial for Breast Cancer Survivors  
University of South Florida  
Office: 813-974-0718  
Fax: 813-974-7903  
Email: [cpaterso@health.usf.edu](mailto:cpaterso@health.usf.edu)<<mailto:cpaterso@health.usf.edu>>

## Appendix E: Institutional Review Board Approval



DIVISION OF RESEARCH INTEGRITY AND COMPLIANCE  
Institutional Review Boards, FWA No. 00001669  
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799  
(813) 974-5638 • FAX (813) 974-5618

December 16, 2011

Cecile Lengacher, RN, PhD  
USF College of Nursing  
12901 Bruce B. Downs Blvd., MDC22  
Tampa, FL 33612

RE: **Approved Modification Request**  
IRB#: 107408  
Title: *MBSR Symptom Cluster Trial for Breast Cancer Survivors*  
Study Approval Period: 11/23/2011 to 11/23/2012

Dear Dr. Lengacher:

On 12/15/2011 the Institutional Review Board (IRB) reviewed and **APPROVED** your Modification Request. The submitted request has been approved from 12/15/2011 to 11/23/2012 for the following:

- 1. Addendum 6 to add Carly Paterson and Julie Daugherty to key personnel.**
- 2. Revised Instruments: BIS, ECog, FSDS-R**
- 3. Revised procedures adding the FSDS-R, the BIS, and ECog to the protocol.**
- 4. A doctoral student will access deidentified data set for secondary analysis purposes.**

Please note, if applicable, the enclosed informed consent/assent documents are valid during the period indicated by the official, IRB-Approval stamp located on page one of the form. Valid consent must be documented on a copy of the most recently IRB-approved consent form. Make copies from the enclosed original.

Please reference the above IRB protocol number in all correspondence to the IRB or the Division of Research Compliance. It is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

A handwritten signature in black ink that reads "E. Jorgensen".

E. Verena Jorgensen, MD, Chairperson  
USF Institutional Review Board

Cc: Vicki Stecher/am, USF IRB Professional Staff

### **About the Author**

Carly Paterson grew up a suburb of Buffalo, New York. She obtained her B.S. in Nursing from the University at Buffalo before earning her M.S. from the University of South Florida with a concentration in Nursing Education. Her research interests include the evaluation of appropriate interventions for effectiveness in reducing symptom burden after treatment. She is particularly interested in the symptoms of sexual distress and body image disturbance, with further investigation into who may derive the most benefit from participating in these interventions.

Carly was a recipient of the National Institute of Nursing Research Ruth L. Kirschstein National Research Service Award for Predoctoral Fellows (1F31NR013585). She is a member of Sigma Theta Tau International, the Honor Society of Nursing. She is also a member of the American Psychosocial Oncology Society and the Oncology Nursing Society, and the Doctoral Nursing Student Organization at the University of South Florida. Carly also serves as a reviewer for the journal *Cancer Nursing: an International Journal for Cancer Care*.