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# Factors Associated with Fear of Breast Cancer Recurrence Among Survivors

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Factors Associated with Fear of Breast Cancer Recurrence Among Survivors

by

Jean Marie Lucas

A dissertation submitted in partial fulfillment  
of the requirements for the degree of  
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University of South Florida

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## Abstract

The purpose of this cross-sectional, secondary data analysis was to explore, non-modifiable (stable) trait factors and modifiable (transient) state factors associated with fear of recurrence (FOR) in breast cancer survivors. Antecedent trait factors included demographic, clinical, social/behavioral factors, postulated mediator state factors included pain, fatigue, sleep disturbances, depression, state anxiety and perceived stress, and FOR was the outcome variable. The study used baseline data from an R-21 NCI funded (grant #R21CA109168) randomized control trial that examined the effects of mindfulness based stress reduction in early stage breast cancer recovery. Instruments from this study for antecedent variables (trait factors) included a Demographic and Clinical History Form, STAI; instruments used for mediator variable (state factors) included CES-D, STAI, PSS and MDASI subscales for pain and fatigue, sleep; the instruments used for the outcome variable FOR - CARS overall fear and nature of worry. The study sample included 82 women within 18 months post breast cancer treatment (stage 0, I, II, III). The Theoretical Model for psychosocial nursing research was used as a heuristic framework to examine the associations between trait factors and state factors and their mediating effects on FOR. Aim 1 explored the relationship between the antecedent (trait) variables associated with FOR (CARS overall fear and CARS nature of worry) using Pearson's and Spearman's correlations and analysis of variance (ANOVA). The findings revealed a negative association between age and FOR, CARS overall fear ( $r = -.236, p = .033$ ) and FOR, CARS nature of worry ( $r = -.269, p = .015$ ). Trait anxiety was positively associated with FOR, CARS overall fear ( $r = .433, p = .000$ ) and FOR, CARS nature of worry ( $r = .358, p < 0.001$ ). Race/ethnicity, education,



marital status, employment, exercise, cancer stage, cancer treatment, exercise, smoking, drinking, hormone use and family history of breast cancer were not associated with FOR. Aim 2 explored the relationship between postulated mediator (state) variables, such as pain, fatigue, sleep disturbances, state anxiety, depression, perceived stress associated with FOR (CARS overall fear and CARS nature of worry) using Pearson's correlations. Findings revealed that depression ( $r = .347, p = .001$ ), state anxiety ( $r = .467, p < 0.001$ ), perceived stress ( $r = .365, p = .001$ ) were positively associated with FOR, CARS overall fear of recurrence, and that pain ( $r = .220, p = .047$ ), fatigue ( $r = .247, p = .025$ ), state anxiety ( $r = .369, p = .001$ ), and perceived stress ( $r = .410, p < 0.001$ ) were positively associated with FOR, CARS nature of worry. Aim 3 used a mediation analysis (bootstrapping method) to examine the indirect effects of the statistically significant modifiable mediator state factors on the statistically significant antecedent trait factors and FOR (CARS overall fear and CARS nature of worry). With trait anxiety as the antecedent variable, state anxiety was indirectly associated (a mediating variable) with FOR, CARS overall fear ( $\beta = .1381, 95\% \text{ CI} = .0053 - .3050, p = .0299$ ). Similarly, with a composite age/trait anxiety antecedent variable, state anxiety was indirectly associated (a mediating variable) with FOR, CARS overall fear ( $\beta = .5579, 95\% \text{ CI} = .1201 - 1.1669, p = .0157$ ). Perceived stress and depression did not mediate the relationship between age and trait anxiety and concerns about recurrence overall fear. With trait anxiety as the antecedent variable, perceived stress was indirectly associated (a mediating variable) with FOR, CARS nature of worry ( $\beta = .5474, 95\% \text{ CI} = .0178 - 1.3298, p = .0294$ ). Similarly, a composite age/trait anxiety antecedent variable, perceived stress was indirectly associated (a mediating variable) with FOR, CARS nature of worry ( $\beta = 2.0375, 95\% \text{ CI} = .1136 - 4.5976, p = .0495$ ). Pain, fatigue and state anxiety did not mediate the relationship between age and trait anxiety and FOR nature of worry.

This study suggests that breast cancer survivors who are anxious at baseline and report a current state of anxiety or perceived stress may be at higher risk for fears of breast cancer recurrence. Understanding the individual patient characteristics such as age, history of anxiety and current status of perceived stress or anxiety and the relationship with fears of recurrence allow nurses to offer individualized interventions for patients at greatest risk for psychological distress.

## **Chapter One**

### **Introduction**

Breast cancer is the second leading cause of cancer in women and survivors comprise the largest population of cancer survivors in the United States (National Cancer Institute, 2013). In 2013 there were estimated to be 232,340 new breast cancer cases in women (National Cancer Institute, 2013). There have been tremendous growth advancements in the screening, diagnosis and treatment of breast cancer that has changed the trajectory of breast cancer management with a major focus on survivorship. A factor contributing to improving the morbidity in breast cancer survivorship is through optimal management of psychological health and well-being. The psychological needs of breast cancer survivors vary across the disease and demographic spectrum. However, one of the most prevalent and consistent psychological stressors is the ever-looming fear of cancer recurrence (FOR). Although there have been advances in early diagnosis and treatment of breast cancer, managing post-treatment psychological distress has proven to be particularly challenging. The sequelae from the diagnosis and treatment of breast cancer and the lingering threats of fear of cancer recurrence create long-term complications and impaired quality of life for breast cancer survivors (Wong & Bramwell, 1992). The findings from this study provides valuable data to assist health care providers with a better understanding of those women who may be at greatest risk for worries about recurrence, the factors that are most associated with fear of cancer recurrence and the effects of the interactions between those factors.

## Statement of the Problem

The most current data from the National Cancer Institute 2009/2010 Progress Report estimates 12 million cancer survivors in the United States in 2008 with breast cancer survivors making up the largest population of 2.8 million survivors with 12.29% (or 1 in 8) of the women born today will be diagnosed with some form of breast cancer in their lifetime (National Cancer Institute, 2013). Breast cancer rates have increased since the early 1990's, however in spite of this, survival rates have continued to climb over the past 20 years partly due to advances in breast cancer screening, early diagnosis and aggressive treatment modalities (National Cancer Institute, 2013). During 2004-2008, the median age at the time of breast cancer diagnosis was 61 years indicating that 50% of women who developed breast cancer were 61 years of age or younger at the time of diagnosis (Howlader et al., 2011). According to the American Cancer Society (2012), women with breast cancer have an 89% survival rate after 5 years of diagnosis, 82% after 10 years and 77% after 15 years. Thus, the majority of breast cancer patients survive an extended period of time after treatment. Since 1975, the breast cancer 5-year relative survival rate has increased significantly for both African American and Caucasian women with a survival rate of 77% for African American women and 90% among White women (Howlader et al., 2011). The survival rate for women diagnosed before age 40 is 84% and 90% in women diagnosed after age 40 (American Cancer Society, 2012). Breast cancer patients from lower-income areas have lower 5-year survival rates than those from higher-income areas at every stage of diagnosis (Harper et al., 2009).

The diagnosis and treatment of breast cancer along with the side effects of pain, fatigue and anxiety and the lingering threats of fear of cancer recurrence create dysregulation of psychological and physiologic mechanisms (Luecken & Compas, 2002; McGregor & Antoni,

2009; Reich, Lesur & Perdrizet-Chevallier, 2008). About 30-40% of patients experience elevated symptoms of anxiety and depression at the time of breast cancer diagnosis and although some of these symptoms dissipate over time, there is a subset of women who continue to experience psychological distress throughout their treatment and recovery, with 3-30% continuing to exhibit signs of moderate to severe emotional distress (Andrykowski, Cordova, Studts, & Miller, 1998; Carver et al., 1993; Cordova et al., 1995; Epping-Jordan et al., 1999; Luecken & Compas, 2002; Reich, et al., 2008). This is an important finding because much of the earlier research has focused on early intervention to address distress in the acute phase of breast cancer treatment but interventions for fear of recurrence has long-term implications requiring more long-term interventions (Lengacher et al., 2009). The previous emphasis on early detection, different treatment modalities and cancer prevention has led to increased survivorship therefore warranting current and future research efforts to focus on the physical, psychological and economic factors associated with quality of life and well-being in survivorship (Baker, Denniston, Smith & West, 2005).

### **Non-Modifiable Trait Factors Associated with FOR**

Age is the one factor that is consistently described in the literature as being strongly associated with fear of recurrence. The relationship of age and fear of recurrence was found to be a common theme throughout the literature however, the parameters that define younger and older patients varies greatly throughout the reviewed literature. Younger age (< 40 years) was found to have more intense fears of cancer recurrence than women who were diagnosed at an older age (>40 years) (Costanzo et al, 2007; Simard & Savard, 2009; Van den Beuken-van Everdigen et al., 2008; Vickberg, 2003; Wade, Nehmy & Koczwara, 2005; Waljee et al., 2008). This may be partly due to the slightly lower 5-year survival rate and the severity of the cancer

diagnosis earlier than age 40; with this comes a greater sense of loss due to work opportunities, childbearing, raising children and lost future opportunities (Wade et al., 2005).

Vickberg (2003) discovered that younger age was the strongest predictor of fear of recurrence and the greatest predictor of distress of fear of recurrence for ages 32-47 years ( $p < 0.001$ ) (Costanzo et al., 2007). This is consistent with other studies that identified age as a factor related to adjustment in older women who reported less fear of recurrence ( $p < 0.05$ ) at 1-year (Stanton, Danoff-Burg, & Burg, 2002); and at time of diagnosis and at their 2-year follow-up than the younger breast cancer survivors (Liu et al., 2011; Van den Beuken-van Everdingen et al., 2008).

### **Modifiable State Factors Associated with Fear of Recurrence**

Triggers of fear of breast cancer recurrence were consistent among the reviewed studies. Of all the triggers identified, pain was reported to be the most frequent trigger for fear of cancer recurrence in breast cancer survivors (Gil et al., 2004; Mast, 1998; Mishel, Germino, & Gil, 2005; Van den Beuken-van Everdigen et al., 2008). Mishel et al., (2005) studied the efficacy of an uncertainty management intervention in 509 North Carolina Caucasian and African-American, older, long-term breast cancer survivors (5-9 years survivorship) and found that the threat of recurrence endures over time. These women reported at least two physical or emotional triggers per month (16 triggers over the course of the 8 months); although the reminders were not constant they persisted over time and the cancer awareness remained continually in their consciousness (Mishel et al., 2005).

### **Fear of Recurrence**

One of the major causes of distress in breast cancer survivors is uncertainty of the future or fear of cancer recurrence (Lee-Jones, Humphries, Dixon, & Hatcher, 1997; Wong &

Bramwell, 1992). Fear of cancer recurrence can be the cause of distress in survivors or it can be the end result of a variety of post-cancer related stressors. Several studies support this theory and suggest that there is a bidirectional relationship between fear of cancer recurrence and emotional distress; in some cases distress (anxiety, depression, fatigue) may precipitate fear of recurrence (Lebel, Rosberger, Edgar, & Devins, 2009; Lee-Jones et al., 1997) or perhaps fear of recurrence may precipitate the distress (Black & White, 2005; Deimling et al., 2006). Regardless of the direction of the pathway several studies have reported a high prevalence of moderate to high fear of recurrence. Vickberg (2003) reported a fear of recurrence prevalence of 55% (n=169) among breast cancer survivors. Van den Beuken-van Everdingen et al. (2008) found 56% (n=136) up to 4 years post treatment and in an earlier study of survivors 5 years after diagnosis, as many as 70% of breast cancer survivors continued to have fears of cancer recurrence (Mast, 1998). Most breast cancer survivors reported moderate cancer related anxiety, concerns about ongoing physical symptoms and fear of cancer recurrence as their top sources of distress during multiple points in their treatment and beyond (as far out as 2-years) (Costanzo et al., 2007; Liu et al., 2011; Stephens et al., 2008). Lee-Jones et al. (1997) identified several precipitating factors that influence fear of recurrence. These factors included the survivor's perspective that periods of emotional distress may directly impact their cancer recurrence, due to symptoms of fatigue or pain interpreted as signs of cancer recurrence, or emotional distress which may heighten the patient's sensitivity to their physical symptoms resulting in fear of recurrence (Lee-Jones et al., 1997). Connell, Patterson, and Newman (2006) reported that fear of recurrence was a major concern for many of their study participants (54%) and a top concern among younger women < 41 years (31.5%). With the numbers of breast cancer survivors continuing to grow, it is imperative to understand the factors that will influence breast cancer survivorship. Stress, both

physical and psychological, are critical factors influencing the immunity in breast cancer quality of life and morbidity (Andersen et al., 2008; Chrousos, 2000; Keicolt-Glaser, McGuire, Robles, & Glaser, 2002; Witek-Janusek, Gabram, & Mathews, 2007). Considerations identified also pose valuable questions regarding the need to identify a standardized definition for clinical levels of fear of recurrence, defining pathological characteristics and levels for fear of recurrence, routine screening and identifying indicators for clinical interventions (Thewes et al., 2012).

The findings from this study provide valuable data to support the understanding of those factors most associated with fear of recurrence, particularly those factors that have the potential mediating effect on fear of recurrence. Outcomes from this research can support future studies that will focus on bio-behavioral associations with fear of recurrence, stress related biomarkers and the effects of early screening and interventions. This is consistent with the recommendations from a study performed by Lebel et al., (2009) suggesting that future research should evaluate the prevalence of comorbid disorders (anxiety, depression, perceived stress) in cancer patients who report high fear of recurrence.

### **Purpose of the Study**

The purpose of this study was to examine the antecedent, non-modifiable (stable) trait factors most associated with fear of breast cancer recurrence and the mediating effects of modifiable (transient) state factors associated with fear of cancer recurrence. This study, a secondary data analysis, used baseline data from an R-21 NCI funded (grant #R21CA109168) randomized control trial that examined the effects of mindfulness based stress reduction in early stage breast cancer recovery (Lengacher et al., 2009). The first aim was to examine the relationship between stable, non-modifiable trait factors (antecedent variables demographic factors such as age, ethnicity/race, marital status, education, employment status), clinical history



(stage of cancer at diagnosis, treatment history, hormone use, family history of breast cancer and trait anxiety), social/behavioral history (drinking, smoking, exercise history) and the outcome variable (fear of breast cancer recurrence). Additionally, the study explored the relationship between modifiable state factors (mediator variable such as state anxiety, depression, perceived stress, pain, fatigue and sleep disturbances) considered to be transient and the outcome variable fear of breast cancer recurrence. The antecedent trait factors associated with FOR and the mediator state factors found to be most associated with fear of breast cancer recurrence were studied by examining the potential mediating effects of those state factors on the trait factors associated with fear of breast cancer recurrence. Understanding the relationship between trait factors associated with fear of breast cancer recurrence that can be mediated by certain state factors most associated with fear of recurrence can inform health care professionals to directly target and prioritize interventions towards those women at risk for psychological distress during survivorship.

### **Aims**

The aims of this study were to:

- 1) Examine the relationship between the antecedent variables (non-modifiable (stable) trait factors) including age, ethnicity/race, marital status, education, employment status, stage of cancer at diagnosis, treatment history, history of smoking, drinking, exercise, hormone use, family history of breast cancer and trait anxiety associated with the outcome variable, fear of breast cancer recurrence (CARS overall fear and CARS nature of worry);
- 2) Examine the relationship between the mediator variables (modifiable (transient) state factors) including state anxiety, depression, perceived stress, pain, fatigue and sleep disturbances associated with the outcome variable, fear of breast cancer recurrence;

3) Examine those state factors that mediate the relationship between trait factors (antecedent variables) associated with fear of breast cancer recurrence (outcome variable).

### **Definition of Terms**

The antecedent, mediator and outcome variables used in this study are outlined and defined specifically in this section. For the purposes of this study, the following definitions were used:

1. Non-modifiable trait factors (antecedent variables): Those trait characteristics that cannot be modified or are not easily modifiable and are stable over time including (age, ethnicity/race, marital status, education, employment status, stage of cancer at diagnosis, treatment history, history of smoking, drinking, exercise, hormone use, family history of breast cancer and trait anxiety).
  - a. Trait anxiety: Defined as the general tendency to respond to perceived threats with anxiety (Spielberger, Gorsuch, & Luschene, 1983).
2. Modifiable state factors (mediator variables): Those physiological states (pain, fatigue, sleep disturbances) and psychological states (depression, perceived stress, state anxiety) that is transient and may be modified through interventions. State is defined as a mode, condition or stage in the physical being of something (Merriam-Webster, 2012).
  - a. Pain: Defined as an unpleasant subjective sensory and emotional experience associated with actual or potential tissue damage (International Association for the Study of Pain, 2013).
  - b. Fatigue: Defined as “a subjective state of overwhelming and sustained exhaustion with a decrease in capacity for physical and mental work not relieved with rest” (Cella, Peterman, Passik, Jacobsen & Breitbart, 1998, p. 369).

- c. Sleep disturbances: Difficulty falling asleep, staying asleep, waking up too early, in ability to resume sleep or sleep that is non-restorative or poor in quality with sleepiness during the day (Berger, 2009).
  - d. Depression: Subjective or observed depressed mood, feelings of guilt, worthlessness, hopelessness, helplessness, change in appetite, sleep disturbances, fatigue or loss of energy (Radloff, 1977).
  - e. Perceived stress: The situations in one's life that are appraised as stressful (Cohen, Kamarck & Mermelstein, 1983).
  - f. State anxiety: The temporary emotional state that is characterized by conscious feelings of tension and apprehension and heightened autonomic system activity (Spielberger et al., 1983).
3. Fear of breast cancer recurrence: Defined as fear that the breast cancer is coming back in the same breast or another area of the body, or a new breast cancer (Vickberg, 2003, p.18). The literature tends to use worry synonymously with fear in fear of recurrence (Vickberg, 2003).

### **Delimitations**

The sample included women who were post-treatment for breast cancer and included the following parameters:

1. Ages 21 or older
2. Diagnosed with breast cancer Stage 0, I, II, III and had undergone; lumpectomy and received adjuvant radiation and/or chemotherapy and were within 18 months post treatment;
3. Able to read and speak English at an 8<sup>th</sup> grade level.

## **Assumptions**

The assumptions of this study support the concept that there are multiple factors independently associated with higher levels of fear of breast cancer recurrence and several factors that mediate the effects of fear of breast cancer recurrence. Some of the factors that may be associated include age at time of diagnosis, stage of cancer at diagnosis, level of education, history of anxiety, depression and perceived stress.

## **Significance of the Study**

The management of breast cancer does not end with the diagnosis and treatment of the disease and fear of breast cancer recurrence remains a persistent threat to cancer survivors. Many studies have explored various influences on fear of cancer recurrence in breast cancer survivors including demographic predictors, triggers, and emotional stressors (Gil et al., 2004; Lee-Jones, et al., 1997; Lengacher et al., 2009; Lengacher et al., 2011; Mast, 1998; Mishel et al., 2005; Van den Beuken-van Everdigen et al., 2008; Vickberg, 2003). However, the existing research has not explored the mediating effects of modifiable state factors such as physical and psychological factors on stable, non-modifiable factors like age, education, stage of cancer, treatment, etc. and outcome of fear of cancer recurrence. Understanding these relationships provides valuable information as health care providers attempt to individually tailor support and psychological interventions early in breast cancer treatment and survivorship, thus reducing unnecessary distress and promoting psychological health and well-being in breast cancer survivors. This study establishes a uniqueness of examining the mediating effects of transient, modifiable state factors on the relationship between stable, non-modifiable factors and fear of breast cancer recurrence that goes beyond the existing published research.

## **Chapter Two**

### **Literature Review**

#### **Introduction**

This chapter describes the theoretical model and framework and the empirical review of the literature. The theoretical framework provides the model guided the empirical review of the literature for the current research study. The review of the literature focused on the prevalence of fear of recurrence in breast cancer survivorship and the main factors associated with fear of recurrence including specific demographic, clinical, social/behavioral, physiological and psychological concerns; this was followed by a summary of the findings.

#### **Theoretical Framework**

The theoretical framework guiding this study was the Theoretical Logic Model for psychosocial nursing research (Evans, 1992). This model was used as a heuristic framework to examine the associations between trait factors and state factors and the mediating effects on fear of breast cancer recurrence. The logic model was designed to examine specific domains of interest, studying specific variables and hypothesized relationships among the variables or domains and the expected client outcomes (Evans, 1992). The model provided a sound framework for this study that supports the examination and identification of factors strongly associated with fear of breast cancer recurrence among breast cancer survivors.

#### **Hypothesized Logic Model**

The Logic Model for psychosocial nursing research was adapted for this study (Evans, 1992). The inputs of the model are comprised of the study subject's baseline stable, non-

modifiable trait factors including demographic factors (age, race/ethnicity, education, marital status, employment), clinical history factors (stage of cancer at diagnosis, treatment type, hormone use, family history of breast cancer, history of trait anxiety) and social/behavioral history (exercise history, smoking and alcohol history).

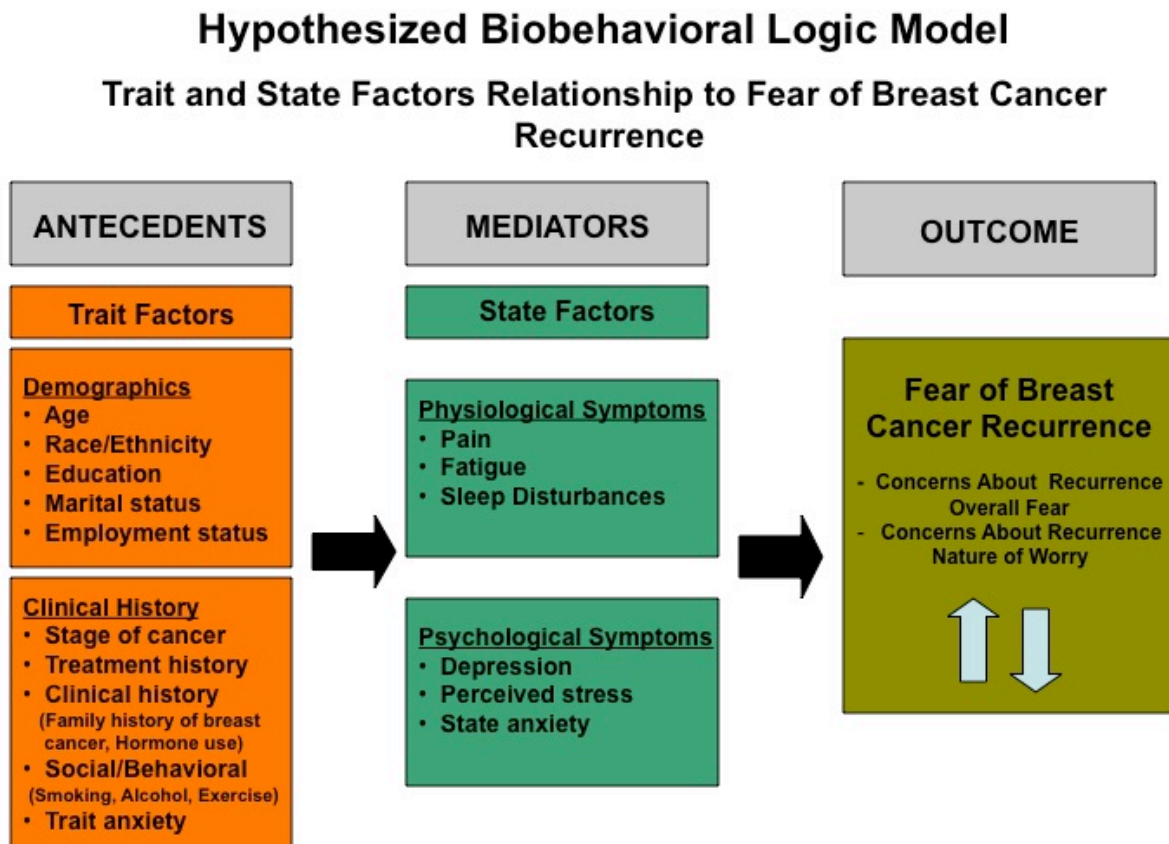
The proposed model explores three pathways as depicted in Figure 1. The first pathway evaluates the relationship between the antecedent variables (non-modifiable trait factors) and outcome variable, fear of breast cancer recurrence (CARS overall fear and CARS nature of worry). The second pathway evaluates the relationship between the mediator variables (modifiable state factors) and the outcome variable, fear of recurrence (CARS overall fear and CARS nature of worry). The antecedent and mediator variables strongly associated with fear of cancer recurrence comprise the third pathway, the model for mediation. The mediation model explains how mediating variables (modifiable state factors) influence the relationship between the antecedent variables (non-modifiable trait factors) and the outcome variable, fear of recurrence.

### **Review of Empirical Literature**

The review of empiric literature for this study has been organized into several sections including: 1) non-modifiable trait factors associated with fear of breast cancer recurrence such as demographic factors (age, race/ethnicity, education, marital status, employment status), clinical factors (stage of cancer at diagnosis, treatment history, hormone use, family history of breast cancer, trait anxiety) and social/behavioral factors (exercise, smoking, alcohol use); 2) modifiable state factors such as physiologic factors (pain, fatigue, sleep disturbances) and psychological factors (depression, perceived stress, state anxiety), and 3) outcome variable fear

of recurrence (CARS overall fear and CARS nature of worry). Many of the variables related to fear of recurrence and breast cancer survivorship tend to be studied together as there tends to be some overlap or clustering of some of the symptoms associated with fear of recurrence therefore this review was organized into the categories most commonly studied in the literature.

Figure 1. Biobehavioral Logic Model



*Note: Trait factors are defined as non-modifiable factors that are stable over time and state factors are defined as modifiable (transient) factors that may be changed with interventions.*

**Demographic/Clinical Factors – Age, Stage, Education, Treatment and Fear of Recurrence in Breast Cancer Survivors.** The research highlights several demographic factors

associated with fear of recurrence in breast cancer survivorship. The two most common demographic factors associated with fear of breast cancer recurrence in survivors are age and level of education.

A quantitative study by Kornblith et al., (2007) of 252 breast and endometrial cancer survivors in Boston, Massachusetts explored differences in adjustment between younger and older survivors. Using the Fear of Recurrence Scale findings confirmed that younger (< 55 years) breast cancer survivors experienced higher FOR ( $p < 0.0001$ ) than older breast cancer survivors (> 65 years) at baseline and for all cancer survivors younger survivors had higher FOR after 1-year than the older women ( $p < 0.01$ ) (Kornblith et al., 2007). It was also noted that breast cancer survivors displayed significantly higher FOR than the endometrial cancer survivors regardless of their age ( $p < 0.0001$ ) (Kornblith et al., 2007).

The interaction of threat appraisal and coping appraisal related to fear of recurrence was studied in a cross-sectional sample of 155 early stage breast cancer patients post-treatment (McGinty, Goldenberg & Jacobsen, 2010). Fear of recurrence was measured using the modified Cancer Worry Scale (mCWS). Younger age ( $r = -0.25$ ,  $p < 0.01$ ) and more advanced disease stage were the only variables that were significantly related to fear of recurrence (McGinty et al., 2010). The interaction of age, disease stage, vulnerability and coping appraisal accounted for 34% of the variance ( $p < 0.001$ ) (McGinty et al., 2010). Threat appraisal accounted for 30% of variance in fear of recurrence ( $p < 0.001$ ) and coping did not account for fear of recurrence, 0% ( $p = 0.64$ ) (McGinty et al., 2010). However, those patients who reported high threat appraisal and low coping appraisal interaction experienced the highest levels of fear of recurrence ( $p = 0.04$ ) (McGinty et al., 2010). Women who reported high perceived vulnerability and low coping appraisal had the highest fear of recurrence ( $p < 0.02$ ) (McGinty et al., 2010).



A 2006 study of women's personal concerns in breast cancer survivorship was performed in a convenience sample of 35 Australian women age 40 years and younger that were within 4 years of their breast cancer diagnosis (Connell et al., 2006). The findings from this exploratory study using semi-structured interviews revealed that for younger women (20 – 40 years of age) showed fear of the future and cancer recurrence was the most common personal concern (54%) and the top-ranking perceived concern (31.5%) (Connell et al., 2006). Twice as many the women who had a lumpectomy reported fear of recurrence as their major personal concern compared to those survivors that had a mastectomy (Connell et al., 2006).

A study of 2290 women with non-metastatic breast cancer in Detroit and Los Angeles examined worry about recurrence related to race/ethnicity and health care experiences (Janz et al., 2011). In the design of this study Latina and African Americans were oversampled (Janz et al., 2011). Using a worry scale created by the researcher, findings revealed that low acculturated Latinas reported more worry than African Americans and Whites and African Americans reported significantly less worry than whites ( $p < 0.001$ ) (Janz et al., 2011). Women who were younger age, Latina, employed, married and less educated experienced greater worry (Janz et al., 2011). Persistent pain and fatigue and higher cancer stage during treatment indicated greater worry ( $P_s < 0.05$ ) (Janz et al., 2011). Patient who had a lumpectomy, radiation and/or chemotherapy reported more worry compared to those that had a mastectomy ( $P_s < 0.05$ ) (Janz et al., 2011).

A qualitative study of 18 Australian women post treatment (6-24 months) for early stage breast cancer was performed using telephone interviews (Thewes, Butow & Pendlebury, 2004). Pain and fatigue were reported most commonly as late effects of their treatment in the younger and older women (Thewes et al., 2004). The women also reported the need to be assured that

their symptoms were normal and reassurance that it was not recurrence of their cancer (Thewes et al., 2004). Many of the women reported fears physical symptoms would indicate that the cancer would return (Thewes et al., 2004). Although most of the fears of recurrence did not impact quality of life, some of the younger women related their fears to the limited ability to plan for the future or to have children (Thewes et al., 2004). It is important to note that some of the younger women reported that the information they received during and after treatment as not completely relevant to their needs, nor were the support groups relevant to the younger age (Thewes et al., 2004). Additionally they requested more information about complimentary therapies, diet, exercise and healthy living than the older women (Thewes et al., 2004).

A prospective, descriptive study of 291 Australian breast cancer survivors was performed to examine characteristics associated with cancer treatments and impact on quality of life (King, Kenny, Hall, & Boyages, 2000). Findings revealed that older women had better body image ( $p < 0.0001$ ), social and emotional functioning ( $p < 0.0001$ ), experienced less pain ( $p < 0.00047$ ) and fear of cancer recurrence ( $p < 0.0001$ ) than younger women (King et al., 2000). Additionally, who more educated (vocational/tertiary education) reported less physical symptoms ( $p = 0.0001$  and  $p = 0.0057$ ), pain ( $p = 0.0057$ ) and better emotional ( $p = 0.015$ ) and physical ( $p = 0.021$ ) functioning than those breast cancer survivors with only secondary school education (King et al., 2000). In general quality of life dimensions for the younger women was less than their older counterparts (King et al., 2000).

Australian women (N =218) ages 18-45 diagnosed with stage 0-2 breast cancer within 1-year of diagnosis participated in a study examining women's fears of breast cancer recurrence (Thewes et al., 2012). Using the Fear of Cancer Recurrence Inventory (FCRI), the researchers found associations between fear of cancer recurrence and frequency of self-breast exams,

doctor's visits and complementary and alternative medicines (CAM). Age at diagnosis was the only confounder associated with fear of cancer recurrence that was adjusted for and was found to be statistically significant (Thewes et al., 2012). The total FCRI decreased by 1.3 for each additional year of age with a (95% CI -2.0, -6.9;  $p < 0.0001$ ) (Thewes et al., 2012). High fear of cancer recurrence has been associated with more unscheduled visits to the doctor, higher frequency of breast screening and cancer screening, counseling and support groups (Thewes et al., 2012). In the same study women who had higher levels of fear of recurrence also used more CAM and spent more money on CAM (Thewes et al., 2012). Higher fear of recurrence was also associated with not having mammograms, ultrasounds or other cancer screening exams unlike those that reported receiving an ultrasound or mammogram in the past year experienced lower levels of fear of recurrence (Thewes et al., 2012). This study found that between 64% and 76% of young women with a history of early breast cancer reported clinical levels of fear of cancer recurrence demonstrating that younger women diagnosed with breast cancer are at greater risk for experiencing greater fear of cancer recurrence (Thewes et al., 2012).

A study of the efficacy of senior peer counseling by telephone for supplemental psychosocial support in a sample of 142 California women ages 50-94 that were newly diagnosed with breast cancer stage 0-3 was done in 2012 by Crane-Okada et al. Using the Fear of Recurrence (FOR) scale by Northouse (1981) findings revealed that there was a significant main effect of age and fear of recurrence and community resource utilization (Crane-Okada et al., 2012). Younger women reported a higher ( $\bar{x} = 75.7$ ,  $SD = 16.4$ ) of fear of recurrence with a higher number of community resources used ( $\bar{x} = 3.1$ ,  $SD = 1.5$ ) than the older women's fear of cancer recurrence ( $\bar{x} = 67.5$ ,  $SD = 15.6$ ) and resources used ( $\bar{x} = 2.4$ ,  $SD = 1.7$ ) (Crane-Okada et al., 2012). Another main effect at baseline that was significant was age; younger patients (aged

50-64 years) used coping by seeking support more than their older counterparts (Crane-Okada et al., 2012). This was consistent at six months among the younger patients who were more likely to use coping strategies than the older participants (Crane-Okada et al., 2012). At each time point during the study fear of recurrence was highest for those patients who were alone and anxious at baseline suggesting this group would be most in need of therapeutic interventions (Crane-Okada et al., 2012).

A study of 714 breast cancer survivors who underwent breast-conserving therapy at the University of Michigan, Ann Arbor, Michigan found that approximately 27% of the women experienced high levels of fear of recurrence and 22% reported depressive symptoms (Waljee et al., 2008). Younger women ( $\leq 40$  years) reported feeling stigmatized from the treatment they received for their breast cancer (Waljee et al., 2008). Fear of recurrence was higher in women with pronounced breast asymmetry post breast cancer treatment opposed to women who experienced minimal and moderate asymmetry (pronounced asymmetry, 40.4%; minimal asymmetry, 19.8%; moderate asymmetry, 19.0%; Wald test = 21.5;  $p < 0.001$ ) (Waljee et al., 2008). Patient age was also significantly related to fear of loss of health ( $p < .001$ ) and disease stage was significantly associated with fear ( $p = 0.05$ ) (Waljee et al., 2008).

An Australian qualitative study using a focus group methodology explored the current needs and concerns of 10 women who recently completed treatment for breast cancer (Oxlad, Wade, Hallsworth & Koczwara, 2008). One of the themes revealed in the study was fear of breast cancer recurrence immediately following primary treatment completion. This concern consisted of specific thoughts about whether the treatment they were receiving was keeping the cancer away, if the cancer would return, how long they would have to live and what would

happen when the treatment (primary and secondary) stopped causing fears about recurrence (Oxlad et al., 2008).

In a descriptive exploratory study using telephone interviews with a convenience sample of 200 breast cancer patients from Illinois found that 39% of the patients reported fear of breast cancer recurrence, including concerns that the cancer had traveled to other parts of the body, concerns about the success of their surgery and that the cancer might return (Stephens et al., 2008). In general, Stephens et al. (2008) found that fear of recurrence was a real threat for patient's receiving any breast cancer surgery leaving concerns about the success of the surgery and the fear of recurrence 1-week post-operative for breast cancer surgery (Stephens et al., 2008).

A cross sectional, descriptive study of 109 women post-treatment for breast cancer in the southeastern United States participated in examining the variables associated with illness uncertainty and emotional distress in survivorship (Mast, 1998). Several main findings were identified, first age was inversely related to fear of cancer recurrence (older women were less likely fear cancer uncertainty than younger women) ( $p < 0.01$ ) and women with four or more years of college had lower illness uncertainty than women with less than two years of college ( $p = 0.008$ ) (Mast, 1998). Secondly, symptom distress (those symptoms residual from cancer treatment or new unknown symptoms) and fear of cancer recurrence contributed to greater emotional distress ( $p = 0.003$ ) (Mast, 1998).

In summary, the younger breast cancer survivors tend to experience greater levels of fear of cancer recurrence than their older survivors (Connell et al., 2006; Crane-Okada et al., 2012; Janz et al., 2011; King et al., 2000; Kornblith et al., 2007; Mast, 1998; McGinty et al., 2010; Thewes et al., 2012; Waljee et al., 2008). In several studies women who were less educated

reported greater FOR than those with some college education (Janz et al., 2011; King et al., 2000; Mast, 1998) and one study found that low acculturated Latinas experienced increased FOR than African American survivors (Janz et al., 2011). In some of the studies increased fear of cancer recurrence was associated with the increased stage of the cancer at diagnosis (McGinty et al., 2010; Waljee et al., 2008). Treatment concerns were associated with FOR regarding type of treatment, esthetics of breasts after treatment and effectiveness of treatment. FOR was increased in those patients who had lumpectomy compared to mastectomy patients (Connell et al., 2006; Janz et al., 2011), more breast asymmetry post treatment (Waljee et al., 2008) and worries about the treatment being effective enough to keep the cancer away (Oxlad et al., 2008; Stephens et al., 2008).

#### **Pain, Fatigue, Sleep Disturbances and Fear of Breast Cancer Recurrence.**

Modifiable state factors associated with fear of breast cancer recurrence include physiological symptoms such as pain, fatigue and sleep disturbances and psychological factors including depression, perceived stress and anxiety.

A qualitative study in 2007 studying 20 breast cancer survivors in the northeastern United States their physical, psychological needs and associated information and support needs during survivorship (Cappiello, Cunningham, Knobf, & Erdos, 2007). The results found that the women in this sample reported fatigue as the greatest physical complaint across all three-time periods (3, 6 and 12 months) and that the fatigue “never stopped” even after treatment (Cappiello et al., 2007, p. 283). Sleep difficulties were also ranked high among the physical symptoms, frequently citing fear of cancer recurrence as a cause for sleep disturbances (Cappiello et al., 2007). The main psychological complaint was fear of recurrence that persisted through the first year post-treatment causing increased anxiety (Cappiello et al., 2007). Overall, anxiety was also a common

concern during the first year, however changes in mood and sadness dissipated over time (Cappiello et al., 2007). Women reported that one of their greatest challenges was “trying to get back to normal” after treatment for breast cancer and that they could have benefited from more information during the transition (Cappiello et al., 2007, p. 287). These findings indicate the need for further information and support for women acclimating from treatment to routine living during the first year post breast cancer treatment (Cappiello et al., 2007).

A descriptive analysis of 203 Caucasian and African American breast cancer survivors 5-9 years post-treatment were studied to assess the influence of symptoms, uncertainty and communication with providers on well-being (Clayton, Mishel, & Belyea, 2006). Results yielded that symptom bother (pain, fatigue and other symptoms) accounting for 11% of the variance related to thoughts of cancer recurrence (Clayton et al., 2006). Age was found to be directly associated with symptom bother (as age increased symptom bother decreased) and indirectly associated with feelings of decreased uncertainty, better mood and lower worry of recurrence (Clayton et al., 2006).

A study of 572 breast cancer survivors in the Western United States investigated patterns of sleep duration change across the breast cancer survivorship period including demographic and clinical predictors and cancer-related symptoms (Alfano et al., 2011). Findings revealed that half of the survivors did not report sleep changes over time however 25% reported sleep changes that were temporary, late-occurring or a sustained change (Alfano et al., 2011). Those survivors with the sustained or temporary change were more likely to have been treated with chemotherapy ( $p<0.001$ ) or experienced weight gain post diagnosis ( $p=0.04$ ) (Alfano et al., 2011). The group who experienced sustained sleep change reported greater fatigue related concerns (severity, affective, and sensory) ( $p<0.0001$ ) compared to the no change group (Alfano et al., 2011). There

were no significant findings between the sleep groups with regard to fatigue, fear of recurrence or perceived stress (Alfano et al., 2011). Their findings suggest that survivors treated with chemotherapy and those with weight gain post breast cancer diagnosis may be at greater risk for sleep pattern changes hence greater risk for fatigue implicating the need for sleep screening and intervention as part of routine cancer survivorship assessment (Alfano et al., 2011).

Triggers of uncertainty regarding breast cancer recurrence were studied in 244 Caucasian and African-American women 5 to 9 years post-breast cancer diagnosis (Gil et al., 2004). The women in this study reported an average of 2 triggers of uncertainty per month consisting of hearing about someone else having cancer, doctor's appointments, and cancer information in the media (news, TV) (Gil et al., 2004). Other triggers included new aches, pains or other physical symptoms, and sights, sounds and smells that reminded them of their breast cancer experience; although their fear of recurrence was not constant the triggers remained persistent over time (Gil et al., 2004). The most common trigger for African-American women was new symptoms and for Caucasian women hearing about someone else with cancer (Gil et al., 2004). Older women reported significantly fewer triggers ( $r = -0.16, p < 0.01$ ) and women with higher education reported more triggers ( $r = 0.21, p < 0.001$ ) (Gil et al., 2004). Caucasian women were more likely to report their fear of recurrence being triggered by hearing about someone else's cancer, environmental factors and information in the media regarding cancer than African-American women (Gil et al., 2004).

An exploratory qualitative analysis of 276 email messages from 60 breast and prostate cancer patients in Norway examined the content of emails sent to oncology nurses (Grimsbo, Finset, & Ruland, 2011). Themes from the 38 breast cancer patients revealed that women expressed fear and anxiety related to relapse or metastases. Their fear was related to physical



changes in their bodies (new experience of pain in their breasts or armpits and tiredness) (Grimsbo et al., 2011). Expressing concerns about every little change in the body, topics they read about in the paper related to cancer and knowing about patients that receive other types of treatment (Grimsbo et al., 2011). A final trigger that was identified was related to topics that patients read about in the newspaper and in their peer-to-peer on-line communication involving the type of cancer treatment they received in comparison to their peers raising concerns about their choices and effectiveness of the treatment they received (Grimsbo et al., 2011).

A cross-sectional study in Italy examined quality of life, fatigue and depression in 255 long-term breast cancer survivors (Romita, Cormio, Giotta, Colucci & Mattioli, 2012). The mean survival time was 10.5 years (range 5 to 32 years), education level was low with less than 8 years of school, most had received combined therapy (surgery, radiation and chemotherapy), the majority did not smoke and also did not exercise (Romita et al., 2012). Sleep patterns in this sample reported regular sleep (50%) and 46% reported disturbed sleep (Romita et al., 2012). Survivors with lower education ( $p=0.007$ ) and two or more comorbidities experienced greater fatigue, fatigued survivors were significantly more depressed ( $p=0.000$ ) and reported more disrupted sleep ( $p=0.000$ ) overall fatigue was found to be moderate and severe (34%) and mild (66%) (Romita et al., 2012). These findings were similar with depression, survivors with depression (37% depressed, 20% moderate to severe depression) were found to have higher fatigue ( $p=0.000$ ) and more disturbed sleep ( $p=0.000$ ) (Romita et al., 2012).

A study of 47 breast cancer survivors within 1 to 14 months post treatment found that the majority of the women experienced persistent and troubling fears about disease recurrence (Allen, Savadatti, & Levy, 2009). These fears were often triggered by physical symptoms of unknown origin, and that sometimes they described their distress or depression as being related

to fear of recurrence (Allen et al., 2009). Fear of recurrence was common and persistent, although women transitioning out of treatment who exhibited fear and distress were also identified as very resilient (Allen et al., 2009). With these findings the researchers recommend that there are implications for nursing and other healthcare providers to consider the transition period post treatment as “window of opportunity” to support women’s coping mechanisms and strategies to promote health and well-being (Allen et al., 2009, p.76).

A qualitative study of semi-structured interviews with sixteen women post- breast cancer treatment examined the nature of thoughts and feelings regarding the possibility of breast cancer recurrence (Vickberg, 2001). Findings revealed that five of the sixteen women experienced strong feelings of recurrence whereas five other women expressed little or no fear of recurrence one citing that she felt blessed and confident that the cancer was not going to come back (Vickberg, 2001). In addition, triggers associated with fear of recurrence were examined with being around others with cancer or hearing about cancer being the most common trigger of fear of recurrence (Vickberg, 2001). Doctor appointments and testing such as mammograms and future oriented activities also created anxiety associated with fears of recurrence (Vickberg, 2001). Three of the women expressed that fear of recurrence was triggered by physical symptoms from the initial breast cancer (Vickberg, 2001).

In summary, physical symptoms such as pain, fatigue, anxiety and symptoms related to the cancer treatment were found to be associated with increased FOR (Allen et al., 2009; Clayton et al., 2006; Gil et al., 2004; Grimsbo et al., 2011; Vickberg, 2001). Older women reported reduced symptom bother or triggers and lower worry of cancer recurrence (Clayton et al., 2006; Gil et al., 2004). Those women with less education reported greater fatigue and fatigued survivors were more depressed and had more disturbed sleep (Romita et al., 2012) and FOR was

reported as the cause for sleep disturbances in some women and was cited to be their main psychological complaint that persisted throughout the first year post treatment creating increased anxiety (Cappiello et al., 2007).

### **Depression, Perceived Stress and Anxiety and Fear of Breast Cancer Recurrence.**

Depression, perceived stress and anxiety and their association with fear of breast cancer recurrence has become a greater concern in the study of breast cancer survivorship in terms of improving quality of life through early screening and intervention. A study of 89 women examined depression, anxiety and cancer related distress post-treatment for breast cancer (Costanzo et al, 2007). They found depression, anxiety and cancer related distress to be true for younger women and those women of any age with some history of college education demonstrated greater distress (Costanzo et al, 2007). Women demonstrated elevated depression with a self-reported history of anxiety, depression or emotional disturbance and also those taking antidepressants were at greater risk for depressive symptoms (Costanzo et al, 2007). Women who received more extensive treatment had greater cancer-related anxiety but not depressive symptoms and those women who received chemotherapy had a greater recurrence worry than those who only received radiation (Costanzo et al, 2007). Stage of cancer was not found to be significant (Costanzo et al, 2007).

Factors contributing to adaptive survivorship were examined in a longitudinal study of 70 women with Stage I and II breast cancer in the Midwest, United States (Stanton et al., 2002). Using the Fear of Recurrence Scale by Northouse the researchers found that older women reported less fear of recurrence at 3-months ( $r=-0.39$ ,  $p<0.001$ ) and 1-year ( $r = -0.52$ ,  $p<0.001$ ) (Stanton et al., 2002). Avoidance-oriented coping at study entry was related to lower Profile of Mood States Distress at 3-months but increased fear of recurrence at 1 year (Stanton et al.,

2002). At 1 year, older women reported less fear of recurrence (partial  $r = -0.29$ ,  $p < 0.05$ ) (Stanton et al., 2002). Women who scored high in hope were predicted to have lower fear of cancer recurrence 3-months later if they coped through positive reinterpretation at diagnosis ( $p < 0.05$ ) (Stanton et al., 2002). Coping through avoidance at diagnosis predicted decreased fear of recurrence distress at 3-months but higher fear of recurrence at 1-year for 70 women with stage I and II breast cancer through their first year of treatment; this finding suggests that avoidance is an important risk factor for cancer specific maladjustment (Stanton et al., 2002).

Post-menopausal women (N=153) in New Zealand with early stage breast cancer participated in a cross-sectional study design to examine the relationship between fear of recurrence and illness perceptions, medication beliefs, treatment side effects, demographic factors and emotional distress (Corter, Findlay, Broom, Porter & Petrie, 2013). Using the Worry About Cancer scale to measure fear of recurrence a significant difference was seen in fear of recurrence between unemployed women (M=15.1, SD = 8.6) and employed women (M=12.9, SD=6.2) ( $p=.03$ ) with unemployed women experiencing greater fear of recurrence (Corter et al., 2013). No differences were noted between younger and older women ( $p=.12$ ), in a relationship or not in a relationship ( $p=.95$ ), ethnicity ( $p=.27$ ) or time since diagnosis ( $p=.07$ ) (Corter et al., 2013). There were no noted differences between women who received chemotherapy and those that did not and those that had radiation and those that did not (Corter et al., 2013). There was significant relationship between mean anxiety and depression scores and fear of recurrence ( $p = 0.001$ ) (Corter et al., 2013). Higher fear of recurrence was associated with more symptoms related to breast cancer ( $p=0.001$ ) and those that believed that their cancer was caused by stress experienced significantly higher fear of recurrence ( $p=.05$ ) than women who did not know what caused their cancer ( $p= .01$ ), lifestyle, hormones, genetics and chance were not significantly

related to fear of cancer recurrence (Corter et al., 2013). In the regression model, fear of recurrence was significantly associated with negative emotions including lower beliefs about treatment control ( $p=0.001$ ), greater timelines of experiencing breast cancer ( $p=0.002$ ) and more symptoms associated with breast cancer ( $p<0.05$ ) (Corter et al., 2013). Illness perceptions, beliefs about medicines, number and severity of reported side effects from aromatase inhibitors, anxiety, depression and employment status comprise about 61% of the variance in fear of recurrence scores (Corter et al., 2013).

A study of 307 women in the Netherlands with early stage breast cancer ( $n=117$ ) or benign breast problems ( $n=190$ ) looking at social, psychological, support factors and predictors of fatigue at 6 and 12 months post-surgical treatment (De Vries, Van der Steeg & Roukema, 2009). In the breast cancer group predictors of fatigue were depressive symptoms, poor social support and neuroticism (De Vries et al., 2009). In the breast cancer group, none of the demographic or clinical factors predicted fatigue at Time 2 and 3 (De Vries et al., 2009). Trait anxiety ( $p < 0.001$ ) and extraversion ( $p < 0.05$ ) at Time 2 and trait anxiety ( $p<0.05$ ), extraversion ( $p<0.05$ ), and depressive symptoms ( $p<0.05$ ) at Time 3 predicted fatigue in the breast cancer group (De Vries et al., 2009). These findings suggest that those individuals that are fatigued early in their diagnosis many will continue to experience fatigue later on in their treatment and post-treatment therefore suggesting early fatigue screening and intervention (De Vries et al., 2009).

In a study of 331 ethnically diverse women in California within 3 to 7 months of diagnosis were examined for depressive symptoms (Wong-Kim & Bloom, 2005). Younger women with higher levels of pain ( $p = 0.035$ ), lower levels of self-esteem ( $p < 0.0005$ ) and lower emotional support ( $p < 0.0005$ ) were at greatest risk for depressive symptoms (Wong-Kim &

Bloom, 2005). However women of any age with severe treatment side effects, low self-esteem and low emotional support were also at risk (Wong-Kim & Bloom, 2005). Only amount of pain predicted depressive symptoms; conversely disease severity, type of surgery, number of positive lymph nodes, nausea were not significant for predicting depressive symptoms (Wong-Kim & Bloom, 2005).

A prospective quality of life study of 506 women diagnosed with ductal carcinoma in situ (DCIS) or early invasive breast cancer (EIBC) stage I – IIA was performed using interviews at 4-6 weeks, 6 months and 2 years post-treatment (Liu et al., 2011). Moderate fear of recurrence was reported in 24.8% of patients and 4% of the women reported high levels of fear of recurrence (Liu et al., 2011). Using three stepwise multivariable linear regression models Liu et al., (2011) found that younger age, EIBC stage IIA breast cancer, lower social support and elevated anxiety was associated with higher fear of cancer recurrence (measured with 4-items from the Concerns About Recurrence Scale (CARS) ( $P < 0.05$ ; final models  $R^2 = 0.25-0.32$ ). DCIS patients had lower FOR than stage IIA patients ( $P \leq 0.01$ ) (Liu et al., 2011). Breast cancer survivors with higher levels of education ( $>$  high school) reported less FOR at baseline and greater depressive symptoms at baseline had higher fear of cancer recurrence; neither of these symptoms were observed at 6-months or 2-years (Liu et al., 2011).

A study of 1,957 breast cancer survivors in California examined the occurrence of fatigue and associated demographic, medical and psychological factors compared to the general population (Bower et al., 2000). Women who were who were fatigued were younger ( $p < 0.05$ ), earned lower annual income ( $p < 0.05$ ) and less likely to be in a significant relationship ( $p < 0.05$ ) (Bower et al., 2000). Women in the fatigue group also experienced more physical complaints such as arthritis ( $p < 0.05$ ), headaches ( $p < 0.05$ ) and heart disease ( $p < 0.05$ ) (Bower

et al., 2000). The women in the fatigue group were also more likely to have been treated with chemotherapy or chemotherapy and radiation than their non-fatigued counterparts (Bower et al., 2000). Women with fatigue reported greater sleep disturbances, more severe and disabling pain and higher level of depressive symptoms (Bower et al., 2000). The greatest predictors of fatigue were depression ( $p = 0.0001$ ) and pain ( $p = 0.0001$ ) (Bower et al., 2000). Although fatigue was not a significant concern for the women in this study, those women that did experience fatigue were more likely to experience depression, bodily pain and sleep disturbances (Bower et al., 2000).

A study of 169 women (81 with breast cancer and 88 benign breast problems) in The Netherlands found that trait anxiety assessed before diagnosis was the only significant predictor of depressive symptoms ( $r = .59$ ,  $p < 0.001$  before diagnosis and  $r = .66$ ,  $p < 0.05$  at 1-month) and fatigue ( $r = .66$ ,  $p < 0.001$  before diagnosis and  $r = .60$ ,  $p < 0.001$  at 1-month) (De Vries, Van der Steeg, & Roukema, 2009). Age, marital status, having children and having paid work were unrelated to trait anxiety, depressive symptoms or fatigue (DeVries et al., 2009). Patients with benign and breast cancer with high trait anxiety also scored high on fatigue (DeVries et al., 2009). The results identified that by incorporating all four time points (pre-diagnosis, 1-month, 3-months, 6-months) among both groups (benign and breast cancer) that patients who scored high on trait anxiety appeared to be at risk for developing depressive symptoms and fatigue (DeVries et al., 2009). The researchers recommend that women with a suspicion of breast cancer should be screened for trait anxiety and for those individuals who score high in trait anxiety psychological therapy should be offered as part of their treatment plan (DeVries et al., 2009).

A study in Scotland examined the prevalence of severe fatigue and associations with activity level and psychological distress in 69 breast cancer survivors at least 6-months post-

treatment (Young & White, 2006). Those patients that experienced cancer related fatigue also reported greater symptoms of anxiety, depression and psychological distress ( $p \leq 0.001$ ) (Young & White, 2006). Fatigue increased as the number of treatment modalities increased for those survivors with fatigue ( $p < 0.05$ ) (Young & White, 2006). Correlations were significant between fatigue and beliefs about activity, psychological distress, and fear of recurrence ( $p < 0.01$ ). Fear of recurrence was found to be a significant predictor of fatigue but was mediated by psychological distress and beliefs about activity and therefore fear of recurrence had an indirect association with fatigue ( $p \leq 0.01$ ) (Young & White, 2006).

A recent cross-sectional study of 1,128 long-term breast cancer survivors in two Midwestern university cancer centers explored the effect of age at diagnosis on fear of breast cancer recurrence and predictors of fear of recurrence (Ziner et al., 2012). Younger women were defined as ages 45 years and younger and older age was considered 55 to 70 years of age (the age gap from 46 – 54 years was deliberate as part of the study design) (Ziner et al., 2012). Findings were based the 505 younger women and 623 older women who participated in the study. Consistent with the literature the younger women experienced greater fear of recurrence than the older women in the study ( $t = 7.7 - 15.4, p < 0.001$ ) (Ziner et al., 2012). Age ( $p = 0.001$ ), perceived risk of recurrence ( $p = 0.001$ ), trait anxiety ( $p = 0.001$ ) and breast cancer reminders ( $p = 0.001$ ) were all associated with fear of recurrence (Ziner et al., 2012). Although age at diagnosis was not associated with breast cancer survivor self-efficacy (ability to manage symptoms, emotions and facilitate support related to breast cancer) breast cancer survivor self-efficacy was inversely related to higher perceived risk of recurrence ( $p = 0.07$ ), symptom bother ( $p < 0.001$ ), and trait anxiety ( $p < 0.001$ ) (Ziner et al., 2012). Breast cancer survivor self-efficacy predicted lower fear of cancer recurrence ( $r = -0.183, p < 0.001$ ) and demonstrated a partial



mediation effect ( $p = 0.05$ ) on the relationship between the antecedent variables age at diagnosis, perceived risk of recurrence, trait anxiety and breast cancer reminders and outcome variable fear of recurrence (Ziner et al., 2012).

Understanding more about fear of recurrence and how the demographic, psychological and physiologic factors influence fear of recurrence will shape the future interventions become more individualized and targeted. The shift from breast cancer diagnosis and treatment to quality of life and well-being related to the psychological needs during survivorship has brought fear of breast cancer recurrence to the forefront as a priority for further investigation.

In summary, psychological symptoms associated with FOR were found to be bidirectional in their relationships and associated with other demographic factors. Anxiety was found in some of the studies to be associated with increased FOR (Corter et al., 2013; Liu et al., 2011; Ziner et al., 2012) and depression (Corter et al., 2013). Trait anxiety predicted fatigue (DeVries et al., 2009) and depressive symptoms (DeVries et al., 2009). Younger women with higher levels of pain, women of any age with severe treatment side effects and both younger and older women with low self-esteem and low social support were at greater risk for depressive symptoms (Wong-Kim & Bloom, 2005). Younger age, lower social support, increased anxiety and greater depressive symptoms at baseline was associated with increased FOR however women with higher education reported less FOR at baseline (Liu et al., 2011). Increased cancer related fatigue was associated with greater anxiety, depression, psychological distress and fear of recurrence (Young & White, 2006).

**Fear of Recurrence and Breast Cancer Survivors.** The National Cancer Institute (2013) defines cancer recurrence as a cancer that returns where it started or in another place in the body after treatment and after a period of time that the cancer could not be detected. The

literature tends to use worry and uncertainty synonymously with fear in fear of recurrence (Simard & Savard, 2009; Vickberg, 2003) and hence the development of various fear of recurrence instruments. In a 2009 study validating a fear of recurrence inventory, the author argued that one of the challenges with researching fear of cancer recurrence was the lack of consensus for an accepted definition for fear of recurrence (Simard & Savard, 2009). Despite some of these differences fear of cancer recurrence has become a legitimate concern related to breast cancer survivorship.

The Concerns About Recurrence Scale (CARS), an instrument developed by Vickberg (2003), was designed to assess the overall fear and the extent and nature of women's fears about the possibility of breast cancer recurrence. The instrument was assessed in 169 breast cancer survivors from five physician practices at a large New York City medical center. Participants needed to be 18-years of age or older, speak English, within 7 years of diagnosis of local or regional breast cancer and have received surgery for breast cancer and post-treatment (Vickberg, 2003). The CARS defines fear of recurrence as "the breast cancer coming back in the same breast or other areas of the body or a new breast cancer on either breast" (Vickberg, 2003, p. 18). The CARS contains two parts: 1) the overall fear of recurrence and 2) the nature of women's fears of recurrence (Vickberg, 2003).

Using exploratory factor analysis conducted to determine the structure of the CARS and to identify meaningful subsets of items the results yielded a four-factor solution that accounted for 70% of the variance (Vickberg, 2003). The overall fear index was found to have a high internal consistency ( $\alpha = .87$ ) and significantly correlated with all four CARS subscales: Death ( $r = .64$ ); Health ( $r = .64$ ); Roles, ( $r = .50$ ), and Womanhood ( $r = .53$ ) (all correlations  $p < .0001$ ) (Vickberg, 2003). Approximately 45% of the women reported moderate levels of fear of

recurrence and 10% high levels of fear; for some of the women recurrence was the biggest fear, aware that disease could recur at any time and others revealed that the fears were subtle yet constant in addition to some revealing that fear of recurrence interfered with their ability to plan for the future (Vickberg, 2003). Finally, the background variable of age was the only significant variable found to be negatively related to overall fear ( $p < .05$ ) (Vickberg, 2003). Vickberg (2003) found that stage of cancer, mastectomy and time since diagnosis were not a predictor of FOR.

A study of 72-breast cancer survivors was studied for severity of four common concerns (fear of the future, physical limitations, pain, problems with family or friends) at 3, 7, 11, 15 months and 6 years after diagnosis (Lebel et al., 2007). They found that fear of the future (fear of recurrence) was the most stressful concern for breast cancer survivors (Lebel et al., 2007). They noted that although the perceived stressfulness of fear of the future appeared to decline during the 3 and 7-month period after diagnosis, it stabilized at a constant state through 6 years (Lebel et al., 2007).

A prospective Dutch study of 136 breast cancer survivors designed to evaluate the psychometric properties of the Dutch version of the Concerns About Recurrence Scale (CARS) and to measure the concerns about disease recurrence and how fear of recurrence effects quality of life (Van den Beuken-van Everdingen et al., 2008). Moderate to high levels of fear were reported by 56% of women with pain found to be a strong predictor of fear of recurrence ( $p < 0.001$ ), overall fear decreased with age ( $p < 0.012$ ) (Van den Beuken-van Everdingen et al., 2008). Women with higher education levels had significantly more health and role worries (on the CARS subscales) than women with lower education (Van den Beuken-van Everdingen et al., 2008).

In a German study of 1083 breast cancer survivors character and frequency of fear of cancer progression was studied with the relationship with cancer-related intrusive cognitions (Menhert, Berg, Henrich & Herschbach, 2009). Findings revealed significant correlations between fear of cancer progression and intrusive thoughts ( $r=0.63$ ), avoidance ( $r= 0.57$ ), hyperarousal ( $r=0.54$ ) and posttraumatic stress disorder diagnosis ( $r=0.42$ ) (Menhert et al., 2009). Intrusive thoughts and being afraid of disease progression demonstrated the highest relationship along with having physical symptoms of anxiety such as rapid heart rate, being afraid of severe medical treatments and being nervous prior to doctor's appointments (Menhert et al., 2009).

An exploratory study describing the extent and nature of fear of cancer recurrence in relation to socio-demographic characteristics, treatment related characteristics, psychological distress and quality of life in 51 African-American breast cancer survivors in Washington D.C. was performed (Taylor et al., 2011). Sixty-seven percent of the women reported some degree of fear of recurrence and low to moderate levels of fear of recurrence ( $M=2.65$ ,  $SD=1.44$ ) using the Concerns About Recurrence Scale (CARS) (Taylor et al., 2011). Overall fear was negatively associated with time since diagnosis ( $r =-.35$ ,  $p < .05$ ) and negatively related to quality of life ( $r=-.38$ ,  $p>.01$ ) (Taylor et al., 2011). In addition, overall fear of recurrence was positively related to global psychological distress ( $r = .43$ ,  $p < .01$ ), younger patients experienced higher levels of fear of cancer recurrence and there was no difference between fear of cancer recurrence worries and surgery type (Taylor et al., 2011).

A qualitative study of 21 breast cancer survivors at least 3-months post-treatment in California exploring the different quality of life experiences and needs (Ferrell, Grant, Funk, Otis-Green & Garcia, 1997). Some of the common shared experiences expressed by the women related to physical well-being were pain, fatigue, insomnia and that their complaints were not

always taken seriously by their health care team (Ferrell et al., 1997). Fear of recurrence was a common shared experience for the women, and although it may dissipate for periods of time throughout survivorship physical reminders of the cancer or hearing about cancer would recreate fears of recurrence; one woman stating “I guess it just never goes away” (Ferrell et al., 1997, p.20). This early study provided a foundation for further exploration, support, management and intervention of quality of life issues in breast cancer survivorship.

A study of 89 breast cancer patients from 5-Midwest treatment centers examined the psychological adjustment during the 3-months following treatment for breast cancer and health related quality of life (Costanzo et al., 2007). Many of these women experienced moderate cancer related anxiety and concerns about ongoing physical symptoms and fear of cancer recurrence using the Concerns About Recurrence Scale (CARS) (Costanzo et al., 2007). Level of education (mainly some college but less than those who completed college or a graduate degree) predicted greater FOR distress ( $p < 0.001$ ) (Costanzo et al., 2007). Aside from side effects and physical problems, fear of recurrence was the greatest source of distress during the post treatment period (Costanzo et al., 2007). Women who reported extensive treatment therapy (mastectomy) were found to be a greater predictor of fear of recurrence distress than women who received lumpectomy ( $p = 0.012$ ) at 3-months in 71 breast cancer survivors (Costanzo et al., 2007).

A study examining factors associated with quality of life in a sample of 246 randomly selected cancer survivors and their family members was performed to identify factors associated with fear of recurrence of cancer survivors and their caregivers and to determine if survivors and family caregivers influenced each other's fears of recurrence (Mellon, Kershaw, Northouse, & Freeman-Gibb, 2007). Study findings identified that fear of recurrence was predominately

determined by the individual not by their partner and that each person's perception had more influence on their individual level of fear of recurrence than the influence on their partner (Mellon et al., 2007). One partner effect finding was that older survivors with younger caregivers and older caregivers with younger partners both experienced increased fear of cancer recurrence ( $p < 0.01$ ) and caregivers who were family members also experienced greater fear of recurrence ( $p < 0.001$ ) (Mellon et al., 2007). Families that reported concurrent family stressors had more fear of recurrence and the lower quality of life ( $p < 0.01$ ) (Mellon et al., 2007). Survivors and caregivers who had more positive meaning with the illness experienced significantly less fear of recurrence ( $p < 0.01$ ) (Mellon et al., 2007).

A study of 231 cancer survivors, including breast cancer survivors ( $n = 94$ ), found fear of recurrence to be a predictor for increased outpatient visits ( $r = .16, p = .025$ ), emergency room visits ( $r = .16, p = .028$ ) and quantity of medications used ( $r = .20, p = .013$ ) (Lebel, Tomei, Feldstain, Beattie, & McCallum, 2013). In particular, both younger and female survivors reported greater fear of recurrence, more visits to health care professionals and medication utilization (female survivors only) (Lebel et al., 2013). Overall results suggest that younger, female cancer survivors reported greater fear of cancer recurrence and greater health care utilization (Lebel et al., 2013).

A randomized controlled trial of 84 breast cancer survivors from Tampa, Florida examined the effects of a 6-week Mindfulness Based Stress Reduction (MBSR) program as an intervention for psychological stressors (perceived stress, anxiety, depression, fear of recurrence) and physical symptoms (pain, fatigue, sleep disturbances) in early breast cancer survivorship (Lengacher et al., 2009). This is the first intervention study using MBSR as an intervention for reducing fear of breast cancer recurrence (Lengacher et al., 2009). Subjects in the MBSR

intervention group demonstrated lower scores at 6-weeks compared to the usual care group in fear of recurrence ( $p = 0.007$ ), fear of recurrence problems ( $p = 0.01$ ), state anxiety ( $p = 0.03$ ), trait anxiety ( $p = 0.004$ ) and depression ( $p = 0.03$ ) (Lengacher et al., 2009).

Another intervention study of 19 women post breast cancer treatment from Tampa, Florida assessed the impact of an 8-week MBSR program as an intervention for fear of recurrence, perceived stress, anxiety, and depression and physical symptoms (Lengacher et al., 2011). This study was designed to assess the feasibility of an 8-week MBSR program on psychological, physical symptoms and quality of life in early breast cancer survivorship. The intervention of the 8-week MBSR program demonstrated a reduction in fear of recurrence ( $p = .01$ ), fear of recurrence concerns ( $p = .04$ ), state anxiety ( $p = .09$ ), trait anxiety ( $p = .01$ ), depression ( $p = .009$ ) and perceived stress ( $p = .01$ ) (Lengacher et al., 2011).

In summary, FOR remains a predominate concern for women post treatment for breast cancer and into survivorship (Costanzo et al., 2007; Ferrell et al., 1997; Lebel et al., 2007; Van den Beuken-van Everdingen et al., 2008). As discussed in the earlier studies, age, physical symptoms and anxiety were associated with fear of recurrence (Ferrell et al., 1997; Lebel et al., 2013; Lengacher et al., 2009; Menhert et al., 2009; Taylor et al., 2011; Vickberg, 2003). In one study younger patients experienced greater FOR and more health care utilization (Lebel et al., 2013) suggesting that there is a relationship between health-related anxiety and increased health care utilization and health care costs (Lebel et al., 2013; Barsky, Ettner, Horský, & Bates, 2001). Other studies revealed that higher levels of education (Costanzo et al., 2007; Van den Beuken-van Everdingen et al., 2008) and patients who received mastectomy (Costanzo et al., 2007) reported greater FOR contradicting findings from previous cited studies where these factors were associated with lower FOR.

## Summary

It is evident in the empirical research reviewed that fear of breast cancer recurrence is a legitimate and consistent concern among breast cancer survivors in the short and long term. Younger age, limited education, increased fatigue, anxiety and depression are some of the more common themes seen in the research to be associated with fears of cancer recurrence. However, there tends to be preliminary findings that some of these factors may be influenced by age, race/ethnicity and psychological influences such as social support and coping skills. Several studies demonstrated that increased psychological concerns, like fear of recurrence particularly in younger women resulted in more medical visits hence driving up the costs of health care. It is clear from these findings and the qualitative requests from the women in these studies that there is substantial opportunity for early screening and intervention related to fear of recurrence and the associated factors.



## Chapter Three

### Methods

This chapter outlines the research methods and procedures used for this study. The first section discusses the research design followed by the methods, setting, population and sample, recruitment, instrumentation and data analysis procedures.

#### Design

A cross-sectional research design was used to conduct a secondary data analysis among 82 women who were post treatment for breast cancer. The original parent study was an R-21 NCI funded (grant #R21CA109168), randomized controlled intervention trial examining the Effects of Mindfulness Based Stress Reduction in Early Stage Breast Cancer Recovery (Lengacher et al., 2009). The current study utilizes the baseline data from the R-21 study for a secondary data analysis examining the relationship between stable, non-modifiable trait factors and transient, modifiable state factors on fear of cancer recurrence in breast cancer survivors. See Figure 1 in the Theoretical Framework section.

**Setting and Subjects.** Study subjects were recruited from the H. Lee Moffitt Cancer Center and Research Institute at the University of South Florida in Tampa, Florida. The H. Lee Moffitt Cancer Center is a National Cancer Institute and a nationally recognized Cancer Center of Excellence for the diagnosis and treatment of breast cancer. The center's catchment area includes nearly 3 million people and serves the largest population of breast cancer patients in the greater metropolitan area of Tampa, Florida. Recruitment for the parent study started March 1, 2006; all data collection was completed July 23, 2007.

**Inclusion/Exclusion Criteria.** This study sample consists of 82 women age 21 or older who were diagnosed with breast cancer Stage 0, I, II, III and had undergone surgery (lumpectomy), received adjuvant radiation and/or chemotherapy and were within 18 months post treatment. Other inclusion criteria included the ability to read and speak English at an 8<sup>th</sup> grade level in order to respond to survey questions. Exclusion criteria included subjects advanced stage breast cancer (Stage IV), history of prophylactic mastectomy prior to current breast cancer treatment, severe psychiatric diagnoses and recurrent treatment for prior breast cancer.

**Power Analysis.** Prior to initiation of this study, the available sample size was reviewed with respect to the specific aims to estimate statistical power and ability to draw reliable inferences from the analysis. For specific aims 1 and 2, the primary analytical method used consisted of Pearson or Spearman correlation coefficients (depending on statistical properties of the continuous variables being evaluated), or analysis of variance (ANOVA) for comparisons of means between levels of categorical variables. In these analyses, fear of recurrence, an approximately normally distributed continuous variable was the dependent variable of interest. Potential predictors of interest consisted of non-modifiable trait factors and modifiable state factors that may be associated with fear of recurrence.

In correlation analyses, a sample size of 82 subjects provided 80% power (2-sided type I error rate of 0.05) to detect a “modest” non-zero correlation coefficient of 0.303 or higher. For ANCOVA, the power estimation assumed that 2 variables are adjusted for in the model that collectively account for 10% of the variation ( $R^2$ ) in ratings of fear of recurrence. With a fixed sample size of 82 subjects and 2-sided type I error rate of 0.05, the study provided 80% power to detect an  $R^2$  value of 0.0786 attributed to one additional independent variable (e.g. a modifiable state factor). This corresponds to a modest correlation coefficient of 0.28 indicating that the

analysis was adequately powered to detect a modest effect size. Thus, the sample size of 82 subjects provided sufficient power to reliably examine specific aims 1 and 2.

For specific aim 3, statistical power was influenced by the correlation (unknown) between the independent variable of interest and mediating variable of interest. With a sample size of 82 subjects, assuming 2-sided type I error rate of 0.05 and a modest correlation of 0.30 between the independent variable and mediating variable (with variance of 1), the study provided 80% power to detect a standardized beta coefficient of 0.32 or higher. This corresponds to a partial  $R^2$  value of 0.10, again indicating adequate power for the analysis.

### **Instrumentation**

The following instruments were used to measure the antecedent, mediator and the primary outcome variable:

#### **Antecedent Variables**

*Demographic data* were obtained using the Demographic Data Form (Lengacher et al., 2009) to capture participant socio-economic demographic data for a description to be the study sample. Data gathered included age, race/ethnicity, education, marital status, and employment status.

*Clinical History data* were obtained using the Clinical History Form (Lengacher et al., 2009) to capture cancer stage at time of diagnosis, treatment type, history of hormone use, family history of breast cancer, social/behavioral history, including exercise habits, history of alcohol, and tobacco use.

#### **Mediator Variables**

*Physiologic Symptom data* (Pain, Fatigue and Disturbed Sleep) were measured using the M.D. Anderson Symptom Inventory (Cleeland et al., 2000). This is a self-

administered questionnaire measuring current symptoms and severity of symptoms experienced by the patient. The scale consists of 13-symptom items rated on presence and severity and 6-symptom interference items that are rated on level of symptom interference with function. For the purposes of this study only the subscales in the first section of the instrument that measures symptoms in the last 24 hours will be used. Each of the subscales consists of one item for each variable (pain, fatigue and disturbed sleep) rated on Likert-type scale from 0 (not present) to 10 (as bad as you can imagine) (Cleeland et al., 2000). Construct validity has been evidenced by principal factor analysis using data from the initial outpatient sample (cross-validation sample) and demonstrated high correlations with independent indicators of general symptom severity factors and gastrointestinal factors. The internal reliability consistency ranges from 0.82 – 0.94 (Cleeland et al., 2000).

**Depression** was measured using the Center for Epidemiological Studies Depression Scale (CES-D) (Radloff, 1977). This is a 20-item instrument that measures depressive symptoms. Respondents rate on a 4-point scale the frequency of their depressive symptoms within the past week (Radloff, 1977). Items are rated from (0) rarely or none of the time to (3) most or all of the time. The scoring provides a total depression score with a range from 0 to 60 of experienced symptoms (0 = not at all to 1 day a week for all 20 items ranging to 60 = 5 to 7 days a week) with the higher scores indicating greater depressive symptoms (Radloff, 1977). The CES-D has demonstrated concurrent validity by clinical and self-report criteria and construct validity (Radloff, 1977). The Cronbach alpha value for the CES-D is 0.92 for breast cancer subjects (Radloff, 1977).

*Perceived Stress* was measured using the Perceived Stress Scale (Cohen, Kamarck, & Mermelstein, 1983). This is a 10-item Likert-type instrument that measures “how often in the past month one appraises life situations as stressful” (Cohen et al., 1983). Items are scored as (0) Never to (4) Very often. Construct and predictive validity has been established with the Perceived Stress Scale and the CES-D and life events scales. The internal consistency and reliability for the Perceived Stress Scale ranged from 0.84 – 0.86 (Cohen et al., 1983).

*Trait and State Anxiety* was measured using the State Trait Anxiety Inventory (Spielberger et al., 1983). This instrument contains two 20-item Likert-type scales that measures both state anxiety (Y1-present experience of anxiety), and is scored as: Not at all, Somewhat, Moderately so, Very much so. Trait anxiety (Y2-trait anxiety the potential of the individual to experience anxiety symptoms when confronted with a threatening situation), scored as: Not at all, Sometimes, Often, Almost always). Concurrent, convergent, divergent and construct validity was represented using contrasted groups, correlations of T-Anxiety scale with other measures of trait anxiety, correlations of the STAI scales with other measures of personality and adjustment and also academic aptitude and achievements and investigations of the effects of different amounts and types of stress on S-Anxiety scores (Spielberger et al., 1983). The internal consistency reliability for the State Trait Anxiety Scale is 0.95 (Spielberger et al., 1983).

### **Outcome Variable**

*Fear of Recurrence* was measured using the Concerns about Recurrence Scale (CARS) (Vickberg, 2003). This is a 30-item Likert-type instrument that measures the extent and nature of women’s fears about the possibility of breast cancer recurrence.

Comprised of 2 subscales overall fear of recurrence and worries related to recurrence. The first section contains 4 items that assesses the overall fear of recurrence, with the scoring (1) “I don’t think about it at all” to (6) “I think about it all the time” (Vickberg, 2003). The second subscale has four subscales comprising 26-items that assesses “what it is” and extent to which they worry about each item regarding death worries, health worries, role worries, role worries and womanhood worries. The overall fear index was found to have a high internal consistency ( $\alpha = .87$ ) and significantly correlated with all four CARS subscales: Death ( $r = .64$ ); Health ( $r = .64$ ); Roles, ( $r = .50$ ), and Womanhood ( $r = .53$ ) (all correlations  $p < .0001$ ) (Vickberg, 2003). Scoring for the second section is on a 5-point scale ranging from (0) not at all to (4) extremely (Vickberg, 2003).

Convergence validity was determined comparing CARS to the Intrusive Thoughts and Avoidance Subscales of the Impact Events Scales (IES) and the Distress and Well-Being subscales of the Mental Health Inventory (MHI) (Vickberg, 2003). Internal consistency for Concerns about Recurrence Scale is 0.87 for breast cancer subjects (Vickberg, 2003).

## **Procedures**

**Approval.** Approval for this study was granted by the Institutional Review Board at the University of South Florida (See Appendices) as a modification to the original study, Effects of Mindfulness Based Stress Reduction in Early Stage Breast Cancer Recovery. This research study analyzes de-identified data collected during 2006 and 2007 R-21 NCI study.

**Data Collection Procedures.** The current study is utilizing the secondary baseline data set from the R-21 (NCI Grant #R21CA109168) Effects of Mindfulness Based Stress Reduction in Early Stage Breast Cancer Recovery (Lengacher et al., 2009). Several recruitment methods were used for the parent study including introduction of the study by healthcare practitioners at

the H. Lee Moffitt Cancer Center in addition to brochures and flyers distributed throughout the cancer center. Patients who expressed interest in the study were asked to complete a HIPAA authorization form that indicated their willingness to be contacted by a member of the trained research team. Interested subjects were provided with an orientation session within the 6 weeks to 6 months post treatment for breast cancer that is the transition period from conventional treatment to adaptation and return to routine daily life and activities. During the orientation session study details were explained, informed consent was obtained, and patients were randomized into the different groups (as a note, in order to maximize enrollment subjects who were randomized to the control group were offered the opportunity to receive the intervention after a wait period). All subjects provided written consent and subjects received nominal compensation for their time of \$50 at the completion and end of the study participation.

**Data Management.** Statistical Product and Service Solutions (SPSS) Version 21.0 was utilized for all data entry, data management and analysis related to this study. Data were de-identified and stored in password protected files secured in the investigator's office to maintain confidentiality. Results were reported using only de-identified data and without patient identifiers.

**Data Analysis.** Data analysis was performed using quantitative statistical procedures in SPSS Version 21.0. The primary outcome variable fear of recurrence (CARS Overall Fear and CARS Nature of Worry) was analyzed three ways using Pearson's correlations, ANOVA and mediation analysis.

**Aim #1** – univariate analysis was used to evaluate the relationship between the antecedent variable (non-modifiable trait factors) including demographic information, clinical history, social/behavioral history and outcome variable, fear of breast cancer

recurrence (CARS overall fear and CARS nature of worry). The dependent variable of interest, fear of breast cancer recurrence, was measured on continuous scale and therefore initially the univariate association was examined by correlation coefficients for continuous covariates and analysis of variance for categorical variables. See Figure 2 and 3.

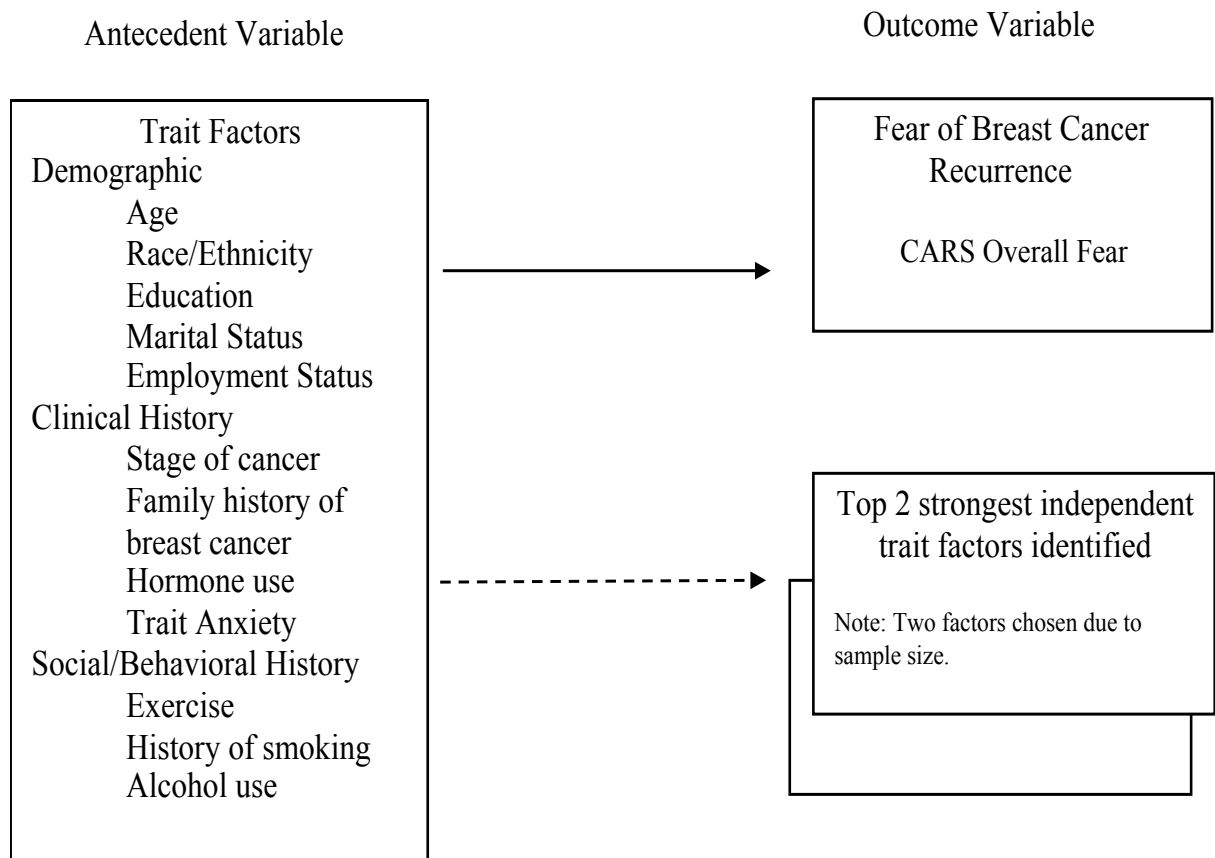


Figure 2. Model for Aim #1



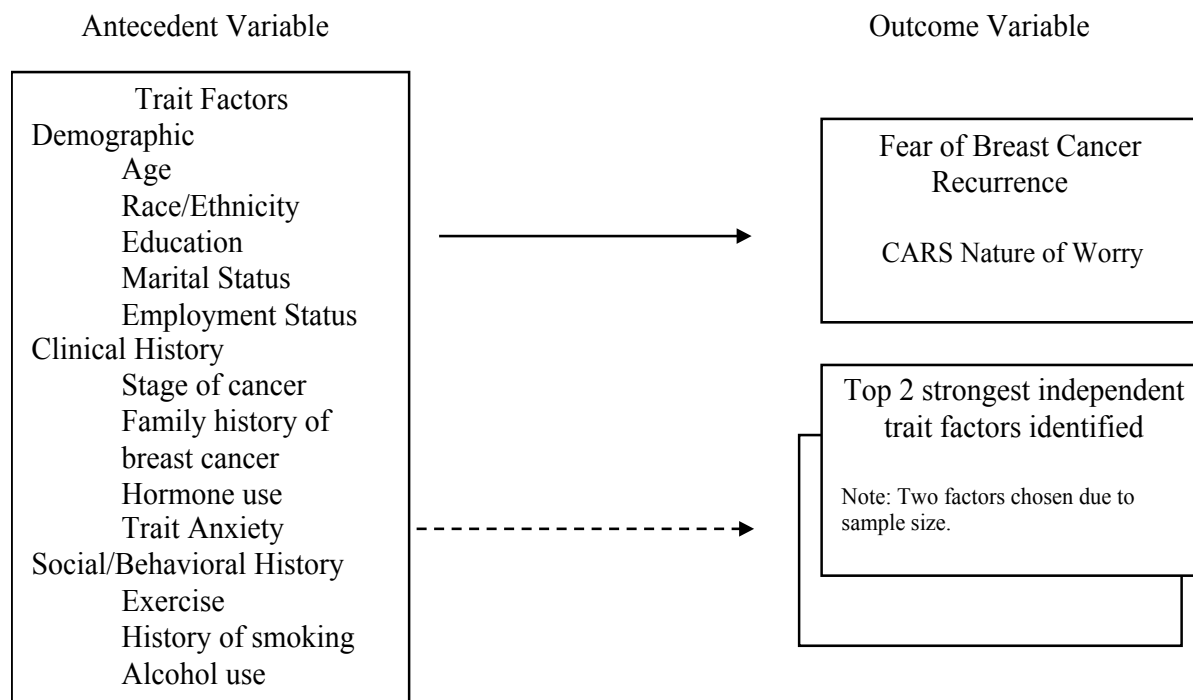


Figure 3. Model for Aim #1

***Aim #2*** – univariate analysis was used to evaluate the relationship between mediator variable (modifiable state factors) such as anxiety, depression, perceived stress, pain, fatigue and sleep disturbances and the outcome variable, fear of recurrence (CARS overall fear and CARS nature of worry). The dependent variable of interest, fear of breast cancer recurrence, was measured on continuous scale and therefore initially the univariate association is examined by correlation coefficients for continuous covariates.

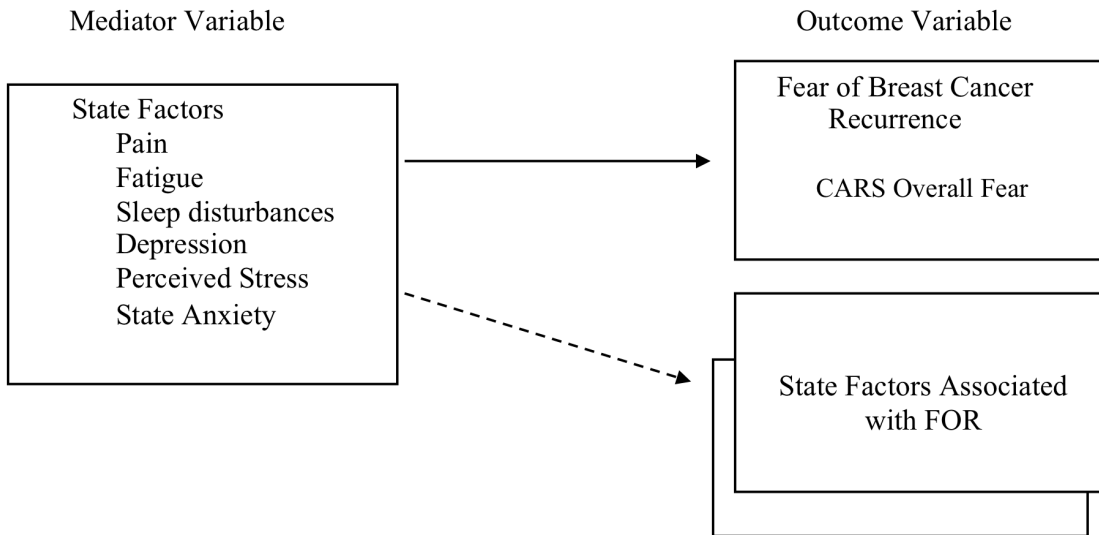


Figure 4. Model for Aim #2

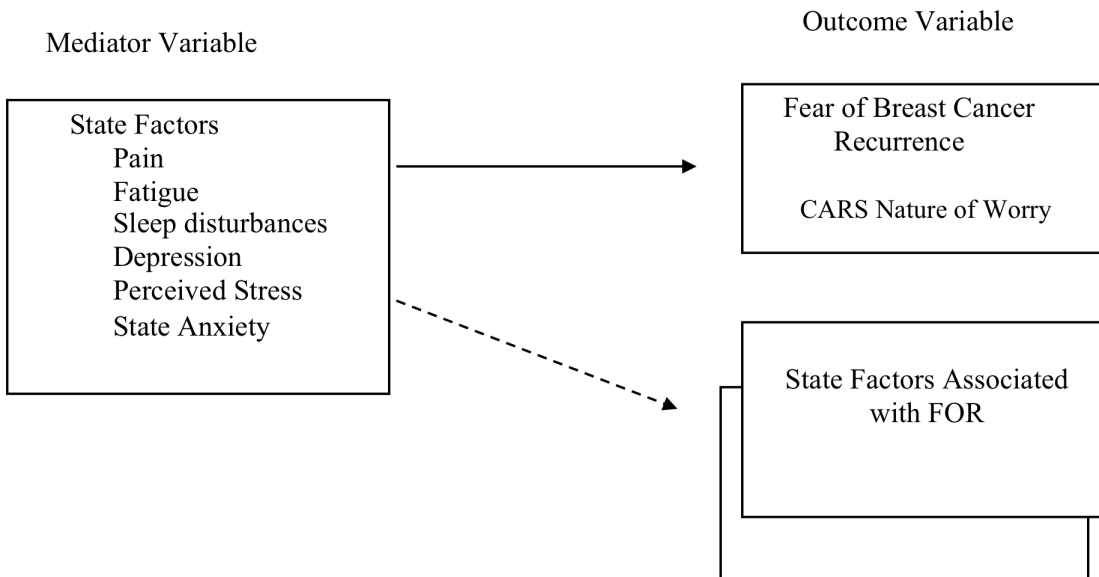


Figure 5. Model for Aim #2

***Aim #3*** - assesses state factors that may mediate the effect on the relationships between antecedent trait factors and the outcome variable fear of recurrence. The conceptual framework (Figure 1) lists postulated mediating variables. Briefly, mediating variables are those that may help to explain “how” state factors mediate (influence) the relationship between the antecedent variable, trait factors and the outcome variable, fear of recurrence. This analytic approach for conducting this type of analysis is depicted in the diagram below. See Figure 6 and 7.

In Figure 6 and 7, trait factors (X1) are assumed to have both a direct and indirect path to the outcome of fear of breast cancer recurrence. “c” is the direct path, and “a to b” is the indirect path, passing through the mediating variable X2 (state factors). The statistical approach to assess mediating effects was first to identify the significant univariate relationships, such as trait factors (i.e. “X1”) that are associated with fear of breast cancer recurrence (i.e. “Y”). The next step adds a potential mediator (state characteristics: “X2”) to the model a linear regression procedure using the Preacher and Hayes (2008) method of assessing the indirect effects in a simple mediation model with bootstrapping of 5,000 iterations to obtain unbiased estimates from the sample of 82, to the extent possible, of the indirect effects of the potential mediating variables.

If the X2 to Y relationship is strong, yet the X1 to Y relationship is substantially attenuated, this is considered an indication that variable X2 is a mediator of the relationship X1 to Y (i.e. X1 to X2 to Y). There also exists the possibility that X1 and X2 are so strongly correlated that they cannot survive in the model together, but in this case, the significance levels of both X1 and X2 are attenuated when they are evaluated simultaneously.

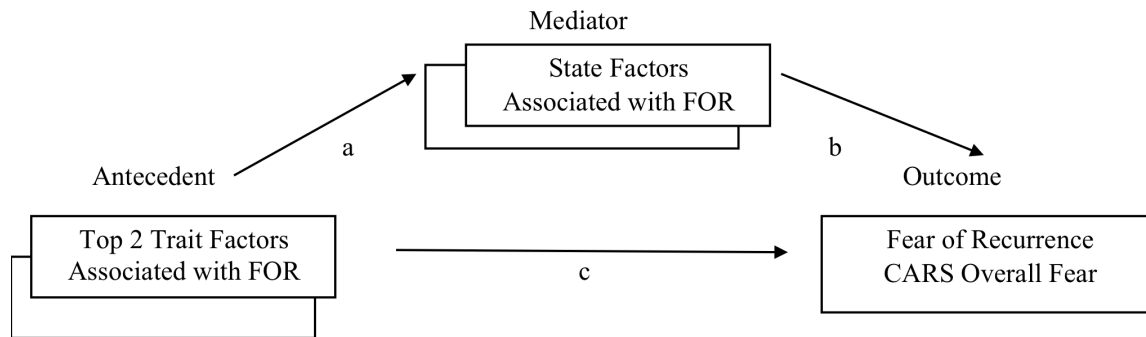


Figure 6. Model for Aim #3

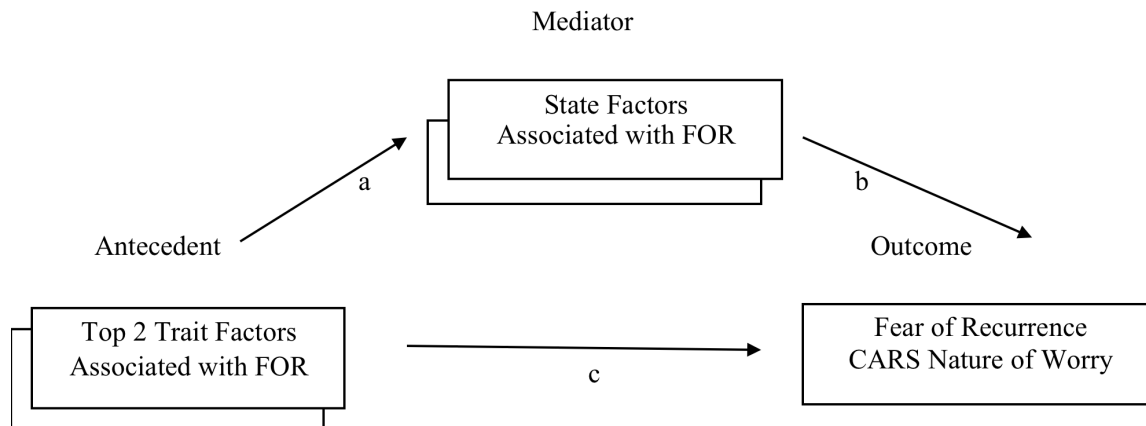


Figure 7. Model for Aim #3

## **Chapter Four**

### **Results**

This chapter summarizes the study findings of factors associated with the fear of breast cancer recurrence (CARS overall fear and CARS nature of worry) and the mediating effects of the mediator variables (modifiable state factors) on the antecedent variables (trait factors). The results are presented by each of the three research aims.

#### **Sample**

The sample size of 82 women post-treatment for breast cancer participated in the study from the H. Lee Moffitt Cancer and Research Institute in Tampa, Florida from March 1, 2006 to July 23, 2007. In the original R-21 study 200 women were pre-screened and approached for the study, 7 were ineligible, and 109 declined participation for a variety of reasons ranging from not interested, distance from home, transportation issues, family obligations and health issues. Two of the participants were lost to follow up. This study used the baseline data for the secondary analysis from the R-21 NCI funded randomized control trial. Eighty-two (N = 82) women completed all the baseline tests comprising the final sample for this study and data analysis.

Participants were recruited from the H. Lee Moffitt Cancer Center and all participants completed a demographic data form, clinical history form, Perceived Stress Scale (PSS), State Trait Anxiety Inventory (STAI), M.D. Anderson Symptom Inventory (MDASI), Center for Epidemiologic Studies Depression Scale (CES-D) and the Concerns About Recurrence Scale (CARS) (CARS overall fear and CARS nature of worry) at their baseline assessment.

The demographic assessment of the participants consisted of the following: age, race/ethnicity, education, marital status and employment status. Tables 1 and 2 displays the demographic characteristics for age with a mean age of 57 years ( $M = 57.18$   $SD \pm 9.136$ ); the majority of the subjects were greater than 55 years of age (59.7%) with the remaining subjects being younger than 55 years of age (40.2%). Eighty seven percent ( $n=72$ ) of the study participants were White (White Hispanic, Ashkenazi Jewish, White non-Hispanic & Native American) and 12.2% ( $n=10$ ) were Black non-Hispanic. The majority of the women who participated in the study were married (68.3%,  $n=56$ ) and the rest of the women were unmarried (31.7%,  $n=26$ ) (divorced, never married or separated). Fifty eight percent ( $n=48$ ) of the women were employed at the start of the study and 41.5% ( $n=34$ ) were not employed. The majority of the women (67.1%) reported some level of higher education ( $n=55$ ) including college, graduate school or professional school; 23.2% of the women ( $n=19$ ) reported some college or associate degree completion, 20.7% ( $n=17$ ) reported a college education, and 23.2% ( $n=19$ ) graduate school or professional schooling. The remaining subjects reported vocational education level and lower, vocation beyond high school (11%,  $n=9$ ), high school (17.1%,  $n=14$ ) and some high school (4.9%,  $n=4$ ).

Table 1  
*Demographics Characteristics (Frequency, Percentage, Mean, Standard Deviation) (N=82)*

Demographics	Frequency	Percent	Mean	SD
<u>Age</u>			57.18	9.136
< 55	33	40.2%		
55-64	28	34.1%		
65-75	20	24.4%		
>75	1	1.2%		
<u>Race and Ethnicity</u>				
White non-Hispanic	59	72.0%		
White Hispanic	9	11.0%		

Table 1 Continued

Black non-Hispanic	10	12.2%
Ashkenazi Jewish	2	2.4%
White non-Hispanic & Native American	2	2.4%

Table 2

*Demographics Characteristics (Frequency, Percentage, Mean) (N=82)*

Demographics	Frequency	Percent
<u>Marital Status</u>		
Married	56	68.3%
Not married	26	31.7%
<u>Employment</u>		
Employed	48	58.5%
Unemployed	34	41.5%
<u>Education</u>		
Some High School	4	4.9%
High School graduate	14	17.1%
Vocation Beyond High School	9	11.0%
Some College or Associates Degree	19	23.2%
College	17	20.7%
Graduate School or Professional school	19	23.2%

Clinical history data were collected for each of the study participants at baseline including stage of cancer at diagnosis, treatment history, history of hormone use, history of trait anxiety and family history of breast cancer; Table 3 represents the frequency and percentage for the study participant's stage of cancer at diagnosis. The majority of the women were diagnosed with early stages of cancer, Stage 0 (17.1%, n=14) and Stage I (52.4%, n=43) the remaining women were diagnosed with Stage II (23.2%, n=19) and Stage III (7.3%, n=6). Of the 82 participants, 49 women (59.8%) received radiation only and 33 women (40.2%) received radiation and chemotherapy. Eighty women responded to the question regarding history of

hormone use. Seventy-two percent ( $n=58$ ) of the women reported a history of hormone use either for fertility, contraception or hormone replacement and 27.5% ( $n=22$ ) denied any history of hormone use. Of the 61 women who responded to the question about family history of breast cancer, 77% ( $n=47$ ) did not report a family history of breast cancer and 23% ( $n=14$ ) reported a family history of breast cancer in a mother, grandmother, sister or aunt.

Table 3  
*Clinical History Characteristics (Frequency and Percentage) (N=82)*

Clinical History	Frequency	Percent
<u>Stage</u> (N=82)		
Stage 0	14	17.1%
Stage I	43	52.4%
Stage II	19	23.2%
Stage III	6	7.3%
<u>Treatment</u> (N=82)		
Radiation only	49	59.8%
Radiation and Chemotherapy	33	40.2%
<u>Hormone Use</u> (N=80)		
Yes	58	72.5%
No	22	27.5%
<u>Family History of Breast Cancer</u> (N=61)		
Yes	14	23.0%
No	47	77.0%

Social/Behavioral history including a history of smoking, alcohol use, beer, wine and liquor consumption and the number of days per week exercised was also studied. Tables 4 and 5 describe the frequency and percentage for each of these variables. Of the 78 women who responded to their frequency of exercise, 21 women (26.9%) reported no weekly exercise, 29 women (34.6%) exercised 3 days per week or less and 30 women (38.4%) exercised 4 days per week or more. The average number of days exercised was 2.77 ( $M = 2.77$   $SD \pm 2.62$ ) days per week. Of the 81 women who responded, the majority of the women were non-smokers ( $n=43$ ,



53.1%), 43.2% ( $n=35$ ) of the women reported being a former smoker and three women (3.7%) were current smokers. Eighty women who responded to the alcohol use question, 49 women (61.3%) reported drinking alcohol and 31 (38.8%) denied drinking alcohol. Regarding consumption of beer, 5 women (9.4%) reported being beer drinkers and 48 women (90.6%) were not, 27 women (47.4%) reported drinking wine and 30 women (52.6%) did not drink wine, lastly 6 women (11.3%) reported drinking liquor and 47 women (88.7%) reported no liquor consumption.

Table 4  
*Social/Behavioral History (Frequency, Percentage, Mean and Standard Deviation)*

Social/Behavioral History	Frequency	Percent	Mean	SD
<u>Days of Exercise (N=78)</u>				
0 days	21	26.9%	2.77	2.62
1 days	5	6.4%		
2 days	10	12.8%		
3 days	12	15.4%		
4 days	11	14.1%		
5 days	9	11.5%		
6 days	4	5.1%		
7 days	6	7.7%		
<u>Smoking History (N=81)</u>				
Current Smoker	3	3.7%		
Former Smoker	35	43.2%		
Non-Smoker	43	53.1%		

Table 5  
*Social/Behavioral History (Frequency and Percentage)*

Social/Behavioral History	Frequency	Percent
<u>Alcohol Consumption (N=80)</u>		
Yes	49	61.3%
No	31	38.8%
<u>Beer Consumption (N=53)</u>		
Yes	5	9.4%
No	48	90.6%

Table 5 Continued

<u>Wine Consumption</u> (N=57)		
Yes	27	47.4%
No	30	52.6%
<u>Liquor Consumption</u> (N=53)		
Yes	6	11.3%
No	47	88.7%

Table 6 lists the means and standard deviations for all the continuous and discrete variables including the antecedent (non-modifiable trait factors), mediator variables (modifiable state factors) and the outcome variable fear of recurrence for the study sample of 82 women.

#### **Antecedent Variable**

The only continuous antecedent variable measured on a Likert-type scale is displayed in Table 6 was trait anxiety and was measured using the State Trait Anxiety Index. The sample of 82 women yielded a mean score of ( $M = 36.88$   $SD \pm 8.53$ ). Compared to the general population of women ages 50-69 ( $M = 31.79$ ) (Spielberger et al., 1983) this corresponded to a z-score in the 72<sup>nd</sup> percentile of the distribution of trait anxiety scores.

#### **Mediator Variables**

The mediator variables (modifiable state factors) displayed in Table 6 included depression, perceived stress, state anxiety, pain, fatigue, sleep disturbances and fear of recurrence for the sample of 82 women. Depression was measured using the Center for Epidemiologic Studies Depression Scale for this study sample yielding a mean score of ( $M = 10.49$   $SD \pm 9.09$ ). Compared to the general population ( $M = 9.25$ ) (Radloff, 1977) this corresponded to a z-score in the 55th percentile of the distribution of depression scores. Perceived stress was measured using the Perceived Stress Scale resulting in a mean score of ( $M = 15.15$   $SD \pm 7.09$ ). Compared to the general population ( $M = 11.9$ ) (Cohen et al., 1983) this

corresponded to a z-score in the 68<sup>th</sup> percentile of the distribution of perceived stress scores. State anxiety was measured using the State Trait Anxiety Index resulting in a mean score of ( $M = 33.71$   $SD \pm 11.39$ ). Compared to the general population of women ages 50-69 ( $M = 32.20$ ) (Spielberger et al., 1983), this corresponds to a z-score in the 55<sup>th</sup> percentile of the distribution of state anxiety scores. Thus on average, women in study scored modestly higher on psychological measures of anxiety, depression and stress compared to women of similar age in the general population. Pain, fatigue and disturbed sleep were all measured using the subscales of the M.D. Anderson Symptom Inventory. Pain yielded a mean score of ( $M = 1.90$   $SD \pm 2.26$ ), fatigue resulted a mean score ( $M = 3.57$   $SD \pm 2.74$ ) and sleep disturbances had a mean score of ( $M = 3.16$   $SD \pm 3.18$ ). Population comparisons were not available but based on instrument scales pain, fatigue and sleep appear to be low to moderate.

### **Outcome Variable**

Fear of recurrence was measured using the Concerns About Recurrence Scale that consists of two scales, Concerns About Recurrence Overall Fear (CARS overall fear) and Concerns About Recurrence Nature of Worry (CARS nature of worry). Table 6 displays the results for the mean and standard deviations for the CARS overall fear ( $M = 11.11$   $SD \pm 4.89$ ) and the CARS nature of worry ( $M = 32.41$   $SD \pm 22.31$ ). Population comparisons were not available but based on the instrument scales revealing fear of recurrence overall and nature of fears were moderate.

In summary, the women in this study at baseline reported higher trait, state anxiety, depression and perceived stress than the general population and low to moderate symptoms of pain, fatigue and sleep disturbances. At baseline, the study participants expressed low to moderate concerns regarding fear of cancer recurrence (CARS overall fear and CARS nature of

worry).

Table 6

*Antecedent, Mediator and Outcome Variables (Means and Standard Deviations) (N=82)*

Variable	Range	Mean	SD
Trait Anxiety	24.00 to 63.00	36.88	8.53
Depression	.00 to 41.00	10.49	9.09
Perceived Stress	2.00 to 33.00	15.15	7.09
State Anxiety	20.00 to 70.00	33.71	11.39
Pain	.00 to 10.00	1.90	2.26
Fatigue	.00 to 10.00	3.57	2.74
Sleep Disturbances	.00 to 10.00	3.16	3.18
Concerns About Recurrence Overall			
Fear	4.00 to 24.00	11.11	4.89
Concerns About Recurrence Nature of Worry	.00 to 98.00	32.41	22.31

### Research Aim Number One

Research aim one explores the relationship between the antecedent variables (trait factors) and fear of recurrence (CARS overall fear and CARS nature of worry). Table 7 and 8 represents the Pearson's and Spearman's correlations conducted for the continuous and discrete antecedent variables and the outcome variable fear of recurrence (CARS overall fear). The findings suggest statistical significance that age ( $r = -.236$ ,  $p = .033$ ) was negatively associated with fear of recurrence (CARS overall fear) meaning as age increases, fear of recurrence decreases. In addition, trait anxiety ( $r = .433$ ,  $p = .000$ ) was positively associated with fear of recurrence (CARS overall fear), meaning as trait anxiety increases, fear of recurrence increases. Education, stage and exercise were not found to be associated with fear of recurrence in this study sample.

Table 7

*Correlations of Parametric Antecedent Variables and Concerns About Recurrence Overall Fear*

Antecedent Variables	N	Pearson (r)	p-value
Age	82	-.236	.033
Trait Anxiety	82	.433	.000
Exercise	78	-.072	.534

Table 8

*Correlations of Nonparametric Antecedent Variables and Concerns About Recurrence Overall Fear*

Antecedent Variables	N	Spearman ( $\rho$ )	p-value
Education	82	-.152	.172
Stage	82	.057	.610

Table 9 and 10 represents the Pearson's and Spearman's correlations conducted for the continuous and discrete antecedent variables within the demographics, clinical and social/behavioral history and the outcome variable fear of recurrence (CARS nature of worry). The findings suggest statistical significance that age ( $r = -.269$ ,  $p = .015$ ) was negatively associated with fear of recurrence (CARS nature of worry) meaning as age increases fear of recurrence (CARS nature of worry) decreases. Additionally, trait anxiety ( $r = .358$ ,  $p = .001$ ) was positively associated with fear of recurrence (CARS nature of worry) meaning as trait anxiety increases fear of recurrence (CARS nature of worry) increases. Education, stage and exercise were not found to be associated with fear of recurrence in this study sample.

Table 9

*Correlations of Antecedent Variables and Concerns About Recurrence Nature of Worry*

Antecedent Variables	N	Pearson (r)	p-value
Age	82	-.269	.015
Trait Anxiety	82	.358	.001
Exercise	78	-.042	.713

Table 10

*Correlations of Nonparametric Antecedent Variables and Concerns About Recurrence Nature of Worry*

Antecedent Variables	N	Spearman ( $\rho$ )	p-value
Education	82	-.184	.098
Stage	82	.196	.078

Analysis of variance (ANOVA) was used to evaluate the relationship between the categorical antecedent variable (non-modifiable trait factors) including race/ethnicity, marital status, employment status, treatment type, smoking, alcohol use, hormone use, family history of breast cancer and the outcome variable (fear of breast cancer recurrence).

Table 11 displays the results for the means and standard deviations for the dependent variable fear of recurrence using the CARS overall fear scale and categorical antecedent variables (demographics). The means were not significantly different for being White ( $M = 11.27$   $SD \pm 4.45$ ) and being non-White ( $M = 10.70$   $SD \pm 8.11$ ) with a p-value of .635. Table 21 displays the results for the means and standard deviations for the dependent variable fear of recurrence using the CARS overall fear scale and marital status. The means were not significantly different for marital status, married ( $M = 11.50$   $SD \pm 4.57$ ) and for not married ( $M = 11.11$   $SD \pm 4.89$ ) with a p-value of .292. The means were not significantly different for employment status, employed ( $M = 11.73$   $SD \pm 4.39$ ) and unemployed ( $M = 10.24$   $SD \pm 4.02$ ) with a p-value of .175.

Table 11

*ANOVA Demographics and Concerns About Recurrence Overall Fear*

Demographics	N	Mean	SD	95% CI for Mean		p-value
				Lower Bound	Upper Bound	
<u>Ethnicity and Race</u>						
White	59	11.27	4.45	10.11	12.43	
Non-White	23	10.70	5.98	8.11	13.28	
Total	82	11.11	4.89	10.03	12.19	.635
<u>Marital Status</u>						
Married	56	11.50	4.57	10.28	12.72	
Not Married	26	10.27	5.52	8.04	12.50	
Total	82	11.11	4.89	10.03	12.19	.292
<u>Employment</u>						
Employed	48	11.73	4.39	10.17	13.29	
Unemployed	34	10.24	4.02	8.83	11.64	
Total	82	11.11	4.89	10.03	12.19	.175

*C.I. = Confidence Interval*

*Note: Each variable evaluated separately*

Table 12 displays the results for the means and standard deviations for the dependent variable fear of recurrence using the CARS overall fear scale and the categorical antecedent variables (clinical history). Means were not significantly different by treatment type, radiation ( $M = 11.27$   $SD \pm 5.15$ ) and for radiation and chemotherapy ( $M = 10.88$   $SD \pm 12.49$ ) with a p-value of .728. The means were not significantly different for hormone use ( $M = 11.26$   $SD \pm 5.07$ ) and no hormone use ( $M = 11.00$   $SD \pm 4.66$ ) with a p-value of .863. The means were not significantly different for family history of breast cancer ( $M = 10.86$   $SD \pm 5.35$ ) and no family history of breast cancer ( $M = 11.26$   $SD \pm 4.88$ ) with a p-value of .794.

Table 12

*ANOVA Clinical History and Concerns About Recurrence Overall Fear*

Clinical History	N	Mean	SD	95% CI for Mean		p-value
				Lower Bound	Upper Bound	
<u>Treatment</u>						
Radiation	49	11.27	5.15	9.79	12.74	
Radiation and Chemotherapy	33	10.88	4.55	9.26	12.49	
Total	82	11.11	4.89	10.03	12.19	.728
<u>Hormone Use</u>						
Yes	58	11.26	5.07	9.93	12.59	
No	22	11.00	4.66	8.93	13.07	
Total	80	11.19	4.93	10.09	12.28	.836
<u>Family History of Breast Cancer</u>						
Yes	14	10.86	5.35	7.77	13.94	
No	47	11.26	4.88	9.82	12.69	
Total	61	11.16	4.95	9.90	12.43	.794

*C.I. = Confidence Interval*

*Note: Each variable evaluated separately*

Table 13 and 14 displays the results for the means and standard deviations for the dependent variable fear of recurrence using the CARS overall fear scale and antecedent variables (social/behavioral history). The means were not significantly different smoking history, currently smoking ( $M = 12.00$   $SD \pm 10.58$ ), former smoker ( $M = 11.60$   $SD \pm 4.72$ ) and non-smoker ( $M = 10.72$   $SD \pm 4.91$ ) with a p-value of .706. The means were not significantly different for alcohol use ( $M = 10.84$   $SD \pm 4.58$ ) and no alcohol use ( $M = 11.81$   $SD \pm 5.41$ ) with a p-value of .393. The means were not significantly different for alcohol use, drinking beer ( $M = 9.00$   $SD \pm 4.00$ ) and not drinking beer ( $M = 11.50$   $SD \pm 4.92$ ) with a p-value of .278; drinking wine ( $M = 10.48$   $SD \pm 4.22$ ) and not drinking wine ( $M = 12.33$   $SD \pm 5.73$ ) with a p-value of .175; drinking liquor ( $M = 12.33$   $SD \pm 4.80$ ) and not drinking liquor ( $M = 11.28$   $SD \pm$



4.95) with a p-value of .623.

Table 13

*ANOVA Social/Behavioral History and Concerns About Recurrence Overall Fear*

Social/Behavioral History	N	Mean	SD	95% CI for Mean		p-value
				Lower Bound	Upper Bound	
<u>Smoking History</u>						
Current Smoker	3	12.00	10.58	-14.29	38.29	
Former Smoker	35	11.60	4.72	9.98	13.22	
Non-Smoker	43	10.72	4.70	9.27	12.17	
Total	81	11.15	4.91	10.06	12.23	.706

*C.I. = Confidence Interval*

*Note: Each variable evaluated separately*

Table 14

*ANOVA Social/Behavioral History and Concerns About Recurrence Overall Fear*

Social/Behavioral History	N	Mean	SD	95% CI for Mean		p-value
				Lower Bound	Upper Bound	
<u>Alcohol Use</u>						
Yes	49	10.84	4.58	9.52	12.15	
No	31	11.81	5.41	9.82	13.79	
Total	80	11.21	4.91	10.12	12.30	.393
<u>Beer Consumption</u>						
Yes	5	9.00	4.00	4.03	13.97	
No	48	11.50	4.92	10.07	12.93	
Total	53	11.26	4.86	9.92	12.60	.278
<u>Wine Consumption</u>						
Yes	27	10.48	4.22	8.81	12.15	
No	30	12.33	5.73	10.19	14.47	
Total	57	11.45	5.11	10.10	12.81	.175
<u>Liquor Consumption</u>						
Yes	6	12.33	4.80	7.29	17.37	
No	47	11.28	4.95	9.82	12.73	
Total	53	11.40	4.90	10.05	12.75	.623

*C.I. = Confidence Interval*

*Note: Each variable evaluated separately*

Table 15 displays the results for the means and standard deviations for the dependent variable fear of recurrence using the CARS nature of worry scale and categorical antecedent variables (demographics). The means were not significantly different for being White ( $M = 31.89$   $SD \pm 19.86$ ) and non-White ( $M = 33.74$   $SD \pm 28.11$ ) with a p-value of .738. The means were not significantly different for marital status, married ( $M = 33.14$   $SD + 20.34$ ) and unemployed ( $M = 30.82$   $SD + 26.44$ ) with a p-value of .664. The means were not significantly different for employment status, employed ( $M = 33.69$   $SD + 24.43$ ) and unemployed ( $M = 30.60$   $SD + 19.13$ ) with a p-value of .540.

Table 15

*ANOVA Demographics and Concerns About Recurrence Nature of Worry*

Demographics	N	Mean	SD	95% CI for Mean		p-value
				Lower Bound	Upper Bound	
<u>Race and Ethnicity</u>						
White	59	31.89	19.86	26.71	37.06	
Non-White	23	33.74	28.11	21.59	45.89	
Total	82	32.41	22.31	27.51	37.31	.738
<u>Marital Status</u>						
Married	56	33.14	20.34	27.70	38.59	
Not Married	26	30.82	26.44	20.15	41.50	
Total	82	32.41	22.31	27.51	37.31	.664
<u>Employment Status</u>						
Employed	48	33.69	24.43	26.59	40.78	
Unemployed	34	30.60	19.13	23.92	37.28	
Total	82	32.41	22.31	27.51	37.31	.540

*C.I. = Confidence Interval*

*Note: Each variable evaluated separately*

Table 16 displays the results for the means and standard deviations for the dependent variable fear of recurrence using the CARS nature of worry scale and the categorical antecedent variables (clinical history). The means were not significantly different for treatment type,

radiation ( $M = 29.78$   $SD \pm 20.90$ ) and radiation and chemotherapy ( $M = 36.30$   $SD \pm 24.05$ ) with a p-value of .196. The means were not significantly different for hormone use ( $M = 32.21$   $SD \pm 21.63$ ) and no hormone use ( $M = 34.05$   $SD \pm 24.93$ ) with a p-value of .747. The means were not significantly different for family history of breast cancer ( $M = 31.36$   $SD \pm 22.89$ ) and no family history of breast cancer ( $M = 33.29$   $SD \pm 23.14$ ) with a p-value of .785.

Table 16

*ANOVA Clinical History and Concerns About Recurrence Nature of Worry*

Clinical History	N	Mean	SD	95% CI for Mean		p-value
				Lower Bound	Upper Bound	
<u>Treatment</u>						
Radiation	49	29.78	20.90	23.78	35.79	
Radiation and Chemotherapy	33	36.30	24.05	27.78	44.83	
Total	82	32.41	22.31	27.51	37.31	.196
<u>Hormone Use</u>						
Yes	58	32.21	21.63	26.53	37.90	
No	22	34.05	24.93	22.99	45.10	
Total	80	32.72	22.43	27.73	37.71	.747
<u>Family History of Breast Cancer</u>						
Yes	14	31.36	22.89	18.14	44.58	
No	47	33.29	23.14	26.49	40.08	
Total	61	32.84	22.91	26.98	38.71	.785

*C.I. = Confidence Interval*

*Note: Each variable evaluated separately*

Table 17 and 18 displays the results for the means and standard deviations for the dependent variable fear of recurrence using the CARS nature of worry Scale and antecedent variables (social/behavioral history). The means were not significantly different for currently smoking ( $M = 36.33$   $SD \pm 37.07$ ), former smoker ( $M = 34.11$   $SD \pm 22.98$ ) and non-smoker ( $M = 30.78$   $SD \pm 21.46$ ) with a p-value of .775; alcohol use ( $M = 30.06$   $SD \pm 21.58$ ) and no alcohol

use (M = 36.79 SD + 23.61) with a p-value of .194; drinking beer (M = 24.60 SD + 15.87) and not drinking beer (M = 32.51 SD + 20.87) with a p-value of .416; drinking wine (M = 28.74 SD + 18.86) and not drinking wine (M = 23.81 SD + 23.65) with a p-value of .221; and drinking liquor (M = 37.67 SD + 24.68) and not drinking liquor (M = 32.20 SD + 20.31) with a p-value of .547.

Table 17

*ANOVA Social/Behavioral History and Concerns About Recurrence Nature of Worry*

Social/Behavioral History	N	Mean	SD	95% CI for Mean		p-value
				Lower Bound	Upper Bound	
<u>Smoking History</u>						
Current Smoker	3	36.33	37.07	-55.76	128.43	
Former Smoker	35	34.11	22.98	26.22	42.00	
Non-Smoker	43	30.78	21.46	24.17	37.38	
Total	81	32.42	22.45	27.46	37.39	.775

*C.I. = Confidence Interval*

*Note: Each variable evaluated separately*

Table 18

*ANOVA Social/Behavioral History and Concerns About Recurrence Nature of Worry*

Social/Behavioral History	N	Mean	SD	95% CI for Mean		p-value
				Lower Bound	Upper Bound	
<u>Alcohol Use</u>						
Yes	49	30.06	21.58	23.86	36.26	
No	31	36.79	23.61	28.13	45.45	
Total	80	32.67	22.48	27.66	37.67	.194
<u>Beer Consumption</u>						
Yes	5	24.60	15.87	4.90	44.30	
No	48	32.51	20.87	26.45	38.57	
Total	53	31.76	20.46	26.12	37.40	.416
<u>Wine Consumption</u>						
Yes	27	28.74	18.86	21.28	36.20	
No	30	35.81	23.65	26.98	44.64	
Total	57	32.46	21.62	26.72	38.20	.221

Table 18 Continued

<u>Liquor Consumption</u>						
Yes	6	37.67	24.68	11.77	63.57	
No	47	32.20	20.31	26.24	38.16	
<u>ANOVA Continued</u>						
Total	53	32.82	20.65	27.13	38.51	.547

*C.I. = Confidence Interval*

*Note: Each variable evaluated separately*

Aim one explored the relationship between the antecedent variables (trait factors) that are typically non-modifiable attributes associated with fear of recurrence (CARS overall fear and CARS nature of worry) using Pearson's and Spearman's correlations and analysis of variance (ANOVA). The findings revealed that age was negatively associated with overall fear of recurrence ( $r = -.236, p = .033$ ) and fear of recurrence nature of worry ( $r = -.269, p = .015$ ). In addition, trait anxiety was associated with overall fear of recurrence ( $r = .433, p = .000$ ) and fear of recurrence nature of worry ( $r = .358, p = .001$ ). Race/ethnicity, education, marital status, employment, exercise, stage, treatment, exercise, smoking, drinking, hormone use and family history of breast cancer were not found to be associated with fear of recurrence in this study sample.

### **Research Aim Two**

A univariate analysis was examined by correlation coefficients for continuous covariates to evaluate the relationship between mediator variables (modifiable state factors) - psychological symptoms such as state anxiety, depression, perceived stress and physiological symptoms such as pain, fatigue, sleep disturbances and the outcome variable (fear of breast cancer recurrence).

The dependent variable of interest, fear of breast cancer recurrence, was measured on continuous scale using Pearson's correlations.

Table 19 represents the Pearson's correlations conducted for the continuous mediator variables and the outcome variable fear of recurrence (CARS overall fear). The findings reveal statistical significance that depression ( $r = .347, p = .001$ ), state anxiety ( $r = .467, p = .000$ ) and perceived stress ( $r = .365, p = .001$ ) were positively associated with fear of recurrence (CARS overall fear).

Table 19

*Correlations of Mediator Variables and Concerns About Recurrence Overall Fear (N=82)*

Mediator Variables	Pearson (r)	p-value
Pain	.202	.069
Fatigue	.114	.308
Sleep disturbances	.162	.145
Depression	.347	.001
State Anxiety	.467	.000
Perceived Stress	.365	.001

Table 20 represents the correlations for the continuous mediator variables and the outcome variable, concerns about recurrence nature of worry. Pearson's correlations conducted for the continuous mediator variables and the outcome variable fear of recurrence (CARS nature of worry). The findings reveal statistical significance that pain ( $r = .220, p = .047$ ), fatigue ( $r = .247, p = .025$ ), state anxiety ( $r = .369, p = .001$ ) and perceived stress ( $r = .410, p = .000$ ) were positively associated with fear of recurrence (CARS nature of worry).

Table 20

*Correlations of Mediator Variables and Concerns About Recurrence Nature of Worry (N=82)*

Mediator Variables	Pearson (r)	p-value
Pain	.220	.047
Fatigue	.247	.025
Sleep	.118	.292
Depression	.213	.055
State Anxiety	.369	.001
Perceived Stress	.410	.000

Aim two explored the relationship between the mediator variables (state factors), typically modifiable attributes such as pain, fatigue, sleep disturbances, state anxiety, depression, perceived stress associated with fear of recurrence (CARS overall fear and CARS nature of worry) using Pearson's correlations. Findings revealed that depression ( $r = .347$ ,  $p = .001$ ), state anxiety ( $r = .467$ ,  $p = .000$ ), perceived stress ( $r = .365$ ,  $p = .001$ ) were associated with overall fear of recurrence and pain ( $r = .220$ ,  $p = .047$ ), fatigue ( $r = .247$ ,  $p = .025$ ), state anxiety ( $r = .369$ ,  $p = .001$ ), and perceived stress ( $r = .410$ ,  $p = .000$ ) were associated with fear of cancer recurrence nature of worry.

### Research Aim Three

Aim three assessed potential mediation effects of the mediating variables (modifiable state factors), meaning the indirect effect of these variables on the direct relationship between antecedent variables (non-modifiable trait factors) and the primary outcome variable, fear of breast cancer recurrence. In this analysis, antecedent (trait) factors are assumed to have both a direct (c' path) and indirect path (a path) to the outcome of fear of breast cancer recurrence through the mediator variable (b path).

The linear regression method described by Preacher and Hayes (2008) was used to assess the indirect effects of potential mediators in a simple mediation model. This approach was used

to determine whether the specific state factors that were most correlated with fear of recurrence (state anxiety, perceived stress and depression) mediated the relationship between the antecedent (non-modifiable trait) factors that were most correlated with fear of recurrence. Given that age and trait anxiety were correlated with both fear of recurrence scales (CARS overall fear and CARS nature of worry), it was determined that having a single antecedent variable and one mediator variable with the outcome variable would allow for the most reliable and interpretable assessment of mediation. Therefore, in addition to examining age and trait anxiety separately as antecedent variables, a composite of these 2 variables was created. Specifically, the standardized Z-score for each variable was obtained and summed, thereby providing equal weight for the 2 variables combined in a single variable. This composite antecedent variable (age/trait anxiety) was analyzed in separate mediation models with fear of recurrence for both CARS overall fear and CARS nature of worry. Because of the relatively modest sample size, bootstrapping with 5,000 iterations was used to obtain unbiased estimates, to the extent possible, of the indirect effects of the potential mediating variables.

The findings in Table 21 indicate that state anxiety mediates the relationship (has an indirect effect) between trait anxiety and fear of recurrence (CARS overall fear). For these results, the notation  $\beta_{a_1b_1}$  is used to denote the unstandardized beta coefficient for the mediating variable representing the previously depicted  $a \rightarrow b \rightarrow Y$  path (i.e. indirect effect). With trait anxiety as the antecedent variable, the indirect effect of state anxiety is statistically associated with CARS overall fear ( $\beta = .1381$ , 95% CI = .0053 - .3050,  $p = .0299$ ). Similarly, with the composite age/trait anxiety antecedent variable, state anxiety is statistically associated with CARS overall fear ( $\beta = .5579$ , 95% CI = .1201 - 1.1669,  $p = .0157$ ). The standardized z-scores for state anxiety were 2.1718 and 2.4159 respectively for the models with trait anxiety alone



versus the composite z-score of age/trait anxiety as the antecedent variable. Therefore, inclusion of age with trait anxiety nominally influenced (improved) the strength of relationship with fear of recurrence (CARS overall fear), as well as the indirect effect of state anxiety. Perceived stress and depression were not statistically significant, and did not provide evidence of mediating the relationship between trait anxiety, age/trait anxiety and concerns about recurrence (CARS overall fear).

Table 21

*Indirect Effects of Antecedent Variables on Concerns About Recurrence Overall Fear through Mediator Variables (ab paths) (N = 82)*

Variables		$\beta$ Coefficient	SE	z	p-value
Antecedent Variable	Mediator Variable				
Age	State Anxiety	-.0046	.0275	-.1682	.8664
Trait Anxiety	State Anxiety	.1381	.0636	2.1718	.0299*
Trait Anxiety and Age **	State Anxiety	.5579	.2309	2.4159	.0157*
Age	Perceived Stress	-.0144	.0211	-.6804	.4962
Trait Anxiety	Perceived Stress	.0517	.0530	.3288	.3288
Trait Anxiety and Age**	Perceived Stress	.2897	.2191	1.3221	.1861
Age	Depression	.0029	.0209	.1373	.8908
Trait Anxiety	Depression	.0284	.0608	.4670	.6405
Trait Anxiety and Age**	Depression	.2521	.2028	1.2433	.2137

\*  $p < .05$

S.E. = Standard Error

\*\*Composite variable - converted to z-score to apply equal weight to each variable

Note: Each model evaluated separately

The findings in Table 22 indicate that perceived stress mediates the relationship (has an indirect effect) between trait anxiety and fear of recurrence (CARS nature of worry). For these results, the notation  $\beta a_1 b_1$  is used to denote the unstandardized beta coefficient for the mediating variable representing the previously depicted  $a \rightarrow b \rightarrow Y$  path (i.e. indirect effect). With trait anxiety as the antecedent variable, the indirect effect of perceived stress is statistically associated

with CARS nature of worry ( $\beta = .5474$ , 95% CI = .0178 - 1.3298,  $p = .0294$ ). Similarly, with the composite age and trait anxiety antecedent variable, perceived stress is statistically associated with concerns about recurrence nature of worry ( $\beta = 2.0375$ , 95% CI = .1136 - 4.5976,  $p = .0495$ ). The standardized regression coefficients for perceived stress were 2.1787 and 1.9644 respectively for the models with trait anxiety alone versus the composite z-score of age/trait anxiety as the antecedent variable. Therefore, inclusion of age with trait anxiety had no incremental increase in the strength of relationship with fear of recurrence (CARS nature of worry), as well as the indirect effect of perceived stress. State anxiety, fatigue and pain were not statistically significant, and did not provide evidence of mediating the relationship between trait anxiety, age/trait anxiety and concerns about recurrence (CARS nature of worry).

Table 22

*Indirect Effects of Antecedent Variables on Concerns About Recurrence Nature of Worry through Mediator Variables (N = 82)*

Variables		$\beta$ Coefficient	SE	z	p-value
Antecedent Variable	Mediator Variable				
Age	State Anxiety	-.0166	.0989	-.1681	.8665
Trait Anxiety	State Anxiety	.4470	.3012	1.4844	.1377
Trait Anxiety and Age **	State Anxiety	1.5524	1.0356	1.4990	.1339
Age	Perceived Stress	-.0735	.1075	-.6837	.4941
Trait Anxiety	Perceived Stress	.5474	.2512	2.1787	.0294*
Trait Anxiety and Age**	Perceived Stress	2.0375	1.0372	1.9644	.0495*
Age	Fatigue	-.0318	.0646	-.4927	.6223
Trait Anxiety	Fatigue	.0915	.0736	1.2430	.2139
Trait Anxiety and Age**	Fatigue	.4804	.4076	1.1785	.2386
Age	Pain	-.0005	.0595	-.0083	.9934
Trait Anxiety	Pain	.0862	.0746	1.1563	.2476
Trait Anxiety and Age**	Pain	.3867	.3656	1.0577	.2902

\*  $p < .05$ .

S.E. = Standard Error

\*\*Composite variable - converted to z-score to apply equal weight to each variable

Note: Each model evaluated separately

## Summary of Findings

After accounting for the direct effects (c' path = a, b, c paths) of trait anxiety and trait anxiety and age combined on fear of cancer recurrence (CARS overall fear and CARS nature of worry) two significant mediation effects were identified. This included state anxiety mediating the relationship between trait anxiety and fear of recurrence (CARS overall fear), and perceived stress mediating the relationship between trait anxiety and fear of recurrence (CARS nature of worry). Whereas similar results were observed when trait anxiety and age were combined as a composite antecedent variable, the results appeared to be driven principally by the effect of trait anxiety with age adding little to the strength of the relationships. In aggregate, these findings suggest that the women in this study who had a history of trait anxiety (and perhaps of younger age) were more likely to experience fear of cancer recurrence (CARS overall) if they also were experiencing anxious symptoms in their current state (state anxiety). Additionally, those women in this study who had a history of trait anxiety (and perhaps of younger age) were more likely to experience fear of cancer recurrence (CARS nature of worry) if they were also experiencing stressful feelings about their life within the past month (perceived stress).

## Chapter Five

### Discussion, Conclusions and Recommendations

#### Introduction

This final chapter presents the synthesis of the research results including the discussion of the findings, conclusions, implications and recommendations for future study. This study explored non-modifiable trait and modifiable factors state factors most associated with fear of breast cancer recurrence and the mediating relationship between those variables. The intent was to establish an understanding of how particular trait and state characteristics can influence a patient's concern about the recurrence of their cancer. Understanding this relationship supports the opportunity for health care providers to offer interventions to those patients at risk for greater fears of recurrence.

#### Summary of the Study

A cross-sectional research design was used to conduct a secondary data analysis among 82 women who were post-treatment for breast cancer. The original parent study was an R-21 NCI funded, randomized controlled intervention trial examining the Effects of Mindfulness Based Stress Reduction in Early Stage Breast Cancer Recovery (Lengacher et al., 2009). The current study utilizes the baseline data from the R-21 study for a secondary data analysis examining the relationship between trait factors and state factors on fear of cancer recurrence in breast cancer survivors.

The study sample consists of 82 out of 84 women age 21 or older who were diagnosed with breast cancer Stage 0, I, II, III and had undergone lumpectomy and received adjuvant

radiation and/or chemotherapy and were within 18 months post treatment. Other inclusion criteria included the ability to read and speak English at an 8<sup>th</sup> grade level in order to respond to survey questions. Several recruitment methods were used including introduction of the study by healthcare practitioners at the H. Lee Moffitt Cancer Center in addition to brochures and flyers distributed throughout the cancer center. Patients who expressed interest in the study were asked to complete a HIPAA authorization form that indicated their willingness to be contacted by a member of the trained research team. Interested subjects were provided with an orientation session within 18 months post treatment for breast cancer, considered to be the transition period from conventional treatment to the adaptation and return to routine daily life and activities. During the orientation session study details were explained, informed consent was obtained, and patients were randomized into the different groups (as a note, in order to maximize enrollment subjects who were randomized to the control group were offered the opportunity to receive the intervention after a wait period).

### **Discussion and Conclusion**

Descriptive data were obtained for the demographics of the study sample including frequencies, percentages, means and standard deviations. The mean age of the women in the study was of 57 years ( $M = 57.18$   $SD \pm 9.136$ ). Eighty seven percent of the study participants were White and 12.2% were Black non-Hispanic. The majority of the women who participated in the study were married (68.3%) and 31.7% were unmarried divorced, never married or separated. Fifty eight percent of the women were employed at the start of the study and the majority of the women (67.1%) reported some level of higher education ( $n=55$ ) including college, graduate school or professional school.

Clinical history revealed that the majority of the women were diagnosed with early stages of cancer, Stage 0 (17.1%) and Stage I (52.4%) with 59.8% received radiation only and 40.2% received radiation and chemotherapy. Fifty-eight women reported a history of hormone use either for fertility, contraception or hormone replacement and 14 women reported a family history of breast cancer in a mother, grandmother, sister or aunt.

Social/Behavioral history including a history of smoking, alcohol use, beer, wine and liquor consumption and the number of days per week exercised was also studied. The average number of days exercised was 2.77 days per week. Of the 81 women who responded, the majority of the women were non-smokers (53.1%), 43.2% of the women reported being a former smoker and 3.7% were current smokers. Of the 80 responses to alcohol consumption, 49 women (61.3%) reported drinking alcohol with wine being predominating beverage of choice over beer and liquor.

In this study sample, the women demonstrated higher levels of perceived stress, state and trait anxiety, and depression compared to the general population. Overall, the women in the study experienced low pain scores and low to moderate fatigue, sleep disturbance levels and fear of recurrence.

Research aim one explored the relationship between the antecedent variables (non-modifiable trait factors) and fear of recurrence (CARS Overall and CARS Nature). The findings revealed statistical significance that age was negatively associated with fear of recurrence (CARS overall fear ( $r = -.236$ ,  $p = 0.033$ ) and CARS nature of worry ( $r = -.269$ ,  $p = .015$ )) meaning as age increases, fear of recurrence decreases which consistent with the literature (Connell et al., 2006; Crane-Okada et al., 2012; Janz et al., 2011; King et al., 2000; McGinty et al., 2010; Thewes et al., 2012; Van den Beuken-van Everdingen et al., 2008; Waljee et al., 2008).

In addition, trait anxiety was positively associated with fear of recurrence (CARS overall fear ( $r = .433, p = .000$ ) and CARS nature of worry ( $r = .358, p = .001$ )), meaning as trait anxiety increases, fear of recurrence increases. Several studies discovered similar findings, suggesting perhaps a bidirectional relationship between anxiety and fear of cancer recurrence (Corter et al., 2013; Costanzo et al., 2007; Crane-Okada et al., 2012; Liu et al., 2011; Young & White, 2006; Ziner et al., 2012). Education, stage and exercise were not found to be associated with fear of recurrence for CARS overall worry or CARS nature of worry. The analysis of variance (ANOVA) did not reveal any significant differences between the groups for the categorical antecedent variables (race/ethnicity, marital status, employment, treatment type, hormone use, family history of cancer, smoking, alcohol use) and the outcome variable fear of recurrence (CARS overall fear and CARS nature of worry).

Research aim two used Pearson's correlations to examine the relationship between mediator variables (modifiable state factors) - psychological symptoms such as state anxiety, depression, perceived stress and physiological symptoms such as pain, fatigue, sleep disturbances and the outcome variable fear of breast cancer recurrence (CARS overall fear and CARS nature of worry). The findings yielded statistical significance for depression ( $r = .347, p = .001$ ), state anxiety ( $r = .467, p = .000$ ) and perceived stress ( $r = .365, p = .001$ ) as having a positive association with fear of recurrence (CARS overall fear). These results support findings from several others studies that women who experience psychological distress (depression, anxiety, perceived stress) are at greater risk for overall fear of cancer recurrence (Allen et al., 2009; Corter et al., 2013; Costanzo et al., 2007; Crane-Okada et al., 2012; Liu et al., 2011; Taylor et al., 2011; Young & White, 2006; Ziner et al., 2012). Analysis of fear of cancer recurrence (CARS nature of worry) revealed statistical significance for pain ( $r = .220, p = .047$ ),

fatigue ( $r = .247, p = .025$ ), state anxiety ( $r = .369, p = .001$ ) and perceived stress ( $r = .410, p = .000$ ) as having a positive association. Pain and fatigue were observed to be associated with fear of recurrence throughout the literature, sometimes referred to as “triggers” these symptoms can create a great deal of distress for breast cancer survivors triggering fears of recurrence (Allen et al., 2009; Clayton et al., 2006; Corter et al., 2013; Ferrell et al., 1997; Grimsbo et al., 2011; Janz et al., 2011; Van den Beuken-van Everdingen et al., 2008; Vickberg, 2001; Young & White, 2006; Ziner et al., 2012)

Research aim three assessed mediating state variables (transient, modifiable state factors) indirect (mediation) effect on the relationships between antecedent trait variables (stable, non-modifiable trait factors) and the outcome variable fear of breast cancer recurrence. Antecedent (trait) factors are assumed to have both a direct (c' path) and indirect path (a path) to the outcome of fear of breast cancer recurrence through the mediator variable (b path).

These findings suggest a statistical significance of the indirect effect of state anxiety on trait anxiety and the composite variable of trait anxiety/age related to fear of recurrence (CARS overall fear). The standardized Z-scores for state anxiety were slightly increased for trait anxiety and for the composite variable of age/trait anxiety suggesting that state anxiety is a mediator of trait anxiety and age/trait anxiety and fear of recurrence (CARS overall fear).

The findings related to CARS nature of worry indicate that perceived stress mediates the relationship between trait anxiety and fear of recurrence (CARS nature of worry). These findings suggest a statistical significance of the indirect effect of perceived stress on trait anxiety and the composite variable trait anxiety/age related to fear of recurrence (CARS nature of worry). The standardized Z-scores for perceived stress were reduced for trait anxiety and for age/trait anxiety



combined suggesting that perceived stress is a partial mediator of trait anxiety and age/trait anxiety combined and fear of recurrence (CARS nature of worry).

The significance of these findings suggest that women who are anxious at baseline and experiencing or at risk for experiencing situational anxiety are at greater risk of overall fears of breast cancer recurrence. Given the relationship between age, trait anxiety and fear of recurrence, younger women could be particularly vulnerable for overall fear of breast cancer recurrence. Similarly, women who are anxious at baseline and are experiencing situations in their life that they perceive to be stressful may be at greater risk for worries related to fear of recurrence such as health worries, role worries, womanhood worries and death worries. As was discussed with the relationship between trait anxiety and fear of recurrence, the findings suggest in this study that younger survivors who are experiencing perceived stressful situations in their life and anxiety at baseline may be at greater risk for fear of breast cancer recurrence.

The relevance of these findings rests in the research to date that has explored the outcomes of psychological distress in cancer survivorship in relation to survivorship well-being, quality of life and utilization of health care resources (Barsky et al., 2001; Ferrell et al., 1997; Gil et al., 2005; Grimsbo et al., 2011; King et al., 2000; Lebel et al., 2007; Lebel et al., 2013; Taylor et al., 2011; Vickberg, 2003; Young & White, 2006). The research to date highlights the reality that breast cancer survivors experience life-long emotional sequelae from their cancer diagnosis and treatment including the concerns that their cancer will return. What is less clear is how to best prepare patients for survivorship, including evidenced based methods for risk screening regarding those physiological and psychological traits and states, like anxiety, perceived stress and fear of recurrence, which may have an impact on survivorship.

In summary, this study was performed utilizing a cross-sectional quantitative research design analyzing secondary data from a previously conducted randomized controlled trial. The Logic Model provided a heuristic framework to examine the associations between trait factors and state factors and the mediating effects on fear of breast cancer recurrence. Relationships between the antecedent variables (trait factors) typically considered stable non-modifiable attributes (demographic, clinical history, social/behavioral) with fear of recurrence (CARS overall fear and CARS nature of worry) were examined using Pearson's and Spearman's correlations and analysis of variance (ANOVA). Secondly, the relationship between the mediator variables (state factors), typically considered to be transient and modifiable attributes such as pain, fatigue, sleep disturbances, state anxiety, depression, perceived stress were examined to determine their associations with fear of recurrence (CARS overall fear and CARS nature of worry) using Pearson's correlations. The final step of analysis employed a mediation model to examine the indirect effects of the statistically significant modifiable state factors on the statistically significant antecedent trait factors and fear of recurrence (CARS overall fear and CARS nature of worry).

### **Limitations**

This study provided preliminary findings related to factors that may interfere with the psychological well-being and recovery of breast cancer survivors. Understanding these relationships can help health care providers initiate meaningful interventions to optimize the well-being and quality of life in survivorship. Limitations of this study may include:

1. The sample size of 82 women limits the strength and generalizability of the findings.
2. The study participants were a homogeneous sample of women enrolled from only one site in the Tampa Bay area of Florida limiting the generalizability to other populations.

3. The use of paper and pencil questionnaires may enhance measurement error.
4. The use of more discrete measurement instruments (for example: the Brief Pain Inventory) could be used to measure physiologic symptoms (pain, fatigue, sleep disturbances).

### **Implications for Nursing**

The findings from this study suggest that breast cancer survivors who are anxious at baseline and report a current state of anxiety or perceived stress (current situations in their life that are deemed to be stressful) may be at higher risk for fears of breast cancer recurrence. The implications of this research for nursing are merely to recognize the existence of these relationships and how they pertain to their patients. Understanding those individual patient characteristics such as age, history of anxiety and current status of perceived stress or anxiety and the relationship with fears of recurrence will allow nurses to offer individualized interventions to those patients at greatest risk for psychological distress. These findings also support the need to for further exploration of the unique survivorship needs of different patient populations based on their demographics, social, behavioral and clinical history.

Early screening of those risk factors for fear of recurrence and identification of patients at greatest risk along with multimodal options for intervention can optimize well-being and quality of life thus reducing unnecessary distress. The findings add to advancing the science associated with fear of recurrence and breast cancer survivorship. As the generation of cancer survivors continues to grow, addressing the psychological and physiological long-term survivorship needs becomes imperative.

## Recommendations for Future Study

The following recommendations for future research are based upon review of the relevant research and findings from the current study:

1. Replicate this research utilizing the subscales within the CARS nature of worry scale to further understand more specifically the mediation of effect and relationship between trait anxiety, perceived stress and fear of recurrence.
2. Due to the limited size and diversity of the current study sample, expanding the study of fear of recurrence to include intervention research in ethnically diverse and international populations at risk for fear of breast cancer recurrence.
3. Study the implementation of early screening and interventions that address, anxiety and perceived stress, which are strongly associated with fear of breast cancer recurrence with the goal of improving the psychological health, well-being and overall quality of life in breast cancer survivorship.
4. Identify and test best practices for risk screening and ongoing support models that include ongoing access to survivorship information and education, integrative/complimentary medicine and social support programs to reduce psychological distress associated with anxiety, perceived stress and fear of recurrence.
5. Study the effectiveness of anxiety, perceived stress and fear of recurrence intervention programs impact on psychological distress and health care utilization.

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## Appendix

### IRB Letter of 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

January 21, 2011

Dr. Cecile Lengacher  
College of Nursing  
MDC 22

Attn: Pinky Budhrani

RE: **Approved Modification Request**  
IRB#: 103924  
Title: Effects of MBSR in Early Stage Breast Cancer Recovery MCC# 14641  
Study Approval Period: 03/02/10 to 03/02/11

Dear Dr. Lengacher:

On 01/18/11 the Institutional Review Board (IRB) reviewed and **APPROVED** your Modification Request. The submitted request has been approved **from 01/18/11 to 03/02/11** for the following:

#### **Submission of secondary data analysis.**

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 813-974-9343.

Sincerely,



Janelle Perkins, PharmD., Chairperson  
USF Institutional Review Board

Enclosure: (If applicable) IRB-Approved, Stamped Informed Consent/Assent Documents(s)

Cc: Sandra Partap, USF IRB Support Staff

MOD-Approved-0801