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Does Sleep Mediate Improvements in Functional Adaptation After a Stress Management Intervention For Women With Breast Cancer?

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DOES SLEEP MEDIATE IMPROVEMENTS IN FUNCTIONAL ADAPTATION
AFTER A STRESS MANAGEMENT INTERVENTION FOR WOMEN WITH
BREAST CANCER?

By

Sara Vargas

A THESIS

Submitted to the Faculty
of the University of Miami
in partial fulfillment of the requirements for
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<u>Does Sleep Mediate Improvements in Functional</u>
<u>Adaptation After a Stress Management Intervention</u>
<u>For Women With Breast Cancer?</u>

Abstract of a thesis at the University of Miami.

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The time of cancer diagnosis and treatment may be marked by an increase in
stressors, which may be associated with poorer psychosocial and physical adaptation and
increased sleep difficulty. Prior work has shown that psychosocial interventions that
teach stress management skills can improve indicators of psychosocial and physical
adaptation in women with breast cancer, mostly in cancer survivors who have completed
treatment. The extant literature does not examine the effects of stress management on
sleep, or the role that sleep plays in mediating psychosocial and physical adaptation
outcomes, among women in the midst of treatment for non-metastatic breast cancer
(BCa). Two hundred forty (240) women, recruited post-surgery from oncology practices,
were randomly assigned to a 10-week group-based cognitive behavioral stress
management intervention (CBSM; n = 120) or 1-day psychoeducation (PE) control (n =
120). The intervention consisted of didactics, CBSM techniques, and relaxation exercises,
but did not specifically target sleep or sleep quality (SQ). Women assigned to the PE
condition attended a one-day group seminar where they learned some of the material
covered in the CBSM intervention, without the therapeutic group environment, role play
techniques, and home practice. Participants completed self-report questionnaires at
baseline, and at 6- and 12-month follow-ups. After controlling for days since surgery,

participants in the CBSM group reported improved SQ, as well as increased positive states of mind, decreased disruption in social recreational functioning, and reduced fatigue-related daytime dysfunction for up to 8 - 12 months after baseline. There were marginally significant improvements in functional well-being and social functioning. CBSM was not associated with improvements in fatigue intensity. Improvements in SQ mediated CBSM-associated improvements in positive states of mind, social disruption, and fatigue-related daytime dysfunction. Thus, the CBSM intervention had beneficial effects on several indicators of functional adaptation that were in part explained by improvements in the quality of sleep. Future work should test the combined effects of stress management and sleep management interventions for women initiating treatment for BCa.

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CHAPTER 1: INTRODUCTION

The time of a cancer diagnosis and the subsequent treatment period may be marked by a sudden increase in internal and external stressors, demanding increased coping with the burdens of the illness, its treatment, and any required lifestyle changes. Stressors related to cancer diagnosis may result in both positive and negative physiological and psychological changes. Negative changes are labeled "distress" (for a review of the concept of distress, see Ridner, 2004). Psychological distress has been shown to be related to poorer psychosocial functioning among breast cancer (BCa) patients. For example, Wong and Fielding (2007) found that distress, particularly depressive symptoms, was associated with lower functional quality of life (QoL) six months after surgery among BCa patients. In another longitudinal study, women experienced sustained problems with cognitive and emotional functioning one year after treatment for BCa (Montazeri et al., 2008).

BCa patients have frequently reported impaired sleep (e.g., poorer sleep quality (SQ) and increased rates of insomnia; e.g., Hartl et al., 2009; Montazeri et al., 2008; Savard & Morin, 2001). These sleep problems may be associated with psychological distress. Heightened levels of hypothalamic-pituitary-adrenal (HPA) activation, in conjunction with other factors, such as pain or anxiety, plays a role in impeding normal sleep patterns (Roth, Roehrs, & Pies, 2007). One longitudinal study by Palesh et al. (2007) found that depression, pain, and stress, measured an average of 32 months after diagnosis, predicted sleep problems (e.g., problems getting to sleep or staying asleep, daytime sleepiness) over a one-year follow-up period among women diagnosed with metastatic BCa. Sleep problems have been associated with a number of other areas of

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psychosocial functioning, including fatigue and functional well-being in cross-sectional samples (Ancoli-Israel et al., 2006; Vargas et al., 2010).

Based on these findings, distress and sleep may be investigated as potential mechanisms of change in psychosocial functioning. Distress and sleep are thus reasonable intervention targets, such that content aimed to reduce distress and improve sleep may affect positive changes in psychosocial functioning. At least two separate lines of intervention research have followed from this work in BCa patients—one in stress management and one in sleep management. Overall, these interventions have demonstrated some success. Stress management interventions have demonstrated positive effects on QoL and functional outcomes among cancer patients (see Namaan, Radwan, Fergusson, & Johnson, 2009), while sleep interventions have improved sleep parameters including sleep latency, duration, efficiency, and quality (e.g., Simeit, Deck, & Conta-Marx, 2004). Given the relationship between stress, sleep, and psychosocial functioning, an interesting question is whether stress management affects sleep among BCa patients.

I begin with a review the prevalence and characteristics of sleep disturbances among BCa patients. Second, I summarize in greater detail the associations between sleep and psychosocial functioning. Third, I review findings from stress management and other psychosocial interventions in cancer populations, with a particular focus on BCa patients. Fourth, I summarize findings from cognitive-behavioral (CB) sleep interventions in cancer populations, again, with a particular focus on BCa patients. Finally, I present the aims of the current analysis in the context of this literature.

Sleep Disturbances Among Cancer Patients

Insomnia is common among cancer populations, with estimates ranging from 30-50% of cancer patients experiencing some insomnia (Savard & Morin, 2001). Rates of insomnia have been shown to be particularly high for women diagnosed with BCa (Ancoli-Israel et al., 2006; Bardwell et al., 2008; Davidson, MacLean, Brundage, & Schulze, 2002; Fiorentino & Ancoli-Israel, 2006; Savard, Simard, Blanchet, Ivers, & Morin, 2001). Fortner, Stepanski, Wang, Kasprowicz, and Durrence (2002) found that 61% of the BCa patients in their study had sleep problems as measured by a commonly used self-report sleep measure, the Pittsburgh Sleep Quality Index (PSQI; Buysse, Reynolds, Monk, Berman, & Kupfer, 1989). Koopman et al. (2002) observed a similar percentage (63%) of women with metastatic BCa reporting sleep disturbance, using selected items from the Sleep Questionnaire based on the Structured Insomnia Interview (Schramm et al., 1993). Patient reports have revealed that some cancer patients believe that sleep disturbances began at the time of cancer diagnosis, while others believe that pre-existing issues were aggravated by the diagnosis (Savard et al., 2001).

The causes of insomnia in BCa patients are not well-understood. A recent study conducted by Bardwell et al. (2008) analyzed baseline data from 2,645 women diagnosed with BCa participating in a dietary intervention study. They found that among a number of theoretically relevant variables that were potential risk factors for insomnia (e.g., cancer-specific variables such as stage and treatment), only depressive symptoms and vasomotor symptoms (such as night sweats) were associated with insomnia. Chemotherapy has been found to be related to increased risk for insomnia (Savard et al., 2001).

Objective and subjective measures of sleep disturbances sometimes have shown that sleep issues manifest before the start of adjuvant treatment (Ancoli-Israel et al., 2006; Vargas et al., 2010). Previous findings from the current sample reported poor SQ and high levels of sleep disruption before beginning adjuvant treatment (Vargas et al., 2010). Most of the women (70.8%) had a PSQI global score above the established cutoff of 5.0 (Buysse et al, 1989). Additionally, more than half of the women scored above the suggested adjusted cutoff of 8.0 ($M = 8.49$) for cancer patients (Carpenter & Andrykowski, 1998). This is higher than had previously been found among women with BCa prior to adjuvant treatment, where the mean score was 7.0 (Ancoli-Israel et al., 2006). It is, however, nearly the same as the average score of 8.45 found among women who were, on average, one-year post-BCa diagnosis (Carlson, Campbell, Garland, & Grossman, 2007).

In sum, sleep disturbances are common among women diagnosed with BCa. The mechanisms are well understood at this point and warrant further research, but it is clear that such sleep problems are common during treatment (e.g., Vargas et al., 2010), and persist at least one year after diagnosis (Carlson et al., 2007). Next, I will review the associations between sleep problems and psychosocial functioning in women with BCa.

Sleep Disturbances and Psychosocial Functioning

A number of studies have shown that sleep disturbances are a common complaint among patients with medical disorders, and that problems with both SQ and quantity may be associated with poorer QoL and greater fatigue (Parish, 2009). In addition, disease-related symptoms, such as pain, may seem worse to patients suffering from sleep disturbances (Parish, 2009).

Flynn et al. (in press) conducted focus groups with cancer patients, including eight BCa patients, to discuss sleep and the consequences of sleep disturbances. The BCa patients discussed numerous sleep problems, including pain, hot flashes, dreams, worry and fear, and positioning difficulties. In addition, these and other sleep problems were associated with numerous functional outcomes among the cancer patients, including daytime sleepiness, fatigue, problems with concentration, and disruption in social functioning and mood. The authors highlighted the need for interventions that address sleep difficulties and their consequences.

Cross-sectional studies with larger sample sizes have shown that sleep is associated with aspects of QoL and daily functioning among BCa patients before beginning adjuvant treatment. Ancoli-Israel and colleagues (2006) showed that sleep disturbances were associated with fatigue and daytime dysfunction prior to adjuvant treatment among a sample of 85 women diagnosed with non-metastatic BCa. Vargas et al. (2010) investigated such associations at the baseline assessment for the 240 women in the sample included in the present study. They found that poorer SQ, as measured by the PSQI global score, was significantly associated with poorer functional well-being, greater fatigue intensity, greater disruptions in social interactions, and lower positive states of mind among BCa patients post-surgery, before initiating any adjuvant treatment. Further investigation using component scores based on a principal component analysis by Buysse et al. (2008) found that an 'SQ' component (composed of the sleep disturbances, sleep latency, daytime dysfunction, and SQ subscales of the PSQI) was more strongly associated with a number of functional outcomes than was a 'sleep efficiency' (SE) component (composed of the sleep duration and sleep efficiency subscales of the PSQI).

Lower SQ was associated with poorer functional QoL, greater fatigue intensity, greater disruption of daily activities by fatigue, greater disruption in social interactions, and less ability to achieve positive states of mind. Poorer SE was associated with poorer functional QoL and greater disruption in social interactions. Based on these findings, it seems that the SQ subscale is more strongly associated with psychosocial outcomes than was the actual number of hours spent in bed and sleeping, and may be a more salient sleep intervention target. In the Vargas et al. report a larger sample size (N = 240) allowed for sufficient power for the inclusion of relevant control variables not included in the study of Ancoli et al. Thus, it presented a clearer picture of the unique contribution of sleep features to psychosocial adaptation.

Based on these cross-sectional findings of Ancoli-Israel et al. (2006) and Vargas et al. (2010), sleep is associated with numerous functional outcomes, including QoL, fatigue, social functioning, and concentration among BCa patients in the midst of treatment. I have now identified distress and sleep as two intervention targets that may led to changes in psychosocial functioning. Next, I will review the current findings from psychosocial and sleep interventions.

Stress Management and Other Psychosocial Interventions

Psychosocial interventions have been developed to help women cope with a BCa diagnosis and to reduce their distress and improve their QoL. Many of these interventions have been shown to improve QoL and functional outcomes among patients with cancer (Meyer & Mark, 1995; Namaan et al., 2009), as well as physiological outcomes such as decreased cortisol and improved immune function (McGregor & Antoni, 2009). A recent review by Naaman et al. (2009) concluded that psychosocial interventions are efficacious

in reducing depression, anxiety, and improving QoL in BCa patients. This review article concluded that short-term, coping-focused treatments are particularly efficacious for patients with early-stage BCa. Similar interventions have been studied internationally in Spain (Manos, Sebastian, Mateos, & Bueno, 2009), France (Dolbeault et al., 2009), and Japan (Maeda, Kurihara, Morishima, & Munakata, 2008), and have shown similar positive effects on psychosocial outcomes. Relaxation interventions have received some support in reviews among randomized studies with cancer patients (Luebbert, Dahme, & Hasenbring, 2001). Luebbert et al. (2001) found that relaxation interventions had positive effects on depression, anxiety, and hostility. Luebbert et al. (2001) also assessed physiological outcomes and found that relaxation interventions had positive effects on nausea, pain, pulse rate, and blood pressure. The study reported no significant effects on vigor, fatigue, or confusion.

Andersen and colleagues (2004, 2007a) studied the effects of a psychosocial intervention for women newly diagnosed with stage 2-3 BCa. Participants (N=227) were first assessed after surgery, but before any planned adjuvant treatment and were randomly assigned to either an intervention condition or an assessment-only control. The intervention consisted of relaxation, coping, and social support training, as well as information on health behavior change and adherence, and were conducted in groups of 8-12 women. The groups met for 18 weekly 90 minute sessions, and then monthly for eight additional 90 minute sessions. The intervention resulted in reduced anxiety, improved perceived social support, improved diet, and a reduction in smoking (Andersen et al., 2004). For some of the measures (e.g., Total Mood Disturbance, Fatigue), the intervention was associated with improvements only among those who had the highest

cancer stress at baseline. Andersen et al. also found stable or greater T-cell proliferation in the intervention group compared to the control group. At a one-year follow-up, Andersen et al. (2007a) found that the intervention improved health status with a direct standardized path coefficient of .18 (z = 2.51, p = .01) after controlling for baseline distress, immune parameters, and health, as well as age/menopausal status, partner status, chemotherapy, and hormonal therapy. These improvements were mediated by lowering emotional distress, and were not significantly mediated by positive changes in immune functioning. At 11-year follow-up, 29% (n = 62/212) reported a cancer recurrence and 24% (n = 54/227) had died (Andersen et al., 2008). Those who had been in the intervention group (versus the assessment-only group) reported a lower rate of cancer recurrence (hazards ratio (HR) = .55, p = .03), and lower rate of death from BCa (HR = .44, p = .02) and all causes (HR = .51, p = .03). In a related study, Andersen, Shelby, and Golden-Kreutz (2007b) used hierarchical linear modeling to examine potential mechanisms of change for the effects found in their 2004 and 2007a papers. They found that group support, presentation of a theory regarding stress and stress management, a relaxation component, and strategies to assist in communication with health care providers co-varied significantly with various outcomes.

Antoni et al. (2006a, 2006b) examined the effects of a 10-week cognitive-behavioral stress management (CBSM) intervention versus a one-day psycho-education (PE) control on a subsample of the participants studied in the current project who were available for analysis at the time (N = 199). Each session of the intervention was approximately two hours in length and consisted of relaxation, cognitive restructuring, and coping skills training (see *Procedures* for more details). The intervention reduced

reports of social disruption, increased emotional well-being, increased positive states of mind, increased benefit finding, increased positive lifestyle change, and increased positive affect for up to one-year follow-up, and these changes were mediated by the participants' confidence in their ability to relax (Antoni et al., 2006a). The intervention also reduced report of thought intrusion, interviewer ratings of anxiety, and emotional distress (Antoni et al., 2006b). Effect sizes for condition effects for most of the various psychosocial outcomes were at or above levels considered clinically meaningful (Hays & Wooley, 2000; Norman, Sloan, & Wyrwich, 2003), ranging from about .3 to .6. Recent analyses conducted on the subset of these participants who provided blood samples for physiological analyses (N=128) found intervention effects on afternoon serum cortisol, such that women who participated in the intervention had greater reductions in cortisol levels over the one-year follow-up (Phillips et al., 2008). Intervention effects have also recently been reported on immune indices such as T-helper type 1 (Th1) cytokine production in a subset of 85 participants, such that those in the CBSM demonstrated greater increases in interleukin-2 (IL-2) and interferon-gamma production and greater IL-2:IL-4 ratio increases (Antoni et al., 2009).

Findings regarding the psychological and physiological effects of psychosocial outcomes have, however, been mixed and some authors have concluded that it is premature to make broad claims about the utility of psychosocial interventions in improving many physical and mental health outcomes (Newell, Sanson-Fisher, & Savoleinen, 2002; Owen, Klapow, Hicken, & Tucket, 2001; Smedslund & Ringdal, 2004). Psychosocial interventions for cancer patients have been criticized for methodological flaws and unwarranted conclusions (Coyne, Lepore, & Palmer, 2006).

Coyne et al. (2006) contended that there is less evidence for the effect of psychosocial interventions for mood-related distress (e.g., depression, thought intrusion) than has been presented in the literature.

Other stress reduction interventions, such as mindfulness-based stress reduction (MBSR), have shown promising results on psychosocial outcomes in cancer patients. However, most of the studies to date have methodological flaws including small sample sizes, lack of randomization, and lack of information regarding study procedures (Smith, Richardson, Hoffman, & Pilkington, 2005). One wait-list controlled randomized study found that among patients with various cancers at various stages (N=90), those in a 7-week, weekly meditation group had lower scores on depression, anxiety, anger, and confusion, as well as fewer symptoms of stress, fewer physical symptoms, and more vigor than those in a wait-list control (Speca, Carlson, Goodey, & Angen, 2000). The group intervention sessions lasted 90 minutes and included MBSR-related materials, home practice, and problem-solving. Other findings from one-group, uncontrolled samples (N = 59 and 42 pre- and post-intervention, respectively) within the same study protocol showed that breast and prostate cancer patients who participated in the intervention had improved QoL, lower symptoms of stress, and improved SQ, as well as decreases in interferon-gamma and IL-10 which the authors note is consistent with decreases in depressive symptoms (Carlson, Speca, Patel, & Goodey, 2003). This study did not find intervention effects on the number of natural killer, T, or B cells. In addition, later studies showed that lowered mood disturbance and fewer symptoms of stress were maintained at 6-month follow-up (Carlson, Ursuliak, Goody, Angen, & Speca, 2001), and that improvements in QoL, reductions in symptoms of stress, and improvements in

cortisol patterns, immune parameters, and systolic blood pressure were maintained at one-year follow-up among those who were diagnosed with stage 0-2 BCa or early stage prostate cancer (Carlson, Speca, Faris, & Patel, 2007).

Lengacher and colleagues (2009) studied 84 women in a randomized study conducted within 18 months after treatment completion for stage 0-3 BCa. They found that participation in an MBSR intervention consisting of meditation and yoga was associated with lower levels of anxiety, lower levels of depression, less fear of recurrence, more energy, and improved physical functioning when measured after treatment compared to a usual care group. The intervention consisted of six, weekly, 2-hour sessions with groups of four to eight women. Witek-Janusek et al. (2008) demonstrated positive effects of MBSR on immune system functioning, as well as reduced cortisol levels, improved QoL, and increased coping effectiveness in women diagnosed with stage 0-3 BCa who were not undergoing chemotherapy. This was a non-randomized study that compared the MBSR intervention group (n = 44) to those who self-selected into an assessment-only control group (n = 31). The MBSR group met for eight, two and half hour weekly group sessions, as well as a full-day session after the fifth week. In a recent pilot study where participants self-selected into either MBSR (n = 36) or cognitive-behavioral stress reduction (CBSR; n = 14), Smith et al. (2008) found that while MBSR and CBSR were both effective in reducing perceived stress and depression, MBSR was more effective in increasing mindfulness and energy, and in reducing pain. The MBSR group (n = 36) consisted of yoga, meditation, and body scanning and met for eight weekly three-hour group sessions plus a six-hour, one-day retreat. The CBSR group

(n = 14) met for the weekly three-hour sessions and reviewed behavioral techniques. However there was no control group to compare these changes against.

MBSR has yielded mixed findings in terms of its efficacy at improving sleep, including some promising findings from uncontrolled studies with cancer patients (Winbush, Gross, & Kreiter, 2007). For example, the uncontrolled MBSR study by Carlson et al. (2003) found that breast and prostate patients who participated in the MBSR intervention demonstrated improved SQ at the post-intervention assessment. In another sample of 63 stage 2 BCa patients drawn from a larger randomized controlled trial, MBSR home practice, not just attending intervention sessions, was associated with improved SQ among women were, on average, approximately one year post-treatment (range = 2 – 25 months; Shapiro, Bootzin, Figueredo, Lopez, & Schwartz, 2003).

Overall, the stress management interventions reviewed demonstrated positive effects on both distress (e.g., depression, anxiety) and psychosocial outcomes including QoL, health status, and functional well-being. While some of the MBSR studies examined sleep as an outcome in cancer populations, the CBSM intervention studies have not examined effects on sleep in this group. In addition, to my knowledge, sleep has not been investigated as a mediator of psychosocial intervention effects on psychosocial and physical adaptation functional outcomes. Interestingly, sleep disturbances in these populations, are often addressed using CB interventions.

Cognitive-Behavioral Sleep Interventions

CB interventions are an alternative to medication in the treatment of insomnia. Common components of CB are cognitive, behavioral, and educational training, using techniques such as cognitive restructuring, changes in sleep environment, and increasing

healthy sleep behaviors (Fiorentino & Ancoli-Israel, 2006). Increasing evidence has found that CB treatments for insomnia are effective and may offer advantages over pharmacologic treatments (Ebben & Spielman, 2009). For example, when compared with pharmacologic treatment, CB interventions have been shown to be overall more effective in treating sleep difficulties, including problems falling asleep and staying asleep, and are more effective at long-term maintenance of better sleep (Jacobs, Pace-Schott, Stickgold, & Otto, 2004). The efficacy of pharmacologic and behavioral interventions has been demonstrated in the treatment of insomnia in healthy individuals. Until recent years, this has been an understudied area in the BCa literature (Fiorentino & Ancoli-Israel, 2006). However, recent studies have found positive effects of behavioral sleep interventions on sleep and QoL outcomes among cancer patients.

One study looked at a group of diverse cancer patients (i.e., patients with breast, kidney, and prostate cancer) who underwent cancer rehabilitation for three to four weeks after surgery, chemotherapy, or radiation treatment (Simeit et al., 2004). In this study, there was an initial wave of a standard treatment control group (n = 78), and then, in the second wave, participants were allowed to choose between a progressive muscle relaxation group (n = 80) and an autogenic training group (n = 71). The interventions consisted of three, one-hour PE sessions which included in-session and at-home relaxation practice. Results showed that, compared to the control group, the intervention groups consisting of relaxation techniques, sleep hygiene, cognitive techniques and advice in stimulus control techniques produced moderate to large improvements (effects sizes ranging from .5 to 1.0) in various aspects of sleep. These included improvements in latency, duration, efficiency, and quality, which were evident up to six months after

completing rehabilitation. In addition, Simeit and colleagues (2004) found small effects for improvements in physical, role, and cognitive functioning; moderate effects for improvements in emotional and social functioning, global QoL, and fatigue; and large effects on sleep disturbances.

A randomized study of 150 male and female patients with mixed cancer diagnoses (i.e., patients with breast, prostate, colorectal, and gynecological cancer) who were an average of two years post-diagnosis found that CB treatment for insomnia was associated with improvements (i.e., reductions in wakefulness) that were sustained up to 6-month follow-up, as well as improvements in QoL outcomes, compared to treatment as usual (Espie et al., 2008). The CB treatment consisted of five, 50 minute weekly sessions in groups of four to six patients. Effect sizes were moderate to large for decreased time to get to sleep at post-treatment (-.96) and 6-month follow-up (-0.66), for decreased wakefulness after sleep onset at post-treatment (-.97) and 6-month follow-up (-.76), and for improved sleep efficiency at post-treatment (1.09) and 6-month follow-up (.88). In addition, improvements in functional QoL were large at post-treatment (.86) and continued to improve at 6-month follow-up (1.17), while fatigue-related interference of daily life was lowered post-treatment (-.81) and sustained at 6-month follow-up (-.82).

Savard, Simard, Ivers, and Morin (2005a) conducted a randomized study of 57 women who had completed radiation therapy or chemotherapy for stage 1-3 BCa at least one month prior to study enrollment. On average, women were assessed 42 months after diagnosis. The CB treatment for insomnia consisted of eight, 90 minute weekly groups of four to six women and included stimulus control, sleep restriction, cognitive restructuring, sleep hygiene, and stress and fatigue management. Women assigned to CB

versus a wait-list control showed improved subjective SQ, less use of sleep medications, lower levels of depression and anxiety, and greater general QoL. Specifically, Savard et al. (2005a) found that participants in the treatment group improved their sleep efficiency from 69% to 84% post-treatment. However, less conclusive findings were noted on the impact of the intervention on biological measures (immune system functioning) and its impact on clinical outcomes (Savard, Simard, Ivers, & Morin, 2005b).

A randomized sleep intervention study of 219 women with stage 1-3a BCa undergoing chemotherapy, compared modified stimulus control, modified sleep restriction, relaxation therapy, and sleep hygiene, versus a healthy eating control (Berger et al., 2009a). The intervention and control conditions were delivered individually in the patient's home over a 30 day period. The sleep intervention was associated with improved SQ over time as compared to the control condition. At one-year follow-up, there was some improvement in global SQ but not in objective sleep or fatigue measures (Berger et al., 2009b). Another CB treatment for insomnia consisted of stimulus control, sleep restriction, and four group sessions (in groups of four to eight participants) and two individual follow-up phone calls regarding sleep education and hygiene. The intervention resulted in improved sleep outcomes compared to a control condition that received only the group and phone sessions for sleep education and hygiene only condition among 72 women who had completed surgery, radiation therapy, or chemotherapy for stage 1-3 BCa (Epstein & Dirksen, 2007). The mean time since treatment completion was 65.0 months for the treatment group, ranging from 9 to 374 months, and was 51.3 months for the control group, ranging from 3 to 213 months. In addition, this randomized trial demonstrated improvements in fatigue, trait anxiety, depression, and QoL (Dirksen &

Epstein, 2008). Effect sizes were in the small to moderate range for reductions in self-reported time in bed (.6), improved sleep efficiency (.4), improved SQ (.4), reductions in fatigue (.43), and improvements in QoL (.37).

CB sleep interventions for cancer patients have been conducted with diverse groups of cancer patients as well as a few studies that have looked specifically at women with BCa. Overall, such interventions have been successful in improving sleep parameters such as sleep efficiency and quality. CB sleep interventions have included distress-related (e.g., depression and anxiety) and functional outcomes (e.g., fatigue and QoL) as well as sleep outcomes. In summarizing these studies, I have included effect sizes whenever possible. This will allow me to later compare effect sizes from the current study to those found in the sleep-targeted interventions.

Summary and Study Aims

Stress related to a BCa diagnosis and treatment can lead to difficulties in psychological and physical adaptation, such as distress and sleep problems, which in turn is associated with poorer QoL and daily functioning. Stress management interventions have been developed to help women cope with the stressors associated with cancer. These interventions, while varied, have generally been effective in improving psychosocial outcomes. Sleep dysfunction is a common complaint among women with BCa, and sleep may play a role in the relationship between stress and poorer QoL and daily functioning, as sleep disruption has been shown to be associated with both stress and poorer psychosocial outcomes. Sleep interventions have been shown to be effective in improving sleep in cancer patients suffering from sleep problems. The structure and components of these stress and sleep interventions were included in this review in order

to compare these studies with the results from the current analyses. This review shows that previous interventions for both psychosocial outcomes and sleep have a number of limitations.

First, there is a noticeable lack of literature regarding the effect of stress management on sleep among BCa patients. Given the association between stress and sleep problems (e.g., Palesh et al., 2007), as well as some positive effects on sleep outcomes in the MBSR studies (e.g., Shapiro et al., 2003), it is hypothesized that stress reduction may be associated with improved sleep outcomes in our sample. Whereas behavioral sleep interventions might improve sleep by bedtime relaxation exercises, sleep hygiene, stimulus control, and cognitive restructuring related specifically to cognitions about sleep, the CBSM intervention may improve sleep using techniques such as relaxation and cognitive restructuring to decrease overall anxiety (Antoni et al., 2006b) and objective indicators of physiological activation (e.g., PM serum cortisol; Phillips et al., 2008)

Second, some studies (e.g., Simeit et al., 2004) have examined heterogeneous samples of cancer patients, including multiple types of cancers (i.e., breast, kidney, and prostate), multiple stages, and varying points in medical treatment. Generalized findings from diverse cancer types may fail to paint a clear picture of the effects of stress management on women diagnosed with BCa, which may be fundamentally different from the experience of those diagnosed with other cancers. For example, treatment for BCa may include specific medications that contribute to sleep difficulties including tamoxifen (Fenlon, Corner, & Haviland, 2009). Also, hot flashes may play a role in sleep disturbance (e.g., Savard et al., 2004), though the evidence is mixed, as other studies have

found little association between hot flashes and sleep among cancer survivors (e.g., Carpenter et al., 2004).

Third, many of the studies outlined above are studies of cancer survivors, that is, women who have completed treatment and are in remission. The inclusionary post-diagnosis or post-treatment time frame can vary up to years in some studies. If not statistically controlled for, these variations can lead to unclear findings, and, at the very least, are likely not relevant to BCa patients in the midst of treatment.

Finally, the current published works concerning the relationship between sleep and psychosocial adaptation, and between sleep and functional outcomes, among women in the midst of treatment for non-metastatic BCa are cross-sectional (Ancoli-Israel et al., 2006; Vargas et al., 2010). It is unclear what effect a stress management intervention may have on such patients' SQ, and what role this plays in their functional well-being.

In light of the limitations of the extant literature, the current work is designed to determine whether a multi-modal intervention targeting stress management, emotional, and interpersonal adaptation to BCa has a parallel effect on sleep, and whether changes in functional well-being can be explained, in part, by changes in sleep. In the current study, I aim to elucidate further the relationship between stress management, sleep, and psychosocial outcomes in a CBSM intervention study for women undergoing treatment for BCa. Specifically, one aim is to determine whether a CBSM intervention for women undergoing treatment for BCa improves indicators of psychosocial adaptation, as well as perceived SQ. These psychosocial outcomes include functional well-being, positive states of mind, fatigue intensity, fatigue-related disruption of daily functioning, and illness-related disruptions in social functioning and in recreational functioning.

Given that Vargas et al. (2010) have shown that sleep quality is associated with functional outcomes in this sample at baseline, I reasoned that intervention-related changes in functional outcomes observed in the present sample may be attributed, at least in part, to changes in sleep. Therefore, a second aim of the present study is to determine whether improvements in SQ mediate CBSM-associated changes in the psychosocial adaptation indicators. I hypothesize that not only will the CBSM intervention affect functional outcomes among women with BCa, but that SQ will mediate at least some of those outcomes because of its relation with stress. To address prior limitations in the intervention literature, I will statistically control for any treatment-related variables (e.g., time since surgery) that may confound study results. Because psychosocial intervention effects may not be linear for many outcomes and may be asymptotic in nature, I will use Latent Growth Modeling (LGM) analyses. LGM not only assesses differential slopes of change over time between intervention and control conditions, but also estimates the point where intervention-associated improvements in adaptation and sleep begin to plateau.

CHAPTER 2: METHOD

Participants

Participants were 240 women diagnosed with BCa at stage 3 or below who had

recently undergone lumpectomy or mastectomy. The women received letters from their

physicians or from the American Cancer Society that described the study as an

opportunity for women under treatment for BCa to learn stress management. Interested

women called and spoke with a female assistant who screened for eligibility. Participants

had to have had surgery for primary BCa at least two weeks before the initial assessment

and had to complete the initial assessment before beginning any adjuvant treatment (e.g.,

chemotherapy or radiation therapy). Exclusion criteria included prior cancer, prior

psychiatric treatment for a serious disorder (hospitalization or diagnosis of psychosis,

major depressive episode, panic attacks, suicidality, or substance dependence), and lack

of fluency in English.[1]

In keeping with the Consolidated Standards of Reporting Trials (CONSORT)

criteria (Altman et al., 2001), a flow diagram of participation was created to illustrate

allocation to study conditions and study attrition (see Figure 1). Attrition did not differ

significantly by condition at Time 2, $\chi^2(1,N=240) = 0.33$, p > .5), or Time 3 $\chi^2(2,N=209)$

= 0.85, p > .3).

At each time point, those who dropped out were compared with those retained on

key variables. Those who had dropped out of the study by Time 2 were more likely to be

Hispanic, $\chi^2(2,N=240) = 20.81$, p<.01), younger, F(1,238) = 12.12, p <.01, and have been

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[1] Project staff are in the process of gathering updated numbers of women who were screened
ineligible and the reasons for ineligibility since the Antoni et al., 2006 publications. These
numbers will be available and accurate in time for submission of a manuscript derived from this
thesis to a peer-reviewed journal.

diagnosed with stage 3 BCa, $\chi^2(3,N=240) = 11.13$, p<.02). There were no significant

differences between those that dropped out and those that remained enrolled in the study

on initial partnership status, $\chi^2(1,N=240) = 1.80$, p>.1), number of positive lymph nodes,

$F(1,237) = 0.22$, p > .6, menopause status (pre versus peri/post), $\chi^2(1,N=240) = 1.52$,

p>.2), pain, $F(1,224) = 0.00$, p > .9, interviewer-rated depression, $F(1,229) = 0.04$, p > .8,

interviewer-rated anxiety, $F(1,229) = 0.15$, p > .7, and whether they planned to undergo

radiation therapy, $\chi^2(1,N=223) = 0.38$, p>.5), chemotherapy, $\chi^2(1,N=225) = 1.20$, p>.2),

planned tamoxifen/hormonal therapy, $\chi^2(1,N=218) = 0.19$, p>.6), or had breast

reconstruction, $\chi^2(1,N=240) = 0.60$, p>.4), at baseline. There were no significant

differences in women retained versus those not retained on the outcome variables

assessed at Time 1 (Fs < 3, ps >.1), with the exception of the Positive States of Mind

measure, $F(1,224) = 3.36$, p < .1). Women who dropped between Times 1 and 2 tended

towards a greater ability to achieve positive states of mind at baseline versus those who

remained in the study. Those who dropped out of the study between Times 2 and 3 were

more likely to be older than those who remained enrolled, $F(1,207) = 6.94$, p < .01).

There were marginally significant differences in interviewer-rated depression, $F(1,199) =$

3.37, p = <.1) and interviewer-rated anxiety, $F(1,199) = 3.58$, p <.1), such that those who

dropped out were more likely to have lower levels of interviewer-rated depression and

anxiety. Those who dropped between Times 2 and 3 did not differ on any outcome

assessed at Time 2 (Fs < 1, ps >.4) or on any medical or demographic variables, with the

exception of the Positive States of Mind measure, $F(1,187) = 3.20$, p <.1). Unlike those

who dropped between Times 1 and 2, those who dropped between Times 2 and 3 tended

towards less positive states of mind versus those who remained in the study.

Procedure

Participants were recruited approximately two to eight weeks after surgery before any planned adjuvant treatment was initiated. Seventy-nine percent of the sample completed their baseline (Time 1) assessment within two to eight weeks post-surgery (the range of the entire sample was 9-140 days). After completing the Time 1 assessment, participants were randomly assigned to the intervention or control condition (always communicated to participants as a one-day seminar rather than a control group). The intervention occurred over a 10-week period and consisted of a structured, manualized intervention aimed at teaching women to cope better with daily stressors and optimize their use of social resources (Antoni, 2003). Groups of up to eight women met weekly for two-hour sessions, which included didactics, CBSM techniques, and relaxation exercises. CBSM techniques included cognitive restructuring, anger management, and assertiveness training. Relaxation techniques included muscle relaxation, imagery, and meditation. The intervention included both in-session experiential exercises and out-of-session assignments (e.g., practicing relaxation).

Participants in the CBSM intervention group attended an average of 6.85 sessions (SD=2.61, Median=7, Range = 1-10). Women in the control group were invited to attend a one-day seminar during this period. This seminar consisted of a five to six hour, condensed educational version of the intervention information. The seminar delivered some information on most of the main components of the intervention, but it lacked the therapeutic group environment, emotional support, opportunity to role play techniques, and also lacked the feedback and modeling from other group members and home practice aspects of the CBSM intervention. A second assessment (Time 2) occurred three months

after the intervention ended (six months after the initial assessment). A third assessment (Time 3) occurred six months later. Thus, the period of follow-up spanned approximately one year after randomization (see Antoni et al. 2006a, 2006b for more details).

Measures

 Sleep Variables. The Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989) is a 19-item, 30-day retrospective self-report questionnaire that measures SQ and sleep disturbances (see Appendix A). A global score is calculated in addition to multiple subscale scores, including subjective SQ, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medications, and daytime dysfunction. A global score greater than 5.0 has been shown to be a sensitive clinical criterion for distinguishing poor sleepers from good sleepers (Buysse et al., 1989). Studies show that a score greater than 8.0 is a more useful cutoff for a sleep disturbance in cancer populations (Carpenter & Andrykowski, 1998). The PSQI has been found to have good psychometric properties in patients with cancer, including women with BCa (Carpenter & Andrykowski, 1998).

 Buysse et al. (2008) performed a principal component analysis on the PSQI and found that the measure could be divided into three component scores. The first component score consisted of the sleep duration and sleep efficiency subscales, which will be referred to as the 'sleep efficiency' (SE) component. The second component score consisted of the sleep disturbances, sleep latency, daytime dysfunction, and sleep quality subscales, which will be referred to as the 'sleep quality' (SQ) component. The third, and final, component score consisted of the use of sleep medications. Because the SQ component was shown to be associated most consistently with psychosocial outcomes in

the current sample at baseline (Vargas et al., 2010), only the SQ component will be used in the current analyses.

    Criterion measures. The measures used to conceptualize psychosocial adaptation are based upon a model comprising indicators of negative and positive adaptation to the BCa experience (Antoni, 2003). The outcomes consist of measures that fall under the domain of functional adaptation, or daily functioning. See Table 1 for Cronbach's alphas for each of the measures at the three time points.

    Cancer-specific functional quality of life. Daily functioning related to cancer diagnosis and treatment was measured for the past seven days by the 7-item, Functional Well-Being subscale of the Functional Assessment of Cancer Therapy – Breast Cancer (FWB; Brady et al., 1997). Respondents were asked to indicate how much a series of statements applied to them on a 5-point Likert scale from "not at all" to "very much" (see Appendix B).

    Positive states of mind. Perceptions of positive life experiences were assessed by the 7-item, self-report Positive States of Mind (PSOM) questionnaire (Horowitz, Adler, & Kegeles, 1988). Respondents were asked to indicate how frequently they had been able to have a number of satisfying states of mind in the past seven days on a 4-point Likert scale from "unable to have it" to "have it well." Domains assessed are focused attention, productivity, responsible caretaking, restful repose, sensuous non-sexual pleasure, sharing, and sensuous sexual pleasure (see Appendix C).

    Fatigue. Fatigue was measured using the 14-item Fatigue Symptom Inventory (Hann et al., 1998), which generates a fatigue intensity (FSI–I) and fatigue disruption (FSI–D) subscale score. The FSI-I measures the most, least, and average levels of fatigue

in the past week, and the level of fatigue at the time of the assessment. The FSI–D measures how much fatigue interferes in a number of domains, including normal activities, interactions with others, life enjoyment, and mood. Respondents are asked to indicate their level of fatigue and interference on 9-point Likert scales from "not at all fatigued" to "as fatigued as I could be" and from "no interference" to "extreme interference," respectively (see Appendix D).

Interpersonal disruption. A 16-item questionnaire comprised of two subscales of the Sickness Impact Profile was used to assess the impact of cancer and cancer treatment on social interactions (SIP–S) and on recreations and pastimes (SIP–R) over the past few weeks (Bergner, Bobbitt, Carter, & Gilson, 1981). Respondents were asked whether or not a series of statements applied to them and were asked to indicate either "no" or "yes, this applies to me." Given the large variance, skewness, and kurtosis in the SIP data, a square root transformation was performed and the transformed data were subsequently used for relevant analyses (see Appendix E).

Hypotheses

Intervention effects on sleep. It was predicted that women assigned to the intervention group would show greater decreases in the SQ component score (indicating improved sleep quality) than those assigned to the control condition over the one-year follow-up period. We expected that effect sizes would be small for sleep improvements in the intervention group over the control group given the lack of sleep-specific content in either condition.

Intervention effects on functional adaptation. It was predicted that women assigned to the intervention group would show greater increases in functional well-being

and the ability to achieve positive states of mind than those assigned to the control condition over the one-year follow-up period. Women assigned to the intervention group will also show greater decreases in fatigue intensity, disruption of daily activities by fatigue, disruption of social interactions, and disruption of recreations and pastimes than those assigned to the control condition over the one-year follow-up period. We expected effect sizes would be moderate to large for improvements in functional adaptation in the intervention over the control group.

Sleep as a mediator of intervention effects on functional adaptation. Based on latent growth-curve models (outlined in the *Data Analytic Plan* below), the SQ component score will partially or fully mediate intervention-related increases in functional well-being and the ability to achieve positive states of mind, and intervention-related decreases in fatigue intensity, disruption of daily activities by fatigue, disruption of social interactions, and disruption of recreations and pastimes.

Data Analytic Plan

Descriptive statistics were calculated for all variables of interest and the intervention and control group were compared to determine if there are any differences between the groups on descriptive characteristics. Cronbach's alphas were calculated for each measure at each of the three time points (baseline, and 6- and 12-month follow-ups) to measure internal reliability of the scales and subscales. Controls were considered for each model if they were associated with the specified outcome at a $p \leq .10$ level in the baseline analysis (Vargas et al., 2010), and if they were theoretically appropriate. Control variables used in the previous analysis included cancer stage (0, 1, 2, or 3), type of surgery (mastectomy or lumpectomy), days between surgery and completion of baseline

assessment, breast reconstruction surgery, menopausal status (pre-, peri-, or post-menopausal), pain, the use of prescription medication (for sleep, pain, depression, or anxiety), age, race/ethnicity (non-Hispanic Black, non-Hispanic White, or Hispanic), partnership status (partnered or not partnered), employment (employed or not employed), education (highest educational level attained), depression, and anxiety. Due to the longitudinal nature of the current analyses, women may have undergone adjuvant treatment, and thus chemotherapy, radiation, and tamoxifen were investigated as control variables as well. Mean correlations between outcome variables were also calculated.

Intervention effects on sleep and adaptation measures were tested using latent growth-curve modeling (LGM; Duncan, Duncan, Strycker, Li, & Alpert, 1999; Llabre, Spitzer, Saab, & Schneiderman, 2001; Muthén, 1997). The intercept (starting point) and slope (change over time) were modeled as latent variables from data at baseline (Time 1), six months after baseline (Time 2), and one year after baseline (Time 3). Residual variances were constrained equal as per the homogeneity of variance assumption unless otherwise specified. The main predictor was intervention versus control condition (coded as 1 vs. 0). The path from condition to intercept reflects the group difference in initial values and should be non-significant (no initial group differences). The path from condition to slope reflects the extent to which change in the dependent variable over time relates to condition. A significant effect indicates a difference in mean trajectories between groups. Missing data was estimated using the full information maximum likelihood (FIML) method, which uses all available data for each person, estimating missing information from relations among variables in the full sample. FIML was utilized as implemented in Mplus (Muthén & Muthén, 1998), and thus all participants were

represented in the analyses. In the current analyses, I began with a model in which Time 3 is specified as 12 months after Time 1; if that model did not fit well, I tested a model in which Time 3 is freely estimated to capture potential nonlinear change. See Figure 2 for an illustration of the models.

Several indices of model fit are reported for the latent growth models, including chi-square (in which the ideal is a non-significant chi-square); comparative fit index (CFI), for which values above .95 indicate good fit; the root-mean-square error of approximation (RMSEA), for which values below .05 indicate good fit; and the standardized root-mean-square residual (SRMR), for which values below .10 indicate good fit (Kline, 2005). Specific effects were tested with the z statistic, with a .05 two-tailed significance level. Standardized effect sizes are reported as Cohen's d, for which values of 0.20 are regarded as small, 0.50 as medium, and 0.80 as large (Cohen, 1992). Effect sizes were calculated without measurement error, as described by Raudenbush and Xiao-Feng (2001).

In addition to the test of intervention effects on sleep and functional adaptation, I tested whether subjective improvements in SQ might mediate the effects of the intervention on the functional outcomes. Each outcome that was shown to be affected by the treatment (i.e., had a condition effect on slope) was reexamined. The final model from the previous analysis of that outcome was elaborated into a more complex model, which simultaneously estimated both the condition effect on the outcome variable and the condition effect on the SQ component. In each case, Time 3 data were handled as they were handled in the final model described earlier: That is, if Time 3 was specified as 12 months in the final model, it was specified as 12 months here; if it was freely estimated

earlier, it was freely estimated here. Also included in these analyses is a predictive path from the slope of the PSQI SQ component to the slope of the outcome variable. See Figure 3 for an illustration of the mediation model.

If the SQ component mediates the effect of condition on the outcome, having the predictive path from the sleep slope to the outcome slope should weaken or eliminate the path from condition to outcome slope. This was tested in two ways. First, I assessed the significance of the condition effect on slope that remained. If the direct effect of the condition on the slope of the outcome variable was greatly reduced after the sleep path was added, mediation was indicated. Second, that elaborated model was compared against a model in which the prediction from condition to outcome slope was fixed to zero. If that model did not differ significantly from the prior one, it indicated that the remaining role of condition is negligible. For all latent growth models, MPLUS-specified modifications were made where appropriate and are noted in the results.

CHAPTER 3: RESULTS

Preliminary Analyses and Descriptive Information

Characteristics of the sample, by condition, are presented in Table 2. Comparisons revealed that days from surgery to the baseline assessment differed between the CBSM and PE control groups, and was thus investigated as a control variable. Mean correlations among outcome variables (i.e., averaged across the assessments) are shown in Table 3. There were significant correlations between a number of outcome variables, and those correlations should be considered in interpreting the results. None of the potential control variables improved model fit (see Footnotes 2-7) and were thus not retained in the final models.

Intervention Effects on Sleep Quality and Functional Outcomes.

Sleep quality. For the SQ component score on the PSQI, when the three time points were specified, the model fit the data, $\chi2(4, N = 240) = 3.85$, $p = .43$ (CFI = 1.00, RMSEA = 0, SRMR = .02). Condition did not predict variation in intercept ($z = -0.38$, p > .7) indicating that the groups did not differ significantly in SQ at the baseline assessment. Condition did have a significant relation with slope ($z = -2.82$, p < .01) indicating differential change over time between the CBSM and control conditions (Table 4 and Figure 4). With the intercept centered at Time 2, there was a significant condition effect on intercept ($z = -2.12$, p < .05) indicating a significant group difference at Time 2. When the intercept was centered at Time 3, there was still a condition effect on intercept ($z = -3.04$, p < .01) indicating a significant group difference at Time 3.

Functional well-being. For FWB subscale on the FACT, when the three time points were specified, the model did not fit the data well, $\chi2(4, N = 240) = 11.79$, p =

.019 (CFI = 0.96, RMSEA = .09, SRMR = .05). When the third time point was freely

estimated, the model fit the data well, χ^2(3, N = 240) = 2.60 p = .46 (CFI = 1.00, RMSEA

= .00, SRMR = .044).[2] Condition did not predict variation in intercept (z = -1.08, p > .2),

but tended toward significance for slope (z = 1.90, p = .06) indicating a marginally

significant differential change in the CBSM and control groups (Table 4). Time 3 was

estimated at 8.29 months after Time 1, indicating that the 12-month data fell at a point

that would be predicted by a purely linear relationship if the 12-month data had been

collected at 8.29 months. With the intercept centered at Time 2, the group difference was

not significant (z = 0.33, p > .7). When the intercept was centered at Time 3, the group

difference was not significant (z = 0.86, p > .3).

Positive states of mind. For the Positive States of Mind measure, when the three

time points were specified, the model did not fit the data, χ^2(4, N = 240) = 13.40, p = .01

(CFI = 0.94, RMSEA = .10, SRMR = .10). When the third time point was freely

estimated, the model fit the data well, χ^2(3, N = 240) = 2.84, p = .42 (CFI = 1.00,

RMSEA = .00, SRMR = .06).[3] Condition did not predict variation in intercept (z = -0.63,

p > .5), but did have a significant relation to slope (z = 2.30, p < .03) indicating a

differential change between CBSM and control over time (see Table 4 and Figure 5).

Time 3 was estimated at 7.92 months after Time 1. With the intercept centered at Time 2,

the group difference was not significant (z = 1.44, p > .1). When the intercept was

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[2] The following controls were separately added to the final FWB model to investigate the effects: stage, time since surgery, chemotherapy, radiation therapy, tamoxifen use, anti-anxiety medication, sleep medication, and the Hamilton Rating Scale for Anxiety (HAM-A; Schwab, Bialow, Clemmons, & Holzer, 1967). None of the control variables significantly improved model fit (chi-squares > 3.2).
[3] The following controls were separately added to the final PSOM model to investigate the effects: time since surgery, chemotherapy, radiation therapy, tamoxifen use, pain, HAM-A, and partnership status. None of the control variables significantly improved model fit (chi-squares > 8.9).

centered at Time 3, there was a significant condition effect on intercept ($z = 2.35$, $p < .02$) indicating significantly greater PSOM scores in the CBSM group at Time 3.

Fatigue intensity. For the Intensity subscale of the FSI, when the three time points were specified, MPLUS generated a non-positive definite warning message for the slope latent variable covariance matrix. When the third time point was freely estimated, the model fit the data well, $\chi2(3, N = 240) = 4.44$, $p = .22$ (CFI $= 0.99$, RMSEA $= .04$, SRMR $= .03$).[4] Condition did not predict variation in intercept ($z = -0.93$, $p > .3$), nor did condition predict variation in slope ($z = -1.21$, $p > .2$) indicating that there was no differential change between groups over time (see Table 4). Time 3 was estimated at 7.84 months since Time 1.

Fatigue disruption. For the Disruption subscale of the FSI, when the three time points were specified, the model did not fit the data, $\chi2(4, N = 240) = 14.97$, $p < .01$ (CFI $= 0.93$, RMSEA $= .11$, SRMR $= .06$). When the third time point was freely estimated, the model fit the data well, $\chi2(3, N = 240) = 5.04$, $p = .17$ (CFI $= 0.99$, RMSEA $= .05$, SRMR $= .04$).[5] Condition did not predict variation in intercept ($z = 0.80$, $p > .4$), but did have a significant relation to slope ($z = -2.46$, $p < .02$) indicating a differential change over time between the CBSM and control conditions (see Table 4 and Figure 6). Time 3 was estimated at 7.99 months after Time 1. With the intercept centered at Time 2, the group difference was not significant ($z = -1.38$, $p > .1$). When the intercept was centered

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[4] The following controls were separately added to the final FSI-I model to investigate the effects: time since surgery, chemotherapy, radiation therapy, tamoxifen use, pain, antidepressant medication, and HAM-A. Only radiation therapy improved model fit (chi-square = 3.25), though this was not a significant improvement (chi-square difference = 1.19, p > .2). None of the other control variables significantly improved model fit (chi-squares > 7.2).

[5] The following controls were separately added to the final FSI-D model to investigate the effects: stage, time since surgery, chemotherapy, radiation therapy, tamoxifen use, pain, planned reconstruction at baseline, anti-depressant medication, pain medication, and HAM-A. None of the other control variables significantly improved model fit (chi-squares > 5.1).

at Time 3, there was a significant condition effect on intercept ($z = -2.49$, $p < .02$) indicating a significant less fatigue-associated disruption in the CBSM condition at Time 3.

Social interaction. For the Social Interaction subscale on the SIP, when the three time points were specified, MPLUS generated a non-positive definite warning message for the slope latent variable covariance matrix. When the third time point was freely estimated, MPLUS again generated a non-positive definite warning message for the slope latent variable covariance matrix. As a next step, the three time points were once again specified and the residual variance of the SIP-S measure at the second time point was unconstrained. This indicates that the homogeneity of variance assumption may not have been met, but the results will be interpreted keeping this in mind. The model fit the data well, $\chi2(3, N = 240) = 1.11$, $p = .78$ (CFI = 1.00, RMSEA = 0, SRMR = .03).[6] Condition did not predict variation in intercept ($z = -0.71$, $p > .4$), but tended toward significance for the slope ($z = -1.85$, $p = .06$) indicating a marginally significant differential change over time in the CBSM and control groups (see Table 4). With the intercept centered at Time 2, the group difference was nearly significant ($z = -1.92$, $p = .06$). When the intercept was centered at Time 3, there was a significant condition effect on intercept ($z = -2.62$, $p < .01$) indicating significantly less disruption in social interactions in the CBSM condition at Time 3.

Recreation and pastimes. For the Recreation and Pastimes subscale on the SIP, when the three time points were specified, the model did not fit the data, $\chi2(4, N = 240) = 13.12$, $p = .01$ (CFI = 0.90, RMSEA = .10, SRMR = .31). When the third time point was

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[6] The following controls were separately added to the final SIP-S model to investigate the effects: time since surgery, chemotherapy, radiation therapy, tamoxifen use, and HAM-A. None of the other control variables significantly improved model fit (chi-squares > 1.6).

freely estimated, the model still did not fit the data, $\chi 2(3, N = 240) = 12.78$, $p < .01$ (CFI = 0.89, RMSEA = .12, SRMR = .33). As a next step, the three time points were once again specified and the residual variance of the SIP-R measure at the third time point was unconstrained. This indicates that the homogeneity of variance assumption may not have been met, but the results will be interpreted keeping this in mind. The model fit the data, $\chi 2(3, N = 240) = 2.87$, $p = .41$ (CFI = 1.00, RMSEA = 0, SRMR = .13).[7] Condition did not predict variation in intercept ($z = 0.70$, $p > .4$), but did have a significant relation with slope ($z = -2.05$, $p < .05$) indicating differential change over time between the CBSM and control groups (see Table 4). With the intercept centered at Time 2, the group difference was not significant ($z = -0.72$, $p > .4$). When the intercept was centered at Time 3, the condition effect on the intercept tended toward significance ($z = -1.90$, $p = .06$) indicating marginally significantly less disruption in recreation and pastime activities in the CBSM group at Time 3.

Mediation Analyses

For each outcome that had been significantly affected by treatment, SQ was examined as a potential mediator. If SQ mediates the effect of condition on the outcome, then adding a predictive path from the slope of SQ to the slope of the outcome variable should weaken or eliminate the path from condition to outcome slope. This was tested using the two methods outlined in the *Data Analytic Plan*. The results of these analyses are summarized in Table 5. Although not specified in the table, these models fit the data well. In the first method, the direct effect of condition on the slope was greatly reduced after adding the SQ path for PSOM, FSI-D, and SIP-R (see Table 5). For each outcome,

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[7] The following controls were separately added to the final SIP-R model to investigate the effects: stage, time since surgery, chemotherapy, radiation therapy, tamoxifen use, and sleep medication. None of the control variables significantly improved model fit (chi-squares > 6.0).

the path from condition to slope was no longer significant.[8] In the second step, the

elaborated model was compared against a model in which the prediction from condition

to outcome slope was fixed to zero. The results of these analyses are summarized in the

final column of Table 5. In each case, the comparison yielded no difference between the

models indicating that the remaining effects of condition on outcomes were negligible.

These findings indicate that CBSM-associated changes in these outcome variables—

positive states of mind, fatigue-associated disruption, and disruption in recreational

activities—were mediated by changes in SQ

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[8] The final mediation models for PSOM and FSI-D included modification indices that were recommended by MPLUS and improved model fit. In the PSOM model, the residual variances of the PSOM and SQ component measures were correlated at Time 2 only. In the FSI-D model, the residual variances of the FSI-D and SQ component measures were correlated at Time 2 only. Without these correlations accounted for in the models, the model did not fit the data. However, the condition effects on the slopes of the outcomes were non-significant in these mediation models (PSOM $z = -0.34$, $p > .7$; FSI-D $z = 0.14$, $p > .8$) before including these modifications indicating that these modifications did not alter the main findings.

CHAPTER 4: DISCUSSION

The current analyses provide evidence that a CBSM intervention for women undergoing treatment for BCa can produce significant changes in both SQ and indicators of functional adaptation. Participants in the CBSM group reported improved SQ, as well as increased positive states of mind, improved recreational functioning, and reduced fatigue-related daytime dysfunction compared to a PE control. There were marginally significant improvements in the areas of functional well-being and social functioning. No intervention effects were found on the intensity of fatigue. Effect sizes ranged from .41 to .78 and fell within the medium to large range. Such effect sizes have previously been considered clinically significant (Antoni et al., 2006a; Hays & Wooley, 2000; Norman, Sloan, & Wyrwich, 2003).

Previous studies of CB interventions for insomnia have found effect sizes between .4 and 1.0 for intervention effects on sleep parameters (Epstein & Dirksen, 2007; Espie et al., 2008; Simeit et al., 2004). In this study, using an intervention that does not directly target sleep, the effect size for intervention-related effects on SQ was higher than expected (-0.78). This effect is within the large range and within the range of previous interventions that directly targeted sleep. It is of note that in the previous studies, participants suffered from clinically significant levels of sleep disruption (i.e., insomnia). In our study, while there was a high rate of sleep disturbance, there was no eligibility criterion related to sleep; as a result, 77% of the cases did not show clinical evidence of sleep disruption problems such as insomnia (as measured by a sleep latency of greater than 30 minutes; Lichstein, Durrence, Taylor, Bush, & Riedel, 2003; Linberger, Carney, Edinger, & Means, 2006). As a result, there was a wider range of sleep characteristics

within this sample indicating that the intervention may improve sleep for a large

proportion of the population, not just those with clinically disordered sleep.

In this sample of women undergoing treatment for BCa, there were large effects

on SQ with an intervention that did not directly target sleep and with participants who

had a wide range of sleep functioning. We previously found baseline associations

between sleep and functional adaptation in this sample (Vargas et al., 2010), and we have

now demonstrated associations between CBSM, sleep, and functional adaptation using

longitudinal data. This raises the question of which component(s) of the CBSM

intervention affected sleep. At least one component of the intervention – relaxation

training –has been previously found to improve SQ (e.g., Berger et al., 2009). In addition,

self-reported confidence in one's ability to relax has been found to mediate intervention

effects on other measures of distress and psychosocial functioning (including some of

those used in the present study, e.g., PSOM, FACT) in a subset of the current sample (see

Antoni et al., 2006a). It is possible that relaxation training may be the vital component to

improvements in sleep. Additionally, the CBSM may have affected sleep by changing

women's coping strategies. This would be consistent with a recent study that related

coping strategies to sleep in women with BCa (Thomas, Bower, Hoyt, & Sepah, 2010).

That study found that avoidance coping strategies predicted poorer sleep outcomes in

BCa patients. The authors suggested the need for interventions that increase the use of

approach coping strategies in an attempt to improve psychosocial outcomes, including

sleep. Consistent with the suggestion to enhance approach coping, a main component of

the CBSM intervention tested in the present study is coping effectiveness training

(Folkman et al., 1991) and group discussions of coping strategies that women are using to

deal with BCa and its treatment (Antoni, 2003). Additionally, the CBSM intervention has previously been found to reduce cancer-related intrusive thoughts and anxiety symptoms (Antoni et al., 2006) and, thus, may influence sleep by reducing thoughts and anxiety that may interfere with sleep.

The intervention was successful at reducing reports of disruption of daily activities due to fatigue, but was not associated with changes in intensity of fatigue. These findings are consistent with previous literature. To address the lack of findings for fatigue intensity, the CBSM intervention did not target fatigue directly. A recent review article found that interventions are generally more effective in reducing fatigue in cancer patients if they contain such content, such as education about fatigue, self-care and coping training, and activity management (Goedendorp, Gielissen, Verhagen, & Bleijenberg, 2009). Studies that take a more generalized approach to address distress and mood have been less successful in improving fatigue (Goedendorp et al., 2009). In another review addressing fatigue interventions in cancer patients (Kangas, Bovbjerg, & Montgomery, 2008), the authors found that psychosocial and exercise interventions that included specific fatigue content had larger effect sizes (-.48) than those studies that did not include fatigue-related specific aims (-.23). The same review also found smaller effects sizes for fatigue in studies that used BCa patients only (-.28) versus mixed cancer groups (-.34), that investigated patients undergoing adjuvant treatment (-.24) versus a post-treatment or mixed group (-.44), and that lasted more than 8 sessions (-.31) versus fewer than 6 (-.40). Therefore, this CBSM intervention, having the characteristics associated with smaller effect sizes for fatigue outcomes, was unlikely to produce significant change in fatigue intensity based on these reviews. However, other authors

have noted that because of the difficulty in targeting fatigue directly in interventions for cancer populations, mood and sleep may be appropriate intervention targets that may bring about some changes in fatigue symptoms (Banthia, Malcarne, Ko, Varni, & Sadler, 2009).

Intervention effects on disruption of daily activities by fatigue were found to be mediated by improvements in sleep (Banthia et al., 2009). Additionally, the intervention may have affected cognitive changes that brought about changes in perceived disruption of fatigue symptoms. In a randomized controlled trial of 60 patients with chronic fatigue syndrome, patients were offered medical care alone or medical care plus CB therapy intervention consisting of 16 weekly, one-hour individual sessions that emphasized the role of psychological and social factors in disease (Sharpe et al., 1996). Sharpe et al. (1996) found that at 12-month follow-up, people in the CB group spent fewer days in bed, felt less fatigued, and had less difficulty with daily activities. Sharpe et al's findings supported the notion that specific illness beliefs and ineffective coping contribute to chronic fatigue symptoms (see Surawy, Hackmann, Hawton, & Sharpe, 1995). In the current analysis of a CBSM intervention, it is possible that improvements in sleep, as well as changes in beliefs about fatigue and the impact of fatigue on their daily functioning, contributed to fatigue-related daily functioning improvements.

Several of the models for intervention effects on the outcomes fit the data when the third time point was estimated by MPLUS (i.e., FWB, PSOM, FSI-I, and FSI-D). This third time point was generally estimated to be about 8 months after the baseline assessment (range 7.8 – 9.2 months). This indicates that the effects of condition on slope were largely driven by change from baseline to approximately eight months with little

change thereafter. One can hypothesize that this waning of intervention effects may be due to a number of factors.

First, the 10-week CBSM intervention ended approximately three months after baseline. Thus, at the 8-month mark, participants would have been approximately five months since the last group meeting. There were no booster sessions after the final session that could have helped sustain the intervention's effects. Andersen et al.'s stress management intervention (see 2004, 2007a) included more weekly group meetings (n = 18) over a four month span, as well as an 8-month maintenance period with monthly group meetings, and demonstrated effects on health via reduced distress that lasted out to the 12-month follow-up period. It is possible that follow-up, or "booster," sessions would have led to more sustained improvements in functional outcomes in the current sample.

A second and related point is that given that some months have elapsed since the conclusion of their group meetings as well as their medical appointments, participants may no longer practice CBSM skills and techniques at home, since they may view them as less salient. Most participants would have ended adjuvant therapy by the 8-month mark and likely had less regular contacts with the healthcare system. Without regular contact, women may have cognitively distanced themselves from the cancer experience, and thus their experiences in the intervention. In addition, less contact with health care providers may have removed reminders of the cancer experience and cues for physical and emotional self-care. This suggests some value in providing participants a rationale for the continued use of these techniques as a "lifestyle change" that will serve them well after their cancer treatment is completed.

The results also showed that SQ mediated changes in positive states of mind, recreational functioning, and fatigue-related daytime dysfunction in the current sample. Intervention-related changes in functional well-being and disruptions in social interactions were only marginally significant and were, therefore, not included in the mediation analysis. In addition, fatigue intensity did not demonstrate intervention effects and was also not included in the mediation analysis.

The SQ measure – the mediator tested in this study – was a component score comprised of four subscales of the PSQI (i.e., sleep disturbances, sleep latency, daytime dysfunction, and SQ). Future work may use individual subscales from the PSQI or other measures (e.g., objective measures of sleep latency using actigraphy) to better understand which specific aspects of sleep are most associated with functional outcomes. Future studies may also investigate whether specific components of the CBSM intervention (e.g., relaxation training, cognitive aspects, non-specific group factors) were instrumental in bringing about changes in these outcomes. Future analyses may look at specific subgroups, for example, patients who experience clinically meaningful levels of sleep disturbance or distress at baseline. Andersen and colleagues (2004) found that some of their intervention effects (e.g., fatigue) were significant only in groups that reported the most stress at baseline. Subgroup analyses may help clinicians identify and target sleep parameters and populations for interventions aimed to improve functional adaptation via improvements in sleep. Future analyses may also investigate whether sleep mediates changes in other psychosocial outcomes, such as thought intrusion and benefit finding, found to be affected by the intervention (Antoni et al., 2006a; Antoni et al., 2006b). Other analyses may investigate whether sleep mediates previously observed intervention-related

changes in stress hormones (i.e., cortisol) and immune functioning (i.e., cytokine production) previously observed in a sub-sample of the women in the present study (Antoni et al., 2009; Phillips et al., 2008).

Limitations

There are several limitations in this study that restricts the degree to which we can draw conclusions from these findings, and the degree to which we can generalize those conclusions to other cancer populations. Some of these limitations concern measurement issues. For example, a major limitation is the varying retrospective time frames for the psychosocial measures. For example, the PSQI is a 30-day retrospective measure of SQ, while the FACT instructs the participant to consider the past 7 days only. These varying time frames may attenuate some of the associations between the SQ mediator and the outcomes. In addition, the retrospective, self-report nature of the sleep variable and all the outcome measures carries its own limitations, including the potential for memory and response biases.

A second limitation involves the generalizability to other groups of BCa patients and survivors. While this study attempts to address the gap in longitudinal studies among women in the midst of treatment for non-metastatic BCa (i.e., in the weeks post-surgery and through adjuvant treatment), it may lack generalizability to women at other phases of cancer treatment and survivorship (see Kreps & Sivaram, 2008 for a discussion of some issues patients face along the cancer continuum). For example, the results may not generalize to women with metastatic BCa since they may have a different prognosis and treatment regimen. In addition, the women in this sample were predominantly non-Hispanic white, partnered, employed, and fairly well educated. This limits our ability to

generalize these findings to the women who may benefit most from a stress management intervention most.

Finally, the current analysis uses SQ as the sole mediator. It is not clear how other potential mediators would fit into the models. For example, previous research from Antoni et al. (2006a) has shown that the CBSM effects on numerous psychosocial outcomes, including some that were investigated in the current study, were mediated by confidence in one's ability to relax. Additionally, Andersen et al. (2007b) found that group support, presentation of a theory regarding stress and stress management, including a relaxation component, and including strategies to assist in communication with health care providers were associated with intervention effects on psychological and health outcomes. Ability to relax was not included in the current analyses, nor were other potential mediators. It is possible that the intervention effects on SQ and functional adaptation were mediated by women's confidence in their ability to relax Additionally, there may be an association between sleep and positive health behaviors (e.g., exercise) that may mediate the association between sleep and functional adaptation. Given these possibilities, more complex models may be warranted and should be investigated in future analyses.

Conclusions

In conclusion, this study has demonstrated that a group-based CBSM intervention can have significant positive effects on functional adaptation and self-perceived SQ in a longitudinal study of women who have undergone treatment for non-metastatic BCa. Despite that fact that the intervention did not directly target sleep problems, CBSM effects on SQ were similar to those found in insomnia interventions for cancer patients.

Furthermore, the effects on adaptation measures were mediated by changes in SQ. It seems reasonable to hypothesize that had there been sleep-targeted content to the intervention, then the mediation effect may have been enhanced and the improvements in functional outcomes may have been further improved. However, the added sleep content may require extended contact time, which could be achieved by extending each weekly session or adding additional sessions. Many sleep interventions are delivered in three to five sessions (e.g., Espie et al., 2008; Simeit et al., 2004) and include sleep restriction and stimulus control, which the participant then implements at home (e.g., Berger et al., 2008). The integration of sleep and stress management content would constitute another challenge. However given the similarity of CB approaches used in both CBSM and many insomnia interventions, the materials would likely be easy to integrate and mutually complementary. For example, the practice of relaxation is used in both CBSM and CB sleep interventions. In addition, cognitive restructuring can be used for coping with stressors as well as addressing maladaptive thoughts around sleep. Additionally, many of the stress management and sleep interventions are conducted at least in part in a group format and offer a supportive group environment.

The current study again suggests that combining sleep-specific interventions with stress management interventions may be a highly efficient approach for women undergoing treatment for BCa (Vargas et al., 2010). In addition, there may be cumulative positive effects of the combined materials on both sleep and psychosocial outcomes. Future interventions aimed to improve psychosocial outcomes for BCa patients could potentially capitalize on the mediating effects of SQ by including sleep-related content in the interventions already shown to be efficacious.

Table 1. *Cronbach's Alphas for All Scales at Three Time Points*

	Baseline	6 Month Follow-Up	12 Month Follow-Up
Functional Well-Being	.84	.85	.86
Positive States of Mind	.78	.77	.79
Fatigue Intensity	.83	.87	.85
Fatigue Disruption	.93	.94	.94
Social Interaction	.81	.87	.87
Recreation/ Pastimes	.71	.78	.76

Table 2. *Demographic and Medical Variables*

Variable	Control	Intervention	Statistic	p
Age at diagnosis	50.99 (9.06)	49.69 (8.98)	F(1,238) = 1.25	.26
Years Education	15.47 (2.26)	15.69 (2.50)	F(1,238) = 0.53	.47
Ethnicity			χ2(2,N=240) = 0.39	.82
non-Hispanic white	79 (66%)	83 (69%)		
Hispanic	31 (26%)	29 (24%)		
African American	10 (8%)	8 (7%)		
Initially Partnered	75 (63%)	75 (63%)	χ2(1,N=240) = 0.00	1.00
Initially Employed	92 (77%)	86 (72%)	χ2(1,N=239) = 1.00	.32
Cancer Stage			χ2(3,N=238) = 2.96	.40
Stage 0	19 (16%)	19 (16%)		
Stage 1	51 (43%)	39 (33%)		
Stage 2	41 (35%)	50 (42%)		
Stage 3	8 (7%)	11 (9%)		
Nodes	39 (33%)	49 (41%)	χ2(1,N=239) = 1.93	.16
(*n* with positive nodes)				
Surgery			χ2(1,N=240) = 3.27	.07
Lumpectomy	68 (57%)	54 (45%)		
Mastectomy	52 (43%)	66 (55%)		
Days From Surgery to Baseline Assessment	43.53 (24.89)	36.85 (19.93)	F(1,224) = 4.98	.03
Received Radiation	60 (50%)	58 (48%)	χ2(1,N=240) = 0.07	.80
Received Chemotherapy	56 (47%)	62 (52%)	χ2(1,N=240) = 0.60	.44
Received Tamoxifen	71(59%)	74(62%)	χ2(1,N=240) = 0.60	.69
Underwent Reconstructive Surgery	40 (33%)	45 (38%)	χ2(1,N=240) = 0.16	.50
Menopause Status			χ2(1,N=240) = 0.02	.90
Pre	53 (44%)	54 (45%)		
Peri/Post	67 (56%)	66 (55%)		
Average Daily Pain at Baseline	2.30 (1.64)	2.26 (1.61)	F(1,224) = 0.03	.86
Hamilton Depression at Baseline	7.30 (5.10)	7.74 (5.80)	F(1,229) = 0.37	.54
Hamilton Anxiety at	7.03 (5.27)	8.09 (5.90)	F(1,229) = 2.10	.15

Baseline				
Prescribed Anti-Depressant Medication				
Time 1	12 (10%)	14 (12%)	χ2(1,N=240) = 0.17	.68
Time 2	14 (15%)	9 (9%)	χ2(1,N=193) = 1.29	.26
Time 3	17 (18%)	12 (12%)	χ2(1,N=190) = 1.14	.28
Prescribed Anti-Anxiety Medication				
Time 1	20 (17%)	22 (18%)	χ2(1,N=240) = 0.12	.73
Time 2	18 (19%)	11 (11%)	χ2(1,N=193) = 2.08	.15
Time 3	24 (26%)	10 (10%)	χ2(1,N=190) = 7.38	.01
Prescribed Sleep Medication				
Time 1	19 (16%)	24 (20%)	χ2(1,N=240) = 0.71	.40
Time 2	11 (12%)	11 (11%)	χ2(1,N=192) = 0.00	.96
Time 3	20 (21%)	8 (8%)	χ2(1,N=191) = 6.18	.01
Prescribed Pain Medication				
Time 1	32 (27%)	28 (23%)	χ2(1,N=240) = 0.36	.55
Time 2	13 (14%)	11 (11%)	χ2(1,N=193) = 0.27	.60
Time 3	14 (15%)	10 (10%)	χ2(1,N=190) = 0.86	.35

Note. Standard deviations and percentages are in parentheses.

Table 3. *Correlations Among Outcome Variables, Averaged Across Three Time Points*

Outcome	Functional Well-Being	Positive States of Mind	Fatigue Intensity	Fatigue Disruption	Social Interaction	Recreation/ Pastimes
Sleep Quality	-.57*	-.46*	.51*	.54*	.40*	.38*
Functional Well-Being	-	.58*	-.48*	-.64*	-.52*	-.51*
Positive States of Mind		-	-.50*	-.66*	-.49*	-.41*
Fatigue Intensity			-	.72*	.35*	.31*
Fatigue Disruption				-	.51*	.46*
Social Interaction					-	.61*

* Correlation is significant at the .01 level (2-tailed)

Table 4. *Estimated Means and Standard Errors of Outcomes at Three Time Points, by Experimental and Control Condition, and Condition Effects on Slope Over Time*

Outcome	Time 1		Time 2		Time 3		Condition effect on slope		
	M	SE	M	SE	M	SE	z	p	d
SQ							-2.82	<.01	-0.78
Control	5.69	0.20	5.26	0.18	4.84	0.23			
Intervention	5.58	0.20	4.72	0.18	3.85	0.23			
FWB							1.90	.06	0.43
Control	18.76	0.52	20.76	0.45	21.52	.52			
Intervention	17.96	0.52	20.96	0.47	22.11	.55			
PSOM							2.30	.02	0.53
Control	21.80	0.36	22.99	0.31	23.37	0.36			
Intervention	21.48	0.36	23.61	0.33	24.29	0.38			
FSI-I							-1.21	.23	-0.71
Control	4.47	0.15	4.15	0.15	4.06	0.17			
Intervention	4.27	0.15	3.72	0.17	3.55	0.21			
FSI-D							-2.46	.01	-0.57
Control	3.52	0.18	2.95	0.15	2.77	0.16			
Intervention	3.72	0.18	2.67	0.16	2.33	0.18			
SIP-S							-1.85	.06	-0.65
Control	29.91	0.23	29.56	0.20	29.21	0.23			
Intervention	29.68	0.23	29.02	0.20	28.37	0.23			
SIP-R							-2.05	.04	-0.41
Control	17.75	0.17	17.36	0.13	16.97	0.16			
Intervention	17.91	0.17	17.23	0.13	16.55	0.16			

SQ = sleep quality; FWB = functional well-being; PSOM = positive states of mind; FSI-I = fatigue intensity; FSI-D = daily disruption due to fatigue; SIP-S = social interactions; SIP-R = recreations and pastimes

Table 5. *Testing Whether Effects of the Intervention on Functional Outcomes Were Mediated by Changes in the 'Sleep Quality' Component of the PSQI*

Outcome	Initial condition effect on slope (z)	Condition effect on slope with control for sleep quality (z)	Chi-square (1,N=240) difference and p change in model fit when condition path set to zero
Functional Well-Being	1.90	N/A	N/A
Positive States of Mind	2.30	-0.26	0.07, p > .7
Fatigue Intensity	-1.21	N/A	N/A
Fatigue Disruption	-2.46	0.08	0.01, p > .9
Social Interaction	-1.85	N/A	N/A
Recreation/Pastimes	-2.05	-0.72	0.49, p > .4

Figure 1. Experimental design and flow diagram of participants. T = Time.
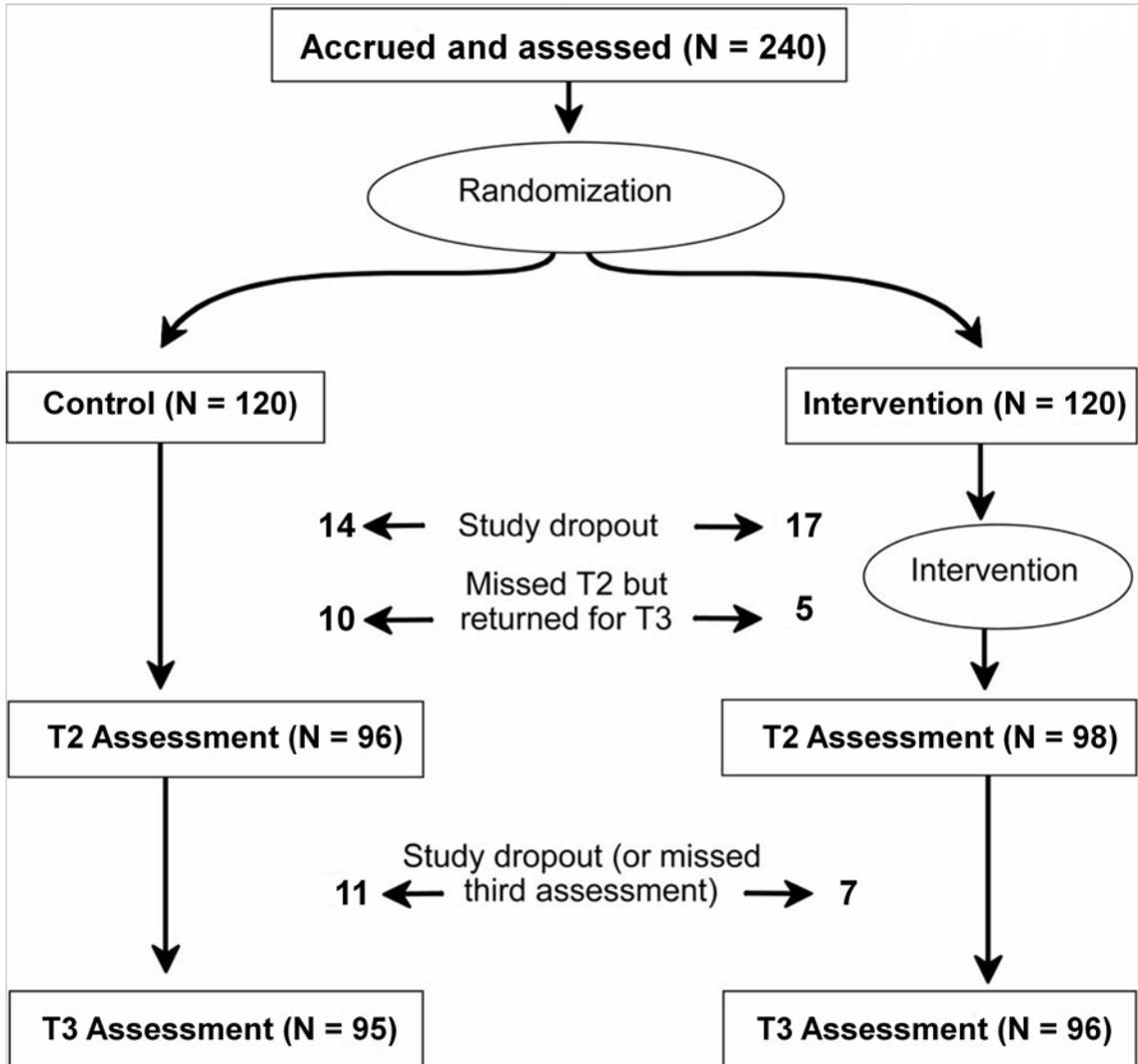
Figure 2. Structural model of latent growth curves in which condition predicts the

intercept and slope of an outcome variable across the three time points (baseline,

and 6- and 12- month follow-ups). M_I is the differential effect of the intervention

on the intercept of the growth curves. M_S is the differential effect of the

intervention on change over time. An asterisk indicates that this time point may be

either specified as 12 months or may be estimated.
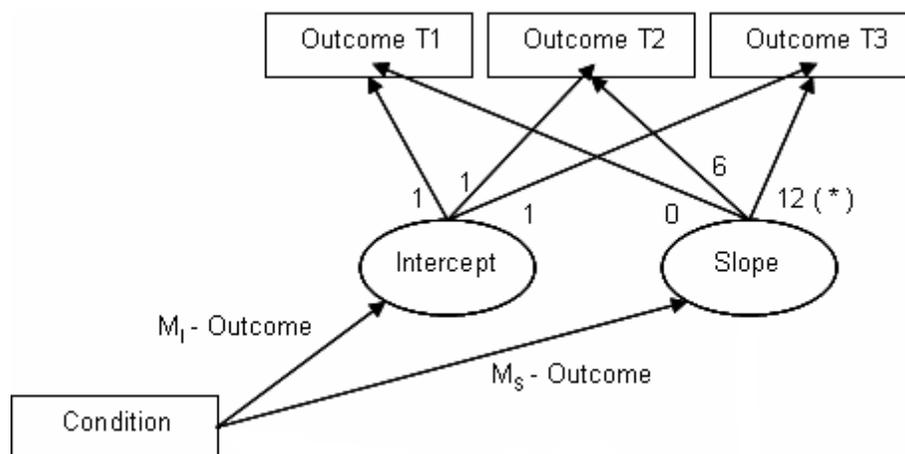
Figure 3. The final meditational model in which condition predicts the intercept and slope of both an outcome variable across the three time points (baseline, and 6- and 12- month follow-ups) and a sleep mediator variable across the same three time points. In addition, the slope of the sleep mediator predicts the slope of the outcome variable. An asterisk indicates that this time point may be either specified as 12 months or may be estimated.
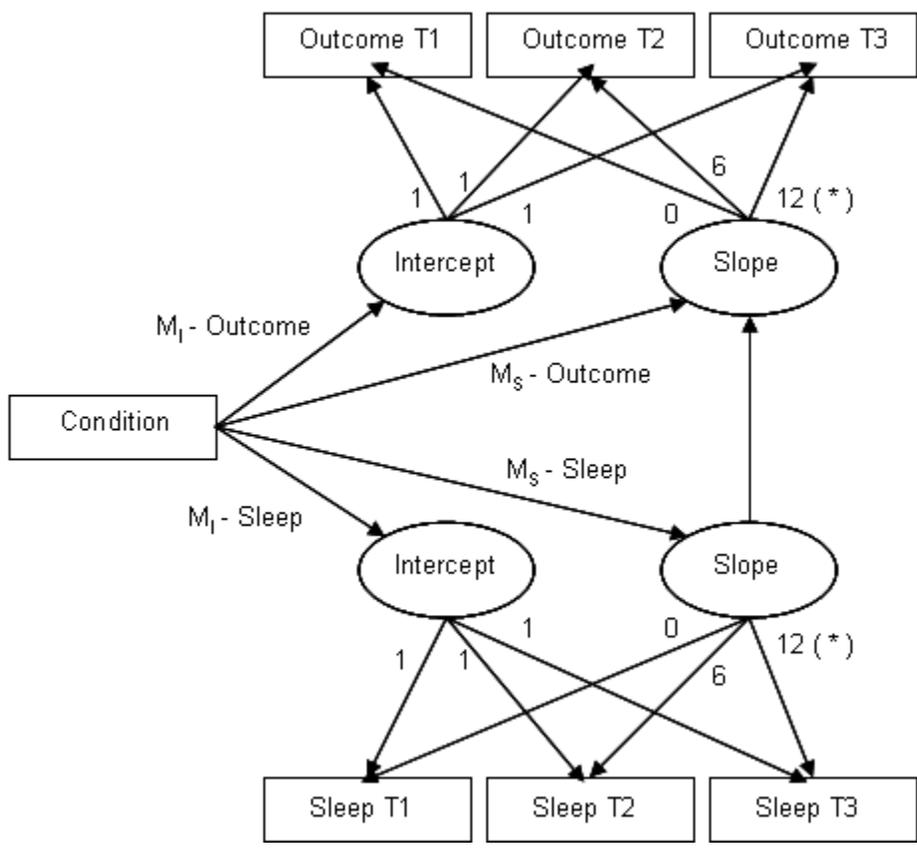
Figure 4. Changes in Sleep Quality among post-surgical non-metastatic breast cancer

patients randomly assigned to either a 10-week CBSM intervention or a 1-day
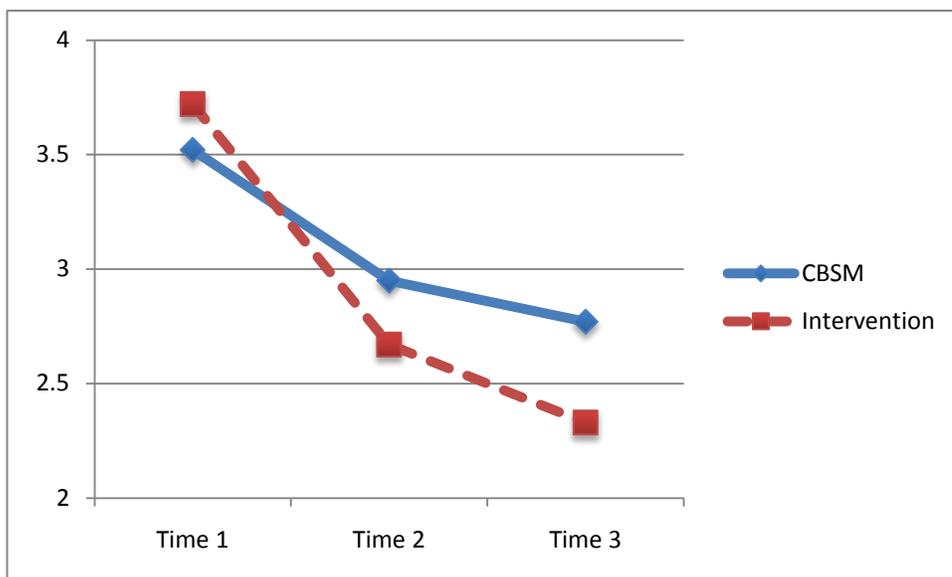
psycho-education control
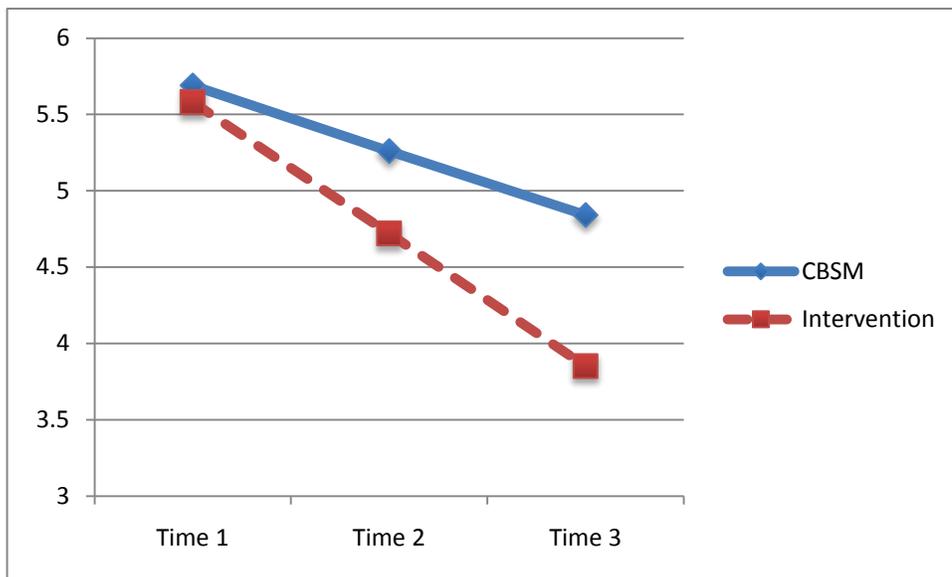
Figure 5. Changes in Positive States of Mind among post-surgical non-metastatic breast cancer patients randomly assigned to either a 10-week CBSM intervention or a 1-day psycho-education control
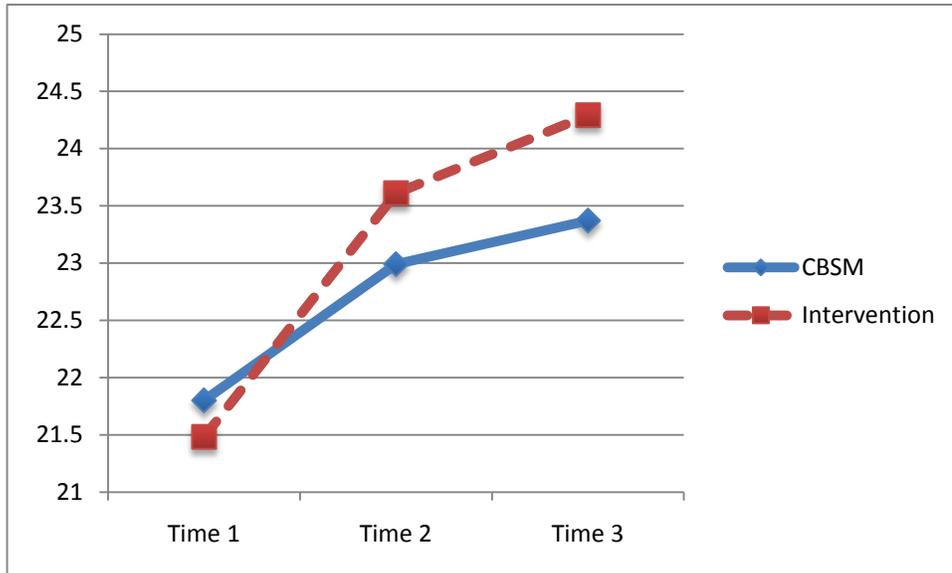
Figure 6. Changes in Fatigue Disruption among post-surgical non-metastatic breast cancer patients randomly assigned to either a 10-week CBSM intervention or a 1-day psycho-education control

Figure 7. Changes in Disruption of Recreations and Pastimes among post-surgical non-metastatic breast cancer patients randomly assigned to either a 10-week CBSM intervention or a 1-day psycho-education control
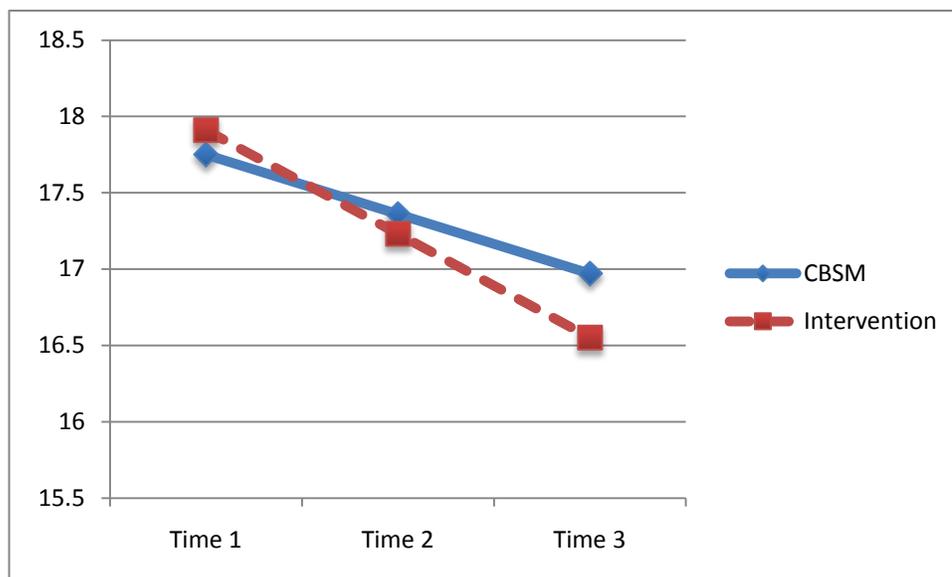
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APPENDIX A

Pittsburgh Sleep Quality Index

Instructions: The following questions relate to your usual sleep habits during the past month *only*. Your answers should indicate the most accurate response for the *majority* of days and nights in the past month. Please answer all questions.

1.   During the past month, when have you usually gone to bed at night?
              USUAL BED TIME: _____

2.   During the past month, how long (in minutes) has it usually taken you to fall asleep each night?
              NUMBER OF MINUTES: _____

3.   During the past month, when have you usually gotten up in the morning?
              USUAL GETTING UP TIME: _____

4.   During the past month, how many hours of *actual sleep* did you get at night? (This may be different than the number of hours you spend in bed.)
              HOURS OF SLEEP PER NIGHT: _____

For each of the remaining questions, check the one best response. Please answer *all* questions.

5.   During the past month, how often have you had trouble sleeping because you…

   (a) Cannot get to sleep within 30 minutes?
   | Not during the past month_____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____ |
   (b) Wake up in the middle of the night or early morning?
   | Not during the past month_____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____ |
   (c) Have to get up to use the bathroom?
   | Not during the past month_____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____ |
   (d) Cannot breathe comfortably?
   | Not during the past month_____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____ |
   (e) Cough or snore loudly?
   | Not during the past month_____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____ |
   (f) Feel too cold?
   | Not during the past month_____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____ |
   (g) Feel too hot?

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| Not during the past month_____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____ |

(h) Had bad dreams?

| Not during the past month_____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____ |

(i) Have pain?

| Not during the past month_____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____ |

(j) Other reason(s), please describe: _____

_____

How often during the past month have you had trouble sleeping because of this?

| Not during the past month_____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____ |

6. During the past month, how would you rate your sleep quality overall?

    Very good   _____
    Fairly good   _____
    Fairly bad   _____
    Very bad   _____

7. During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?

    Not during the past month   _____
    Less than once a week   _____
    Once or twice a week   _____
    Three or more times a week   _____

8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

    Not during the past month   _____
    Less than once a week   _____
    Once or twice a week   _____
    Three or more times a week   _____

9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

    No problem at all   _____
    Only a very slight problem   _____
    Somewhat of a problem   _____
    A very big problem   _____

APPENDIX B

Functional Assessment of Cancer Therapy – Breast (Functional Well-Being subscale)

Below is a list of statements that other women with breast cancer have said are important. By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days.</u>

	Not at all	A little bit	Some-what	Quite a bit	Very much
1. I am able to work (include work at home).	1	2	3	4	5
2. My work (include work at home) is fulfilling.	1	2	3	4	5
3. I am able to enjoy life.	1	2	3	4	5
4. I have accepted my illness.	1	2	3	4	5
5. I am sleeping well.	1	2	3	4	5
6. I am enjoying the things I usually do for fun.	1	2	3	4	5
7. I am content with the quality of my life right now.	1	2	3	4	5

APPENDIX C

Positive States of Mind

This questionnaire is about the kind of satisfying states of mind that you may have experienced **in the past week**. Read each item and think about how much trouble, if any, you've had in having this state of mind. Just give a general estimate. Please choose **one** number for each of the following.

>   0 = unable to have it
>   1 = a lot of trouble having it
>   2 = some trouble having it
>   3 = have it easily

1. Focused Attention: Feeling able to attend to a task you want or need to do, without many distractions from within yourself.

2. Productivity: Feeling of being able to stay at work until a task is finished, do something new to solve problems, or express yourself creatively.

3. Responsible Caretaking: Feeling that you are doing what you should do to take care of yourself or someone else.

4. Restful Repose: Feeling relaxed, without distractions or excessive tension.

5. Sensuous Nonsexual Pleasure: Being able to enjoy bodily senses, enjoyable intellectual activity, doing things you ordinarily like, such as listening to music, enjoying the outdoors, lounging in a hot bath.

6. Sharing: Being able to commune with others in an empathic, close way as in talking, walking, going out, or just being together.

7. Sensuous Sexual Pleasure: Being able to feel erotic, enjoy sexual exchange, as in any form of kissing, caressing, self-stimulation, or intercourse.

Fatigue Symptom Inventory

For each of the following, choose one number that best indicates how that item applies to you. Choose a number on a scale ranging from

$\boxed{1}$ = Not at all fatigued … to … $\boxed{9}$ = As fatigued as I could be

_____ 1. Rate your level of fatigue on the day you felt **most** fatigued during the past week.

_____ 2. Rate your level of fatigue on the day you felt **least** fatigued during the past week.

_____ 3. Rate your level of fatigue on the **average** in the last week.

_____ 4. Rate your level of fatigue **right now**.

For the next items, choose a number on a scale ranging from

1 = No interference … to … 9 = Extreme interference

_____ 5. Rate how much, in the past week, fatigue interfered with your **general level of activity**.

_____ 6. Rate how much, in the past week, fatigue interfered with your **ability to bathe and dress yourself**.

_____ 7. Rate how much, in the past week, fatigue interfered with your **normal work activity (includes both work outside the home and housework)**.

_____ 8. Rate how much, in the past week, fatigue interfered with your **ability to concentrate**.

_____ 9. Rate how much, in the past week, fatigue interfered with your **relations to other people**.

_____ 10. Rate how much, in the past week, fatigue interfered with your **enjoyment of life**.

_____ 11. Rate how much, in the past week, fatigue interfered with your **mood**.

_____ 12. Indicate **how many days**, in the past week, you felt fatigued for any part of the day.

_____ 13. Rate **how much of the day**, on average, you felt fatigued in the past week.
Rate this on a scale where $\boxed{1}$ = None of the day and $\boxed{7}$ = the entire day

_____ 14. Indicate which of the following best describes the **daily pattern** of your fatigue.

1	2	3	4	5
Not at all fatigued	Worse in the morning	Worse mid-afternoon	Worse in the evening	No consistent daily pattern of fatigue

Sickness Impact Profile
(Social Interactions and Recreations and Pastimes subscales)

Let me now ask some questions about how well you've resumed your normal activities. I'm going to read a list of statements, and I want you to tell me which, if any, apply to you. In each case, the statement refers to a negative change in some activity or behavior, compared to what you did before you were diagnosed. Think about the statements as they apply to your activities of the past few weeks, and think of them specifically as they relate to your illness. That is, if there's some other reason why you haven't been doing an activity or have been behaving differently, something that has nothing to do with your illness or your surgery, then we shouldn't count that one.

      [1] no,   [2] yes, this applies to me

1. I am going out less to visit people.
2. I am not going out to visit people at all.
3. I show less interest in other people's problems, for example, don't listen when they tell me about their problems, don't offer to help.
4. I often act irritable toward those around me, for example, snap at people, give sharp answers, criticize easily.
5. I show less affection.
6. I am doing fewer social activities with groups of people.
7. I am cutting down the length of visits with friends.
8. I am avoiding social visits from others.
9. I talk less with those around me.
10. I stay alone much of the time.
11. I isolate myself as much as I can from the rest of the family.
12. I do my hobbies and recreation for shorter periods of time.
13. I am going out for entertainment less often.
14. I am cutting down on some of my usual recreation and pastimes, for example, watching TV or reading.
15. I am not doing any of my usual recreation and pastimes, for example, watching TV or reading.
16. I am doing fewer community activities.