EXAMINING PSYCHOLOGICAL SYMPTOMS AS MODERATORS OF THE EFFECT OF A YOGA INTERVENTION ON SLEEP AND FATIGUE FOR WOMEN WOTH BREAT CANCER UNDERGOING CHEMOTHERAPY

_____

A Thesis

Presented to

The Faculty of the Department of Psychology and Philosophy

Sam Houston State University

_____

In Partial Fulfillment

of the Requirements for the Degree of

Master of Arts

_____

by

Kelsey L. Sinclair

May, 2020

EXAMINING PSYCHOLOGICAL SYMPTOMS AS MODERATORS OF THE EFFECT OF A YOGA INTERVENTION ON SLEEP AND FATIGUE FOR WOMEN WOTH BREAT CANCER UNDERGOING CHEMOTHERAPY

by

Kelsey L. Sinclair

_____

APPROVED:

Chelsea Ratcliff, PhD
Committee Director

Craig Henderson, PhD
Committee Member

David Nelson, PhD
Committee Member

Abbey Zink, PhD
Dean, College of Humanities and Social Sciences

DEDICATION

I want to dedicate this thesis to my parents. You have supported me through this entire process, from the late-night phone calls to times where you just let me talk out my ideas, even though you probably had no idea what I was talking about. Thank you for always being there for me and for believing in me, even when I did not always believe in myself.

To my partner, Clayton, thank you for allowing me to follow my dreams, even though it meant being nine hours apart. Through the separation, you have shown unwavering support for me and my goals.

Finally, I want to dedicate my thesis to my great friends, Mayra and Erica. I truly would not have been able to make it through this program without your support and friendship. Without you, I don't know where I would have found the motivation to finish this thing. This is dedicated to you both, because without you it truly would not have been possible!

ABSTRACT

Sinclair, Kelsey L., *Examining psychological symptoms as moderators of the effects of a yoga intervention on sleep and fatigue for women with breast cancer undergoing chemotherapy*. Master of Arts (Clinical Psychology), May, 2020, Sam Houston State University, Huntsville, Texas.

Chemotherapy has been shown to be an effective treatment option for breast cancer patients; however, there are various side effects that often impact patients during and after treatment, including sleep disturbance and fatigue (Davidson et al., 2002). Yoga shows promise for reducing sleep disturbances (Cohen et al., 2004; Mustain et al., 2013) and fatigue among breast cancer patients. Mental health has been shown to be a consistent moderator of other supportive interventions in cancer patients (Schneider et al., 2010), and two studies suggest baseline mental health may also moderate the effect of yoga interventions (Ratcliff et al., 2016; Danhauer et al, 2009). This study examined the moderating effects of baseline mental health (i.e., anxiety and depression) on the effect of a Tibetan yoga (TYP) intervention compared to a stretching condition (STP) and a waitlist control (UC) indicated that baseline condition on sleep and fatigue in patients undergoing chemotherapy for breast cancer at 1-week post-intervention. The moderating effects of mental health at later time points (i.e., 3, 6, and 12-months post intervention) along with sleep and fatigue at 1-week and follow-up time points were examined as exploratory analyses. Significant results indicated that baseline global sleep disturbance moderated the effect of group on global sleep disturbance at 1-week follow-up, When compared between groups there were significant differences between UC and TYP (β=-.337, p = .001) and UC and STP (β=-.292, p = .003). Additional, significant analyses were shown between baseline sleep efficiency, global sleep, and anxiety symptoms on the effect of group on sleep disturbances at various follow-up time points; however, group

differences were not significant. This study indicated that when allocating yoga or stretching related resources to patients with breast cancer, baseline sleep should be assessed to determine which patients would receive the most benefit.

KEY WORDS: Yoga, Chemotherapy, Sleep, Fatigue, Breast cancer, Women

ACKNOWLEDGEMENTS

I would like to thank my thesis chair, Dr. Chelsea Ratcliff, for all her help on this project. I would not have been able to achieve all I have without her mentorship and help through this process. I would also like to thank Dr. Craig Henderson and Dr. David Nelson for serving as committee members. Their feedback and contributions throughout this process have been invaluable and have made me a better researcher.

I would also like to thank the authors of the original paper for their permission to use their data in this secondary analysis.

Finally, I would like to thank my cohort for all the friendship and support they have given me over the past two years.

TABLE OF CONTENTS

Page

LIST OF TABLES

LIST OF FIGURES

Page

CHAPTER I

Introduction

Approximately 63% of patients diagnosed with breast cancer undergo chemotherapy as a part of their treatment routine along with other forms of treatment including surgery and radiotherapy (American Cancer Society, 2017). Chemotherapy is typically incorporated into a treatment plan under three conditions: after the patient has undergone a surgical procedure (either breast-conserving surgery or a mastectomy to remove the cancerous body), before surgery in an attempt to minimize the tumor and make surgical efforts less extensive, or for patients with advanced breast cancer that has spread outside of the breast and the underarm area (American Cancer Society, 2017). While chemotherapy is a very common treatment option, it is associated with side effects that can be difficult for patients to tolerate.

Chemotherapy and Psychological Stress

One study found that the most frequently expressed concerns among patients undergoing chemotherapy were anxiety and concerns about how their treatment and diagnosis were affecting their families (Sasaki et al., 2017). Indeed, another study found that approximately 50% of women with early stages of breast cancer experienced clinical depression, anxiety, or both in the year following diagnosis, and 15% were still experiencing depression and anxiety five years after initial diagnosis (Burgess et al., 2005). Other studies have also found distress levels to be higher at the beginning of treatment and over the course of receiving treatment, compared to later in the treatment trajectory, likely due to decreased health-related QOL at the beginning of treatment (Schrier & Williams, 2004). In fact, patients undergoing chemotherapy for breast cancer

had higher rates of depression and anxiety and lower overall QOL compared with patients undergoing radiotherapy for breast cancer (So et al., 2010). This difference is likely due to greater severity in side-effects, greater impact on physical appearance (e.g., hair loss), and greater uncertainty of diagnosis experienced by women undergoing chemotherapy compared to radiotherapy (So et al, 2010). Thus, psychological distress is an important issue affecting patients undergoing chemotherapy and for many, this distress persists even after treatment has ceased. As such, treating psychological symptoms can ultimately lessen the psychological distress that patients experience.

Chemotherapy and Sleep and Fatigue

Chemotherapy-related symptoms can also include fatigue, sleep disturbance, hair loss, easy bleeding or bruising, infection, anemia, nausea, vomiting, appetite changes, constipation, diarrhea, skin and nail changes, pain, mood changes, and difficulty concentrating (National Cancer Institute, 2019). Sleep disturbances and fatigue are among the most prevalent and disturbing of these symptoms. In a study that examined cancer patients with various cancer diagnoses, it was found that 44% of patients suffered from excessive fatigue, 31% suffered from insomnia, and 28% reported excessive sleepiness (Davidson et al., 2002). While sleep disturbances and fatigue are interrelated, they are not the same.

The sleep-wake cycle can be influenced by several internal and external factors among patients with cancer (Vena et al., 2004). Diagnosis, type and stage of cancer, pain, and treatment side effects have been shown to contribute to sleep disturbances, especially insomnia, in patients with cancer (Roscoe et al., 2007). These sleep problems have been shown to persist months and even years after treatment has ended (Roscoe et al., 2007).

Pharmacological approaches have attempted to combat this issue and one study noted that up to 48% of all of the total prescriptions written for cancer patients were written to help treat sleep disturbances (Forentino & Ancoli-Israel, 2007). However, cancer survivors may be hesitant to take more medication, though most believe that medication is the only option for treating insomnia (Garland et al., 2018). In reality, psychological approaches alone showed a greater reduction in sleep disturbances over time compared to both a combination of pharmacotherapy and psychological approaches and pharmacotherapy alone (Fiorentino & Ancoli-Israel, 2007). Sleep disturbances are a common and distressing symptom of cancer treatment, and most cancer survivors experiencing sleep difficulties do not report their sleep disturbances to their doctors, which can result in inadequate treatment (Fiorentino & Ancoli-Israel, 2007). Left untreated, sleep disturbances can also contribute to and exacerbate another common problem that cancer patients face: fatigue.

Fatigue is positively related to various other symptoms including physical symptoms, functional disability, quality of sleep, psychological distress, and depression (Smets et al., 1998). Smets et al. found that while fatigue scores did improve once cancer treatment concluded, fatigue scores worsened over the course of treatment and significantly accounted for patients reported QOL. Another study examining cancer-related fatigue in 577 patients with various cancer diagnoses found that female participants reported significantly higher physical, emotional, and cognitive fatigue compared to male patients, and breast cancer patients reported higher scores in emotional and cognitive fatigue compared to patients with other diagnoses, indicating that women with breast cancer may be particularly vulnerable to cancer-related fatigue (Nowe et al.,

2019). Oh and Cho (2018) found a significant increase in fatigue from pre- and post-chemotherapy in a sample of breast cancer patients, which impacted post-chemotherapy QOL (Oh & Cho, 2018). Though fatigue seemed to improve after six-months after chemotherapy, fatigue experienced during chemotherapy still had a greater impact on QOL post-chemotherapy than psychological symptoms (Oh &Cho, 2018). These studies indicate that fatigue worsens over the course of chemotherapy and can impact patients' QOL after treatment has ended. A meta-analysis conducted by Minton, Richardson, Sharpe, Hotopf, and Stone (2010) found that psychostimulants were shown to be the most effective pharmacological treatment in treating fatigue. Thekdi, Trinidad, and Roth (2014) note that of the psychostimulants used, methylphenidate (sold under the brand names Ritalin and Concerta) has been studied the most in cancer populations. While methylphenidate has been shown to reduce fatigue, specifically in patients experiencing severe fatigue, it is also associated with a number of side effects including agitation, anxiety, insomnia, xerostomia, appetite suppression, tremors, palpitations, rebound fatigue, and mood disturbance (Thekdi et al, 2014). These symptoms may further exacerbate symptoms that patients are experiencing due to chemotherapy treatment (eg. anxiety, insomnia, fatigue, and mood disturbances), and therefore patients may want to seek alternative methods to pharmacological treatment to relieve fatigue symptoms.

Treating the Symptoms

Due to the many symptoms associated with cancer treatment, a variety of nonpharmacologic interventions, including yoga-based interventions, are being examined to help patients alleviate symptoms of chemotherapy. In a randomized control trial (RCT) comparing yoga to brief supportive therapy before radiotherapy for breast cancer, yoga

improved post-radiotherapy fatigue, insomnia, distress, appetite, and physical activity levels compared to brief supportive therapy (Vadiraja et al., 2009). Another RCT found that breast cancer patients randomized to a yoga intervention during the course of their chemotherapy treatment experienced reduced nausea, anxiety, depression, and perceived stress after chemotherapy compared to a control group that received supportive therapy, which included counseling and coping preparation (Raghavendra et al., 2007). Further research conducted by Raghavendra and colleagues (2009) found that participants in the yoga intervention experienced a decrease in cortisol levels which corresponded with a decrease in anxiety and depression scores, which was not seen in the brief support control group. Though these studies demonstrate that yoga may be an effect intervention for relieving physical symptoms related to cancer treatment, a meta-analysis of 10 RCTs of yoga compared with wait-list controls and supportive therapy conditions for cancer patients found that yoga was associated with significant improvements in mental health-related outcomes (i.e., anxiety, depression, distress, and stress), but not physical health-related outcomes (i.e., physical health-related QOL and fatigue) (Lin et al., 2011).

However, several studies, most of which are not included in the meta-analysis by Lin et al., suggest that yoga delivered during cancer treatments does indeed lead to improved sleep disturbances and fatigue. For example, an RCT of a Tibetan yoga intervention for patients with lymphoma led to improvements in sleep disturbance, sleep quality, sleep latency, sleep duration, and the reliance on medications in aiding sleep compared to a waitlist control group (Cohen et al., 2004). Another RCT found that yoga led to greater improvements in global sleep and subjective sleep quality, daytime dysfunction, waking after sleep onset, sleep efficiency, and a decrease in use of sleep

medication compared to the standard care condition in cancer survivors (Mustain et al., 2013). Chaoul et al. (2018) examined the impact of a Tibetan yoga intervention for breast cancer patients undergoing chemotherapy and found that patients in the Tibetan yoga intervention group reported fewer daily sleep disturbances when compared to an active control group (a stretching program) and a wait-list control group in a one-week follow-up after the completion of the intervention. Additionally, an RCT of a yoga intervention compared to health education for breast cancer survivors experiencing post-treatment fatigue found that yoga led to decreased fatigue symptoms (Bower et al. 2012). Finally, a meta-analysis of RCTs of yoga interventions compared with other methods of physical activity in both diseased and healthy samples found that yoga was as effective or more effective in not only improving psychological symptoms, but also sleep disturbances, fatigue, and other physical symptoms including heart rate, blood pressure, pain, and menopausal symptoms (Ross & Thomas, 2010).Thus, in addition to improving mental health-related QOL (Lin et al, 2011), yoga interventions show great promise for alleviating the fatigue and sleep disturbances experienced by so many cancer patients.

While these yoga interventions provide symptom relief for patients undergoing cancer treatment, resources for providing such interventions in hospitals can be scarce. Moderating factors must be examined to determine who most benefits from yoga interventions in order for resources to be delegated to the patients who will experience the greatest benefits from resource-intensive interventions. By identifying pre-treatment variables that moderate the effect of yoga on outcome variables (e.g., physical and mental health-related outcomes) screening procedures can be updated in order to provide the most effective care for patients.

Moderating Factors

Meta-analyses have been conducted to look at the effect of moderators in a variety of non-pharmacologic interventions delivered to cancer patients. For example, a meta-analysis conducted by Schneider et al. (2010) found that baseline scores on the Hospital Anxiety and Depression Scale (HADS) and the State Trait Anxiety Inventory (STAI-S) moderated the effects of various psychosocial interventions (e.g., cognitive behavioral therapy (CBT) as well as non-behavioral psychotherapy, educational, social support, and complementary and alternative medicine techniques), such that patients with higher anxiety and depression levels reported greater impact from the interventions. However, few studies have examined potential moderators of the effects of yoga-based interventions. One study found that women with higher depressive symptoms and greater sleep disturbances at baseline derived the greatest mental health related-QOL benefit from a yoga intervention delivered during radiotherapy (Ratcliff et al, 2016). Similarly, Danhauer et al. (2009) found that patients who reported lower emotional well-being and higher negative affect at baseline, gained the most benefit from a yoga intervention delivered during active chemotherapy. These two studies suggest that, as with other nonpharmacologic interventions (e.g., Schneider et al., 2010), mental health-related QOL may predict who benefits most from yoga interventions delivered during chemotherapy for breast cancer. The present study hopes to add to the previous moderation literature and provide more insight on how pre-chemotherapy mental health may predict who benefit most from a yoga intervention designed to reduce common side effects of chemotherapy: fatigue, sleep disturbance, and poor health-related QOL.

The Present Study

This study will be a secondary data analysis examining moderating factors related to the outcomes of the primary study (Chaoul et al., 2018). The primary study looked at the effect of a yoga intervention compared to active and waitlist control conditions on sleep and fatigue in a sample of women undergoing chemotherapy for breast cancer (Chaoul et al, 2018). The primary study found that the yoga intervention significantly improved sleep at the 1 week follow up compared to the stretching and waitlist control groups. However, this between-group difference was only seen at later follow-up times (i.e. 3 and 6 months) for women who practiced yoga at least twice a week. The intervention did not significantly impact fatigue scores.

The current study will examine moderators of the effect of the intervention on sleep and fatigue at the 1-week follow-up, as this was the time point at which the original study identified a significant group effect. It is hypothesized that baseline mental health (i.e., anxiety and depression) will moderate the effect of the intervention on sleep and fatigue reported one week after completing the intervention. Specifically, there would be a positive relationship between baseline mental health symptoms and posttreatment sleep disturbance and fatigue, with participants in the yoga treatment experiencing a weaker association between baseline mental health symptoms and posttreatment sleep quality and fatigue compared to participants in the stretching or waitlist (usual care) groups. Additional exploratory analyses was conducted to investigate baseline sleep as a moderator of the yoga intervention's effect on sleep and fatigue. Specifically, there would be a positive relationship between baseline sleep disturbance and posttreatment sleep disturbance and fatigue, with participants in the yoga treatment experiencing a weaker association between baseline sleep disturbance and posttreatment sleep quality and

fatigue compared to participants in the stretching or waitlist (usual care) groups. Furthermore, health-related QOL was examined as an exploratory outcome variable for the primary moderators (anxiety and depression) and for the exploratory moderator (sleep). It was predicted that there will be a significant moderating relationship between group and baseline mental health (anxiety and depression) and sleep scores on the health-related QOL. Additionally, as exploratory analyses, moderation results were examined at 3, 6, and 12-month time points for sleep and fatigue.

CHAPTER II

Methods

Participants

Prior to chemotherapy treatment, women who met inclusion criteria were recruited from MD Anderson Cancer Center. The inclusion criteria included women who were at least 18 years of age or older and were able to read, write, and speak English. These women also had to be diagnosed with breast cancer, from stage 0 to III, and scheduled for daily chemotherapy treatment for 6 weeks to be included. Patients who had lymphedema, metastatic bone disease, deep vein thrombosis, a documented diagnosis of a formal thought disorder, and/or extreme mobility problems were excluded. Patients were also excluded if they had practiced yoga within the past year.

Procedures

Once informed consent was obtained, patients completed a 60-minute baseline assessment and were given actigraphy watches to wear for 24 hours a day for the following seven days in order to assess baseline sleep. Participants were then randomized into one of the three groups: the Tibetan yoga group (n =74), the stretching control group (n =68), or the waitlist control group (n =85). This was done using a form of adaptive randomization according to age, stage of disease, time since diagnosis, baseline fatigue scores, menopausal status, type of surgery, and chemotherapy type. Follow-up assessments were given 1 week after the intervention and again after 3, 6, and 12 months. The waitlisted participants were given the usual care and completed all assessments on the same timeline as the other groups. These participants were also offered yoga classes at the end of the study. Participants in all groups were asked to refrain from participating

in any other yoga classes during the duration of the study. Participants assigned to the yoga and stretching control groups attended 4 classes during their chemotherapy treatment, approximately 1 class per week, with classes ranging from 75-90 minutes. The majority of classes were on a one-on-one basis to accommodate the patient's schedules. While sessions were completed based on the patient's schedule, patients were encouraged to practice on their own between sessions and were given resources (printed materials, audio recordings, and videos) to assist them. Additionally, three booster sessions were given in follow-up for both the yoga and stretching groups. Booster sessions were given at 1 and 2 months after the last session and within 3 weeks of the 6-month follow-up assessment and will consist of a review and practice of the entirety of the program.

Intervention Groups

The Tibetan yoga program included the following: mindfulness and focused attention, nostril breathing practice, gentle movements involving rotating and stretching different parts of the body, and compassion-based mindfulness. This was led by one of four trained instructors who had at least 3-years of practice experience along with relevant oncology training and special training in protocol for working with patients with breast cancer. The stretching program included exercises that were specifically recommended for women undergoing or recovering from breast cancer treatment. A physiotherapist and physical therapist, with over 10 years of experience, taught the majority of sessions for this intervention.

Measures

Proposed Moderators: Mental Health. The primary proposed moderator of this study is baseline mental health, specifically anxiety and depression. *Anxiety* assessed

using the State Trait Anxiety Inventory (STAI-S; Spielberger, 2010) (Cronbach's alpha = .92; Dirkson, Belyea, & Epstein, 2009), a 20-item self-report measure that asks patients to indicate how they relate to each item in that moment. Scores on each item can range from 1 (not at all) to 4 (very much so). *Depression* will be assessed using the Center for Epidemiologic Studies Depression scale (CES-D; Radloff, 1977), a 20-item self-report measure that asks patients to rate how often they felt or behaved in the past week (Cronbach's alpha = .90; Klemp et al., 2017). Responses range from "Rarely or none of the time (less than 1 day)" to "Most or all of the time (5-7 days)".

The secondary, and exploratory, proposed moderator of this study is baseline sleep. To asses baseline sleep, global PSQI (Buysse et al., 1989) scores along with actigraphy sleep efficiency will be examined, both of which are described in greater detail below.

Primary Intervention Outcome: Sleep. *Subjective sleep quality* was measured using the Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989). The PSQI is an 18-item self-report questionnaire that assess sleep quality and disturbances over a month-long period. It is comprised of three subscales: sleep efficiency, perceived sleep quality, and daily disturbances. Cronbach's alpha coefficients for the PSOI are high (.80) and global scores are moderately to highly correlated to the subscales of the PSQI (Carpenter & Andrykowski, 1998). Total scores of 5 and above indicate clinically significant sleep disturbances.

Objective sleep quality was assed using actigraphy. Patients wore the actigraphy on their non-dominant wrist for 24 hours seven days of the week. Daily actigraphy reports were taken and composited into a weekly score. Actigraphy measured a number

of sleep patterns, however, this study will be looking specifically at scores related to sleep efficiency. Sleep efficiency relates to the amount of time patients spend asleep during the sleep period.

Secondary Intervention Outcome: Fatigue. Fatigue was measured using the Brief Fatigue Inventory (BFI; Mendoza et al., 1999). The BFI is a 9-item measure that examines the severity of fatigue. Items are scored from 0-10, with 0 indicating "no fatigue" and 10 indicating "fatigue as bad as you can imagine". Higher scores indicate greater clinical significance of fatigue. The BFI has shown high internal reliability with Cronbach's alphas between .95 and .96 (Klemp et al., 2017).

Exploratory Intervention Outcome: Health-Related QOL. Health-related QOL was measured using the Medical Outcomes Study 36-item short-form survey (SF-36; Ware et al., 1993), specifically the physical component scale (PCS) and the mental component scale (MCS). The PCS contains subscales that measure physical impediment to role functioning, bodily pain, general health perception, and vitality. The MCS subscale includes social functioning, emotional impediments to role functions, and mental health. Higher scores indicate a greater QOL score. The SF-36 and the PCS and MCS components have high reliability and validity when examining an oncology population, with Cronbach's alphas ranging between .70 and .90 (Klemp et al., 2017).

Clinical and Demographic Information. Patients also completed demographic factors and medical information was obtained from medical records. Specific demographics examined included: age, stage of disease, time since diagnosis, menopausal status, type of surgical procedure, and chemotherapy treatment and regimen.

These factors were used as randomization factors and will be used as covariates in the current study.

Statistical Analysis Plan

The data from the original study was checked and cleaned before undergoing secondary analyses. Randomization factors were included as covariates if they were found to be significantly associated with study variables.

To determine power to detect a significant moderation effect, G*Power was used to conduct a post-hoc sensitivity analysis. Given the sample size (N = 202), an estimated seven covariates (the number of randomization factors), and the critical p-value of $p \leq .01$ (to correct for 6 independent analyses [i.e., the group x moderator (STAI and CES-D) effect on 3 outcome variables (PSQI-Global, Actigraphy-SE, and BFI) it was determined that the present study will have 80% power to detect a medium interaction effect (i.e., moderator x group effect of Cohen's $f = .282$) as statistically significant.

To evaluate the first hypotheses and examine the moderating impact of baseline mental health (STAI-S and CES-D) on the effect of group (yoga; YTP, stretching; STP, usual care; UC) on sleep (PSQI-Global Actigraphy-SE) and fatigue (BFI), a linear regression frame-work was used. Group was dummy coded into two categories with UC being used as the reference category. Proposed moderators were mean centered and multiplied by both dummy codes to create the interaction terms. First, separate linear regressions will be run to examine the moderating effect of baseline STAI-S by group effect on each of the 3 outcome measures (global PSQI, actigraphy SE, BFI) one week after the intervention (Hypothesis 1a.). Next, separate linear regression models will be

run to examine the moderating effect of CES-D by group effect on each of the 3 outcome measures (global PSQI, actigraphy SE, BFI) (Hypothesis 1b.).

The exploratory analyses examining the moderating effects of baseline sleep (baseline global PSQI scores and actigraphy SE) (Hypothesis 2) on each of the 3 outcome measures (global PSQI, actigraphy SE, BFI) one week after the intervention will be examined similarly. (Hypotheses 2: 6 regression models).

Exploratory analyses will be conducted to examine the moderating effects of baseline mental health (STAI-S, CES-D) scores on two additional outcome measures (PCS and MCS) at the one-week follow up (Hypothesis 3: 4 regression models).

Finally, the moderating effect of baseline mental health (STAI-S and CES-D) and sleep (global PSQI) on the effect of group on each of the 3 outcome measures (global PSQI, actigraphy SE, BFI) at the 3, 6, and 12 month time points will be examined as exploratory analyses (Hypothesis 4: 36 regression models).

The regression models included group (2 dummy coded variables), the mean centered moderator, the interaction term (moderator x dummy group variable 1; moderator x dummy group variable 2), and the covariates (stage, diagnosis time, and chemotherapy regimen (for Hypothesis 3 age and menopausal status were also included as covariates) and the baseline level of the outcome variable. Interaction effects significant at the $p \leq .05$ level were further decomposed by conducting pairwise comparisons between the three groups. Specifically, regressions models were run excluding one group to allow for the comparison of the moderation effect between two groups. Significant moderation effects were also plotted. To plot the effects, regression models were run separately for each group (models including just the moderator and

covariates were run separately for each group). The intercept (constant) and regression coefficient (b-weight) from the models run for each group were used to plot the moderation effects. Finally, to further aid in interpretation of interaction effects, Pearson correlations between the moderator variable and outcome variable at each level of group are reported.

CHAPTER III

Results

Sample Characteristics

933 potentially eligible patients were approached to participate. Of these participants, 349 refused to participate and 132 patients were not eligible for participation. 452 patients consented, but only 352 participants completed baseline and were randomized. Of the 352 participants with completed baseline measurements and were randomized, 94 participants were eliminated because follow-up data was missing and/or participants were not undergoing chemotherapy at baseline and 7 were eliminated because they were deemed outliers of the data. This resulted in a sample of 251 participants. Dropout rates were similar in each group and no differences were found among demographic factors, medical factors, or baseline study variables.

Hypothesis I: Baseline Mental Health Symptoms as Moderators of the Effect of Group on Sleep and Fatigue at One-Week Follow-up

Four multiple linear regressions models were conducted to determine the moderating effect of baseline anxiety (STAI-S) and depression (CES-D) symptoms on the relationship between group and sleep (PSQI and actigraphy SE) and fatigue (BFI). Diagnosis time, chemotherapy regimen, and stage of cancer were found to significant covariates and included in the multiple linear regression analyses. The regression established that STAI-S did not significantly moderate the effect of group on BFI (D1 ß= .055, p = .693; D2 ß=-.010 , p = .934), PSQI (D1 ß=-.097, p = .475; D2 ß= .077 , p = .534), or SE (D1 ß= -.112, p =.709; D2 ß= .281, p = .299) at the one-week follow-up. Additionally, there were no significant moderation effects of group and CESD on BFI

(D1 ß= -081, *p* = .331; D2 ß= -.128 , *p* = .180), PSQI (D1 ß=-.154, *p* = .067; D2 ß= -.118, *p* = .204) or SE (D1 ß= -.037, *p* =.809; D2 ß= -.114 , *p* = .605) on a yoga intervention 1-week post-intervention.

Hypothesis 2: Baseline Sleep Symptoms as Moderators of the Effect of Group on Sleep and Fatigue at One-Week Follow-Up

Six regression models were run examining baseline sleep (PSQI and actigraphy SE) as moderators of the effect of group on sleep (PSQI and actigraphy SE) and fatigue (BFI) at the one-week follow up (Table 4). Stage, treatment regimen, and diagnosis time were found to be significant covariate factors included in analyses, along with baseline score of the outcome variable. Baseline PSQI was found to moderate the effect of group on PSQI 1-week post intervention (D1 and D2 p's < .01). Specifically, baseline PSQI was more positively associated with 1-week PSQI for women in UC (r = .739, p < 001) compared to TYP (r = .538, p < .001; β = -.337, p = .001) and STP (r = .496, p < .001; β = -.292, p = .003). In other words, TYP and STP buffered the effect of baseline sleep disturbance on 1-week sleep disturbance compared to UC (Figure 1). Additionally, baseline SE was found to moderate the effect of group on PSQI 1-week post intervention (D1 p = .024), though it did not meet the Bonferroni-corrected critical p-value of $\leq$.01. The association between baseline SE and 1-week PSQI was more negative for women in UC (r = -.738, p < .001) compared to women in TYP (r = .238, p = .357; β = .035; p = .685and STP (r = -.376, p = .093; β = -.131; p = .109, though these pairwise comparisons were not statistically significant (Figure 2). There were no significant moderation effects for baseline PSQI and SE on group and BFI at 1-week post-intervention. Additionally,

baseline PSQI and baseline SE did not moderate the effect of SE at 1-week post-intervention.

Hypothesis 3: Baseline Mental Health as Moderators of the Effect of Group on Health-Related Quality of Life at One-Week Follow-Up

Four regression models were run examining baseline anxiety (STAI-S) and depression (CES-D) as moderators of the effect of group on health-related QOL (SF-36 MCS and PCS) at the one-week follow up (Table 5). Stage, treatment regimen, diagnosis time, menopausal status, and age were found to be significant covariate factors included in analyses, along with baseline score of the outcome variable. Baseline anxiety and depression did not significantly moderate the relationship between group and Health Related Quality of Life at 1-week post-intervention.

Hypothesis 4: Baseline Mental Health Symptoms and Baseline Sleep as Moderators of the Effect of Group on Sleep and Fatigue at 3, 6, and 12 Month Follow-ups

Thirty-six regression models were run examining baseline anxiety (STAI-S), depression (CES-D), and sleep (PSQI and actigraphy SE) as moderators of the effect of group on sleep (PSQI and actigraphy SE) and fatigue (BFI) at the three-, six-, and 12-month follow-ups (Table 6). Stage, treatment regimen, and diagnosis time were found to be significant covariate factors included in analyses, along with baseline score of the outcome variable. Baseline SE was found to moderate the effect of group on PSQI 3-months post intervention (D1, $p = .010$). The association between baseline SE and 3-month PSQI was more negative for women in UC ($r = -.700$, $p < .01$) compared to women in TYP ($r = .195$, $p = .424$; $\beta = .118$, $p = .234$) and STP ($r = -.436$, $p = .062$; $\beta = -$

.188, p = .072), though the pairwise comparisons were not statistically significant (Figure 3). Furthermore, baseline SE was found to moderate the effect of group on BFI 6-months post intervention (D1, *p* =.032), though it did not meet the Bonferroni-corrected critical p-value of $\leq$.01. The association was more negative between baseline SE and 6-month BFI post-intervention for women in STP (r = -.639, p =.025) compared to women in TYP (r = .369, p = .194) and UC (r= -.519, p = .047); however, pairwise comparisons were not significant (Figure 4). Additionally, baseline STAI-S moderated the effect of group on SE 12-months post intervention (D2, p = .019), though it did not meet the Bonferroni-corrected critical p-value of $\leq$.01. The association between baseline STAI-S and 12-month SE was more negative for women in UC (r = -.887, p = .018) compared to women in TYP (r = .670, p = .330; β = .089, p = .766) and STP (r = .510, p = .381; β = .351, p = .324), though the pairwise comparisons were not statistically significant (Figure 5). There were no other significant moderating relationships at the follow-up time points.

CHAPTER IV

Discussion

The purpose of this study was to determine the moderating effect of baseline anxiety and depression on the effect of group and fatigue and sleep outcomes one-week post-intervention for women with breast cancer undergoing chemotherapy. Additional exploratory analyses were conducted to determine the moderating effect of baseline sleep and fatigue on the effect of group and fatigue and sleep outcomes at 1-week follow-up. Furthermore, these hypotheses were also examined at 3-month, 6-monthl, and 12-month post-intervention time points. Other exploratory analyses were conducted to determine the moderating effect of baseline anxiety and depression on the effect of group on health related QOL.

The present study did not find results consistent with the previous literature regarding baseline mental health symptoms. Previous literature has suggested that baseline mental health, specifically depressive symptoms, has moderated both yoga interventions and non-pharmacological interventions when compared to waitlist or control groups (Danhauer et al.,2009; Ratcliff et al, 2016; Schneider et al., 2010). It was hypothesized that depressive symptoms would moderate this relationship because the literature has suggested that yoga has been beneficial in managing depressive symptoms (Lin et al., 2011; Raghavendra et al., 2007;2009). Additionally, it was hypothesized that depressive symptoms would impact both sleep and fatigue outcomes due to the symptoms associated with depression, such as changes in sleep, and the positive association that has been recognized between fatigue and depression (Smets et al., 1998). While results of the current study were not significant, it appeared that the results trended toward

significance, specifically when TYP was used as the dummy coded variable. This suggests that depressive symptoms may have short term moderation effects on a yoga intervention for women with breast cancer undergoing chemotherapy. Additionally, this relationship needs further exploration. Exploratory analyses at the 3-month, 6-month, and 12-month time points did not find statistically significant results regarding depressive symptoms as a moderating factor, though significance was approached in the 12-month follow-up. It is hypothesized that time after treatment may be a contributing factor to this relationship.

Similarly, it was hypothesized that anxiety would moderate the effect of group on a yoga intervention at the 1-week time point. It was hypothesized that anxiety would impact the outcome variables due to symptoms associated with anxiety. Additionally, anxiety was hypothesized to buffer the relationship between group and a yoga intervention because of the positive impact that yoga has on anxiety symptoms (Lin et al., 2011; Raghavendra et al., 2007;2009). However, results were not significant. This may be due to a number of factors. An impacting factor may be baseline sample size. There are missing baseline points across multiple participants, which means the current data may not be representative of this sample. Referring to the literature, a metanalysis conducted by Cramer, Lauche, Klose, Lange, Langhorst, and Dobos (2017) analyzed several outcomes across various studies of yoga interventions for patients with breast cancer. This analysis examined several studies that assessed anxiety, either assessed by a validated self-report measure or by a clinician-rated scale, as an outcome measure of yoga interventions. Cramer et al. found that of the six studies assessed there were not statistically significant group differences. Additionally, it was noted that there were

inconsistencies regarding treatment effects and imprecise confidence intervals across studies. Further research is needed to determine if anxiety would moderate the relationship in the present study at the 1-week time point. Anxiety was a statistically significant moderator of sleep efficiency at the 12-month follow up, specifically when STP was the dummy coded group. When the groups were compared there were no significant differences between TYP, STP, and UC. These findings could be a result of time and a general decrease in state anxiety over the course of treatment. The literature has suggested that anxiety can decrease over the course of treatment trajectory (Schrier & Williams, 2004). This may give further explanation for the results seen in the present study.

Baseline self-reported global sleep disturbance scores moderated the effect on group and self-reported sleep at the 1-week time point. It was hypothesized that this would be a significant moderating factor due to the support in the literature of yoga being effective at managing sleep side effects (Chaoul et al., 2018; Cohen et al., 2004; Mustain et al., 2013). As hypothesized, for patients in the TYP and STP groups, baseline self-reported sleep had a weaker association with posttreatment self-reported sleep compared to the UC group. Furthermore, though the results showed that there were significant differences between TYP and UC and STP and UC; however, there were no significant differences between TYP and STP. This indicates that both interventions are more beneficial for short-term sleep outcomes than UC. This is supported further by the meta-analysis conducted by Cramer et al. (2017) along with the previous literature cited. Cramer et al. found that across 6 studies, yoga interventions significantly reduced short-term sleep disturbances when compared to no-therapy control groups. Additionally, when

yoga was compared to other exercise interventions, Cramer et al. found that there were no group differences. This implicates that baseline sleep quality may be an indicator of which patients would derive the most benefit from a yoga or stretching based intervention.

Similarly, the present study found that baseline sleep efficiency moderated the effect of group on self-reported sleep disturbance at the 1-week time point, specifically when yoga was defined as the dummy coded variable. However, the decomposed comparisons between groups found no significant differences, making this interaction difficult to interpret. Differences between actigraphy-assessed sleep efficiency and self-reported global sleep disturbance may be due to the different methods of collecting the data. Patients may have found the self-report measure more accessible for reporting sleep. Additionally, patients may have reported sleep disturbances from a broader basis or may not have identified that sleep efficiency was the main issue of their sleep disturbances.

Baseline self-reported global sleep disturbance and baseline actigraphy-assessed sleep efficiency were not significant moderators of the effect of the intervention on fatigue at 1- week, 3-months, and 12 months. Actigraphy-assessed sleep efficiency did moderate the effect of group on fatigue at the 6-month time point. However, there were no significant differences in the pairwise comparisons between groups, making the interaction difficult to interpret. Although, there was a positive association between baseline sleep efficiency and fatigue scores in the TYP group compared to STP and UC. It was hypothesized that these factors would impact this relationship due to the positive association between sleep disturbances and fatigue (Smets et al., 1998) and impact of

yoga on sleep. This may be a factor to why there was some significance of baseline sleep efficiency on fatigue at the 6-month follow-up.

Baseline depression and anxiety did not have significant moderation effect on health- related quality of life at the 1-week follow-up. It was hypothesized that there would be a moderation effect due to the many symptoms associated with chemotherapy (National Cancer Institute, 2019) and the impact that anxiety and depression may have on these side effects. Additionally, it was hypothesized that there would be an effect due to the impact of yoga on depressive and anxious symptoms. While, this study did not find statistical significance, these results seemed to conflict with the literature. The meta-analysis conducted by Cramer et al. (2017), found that when comparing different studies that compared yoga to no-therapy there was moderate statistical significance indicating that yoga was more beneficial to health -related quality of life. However, when comparing studies examining yoga and exercise there were no significant differences between the groups regarding health-related quality of life. While, the literature implies a relationship between yoga and health related QOL, there may be other factors that contribute to this aside from baseline anxiety and depression.

Limitations

Limited access to the data was considered a limitation of the study. Because this was a secondary analysis full scores for participants were not available. Thus, it was not established if measures were fully complete. Furthermore, data was missing from 94 participants resulting in the elimination of those participants from analyses. The primary analysis of this data also cited attrition of participants as a limitation of this data. Chaoul et al. (2018) reported that, while there were no systematic

differences between participants who provided follow-up data and those who did not provide follow-up data, 20% of participants did not provide follow-up data. Additionally, 22% of participants did not participate after randomization. Another noted limitation was the recruitment process. Of the eligible patients only 56% agree to participate (Chaoul et al., 2018).

Additional limitations were noted in regard to the administration of the yoga intervention. Chaoul et al. noted that the lack of instructor and patient interaction may have decreased the effectiveness of the yoga intervention when compared to the UC condition. Furthermore, the yoga intervention was administered individually, which may have resulted in a decrease of benefits due to the lack of the social support that can be gained from group participation in yoga. Additionally, group assignment was not blinded, and the researchers noted that participants could have been influenced by the active control and perceived they were receiving the experimental intervention. Thus, potentially impacting result of the primary study.

Conclusion and Implications

Baseline self-reported global sleep disturbance significantly moderated the effect of group on self-reported global sleep disturbance at the 1-week follow-up. Women with breast cancer undergoing chemotherapy with poorer baseline global sleep benefited more from a yoga intervention and a stretching control regarding short-term global sleep compared to women undergoing usual care. While both were shown to have statistically significant effects, participants in the TYP condition experienced a greater buffering effect. This indicates, that when allocating yoga related resources to patients with breast cancer, baseline sleep should be assessed to determine which patients would receive the

most benefit. Additionally, it implicates that even if yoga resources are not available a stretching intervention may also be more beneficial to these patients in decreasing global sleep disturbances.

REFERENCES

American Cancer Society, (2017). Chemotherapy for breast cancer. Retrieved from: https://www.cancer.org/cancer/breast-cancer/treatment/chemotherapy-for-breast-cancer.html#written_by.

Bower, J. E., Garet, D., Sternlieb, B., Ganz, P. A., Irwin, M. R., Olmstead, R., & Greendale, G. (2012). Yoga for persistent fatigue in breast cancer survivors: a randomized controlled trial. *Cancer*, *118*(15), 3766-3775.

Burgess, C., Cornelius, V., Love, S., Graham, J., Richards, M., & Ramirez, A. (2005). Depression and anxiety in women with early breast cancer: five year observational cohort study. *Bmj*, *330*(7493), 702.

Buysse DJ, Reynolds CF, Monk TH, Berman SR. Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatr Res*. 1989;28:193-213.

Carpenter, J. S., & Andrykowski, M. A. (1998). Psychometric evaluation of the pittsburgh sleep quality index. *Journal of Psychosomatic Research, 45*(1), 5-13. doi:10.1016/s0022-3999(97)00298-5

Cleeland, C. S., Mendoza, T. R., Wang, X. S., Chou, C., Harle, M. T., Morrissey, M., & Engstrom:, M. C. (2001). Assessing symptom distress in cancer patients. The M.D. Anderson symptom inventory. (The University of Texas M. D. Anderson Cancer Center, Houston, Texas) Cancer 2000;89:1634-1646. *Pain Practice, 1*(2), 207-207. doi:10.1046/j.1533-2500.2001.01023-30.x

Chaoul, A., Milbury, K., Spelman, A., Basen-Engquist, K., Hall, M. H., Wei, Q., … Cohen, L. (2017). Randomized trial of Tibetan yoga in patients with breast cancer undergoing chemotherapy. *Cancer, 124*(1), 36–45. doi: 10.1002/cncr.30938

Cohen, L., Warneke, C., Fouladi, R.T., Rodriguez, M.A., & Chaoul-Reich, A. (2004). Psychological adjustment and sleep quality in a randomized trial of the effects of a Tibetan yoga intervention in patients with lymphoma. *Cancer, 100*(10). 2253–2260.

Dirksen, S. R., Belyea, M. J., & Epstein, D. R. (2009). Fatigue-Based Subgroups of Breast Cancer Survivors With Insomnia. *Cancer Nursing*, *32*(5), 404-411. doi:10.1097/ncc.0b013e3181a5d05e

Danhauer, S. C., Mihalko, S.L., Russell G.B., et al. (2009), "Restorative yoga for women with breast cancer: finding from a randomized pilot study," *Psycho-Oncology*, vol. 18, no. 4, pp. 360–368.

Davidson, J. R., MacLean, A. W., Brundage, M. D., & Schulze, K. (2002). Sleep disturbance in cancer patients. *Social science & medicine*, *54*(9), 1309-1321.

Fiorentino, L., & Ancoli-Israel, S. (2007). Sleep dysfunction in patients with cancer. *Current treatment options in neurology*, *9*(5), 337–346.

Garland, S. N., Barg, F. K., Cakouros, B., Gehrman, P., Duhamel, K. N., & Mao, J. J. (2018). A qualitative examination of the factors related to the development and maintenance of insomnia in cancer survivors. *Palliative and Supportive Care*, *17*(2), 221-226. doi:10.1017/s1478951518000135

Klemp, J. R., Myers, J. S., Fabian, C. J., Kimler, B. F., Khan, Q. J., Sereika, S. M., & Stanton, A. L. (2017). Cognitive functioning and quality of life following chemotherapy in pre- and peri-menopausal women with breast cancer. *Supportive Care in Cancer*, *26*(2), 575-583. doi:10.1007/s00520-017-3869-3

Lin, K. Y., Hu, Y. T., Chang, K. J., Lin, H. F., & Tsauo, J. Y. (2011). Effects of yoga on psychological health, quality of life, and physical health of patients with cancer: a meta-analysis. *Evidence-Based Complementary and Alternative Medicine, 2011*.

Mendoza, T. R., Zhao, F., Cleeland, C. S., Wagner, L. I., Patrick-Miller, L. J., & Fisch, M. J. (2013). The validity and utility of the MD Anderson Symptom Inventory in patients with breast cancer: evidence from the symptom outcomes and practice patterns data from the Eastern Cooperative Oncology Group. *Clinical breast cancer, 13*(5), 325-334.

Mendoza, T. R., Wang, X. S., Cleeland, C. S., Morrissey, M., Johnson, B. A., Wendt, J. K., & Huber, S. L. (1999). The rapid assessment of fatigue severity in cancer patients. *Cancer, 85*(5), 1186-1196. doi:10.1002/(sici)1097-0142(19990301)85:53.0.co;2-n

Minton, O., Richardson, A., Sharpe, M., Hotopf, M., & Stone, P. (2008). A Systematic Review and Meta-Analysis of the Pharmacological Treatment of Cancer-Related Fatigue. *JNCI Journal of the National Cancer Institute, 100*(16), 1155–1166. doi: 10.1093/jnci/djn250

Mustian, K. M., Sprod, L. K., Janelsins, M., Peppone, L. J., Palesh, O. G., Chandwani, K., ... & Morrow, G. R. (2013). Multicenter, randomized controlled trial of yoga for sleep quality among cancer survivors. *Journal of Clinical Oncology, 31*(26), 3233

National Cancer Institute. (2019, April 12). Breast Cancer Treatment (PDQ®)–Patient Version. Retrieved April 02, 2019, from https://www.cancer.gov/types/breast/patient/breast-treatment-pdq

Nowe, E., Friedrich, M., Leuteritz, K., Sender, A., Stöbel-Richter, Y., Schulte, T., . . . Geue, K. (2019). Cancer-Related Fatigue and Associated Factors in Young Adult Cancer Patients. *Journal of Adolescent and Young Adult Oncology*. doi:10.1089/jayao.2018.0091

Oh, P., & Cho, J. (2018). Changes in Fatigue, Psychological Distress, and Quality of Life After Chemotherapy in Women with Breast Cancer. *Cancer Nursing,* 1. doi:10.1097/ncc.0000000000000689

Radloff, L. S. (1977). The CES-D scale: a self-report depression scale for research in the general population. *Applied psychological measurement*, *1*(3), 385-401.

Raghavendra, R. M., Nagarathna, R., Nagendra, H. R., Gopinath, K. S., Srinath, B. S., Ravi, B. D., ... & Nalini, R. (2007). Effects of an integrated yoga programme on chemotherapy-induced nausea and emesis in breast cancer patients. *European journal of cancer care*, *16*(6), 462-474.

Raghavendra, R. M., Vadiraja, H. S., Nagarathna, R., Nagendra, H. R., Rekha, M., Vanitha, N., ... & Ajaikumar, B. S. (2009). Effects of a yoga program on cortisol rhythm and mood states in early breast cancer patients undergoing adjuvant radiotherapy: a randomized controlled trial. *Integrative cancer therapies*, *8*(1), 37-46.

Ratcliff, C. G., Milbury, K., Chandwani, K. D., Chaoul, A., Perkins, G., Nagarathna, R., Haddad, R., Nagendra, H. R., Raghuram, N. V., Spelman, A., Arun, B., Wei, Q., … Cohen, L. (2016). Examining Mediators and Moderators of Yoga for Women With Breast Cancer Undergoing Radiotherapy. *Integrative cancer therapies*, *15*(3), 250-62.

Roscoe, J. A., Kaufman, M. E., Matteson-Rusby, S. E., Palesh, O. G., Ryan, J. L., Kohli, S., ... & Morrow, G. R. (2007). Cancer-related fatigue and sleep disorders. *The oncologist*, *12*(Supplement 1), 35-42.

Ross, A., & Thomas, S. (2010). The Health Benefits of Yoga and Exercise: A Review of Comparison Studies. *The Journal of Alternative and Complementary Medicine*, *16*(1), 3–12. doi: 10.1089/acm.2009.0044

Sasaki, H., Tamura, K., Naito, Y., Ogata, K., Mogi, A., Tanaka, T., Ikari, Y., Masaki, M., Nakashima, Y., … Takamatsu, Y. (2017). Patient perceptions of symptoms and concerns during cancer chemotherapy: 'affects my family' is the most important. *International journal of clinical oncology*, *22*(4), 793-800.

Schneider, S., Moyer, A., Knapp-Oliver, S., Sohl, S., Cannella, D., & Targhetta, V. (2010). Pre-intervention distress moderates the efficacy of psychosocial treatment for cancer patients: A meta-analysis. *Journal of Behavioral Medicine, 33*(1), 1-14. doi:10.1007/s10865-009-9227-2

Schreier, A. M., & Williams, S. A. (2004, February). Anxiety and quality of life of women who received radiation or chemotherapy for breast cancer. In *Oncology nursing forum*(Vol. 31, No. 1, pp. 127-130). *Oncology Nursing Society.*

Smets, E. M. A., Visser, M. R. M., Willems-Groot, A. F. M. N., Garssen, B., Oldenburger, F., Van Tienhoven, G., & De Haes, J. C. J. M. (1998). Fatigue and radiotherapy:(A) experience in patients undergoing treatment. *British journal of cancer*, *78*(7), 899.

So, W. K., Marsh, G., Ling, W. M., Leung, F. Y., Lo, J. C., Yeung, M., & Li, G. K. (2010). Anxiety, depression and quality of life among Chinese breast cancer

patients during adjuvant therapy. *European Journal of Oncology Nursing*, *14*(1), 17-22.

Spielberger, C. D. (2010). State-Trait anxiety inventory. *The Corsini encyclopedia of psychology*, 1-1.

Tamagawa, R., Garland, S., Vaska, M., & Carlson, L. E. (2012). Who benefits from psychosocial interventions in oncology? A systematic review of psychological moderators of treatment outcome. *Journal of Behavioral Medicine*, *35*(6), 658-673.

Thekdi, S. M., Trinidad, A., & Roth, A. (2015). Psychopharmacology in cancer. *Current psychiatry reports*, *17*(1), 529.

Vadiraja HS, Rao RM, Hongasandra NR, Nagarathna R, Rekha M, Vanitha N, et al: Effects of yoga on symptom management in breast cancer patients: A randomized controlled trial. Int J Yoga. 2009, 2: 73-79. 10.4103/0973-6131.60048.

Vena, C., Parker, K., Cunningham, M., Clark, J., & McMillan, S. (2004, July). Sleep-wake disturbances in people with cancer part I: an overview of sleep, sleep regulation, and effects of disease and treatment. In *Oncology nursing forum*(Vol. 31, No. 4).

Ware JE Jr, Snow KK, Kosinski M, Gandek B. *SF-36 Health Survey Manual and Interpretation Guide*. Boston, MA: The Health Institute, New England Medical Center Hospitals; 1993.

Appendix A

Table 1
Participant Demographic and Clinical Characteristics at Baseline

	TYP (n=79)	STP (n=77).	UC (n=95)	*p*
Mean Age (SD), y	49.96 (9.83)	50.35 (10.19)	48.95 (10.32)	.640
Ethnicity (n =251)				.500
White	44 (55.7)	45 (58.4)	53 (55.8)	
Black	9 (11.4)	11 (14.3)	13 (13.7)	
Asian	6 (7.6)	3 (3.9)	1 (1.1)	
Other/Unknown	9 (11.4)	12 (15.6)	15 (15.8)	
Mean Time Since Diagnosis (SD), d.	19.24 (28.19)	16.51 (16.19)	15.94 (10.08)	.514
Stage of Cancer				.852
Stage I	18 (22.8)	17 (22.1)	19 (20.0)	
Stage II	44 (55.7)	46 (59.7)	52 (54.7)	
Stage III	17 (21.5)	14 (18.2)	24 (25.3)	
Chemotherapy Regimen				.168
Weekly	61 (77.2)	54 (70.1)	79 (83.2)	
Every 3-wks	18 (22.8)	22 (28.6)	16 (16.8)	
Menopausal Status				.880
Premenopausal	35 (44.3)	37 (48.1)	45 (47.4)	
Menopausal	44 (55.7)	40 (51.9)	50 (52.6)	

Appendix B

Table 2

Hypothesis 1. Examining Baseline Anxiety and Depression as Moderators of Group on Sleep and Fatigue at 1-Week

	Moderator x D1*		Moderator x D2**		TYP vs. STP		STP vs. UC		TYP vs. UC	
	β	*p*	β	*p*	β	*p*	β	*p*	β	*p*
Group x STAI-S = BFI_1	.055	.693	.010	.934	-	-	-	-	-	-
Group x STAI-S = PSQI_1	-.097	.475	.077	.534	-	-	-	-	-	-
Group x STAI-S = SE_1	-.112	.709	.281	.299	-	-	-	-	-	-
Group x CESD = BFI_1	-.081	.331	-.128	.180	-	-	-	-	-	-
Group x CESD = PSQI_1	-.154	.067	-.118	.204	-	-	-	-	-	-
Group x CESD = SE_1	.037	.809	-.114	.605	-	-	-	-	-	-

*D1 = Dummy code 1, in which TYP was coded as 1, STP was coded as 0, and UC was coded as 0.

**D2 = Dummy code 2, in which TYP was coded as 0, STP was coded as 1, and UC was coded as 0.

Appendix C

Table 3

Pearson's Correlations Between Baseline Anxiety and Depression and 1-Week Sleep and Fatigue

	BFI at 1 Week			PSQI at 1 Week			SE at 1 Week		
	TYP	STP	UC	TYP	STP	UC	TYP	STP	UC
STAI-S	.144	.134	.213	.171	.247	.423*	-.075	.348	-.409*
CESD	.442**	.457**	.430**	.288*	.452**	.533**	-.022	-.088	-.224

*p < .05, **p < .01

Appendix D

Table 4

Examining Baseline Sleep as Moderators of Group on Sleep and Fatigue at 1 Week

	Moderator x D1*		Moderator x D2**		YG vs. ST		ST vs. WL		YG vs. WL	
	β	*p*	β	*p*	β	*p*	β	*p*	β	*p*
Group x PSQI = BFI 1	-.082	.363	-.064	.450	-	-	-	-	-	-
Group x PSQI = PSQI_1	-.277	**.002**	-.226	**.007**	-.073	.576	-.292	**.003**	-.337	**.001**
Group x PSQI = SE_1	.023	.892	.138	.510	-	-	-	-	-	-
Group x SE = BFI_1	.138	.458	.-.002	.992	-	-	-	-	-	-
Group x SE = PSQI_1	.506	**.006**	.215	.180	-.034	.783	-.131	.109	.035	.685
Group x SE = SE_1	-.237	.178	-.034	.865	-	-	-	-	-	-

*D1 = Dummy code 1, in which TYP was coded as 1, STP was coded as 0, and UC was coded as 0.

**D2 = Dummy code 2, in which TYP was coded as 0, STP was coded as 1, and UC was coded as 0.

Appendix E

Table 5
Examining Baseline Anxiety and Depression as Moderators of Group on Health-Related QOL at 1-Week

	Moderator x D1*		Moderator x D2**		YG vs. ST		ST vs. WL		YG vs. WL	
	β	*p*	β	*p*	β	*p*	β	*p*	β	*p*
Group x STAI-S = PCS_1	-.090	.557	-.059	.678	-	-	-	-	-	-
Group x STAI-S = MCS_1	.140	.264	.038	.737	-	-	-	-	-	-
Group x CESD = PCS_1	.078	.423	.078	.485	-	-	-	-	-	-
Group x CESD = MCS_1	-.012	.879	.014	.874	-	-	-	-	-	-

*D1 = Dummy code 1, in which TYP was coded as 1, STP was coded as 0, and UC was coded as 0.
**D2 = Dummy code 2, in which TYP was coded as 0, STP was coded as 1, and UC was coded as 0.

Appendix F

Table 6

Examining Baseline Anxiety, Depression, and Sleep as Moderators of Group on Sleep and Fatigue across Follow-up

	Moderator x D1*		Moderator x D2**		YG vs. ST		ST vs. WL		YG vs. WL	
	β	*p*	β	*p*	β	*p*	β	*p*	β	*p*
Group x STAI-S = BFI_2	.004	.980	-.142	.326	-	-	-	-	-	-
Group x STAI-S = BFI_3	-.100	.565	.128	.397	-	-	-	-	-	-
Group x STAI-S = BFI_4	-.191	.303	.020	.898	-	-	-	-	-	-
Group x STAI-S = PSQI_2	-.028	.862	-.149	.303	-	-	-	-	-	-
Group x STAI-S = PSQI_3	-.179	.332	-.104	.515	-	-	-	-	-	-
Group x STAI-S = PSQI_4	.084	.653	.088	.580	-	-	-	-	-	-
Group x STAI-S = SE_2	.845		2.415		-	-	-	-	-	-
Group x STAI-S = SE_3	-3.439		-2.585		-	-	-	-	-	-
Group x STAI-S = SE_4	.357	.267	.975	**.019**	.101	.594	.351	.324	.089	.766
Group x CESD = BFI_2	-.062	.497	-.072	.472	-	-	-	-	-	-
Group x CESD = BFI_3	-.049	.604	-.001	.992	-	-	-	-	-	-
Group x CESD = BFI_4	-.180	.090	-.161	.151	-	-	-	-	-	-
Group x CESD = PSQI_2	-.103	.245	-.044	.644	-	-	-	-	-	-
Group x CESD = PSQI_3	-.092	.383	-.007	.958	-	-	-	-	-	-
Group x CESD = PSQI_4	-.202	.053	-.187	.078	-	-	-	-	-	-
Group x CESD = SE_2	.196	.498	-.098	.724	-	-	-	-	-	-
Group x CESD = SE_3	-.106	.687	-.394	.221	-	-	-	-	-	-
Group x CESD = SE_4	.148	.577	.057	.857	-	-	-	-	-	-
Group x PSQI = BFI_2	-.119	.271	-.022	.821	-	-	-	-	-	-
Group x PSQI = BFI_3	.062	**.**572	.031	.760	-	-	-	-	-	-
Group x PSQI = BFI_4	-.074	.508	-.180	.069	-	-	-	-	-	-
Group x PSQI = PSQI_2	-.043	.684	-.074	.424	-	-	-	-	-	-
Group x PSQI = PSQI_3	-.093	.437	.071	.515	-	-	-	-	-	-
Group x PSQI = PSQI_4	-.155	.174	-.182	.069	-	-	-	-	-	-
Group x PSQI = SE_2	.242	.448	.105	.736	-	-	-	-	-	-
Group x PSQI = SE_3	.164	.459	-.236	.361	-	-	-	-	-	-
Group x PSQI = SE_4	.006	.985	.001	.999	-	-	-	-	-	-
Group x SE = BFI_2	.279	.406	.221	.440	-	-	-	-	-	-
Group x SE = BFI_3	.376	**.032**	-.022	.876	.129	.290	-.115	.297	.160	.138
Group x SE = BFI_4	.434	.128	.433	.084	-	-	-	-	-	-
Group x SE = PSQI_2	.632	**.010**	.046	.789	.084	.511	-.188	.072	.118	.234
Group x SE = PSQI_3	.647	.079	.036	.892	-	-	-	-	-	-
Group x SE = PSQI_4	.472	.374	.092	.821	-	-	-	-	-	-
Group x SE = SE_2	-.208	.411	.015	.939	-	-	-	-	-	-
Group x SE = SE_3	.220	.519	.111	.730	-	-	-	-	-	-
Group x SE = SE_4	.128	.654	.253	.318	-	-	-	-	-	-

*D1 = Dummy code 1, in which TYP was coded as 1, STP was coded as 0, and UC was coded as 0.

**D2 = Dummy code 2, in which TYP was coded as 0, STP was coded as 1, and UC was coded as 0.

Appendix G

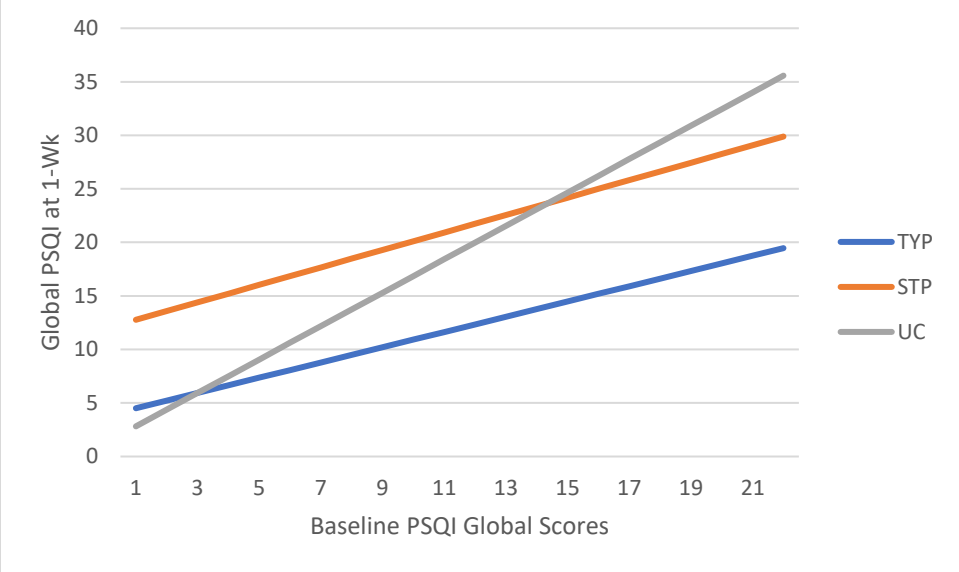

Figure 1. Baseline global sleep moderates the effect of group on global sleep at 1-week post-intervention.

Appendix H

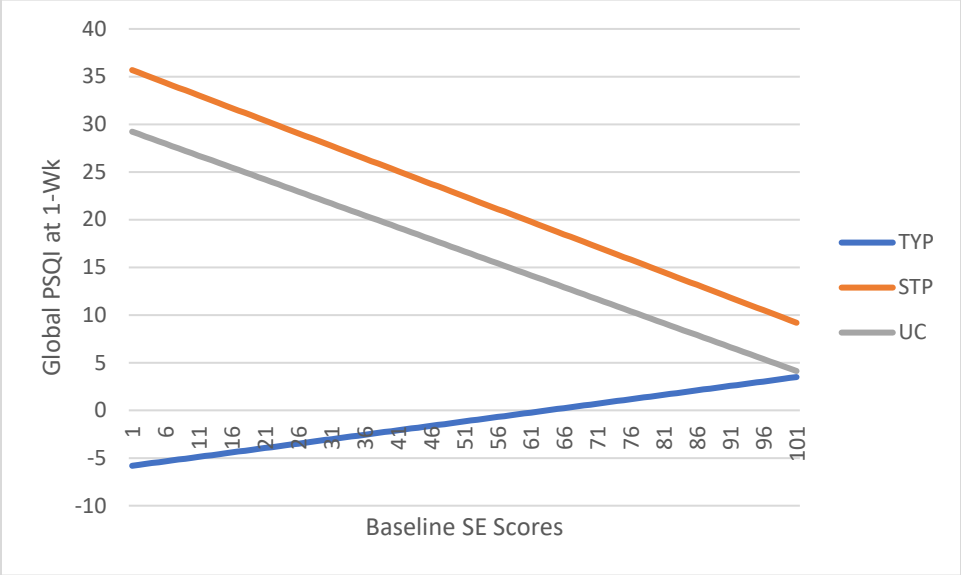

Figure 2. Baseline sleep efficiency moderates the effect of group on global sleep at 1-week post-intervention.

Appendix I

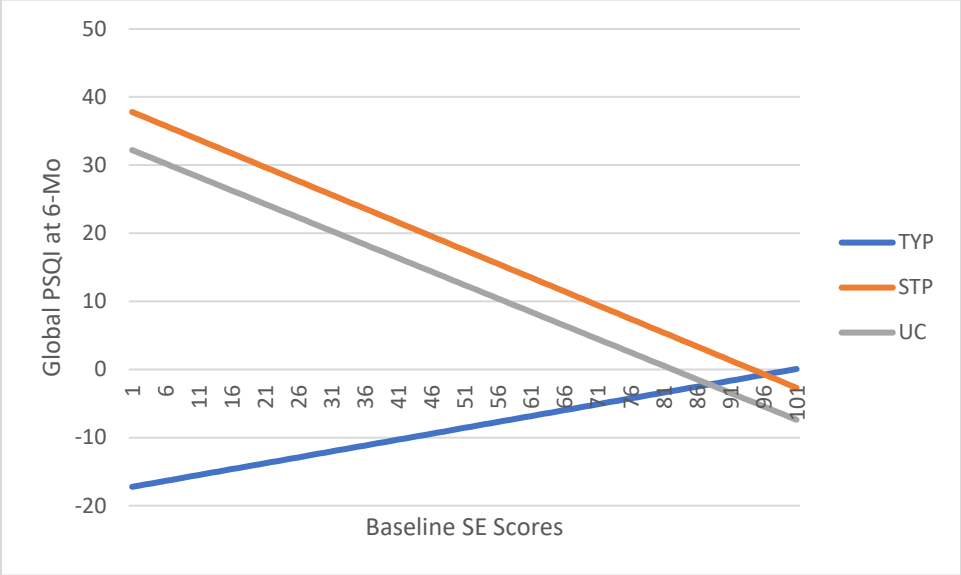

Figure 3. Baseline sleep efficiency moderates global sleep at 3-months post-intervention.

Appendix J

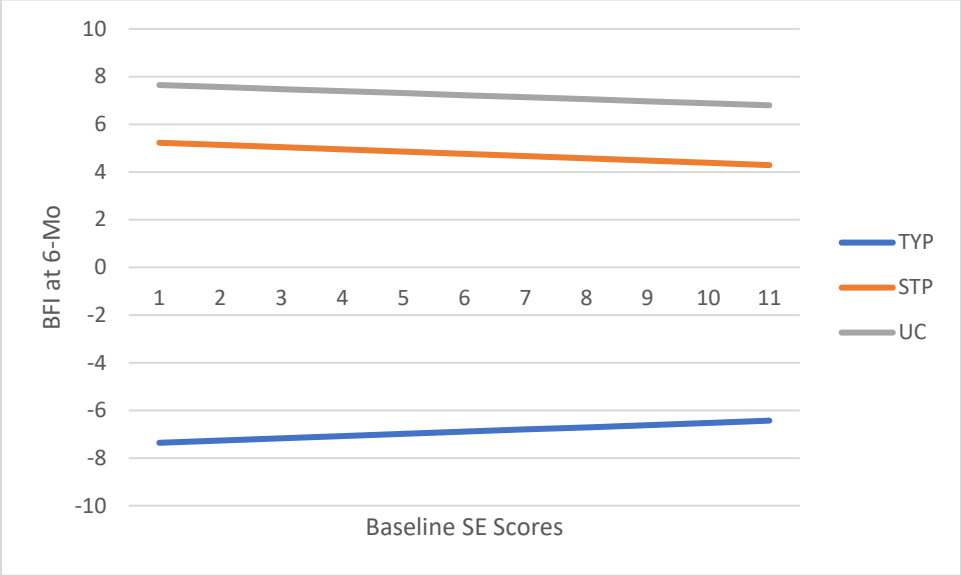

Figure 4. Baseline sleep efficiency moderates fatigue at 6-months post-intervention.

Appendix K

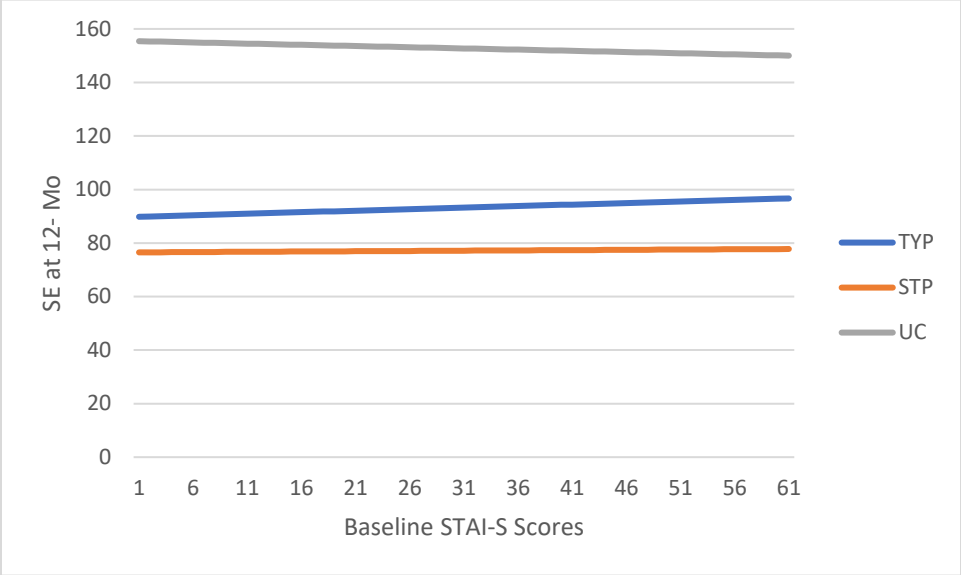

Figure 5. Baseline anxiety symptoms moderates the effect of group on sleep efficiency at 12-months post-intervention.

VITA

EDUCATION

Sam Houston State University Expected May 2020

M.A. Clinical Psychology
GPA: 3.88

Thesis: *Examining psychological symptoms as moderators of the effect of a yoga intervention on sleep and fatigue for women with breast cancer undergoing chemotherapy.*

Chair: Chelsea Ratcliff, Ph.D.
Proposed: October 2019
Anticipated Defense: February 2020

Drury University 2014-2018

B.A. Psychology, B.A. Music
Magna Cum Laude
GPA: 3.8

RESEARCH EXPERIENCE

Laboratory Experience

Graduate Research Assistant Fall 2018-Present

Integrative Health Lab
Department of Psychology, Sam Houston State University
Mentor: Chelsea Ratcliff, Ph.D.

- Collaborated with fellow lab members on study relating to moderating factors relating to stereotactic breast biopsy.
    - Assisted in research, presentation, and writing of the manuscript.
- Worked with lab members on a study relating to body focused repetitive behaviors and eating patterns in undergraduate students.
    - Assisted with reviewing the literature, statistical analyses using SPSS, and assisted in manuscript writing.
- Managed independent research study relating to moderation of a yoga intervention and outcome variables for women undergoing treatment for breast cancer.
    - Designed the project, researched the literature, drafted proposal, proposed project to a committee, analyzed data using SPSS software.

Manuscripts in Progress

Ratcliff, C. G., Fowler, S., **Sinclair, K. L.**, Prinsloo, S., Chaoul, A., Zepeda, S. G., Spelman, A., Wei, Y., Cohen, L. (in prep). Who benefits most from a brief mindfulness intervention to reduce anxiety during stereotactic breast biopsy: The moderating effect of trait mindfulness, distress tolerance and spiritual well-being.

Kiser, E.T., **Sinclair, K.L.**, Tullos, E.A., Ratcliff, C.G. (in prep). Associations between eating patterns and body focused repetitive behaviors.

Presentations

Sinclair, K., Ratcliff, C.G**.,** Prinsloo, S., Chaoul, A., Yang, W., Cohen, L. (2019 March). The impact of distress tolerance and expectation on a mindfulness intervention during stereotactic breast biopsy. Selected for oral presentation at the Annual Meeting of the American Psychosomatic Society, Vancouver, BC.

Sinclair, K. L., Pamperien, B. M., Hedrick, L. A. (2018 April). Influence of question order and external stimuli on perceptions of sexual and life satisfaction. Oral Presentation at the Mid-America Undergraduate Psychology Research Conference, Charleston, IL

CLINICAL AND PROFESSIONAL EXPERIENCE

Clinical Practica II/III

Eating Recovery Center, The Woodlands, TX Spring 2020

Will assist with Intensive Outpatient Program and Partial Hospitalization Program needs for adolescence and adults with eating disorders and associated conditions. This will include attending group therapy sessions, family therapy sessions, seminars, and team and staff meetings

Clinical Practica I

Tri-County Behavioral Healthcare, Conroe, TX Fall 2019

Shadowed current Tri-County employees, including case managers, on-site doctors, and licensed professional councelors, and substance abuse counselors. Observed treatment plans and needs assessments being done for clients. Observed intake procedures and medication assessment process.

Mock Therapy Sessions

Sam Houston State University, Huntsville, TX. Fall 2019

Conducted mock counseling sessions with undergraduate students to practice and apply skills in therapeutic setting.

Kids Learning About Social Skills (KLASS) Program Intern
Burrell Health Center, Springfield, MO Fall 2017

Worked with kids between the ages of six and fourteen, diagnosed with various behavioral or emotional disorders. Worked with clients to improve social and behavioral functioning to improve the clients' behaviors at home and at school. Each month a new topic was introduced that talks about a new social skill for the client to work on.

Music Therapy Intern
Arts Inspired Academy, Springfield, MO Fall 2016

Planned various evidence-based musical interventions and treatment plans for clients with various developmental disabilities and for children of the community. Assessed their capacities for the interventions presented and adapted the interventions to match the client's abilities.

Elfindale Assisted Living Facility, Springfield, MO Fall 2015

Planned various musical interventions and treatment plans for a wellness group and a memory care group. Interventions were planned were based on observation of clients' abilities and research in order to achieve success with both groups. Both groups utilized the same interventions, but were adjusted weekly, based on clients' efficacy.

TEACHING EXPERIENCE

Statistics Graduate Assistant Spring 2019- Present
Sam Houston State University

Provided demonstrations to undergraduate students in Excel and SPSS. Graded homework assignments and entered grades into the Blackboard system. Facilitated study sessions for students before lecture class exams.

HONORS AND AWARDS

Gamma Sigma Alpha, Greek Honor Society, Drury University Spring 2017
Alpha Lambda Delta, Freshman Honor Society, Drury University Spring 2015
Dean's List, Drury University Fall 2014-Spring 2018

ASSOCIATION MEMBERSHIP

Graduate Student Psychology Organization, Fall 2018-Present
Sam Houston State University

Psi Chi, Psychology Honor Society, Drury University Fall 2017-Spring 2018

Drury Ambassadors, Drury University Spring 2015-Spring 2018

Zeta Tau Alpha, Drury University Fall 2014- Spring 2018

LEADERSHIP EXPERIENCE

Drury Ambassadors

Breakfast with Santa Chair Spring 2017-Fall 2017

Planned an annual event for Drury Alumni and their families to participate in based around a Christmas theme. Effectively met with others to achieve goals to make the event a success.

Zeta Tau Alpha

Secretary Spring 2017

Organized calendars for the chapter and recorded minutes during meetings. Facilitated communication throughout the chapter by sending out tri-weekly emails to provide information for the week.

Vice President II- New Member Coordinator Spring 2016-Fall 2016

Planned and facilitated weekly meetings for chapter's New Members and educated New Members about the responsibilities and values of the fraternity. Acted as a liaison between new members and the rest of the chapter. Relayed

questions and concerns to the rest of the chapter and Executive Committee on behalf of the New Members. Discussed with New Members about conflicts they were experiencing during their first year at Drury and helped to resolve concerns or provided resources offered by the university and the fraternity.

Sunshine Chair Spring 2015- Fall 2015

Educated my chapter on the importance of mental health in college women. Utilized Zeta Tau Alpha's national program, Behind Happy Faces, and facilitated discussions about the importance of awareness and how to recognize when the people around us may be affected by mental illness. Effectively provided resources, either through the university or the fraternity, to help someone struggling with mental health.

Director of Membership Enrichment Spring 2015- Fall

Planned and organized various leadership workshops for the different grade levels in the sorority.