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The Effects of Mindfulness-Based Stress Reduction (MBSR(BC)) on Objective and Subjective Sleep Parameters in Women with Breast Cancer: A Randomized Controlled Trial

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Abstract

Objective—The purpose of this study was to investigate the effects of MBSR(BC) on multiple measures of objective and subjective sleep parameters among breast cancer survivors (BCS).

Methods—Data were collected using a two-armed randomized controlled design among BCS enrolled in either a six week MBSR(BC) program or a Usual Care (UC) group with a 12-week follow-up. The present analysis is a subset of the larger parent trial (ClinicalTrials.gov Identifier: NCT01177124). Seventy-nine BCS participants (mean age 57 years), stages 0-III, were randomly assigned to either the formal (in-class) six week MBSR(BC) program or UC. Subjective sleep parameters (SSP) (i.e., sleep diaries and the Pittsburg Sleep Quality Index (PSQI)) and objective sleep parameters (OSP) (i.e., actigraphy) were measured at baseline, six weeks and 12 weeks after completing the MBSR(BC) or UC program.

Results—Results showed indications of a positive effect of MBSR(BC) on OSP at 12 weeks on sleep efficiency (78.2% MBSR(BC) group vs. 74.6% UC group, p=0.04), percent of sleep time (81.0% MBSR(BC) vs. 77.4% UC, p=0.02) and less number waking bouts (93.5 in MBSR(BC) vs. 118.6 in the UC group, p<0.01). Small non-significant improvements were found in SSP in the MBSR(BC) group from baseline to 6 weeks (PSQI total score, p=0.09). No significant relationship was observed between minutes of MBSR(BC) practice and SSP or OSP.

Conclusions—These data suggest that MBSR(BC) may be an efficacious treatment to improve objective and subjective sleep parameters in BCS.

Keywords

objective and subjective sleep parameter; breast cancer; Mindfulness-Based Stress Reduction; MBSR(BC)

Sleep difficulties are a common, distressing problem that affects 38-56% of cancer survivors [1]. Sleep disturbance is a broad term that encompasses difficulties initiating and maintaining sleep, and, furthermore, individuals with sleep disturbance may or may not have a clinical diagnosis of insomnia or other sleep disorder. The prevalence of a clinical diagnosis of insomnia is highest in breast cancer survivors (BCS) (68%), with symptoms persisting at least two to five years after treatment [4-6].

Sleep disturbances among survivors are associated with high levels of distress [7] and are often untreated or undertreated [8, 9]. This is concerning because sleep disruption often contributes to fatigue, depression, poorer treatment outcomes [10], reduced quality of life (QOL) [11] and disrupted daily functioning [9, 12]. Left unresolved, sleep problems may result in diminished work productivity and increased health care utilization costs [13, 14].

Mindfulness-Based Stress Reduction

Mindfulness-based stress reduction (MBSR), a standardized stress reduction program that emphasizes mindfulness meditation, has the potential to improve sleep [15]. While cognitive behavioral therapy for insomnia is considered the gold standard non-pharmacological treatment for insomnia, it may not target the increased psychological distress and fears of recurrence among cancer survivors [8, 16, 17]. MBSR(BC), specifically adapted for BCS, has demonstrated reductions in distress, fatigue, depression and fears of recurrence while improving drowsiness and sleep disturbance [18, 19].

Use in cancer populations

The effects of MBSR on SSP among cancer survivors were examined in three randomized controlled trials (RCT) [19-21] and three uncontrolled trials [22-24]. These six studies showed MBSR significantly improved measures of subjective sleep parameters (SSP). To date, however, no studies have examined the effects of MBSR on objective sleep parameters (OSP) in cancer survivors.

Use in non-cancer populations

Subjective and objective measurements of sleep improvement after MBSR therapy have been documented in three RCT [27, 29, 30] and four uncontrolled trials [25, 26, 28, 31] of non-cancer populations. Of the seven studies that examined SSP changes, six found significant improvements in SSP in the MBSR group [25-30]. Only one trial showed no improvement in SSP following MBSR therapy [31]. A systematic review found associations between the benefits of MBSR treatment, improved sleep quality and decreased rumination, but due to limitations of the studies reviewed, the authors identified a need for additional well-designed controlled trials to confirm these associations [32].

Of the three studies [33-35] measuring changes in OSP in non-cancer populations, one study found significant improvement following MBSR. An RCT compared MBSR to eszopiclone pharmaceutical therapy in 30 adults with primary insomnia and found similar improvements in total sleep time (TST) and sleep efficiency in both groups with the MBSR group having greater reductions in sleep onset latency [33]. In a study of 70 adults, MBSR improved SSP but did not improve OSP measures [34]. Similarly, MBSR improved SSP among adolescents with substance abuse problems, but actigraphy results were not significant ($p=0.06$) [35].

The purpose of this study was to conduct a subset analysis of the larger parent trial (ClinicalTrials.gov Identifier: NCT01177124). We hypothesized that compared to the Usual Care (UC) group, participants who were randomly assigned to the MBSR(BC) program would experience greater improvements in SSP and OSP at 6 weeks and sustained

improvements at 12 weeks. This postulated effect would enhance the clinical significance of MBSR(BC) and provide an additional evidence-based, non-pharmacological treatment to improve sleep.

Methods

Participants

Seventy-nine participants were recruited for this study from the Moffitt Cancer Center and the Carol and Frank Morsani Center, located in Tampa, Florida. The sample was composed of individuals who met inclusion criteria and were enrolled in the parent study (Mindfulness-based Stress Reduction (MBSR) Symptom Cluster Trial for Breast Cancer Survivors, ClinicalTrials.gov: Identifier: NCT01177124). The purpose of the parent study was threefold: (i) to evaluate the efficacy of the MBSR(BC) program in improving psychological and physical symptoms, QOL and measures of immune function and a stress hormone (cortisol); (ii) to test whether positive effects achieved from the MBSR(BC) program are mediated through changes in mindfulness and fear of recurrence of breast cancer; and (iii) to evaluate whether positive effects achieved from the MBSR(BC) program are modified by specific patient characteristics measured at baseline. The participants for this subset analysis were enrolled from January 1, 2010 through December 31, 2010, the budget period of the sleep supplement grant as part of the parent study (Figure 1). Inclusion criteria consisted of the following: (1) women aged 21 years or older; (2) a previous diagnosis of Stage 0-III BC; (3) treatment of lumpectomy and/or a mastectomy; (4) completed adjuvant radiation and/or chemotherapy between two weeks and two years prior to study enrollment; and (5) English proficiency at the eighth grade level. Having sleep disturbance was not an inclusion criteria for participation in the trial. Individuals were ineligible if they had Stage IV cancer, a current, severe psychiatric diagnosis as indicated by referring clinicians or a cancer recurrence.

Study design and randomization

A two-armed RCT randomized participants to either the MBSR(BC) program or UC. After participants were enrolled by assigned research staff, a computer-generated random number system was used to randomly assign subjects stratified by stage of cancer (Stage 0 or I versus II or III) and types of treatment (lumpectomy versus mastectomy and radiation with or without chemotherapy). With the randomization strata of type of surgery and type of BC treatment, subjects were randomly assigned to the two treatment arms in variables blocks of six and eight subjects, as provided by the project methodologist. To maintain allocation concealment, assignments were enclosed in a letter to the participant that was sequentially numbered and placed in an opaque sealed envelope by assigned research staff. Research personnel as well as participants were blinded to study assignment until after completion of baseline assessment. The Institutional Review Board at the University of South Florida approved the study protocol.

Recruitment and data collection procedures

Clinic nurses assisted in identifying eligible patients. Those who met inclusion criteria were invited to an informative orientation session. Informed consent and baseline data were

collected from interested individuals at orientation, then participants were randomized to either MBSR(BC) or UC. Participants were asked to wear an actigraph on their non-dominant wrist and complete a sleep diary for three continuous 24-hour periods immediately following the baseline and follow-up assessments. This time frame was chosen in order to minimize participant burden and is in accordance with previous recommendations that actigraphic monitoring be conducted for at least 72 hours [36, 37]; in addition, it is consistent with previously conducted studies using actigraphy [38, 39].

Demographics, clinical history and assessments of subjective and objective sleep parameters were collected at baseline, post-treatment and 12 weeks. Participants received an incentive of $30 for data completion at each time point.

MBSR(BC) intervention

The MBSR(BC) program was adapted for BCS from the MBSR program developed by Jon Kabat-Zinn and his colleagues [40, 41]. MBSR(BC) teaches BCS to take an active role in stress reduction and symptom management through six, two-hour weekly sessions that include: (a) educational materials related to relaxation, meditation, the mind-body connection and healthy lifestyles; (b) practice of meditation, yoga, body scan, and walking meditation; and (c) supportive group interaction and discussion [18, 19]. MBSR(BC) participants were requested to formally and informally practice the meditative techniques for 15-45 minutes per day and to record their practice time during the 12-week study. CDs and a diary were provided to facilitate meditative practices and documentation.

UC control group

Participants in the UC group underwent normal post-treatment clinic visits and were asked to refrain from the practice of meditation, yoga techniques and/or MBSR during the study, with reminders to refrain from these practices occurring at all assessment time points. The UC group was waitlisted to receive the MBSR(BC) intervention within six months of study enrollment.

Measures

Demographic and medical history data

Demographic and medical history data was obtained from participants through self-report questionnaires. Demographic data included age, ethnicity, educational attainment and marital, income and employment status. Medical history data included type and dates of cancer diagnosis and treatments.

Objective sleep parameters

The Actiwatch®-Score (MiniMitter, Bend, OR) actigraph was used to quantify OSP parameters. The actigraph uses an accelerometer to sense and record motion [42] and is a reliable and valid measure of sleep parameters in healthy adult populations [42, 43]. Actigraphy scores agree with EEG sleep/wake status 95% of the time [42].

Actigraphy has been used among cancer patients and provides good predictive validity of clinical outcomes (i.e., survival, QOL). It is generally well-tolerated and has estimates of compliance at 88% over a five day period [44]. Sleep parameters are measured by actigraphy in combination with patient recordings of bedtime and rising time. Information regarding bedtimes and rising times was manually inputted into the scoring program based on participants' self-reported bedtimes and rising times. Actigraphy software then determined sleep and wakefulness using previously validated algorithms. In accordance with recommendations [45], sleep parameters were assessed using five measures: (a) latency to fall asleep (number of minutes to fall asleep); (b) sleep efficiency (the percentage of time in bed spent sleeping); (c) minutes of wake after sleep onset (WASO); (d) number of waking bouts; and (e) number of minutes asleep at night.

Subjective sleep parameters

The Pittsburgh Sleep Quality Index (PSQI) measured SSP and quantity based on the participant's recall of sleep patterns and behaviors during the past month [47]. The PSQI's 19 questions measure seven domains of sleep: quality, latency, duration, efficiency, disturbances, use of sleep medications and daytime sleep function [46]. Reliability of the PSQI ranges from 0.70-0.78 for sleep disturbance [47].

Sleep diaries

While wearing the actigraph, patients recorded in a diary the following: (1) time they went to bed; (2) time it took to fall asleep, (3) rising time; (4) number of hours slept; and (5) consequences of sleep difficulty (e.g., fatigue, depression). These diaries were designed by Carpenter for use in studying hot flashes and were modified by our team to be used with the actigraphy software to ensure accurate interpretation of data [48].

Statistical Analyses

Student t-tests and Chi-square tests were used to compare baseline characteristics of the randomly assigned groups. Analysis of covariance (ANCOVA), adjusting for baseline values, was used to compare means scores of subjective and objective measures of sleep by random assignment. Analyses focused on comparisons from baseline to 6-weeks and 6 weeks to 12-weeks. Among participants assigned to MBSR(BC), Spearman correlation coefficients were calculated to examine the association between minutes of MBSR practice and change in SSP and OSP measures. A two-sided p-value of <0.05 was used to define statistical significance for all analyses.

Results

Participants

Tables 1a and 1b describe baseline characteristics of the 79 participants. Participants randomized to the MBSR(BC) intervention (n=38) did not differ statistically at baseline from participants randomized to the UC group (n=41). The mean age of the sample was 57 years (SD= 9.7). Most participants (73.4%) were White Non-Hispanic, had Stage I or Stage II BC (n=54, 68.4%) and had a mastectomy (57%). Ten women (12.7%) received

chemotherapy, 22 participants (27.8%) received radiation, 23 participants (29.1%) received both chemotherapy and radiation and 24 participants (30.4%) underwent surgery without either adjunctive therapy.

For the subjective analysis (PSQI), 79 participants were assessed at baseline, 76 were assessed at six weeks and 77 were assessed at 12 weeks. Seventy-eight participants completed the actigraphy measures at baseline because one person who worked nights was unable to use the device. Seventy-seven participants completed actigraphy measures at six weeks, and 72 completed at 12 weeks.

Effect of MBSR(BC) on SSP

ANCOVA results of MBSR(BC) on SSP over time are shown in Table 2. When examining changes from baseline to 6-weeks for the PSQI standardized total score, nearly all means favored the MBSR(BC) group (lower mean scores at both time points). However, none of these differences reached statistical significance.

Effect of MBSR(BC) on OSP

Objective sleep/wake, activity/rest values from actigraphy assessments are displayed in Table 2. From baseline to six weeks, change in OSP did not differ by random assignment, although there was a counterintuitive trend of longer wake periods in the MBSR(BC) group (61.3 minutes) versus UC (51.4 minutes, p=0.07).

Indications of a positive effect of MBSR(BC) on OSP were observed in the six-week to 12-week objective assessment. From six to 12 weeks, there were statistically significant improvements in the MBSR(BC) group in actigraphy measures of sleep efficiency and number of waking bouts. The magnitude of these differences was moderate. Sleep efficiency, or the percent of time in bed actually spent asleep, was 78.2% in the MBSR(BC) group compared to 74.6% among the UC group (between groups Cohen's d=0.33; p=0.04). Additionally, the average number of waking bouts was significantly reduced in the MBSR(BC) group (93.5 versus 118.6, between groups Cohen's d=0.38; p<0.01).

Effect of MBSR(BC) on diary data

Although means were in the expected direction, no statistically significant differences were observed in sleep diary data reports (see Table 2).

Comparison of sleep diaries to actigraphy data

Sleep diaries confirmed sleep disruption among MBSR(BC) and UC groups. Sleep diary reports were largely similar to actigraphy data. TST for actigraphy and diary were significantly correlated (r=0.58; $p < 0.001$). Participants were less able to estimate how long it took them to fall asleep, with actigraphy and diary accounts of latency not as strongly correlated compared to other measures; however, the correlation was still significant (r=0.28; p=0.02).

MBSR(BC) adherence and sleep parameters

No statistically significant correlations were observed between the amount of MBSR(BC) practice (of any type) and measures of sleep parameters. These results were consistent for minutes of practice of individual components of MBSR and combined practice.

Discussion

Our objective sleep (actigraphy) results indicated greater sleep efficiency and less sleep disturbance in MBSR(BC) participants compared to UC participants. These results are unique because very few studies have examined MBSR using OSP. Objective actigraphy data were consistent with one non-cancer population study [33]. When MBSR was compared to eszopiclone pharmaceutical therapy, improvements were found in both groups, and the MBSR group had a shorter latency to sleep onset [33]. In contrast to our findings, MBSR was not found to improve measures of OSP in a nonrandomized study of 70 adults [34] or adolescents (p=0.06) Thus, to our knowledge, our study provides the strongest empirical support for a positive relationship between MBSR(BC) and OSP improvement.

Although not statistically significant, SSP results tended to be in the direction of improvement following MBSR(BC). These trends were in a consistent direction with previous studies. For example, Andersen et al. (2012) [20], found improvements from baseline to post- MBSR intervention in sleep disturbance and sleep problems among BCS, and our team's previous findings of improved drowsiness and sleep disturbance among 84 BCS [19]. Other studies demonstrating beneficial effects of MBSR on sleep included: (1) Carlson et al. (2003) [22], who found improved subjective sleep duration and efficiency with use of MBSR among breast and prostate cancer patients; (2) Carlson et al. 2004 [24], who found improved self-rated sleep parameters among BCS; and 3) Carlson and Garland (2005) [23], who found reduced incidence of sleep disturbances. The potential and proposed mechanism of action of MBSR(BC) on improvement in sleep parameters is thought to occur through self-regulation processes of focused awareness and attention, diminished emotional reactivity to negative states and increased acceptance of experiences without judgment and non-elaborative awareness of thoughts, feelings and sensations [49, 50]. Improved self-regulation of emotional bias and increased openness to the current experience often decreases rumination over fears of recurrence that plague BCS. All these processes may contribute to improvements in falling asleep, staying asleep and undesired waking.

Potential clinical significance

Although there were few statistically significant results, our findings suggest the potential of MBSR(BC) for clinically meaningful improvements in sleep parameters, particularly for improvement in objective sleep quality. This is tentatively prefaced by the context that the BCS enrolled in this study had a reasonably good sleep efficiency overall, which may have created a potential ceiling effect and also there could be a consideration this was due to chance. Future studies should continue to further evaluate the magnitude of these effects, particularly among cancer survivors with substantially impaired sleep function (e.g., advanced stage cancer survivors and also among survivors who are on treatment). Thus, although we have identified that MBSR(BC) offers some non-pharmacological beneficial

effects for sleep problems among BCS, whether it is a treatment for insomnia remains yet to be determined.

Limitations and directions for future research

While restricted to BCS, our sample was heterogeneous in terms of types of treatment (i.e., radiation and/or chemotherapy) and time since treatment completion. Actigraphy may underestimate sleep latency and overestimate total sleep time. Also, having performed actigraphy monitoring for 72 hours in order to limit participant burden leads to the potential to be adversely affected by one night of good or poor sleep and may not be entirely representative. Type 1 error may have been a concern due to multiple outcome comparisons. These concerns were somewhat mitigated by two characteristics of the results: (1) the direction of both significant and non-significant results were in a consistent direction; and (2) these results were in the hypothesized direction. Regarding Type 2 error, the relatively small sample size may have negatively impacted statistical power. Another potential reason for type 2 error was ceiling effects. With sleep efficiency scores close to 80%, participants in both groups started the study with relatively good sleeping habits. These high baseline values may have decreased the study's sensitivity to detect small effects and may have constrained the size of the effects observed as statistically significant. Also, 12 weeks may not be sufficient to test whether improvements resulting from MBSR(BC) can be sustained for longer periods of time. For the future, a longer, larger trial is recommended, either six months or one-year post-intervention.

Future study needs to be completed on the benefits of formal versus informal MBSR practice to determine if a specific meditation technique is more beneficial for sleep improvement. Furthermore, the modest associations we observed between subjective and objective measures of sleep indicate the need for improved outcome measurement, including both self-report and objective measures of sleep. Specifically, the results of this study support the need for further examination of objective assessment of sleep through actigraphy, and more specifically the identification of other reliable and valid subjective sleep measurements instruments that may be sensitive to cancer survivors. Future recommendations are to explore the relationship of biological mechanisms associated with improvements in objective and subjective sleep parameters.

Conclusions

In addition to the established effects of MBSR(BC) in reducing psychological and physical symptoms in BCS, this randomized controlled study provided evidence that MBSR(BC) favorably influences sleep as measured by actigraphy.

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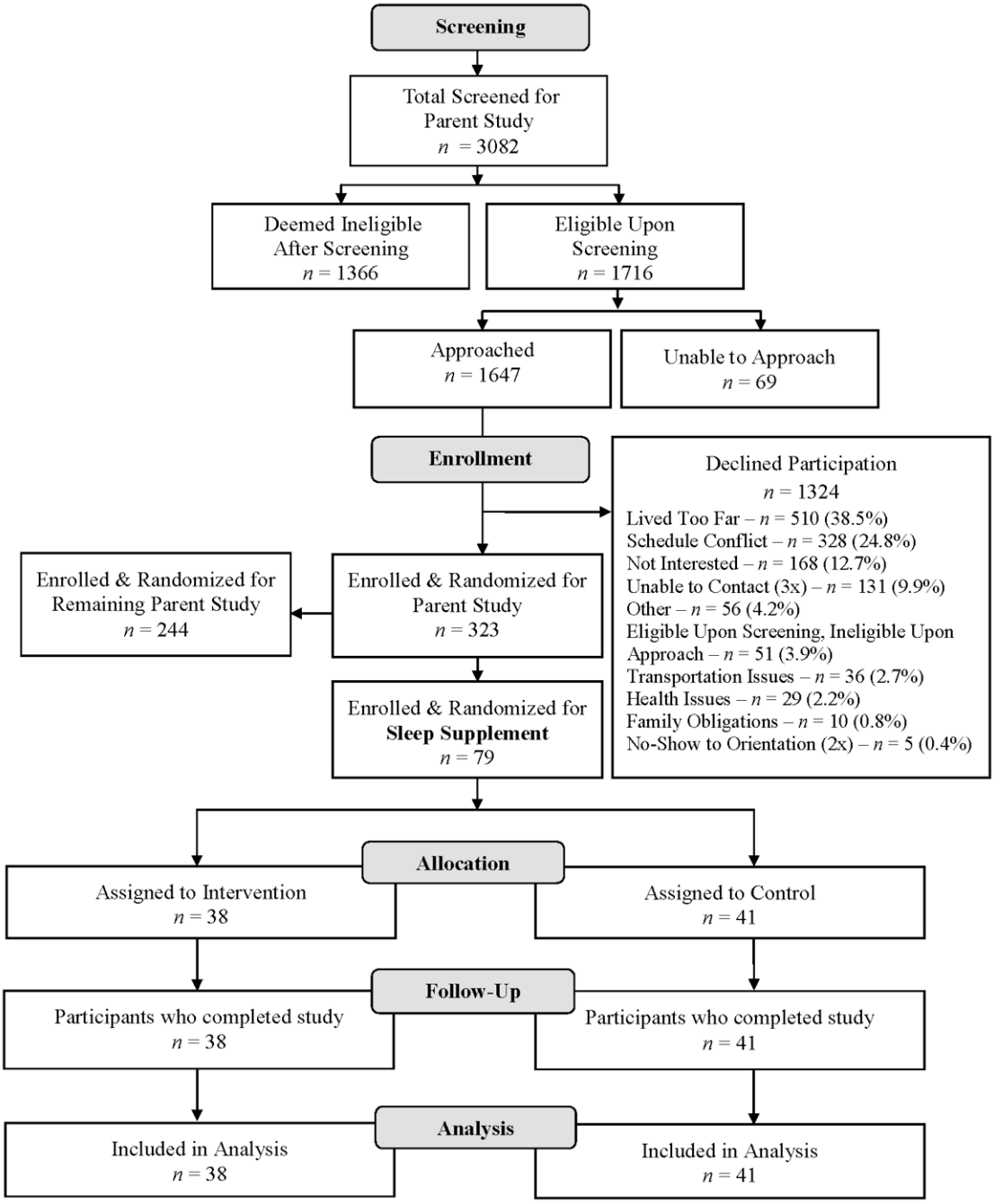

Figure 1.

Flowchart showing recruitment and enrollment of the 79 subjects into the sleep supplement study, the 79 subjects completed the study and were included in outcome analyses.

Table 1a

Baseline demographic characteristics of participants in the sleep supplement of a randomized controlled trial.

Characteristic	Total (*n*=79)	UC (*n*=41)	MBSR(BC) (*n*=38)	*p*-value	Linear Trend
Age, mean, years (Standard Deviation)	57.0 (9.7)	58.0 (10.2)	56.1 (9.1)	0.39	
Race/Ethnicity, n (%)					
White, non-Hispanic	58 (73.4)	31 (75.6)	27 (71.0)	0.94	
White, Hispanic	9 (11.4)	4 (9.8)	4 (10.5)		
Black, non-Hispanic	8 (10.1)	4 (9.8)	5 (13.2)		
Other single race/ethnicity	1 (1.3)	1 (2.4)	0 (0.0)		
Multiple race/ethnicity	3 (3.8)	1 (2.4)	2 (5.3)		
Cancer Stage, n (%)					
0	13 (16.5)	8 (19.5)	5 (13.2)	0.28	0.68
1	27 (34.2)	15 (36.6)	12 (31.6)		
2	27 (34.2)	10 (24.4)	17 (44.7)		
3	12 (15.2)	8 (19.5)	4 (10.5)		
Type of Breast Cancer, n (%)					
Lobular Carcinoma In Situ	3 (3.8)	1 (2.4)	2 (5.3)	0.61	
Ductal Carcinoma In Situ	35 (44.3)	19 (46.3)	16 (42.1)		
Invasive lobular	4 (5.1)	3 (7.3)	1 (2.6)		
Invasive ductal	22 (27.8)	9 (22.0)	13(34.2)		
Not specified/unknown/other	15 (19.0)	9 (22.0)	6 (15.8)		
Surgery Type, n (%)					
Lumpectomy	34 (43.0)	18 (43,9)	16 (42.1)	1.0	
Mastectomy	45 (57.0)	23 (56.1)	22 (57.9)		
Treatment Type, n (%)					
Chemotherapy	10 (12.7)	3 (7.3)	7 (18.4)	0.55	
Radiation	22 (27.8)	12 (29.3)	10 (26.3)		
Chemotherapy and Radiation	23 (29.1)	13 (31.7)	10 (26.3)		

Characteristic	Total (*n*=79)	UC (*n*=41)	MBSR(BC) (*n*=38)	*p*-value	Linear Trend
Surgery only	24 (30.4)	13 (31.7)	11 (29.0)		
Marital Status, n (%)					
Married	47 (59.5)	24 (58.5)	23 (60.5)	0.72	
Divorced	7 (8.9)	3 (7.3)	4 (10.5)		
Single	8 (10.1)	6 (14.6)	2 (5.3)		
Widowed	12 (15.2)	6 (14.6)	6 (15.8)		
Other	5 (6.3)	2 (4.9)	3 (7.9)		
Education Status, n (%)					
High school or less	16 (20.2)	11 (26.8)	5 (13.2)	0.30	0.33
Some college/vocational	27 (34.2)	12 (29.3)	15 (39.5)		
College and above	36 (46.6)	18 (43.9	18 (47.4)		
Income, n (%)					
< $10,000	9 (11.7)	5 (12.5)	4 (10.8)		
$10,000 - < $20,000	16 (20.8)	7 (17.5)	9 (24.3)		
$20,000 - < $40,000	20 (26.0)	11 (27.5)	9 (4.3)	0.89	0.95
$40,000 - <$80,000	18 (23.4)	10 (25.0)	8 (21.6)		
$80,000 - < $100,000	8 (10.5)	5 (12.5)	3 (8.1)		
$100,000 or more	6 (7.8)	2 (5.0)	4 (10.8)		
Employment, n (%)					
>32 hours/week	24 (30.4)	12 (29.3)	12 (31.6)	0.54	
<32 hours/week	5 (6.3)	4 (9.8)	1 (2.6)		
Retired	29 (36.7)	16 (39.0)	13 (34.2)		
Medical leave/disabled	7 (8.9)	4 (9.8)	3 (7.9)		
Other	14 (7.7)	5 (12.2)	9 (23.7)		

MBSR(BC) = Mindfulness-Based Stress Reduction for breast cancer survivors

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Table 1b

Baseline objective and subjective sleep parameter characteristics of participants in the sleep supplement of a randomized controlled trial.

Measure	Characteristic	Total (*n*=79)	UC *n*=41)	MBSR(BC) (*n*=38)	*p*-value
	Sleep Outcome	**(mean ± SD)**			
PSQI	Sleep disturbance	1.87 (0.65)	1.88 (0.56)	1.87 (0.74)	0.95
	Sleep duration	0.57 (0.84)	0.59 (0.77)	0.55 (0.92)	0.86
	Sleep dysfunction	1.04 (0.71)	1.02 (0.65)	1.05 (0.77)	0.86
	Latency to fall asleep	1.46 (1.08)	1.39 (1.07)	1.53 (1.11)	0.58
	Efficiency	0.80 (1.04)	0.90 (1.11)	0.68 (0.96)	0.42
	Total score (standardized)	8.19 (4.36)	8.39 (3.63)	7.97 (5.06)	0.49
Actigraphy	Latency to fall asleep (minutes)	25.4 (26.0)	26.3 (22.9)	24.4 (29.3)	0.75
	Percent of time in bed sleeping	78.8 (7.6)	77.4 (7.3)	80.4 (7.7)	0.08
	Minutes of wake after sleep onset	61.8 (28.0)	69.8 (30.8)	53.2 (21.7)	0.007
	Number of waking bouts	94.1 (41.6)	101.8 (40.3)	85.7 (38.6)	0.08
	Average activity non rest periods	340 (124)	331 (139)	349 (105)	0.53
	Minutes sleep at night	486 (71)	492 (78)	479 (62)	0.42
Sleep Diary	Sleep Duration	7.09 (1.32)	7.04 (1.38)	7.15 (1.26)	0.55
	Latency to fall asleep	34.2 (16.2)	30.9 (23.7)	37.7 (62.2)	0.63

Table 2

Efficacy of MBSR(BC) program on subjective and objective sleep parameters

		N	Adjusted* 6-week Mean (95% C.I.)			Adjusted* 12-Week Mean (95% C.I.)		
			UC	MBSR(BC)	p-value	UC	MBSR(BC)	p-value
PSQI	Sleep disturbance	79	1.63 (1.46, 1.80)	1.53 (1.35, 1.70)	0.38	1.68 (1.51, 1.85)	1.56 (1.38, 1.73)	0.59
	Sleep duration	78	0.58 (0.40, 0.76)	0.44 (0.24, 0.63)	0.62	0.39 (0.22, 0.56)	0.31 (0.13, 0.48)	0.96
	Daytime dysfunction	79	0.79 (0.58, 0.99)	1.02 (0.81, 1.24)	0.95	0.91 (0.71, 1.11)	0.91 (0.71, 1.12)	0.35
	Latency to fall asleep	79	1.43 (1.20, 1.67)	1.19 (0.95, 1.43)	0.22	1.29 (1.05, 1.52)	1.1 (0.87, 1.36)	0.84
	Efficiency	79	0.82 (0.53, 1.10)	0.65 (0.35, 0.95)	0.89	0.73 (0.47, 1.00)	.0.57 (0.30, 0.85)	0.90
	Total score (standardized)	79	7.79 (6.59, 8.99)	7.37 (6.12, 8.62)	0.98	7.41 (6.26, 8.56)	6.91 (5.71, 8.11)	0.97
Actigraphy	Latency to fall asleep (minutes)	77	31.9 (23.3, 40.5)	29.5 (20.6, 38.4)	0.07	43.2 (31.7, 54.6)	27.9 (16.5, 39.4)	0.10
	Efficiency	77	77.5 (75.1, 79.8)	76.5 (74.1, 79.9)	0.32	74.8 (72.0, 77.5)	77.9 (75.2, 80.7)	0.04
	Minutes of wake after sleep onset	77	51.4 (44.4, 58.8)	61.3 (53.9, 68.6)	0.07	60.5 (53.2, 67.8)	62.7 (53.4, 70.0)	0.24
	Number of waking bouts	77	90.9 (79.5, 102.4)	100.3 (88.4, 112.2)	0.27	115.8 (100.6, 131.1)	96.8 (81.6, 112.1)	0.01
	Minutes sleep at night	77	467 (448, 486)	482 (462, 501)	0.62	494 (473, 515)	494 (473, 514)	0.55
Sleep Diary	Sleep duration	79	6.93 (6.56, 7.29)	7.18 (6.80, 7.56)	0.65	7.13 (6.62, 7.45)	7.26 (6.86, 7.67)	0.40
	Sleep latency	79	33.1 (21.5, 44.6)	28.9 (16.9, 40.9)	0.31	27.9 (19.9, 35.93)	24.2 (15.9, 32.5)	0.54

*Adjusted for baseline values.