Cognitive Behavioral Therapy for Insomnia Outcomes in Women After Primary Breast Cancer Treatment: A Randomized, Controlled Trial

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About 30%–50% of women with breast cancer experience insomnia (Savard, Villa, Ivers, Simard, & Morin, 2009), which is twice the rate than in the general population (Berger, 2009). Compared to other cancers, insomnia is more prevalent in women with breast cancer (Palesh et al., 2010; Savard, Ivers, Villa, Caplette-Gingras, & Morin, 2011). For those with cancer, insomnia can affect treatment recovery and quality of survivorship. Women with breast cancer are thrust into early menopause from chemotherapy or endocrine treatments, and report new or worsening insomnia with frequent nocturnal awakenings (Berger, Kuhn, Farr, Von Essen, et al., 2009b). Disrupted sleep has been documented in all phases of the cancer trajectory, including long-term survivorship.

Insomnia is characterized by complaints of difficulty initiating or maintaining sleep, or nonrestorative sleep, lasting for at least one month and causing significant distress or impairment in functioning (Buysse, 2013). Some women are predisposed to insomnia; others report that insomnia was precipitated by the stress of a breast cancer diagnosis and/or treatment. Evidence suggests that insomnia has a consistent negative impact on immune functioning (Blask et al., 2011; Payne, Piper, Rabinowitz, & Zimmerman, 2006) and may even have implications for tumor progression (Filipski et al., 2002, 2003) and survival after a cancer diagnosis (Innominato et al., 2009; Mormont et al., 2000). Breast cancer-related insomnia has been shown to have a profound effect on quality of life (QOL) and daily functioning (Ancoli-Israel et al., 2006; Arndt, Merx, Stegmaier, Ziegler, & Brenner, 2005).

In a population-based sample of patients with differing cancers (N = 991), 31% of the total sample reported insomnia symptoms at the perioperative period, a rate

Purpose/Objectives: To examine the effect of cognitive-behavioral therapy for insomnia (CBTI) on sleep improvement, daytime symptoms, and quality of life (QOL) in breast cancer survivors (BCSs) after cancer treatment.

Design: A prospective, longitudinal, randomized, controlled trial.

Setting: Oncology clinics, breast cancer support groups, and communities in Colorado.

Sample: 56 middle-aged BCSs with chronic insomnia.

Methods: Women were randomly assigned to CBTI or behavioral placebo treatment (BPT) and completed measures of sleep, QOL, functioning, fatigue, and mood at baseline, postintervention, and at three- and six-month follow-ups.

Main Research Variables: Sleep outcomes (e.g., sleep efficiency, sleep latency, total sleep time, wake after sleep onset, number of nightly awakenings); secondary variables included sleep medication use, insomnia severity, QOL, physical function, cognitive function, fatigue, depression, anxiety, and sleep attitudes or knowledge.

Findings: Sleep efficiency and latency improved more in the CBTI group than the BPT group; this difference was maintained during follow-up. Women in the CBTI group had less subjective insomnia, greater improvements in physical and cognitive functioning, positive sleep attitudes, and increased sleep hygiene knowledge. No group differences in improvement were noted relative to QOL, fatigue, or mood.

Conclusions: Nurse-delivered CBTI appears to be beneficial for BCSs' sleep latency/efficiency, insomnia severity, functioning, sleep knowledge, and attitudes more than active placebo, with sustained benefit over time.

Implications for Nursing: Oncology nurses are in a unique position to identify insomnia in cancer survivors. When sleep disturbances become chronic, nurses need to make recommendations and referrals.

Key Words: breast cancer; fatigue; outcomes research; survivorship; late effects of cancer treatment

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that slightly decreased to 26% two months later. Women with breast cancer (n = 466) displayed the highest rates of insomnia symptoms at both the perioperative period (70%) and two months later (60%) (Savard et al., 2009). Similarly, in a sample of 300 women at least two months post-radiotherapy for breast cancer, 51% (n = 154) displayed insomnia symptoms and 19% (n = 56) met diagnostic criteria for more severe insomnia syndrome. The criteria for the diagnosis of chronic insomnia syndrome is sleep disturbance that occurs at least three nights per week, lasts at least one month, and causes significant distress or impairment of daytime functioning (Morin & Benca, 2012). Among all women reporting insomnia symptoms, the median duration of sleep difficulties was 48 months, whereas the median duration was 60 months among those with insomnia syndrome (Savard, Simard, Blanchet, Ivers, & Morin, 2001). Even disease-free breast cancer survivors have higher rates of insomnia compared to the general population, suggesting chronic insomnia is a substantial problem in long-term recovery and QOL (Ahn et al., 2006). The need for effective insomnia interventions for breast cancer survivors is supported by the growing number of women who are surviving breast cancer worldwide (Bray, Ren, Masuyer, & Ferlay, 2013).

Insomnia in women with breast cancer has been associated with greater fatigue, mood disturbance, sleep aid use, and reduced quality of life (Ancoli-Israel et al., 2006; Dirksen, Belyea, & Epstein, 2009; Fiorentino & Ancoli-Israel, 2006; Fortner, Stepanski, Wang, Kasprowicz, & Durrence, 2002). Coping with side effects of cancer treatment, such as low blood counts and nausea, may take precedence over sleep assessment and management. Underreporting may be caused by the mistaken belief that insomnia and associated symptoms are normal and transient reactions to cancer treatment (Berger, 2009). Previous studies showed that sleep symptoms rarely are assessed in a typical patient evaluation (Nakaguchi et al., 2013; Okuyama et al., 2011).

Nonpharmacologic treatments appear well suited to women with breast cancer because of the greater insomnia susceptibility and high acceptability of these interventions, even during cancer treatment (Berger et al., 2002). Improvements are sustained longer than pharmacologic therapies because the root cause of insomnia is addressed, and strategies can be used for a lifetime (Morin et al., 2006).

CBTI is considered an established treatment for primary insomnia by the American Academy of Sleep Medicine (Schutte-Rodin, Broch, Buysse, Dorsey, & Sateia, 2008) and is in the "likely to be effective" category of the Oncology Nursing Society's Putting Evidence Into Practice series (Page & Berger, 2009). Several studies of women with breast cancer have tested personalized sleep interventions (Berger et al., 2002; Cohen & Fried, 2007) and standard CBTI (Dirksen & Epstein, 2008; Quesnel, Savard, Simard, Ivers, & Morin, 2003; Savard, Simard, Ivers, & Morin, 2005; Tremblay, Savard, & Ivers, 2009). Few studies, however, examine sleep aid use and comprehensive outcomes in breast cancer survivors. One study (Moore, Berger, & Dizona, 2011) evaluated sleep aid use in 219 women during and after adjuvant chemotherapy for breast cancer and found that 20% took at least one sleep aid before the first chemotherapy treatment, but use declined over time by 12%–18%. The most common sleep aids were prescription sedatives or hypnotics (46%) and nonprescription analgesics (24%) (Moore et al., 2011), suggesting the importance of sleep aid assessment in clinical trials. Examining improvements in QOL, physical and cognitive functioning, fatigue, and mood is needed to further refine sleep therapies. To the authors' knowledge, the current study is one of the few randomized, controlled trials (RCTs) to use a specially trained nurse to deliver comprehensive CBTI to patients with cancer. Effectiveness studies are needed to validate the therapies implemented by nurses (Espie, 2009).

Based on the Behavioral Model of Insomnia (Spielman, Saskin, & Thorpy, 1987), this small-scale RCT compared the effect of CBTI to active behavioral placebo treatment (BPT). Spielman's model posits three factors in the development of insomnia: predisposing, precipitating, and perpetuating; CBTI is designed to target perpetuating factors. The authors hypothesized that CBTI, compared to BPT, would reduce sleep latency (SL, defined as the time to fall asleep after lights out), sleep aid use, and dysfunctional sleep beliefs; increase sleep efficiency (SE, defined as the ratio of actual sleep time to time spent in bed multiplied by 100); and improve perceived sleep quality, QOL, functioning, fatigue, mood, and sleep knowledge. The authors examined other sleep parameters, including wake after sleep onset (WASO, the sum of minutes awake during nocturnal awakenings), total sleep time (TST, the time in bed minus SL and WASO), and nocturnal awakenings.

Methods

Participants

Women were recruited from local ambulatory oncology clinics, breast cancer support groups, and the community via newspaper advertisement in the Denver metropolitan area. Study procedures were approved by the Colorado Multi-Institutional Review Board. Women were eligible if they completed primary treatment for stage I–III breast cancer within 1–36 months and met study criteria for chronic insomnia, including a self-reported SL or WASO greater than 30 minutes on three or more nights per week for one month or longer plus

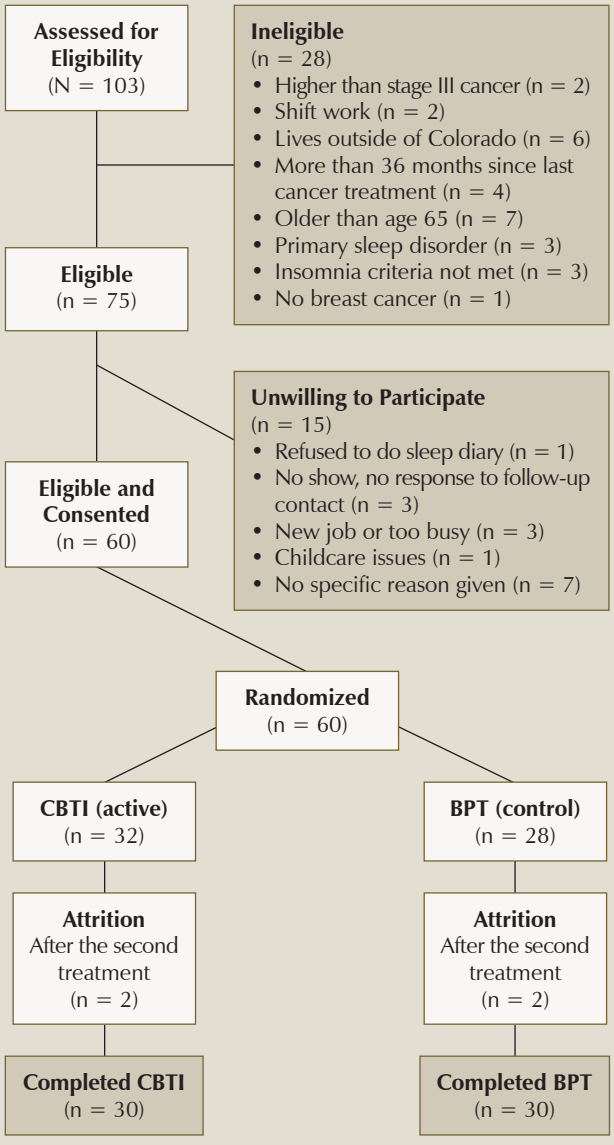
a score of 8 or higher on the Insomnia Severity Index (ISI) (scores range from 0–28; a score of 8 indicates subthreshold insomnia) (Morin, 1993; Savard, Savard, Simard, & Ivers, 2005). Other inclusion criteria were being aged 21–65 years, having insomnia that started or worsened at diagnosis as determined by a clinical interview, and being fluent in English. Women using hypnotic medications were eligible because these medications have not been shown to significantly modify the effect of CBTI (Savard, Simard, et al., 2005).

Exclusion criteria were unstable, major psychiatric or non-cancer medical illness, primary sleep disorder(s) other than insomnia, unstable doses of medications that affect sleep, and night-shift employment. Of the 103 women who responded to recruitment efforts, 28 did not meet eligibility criteria, and 15 were unwilling to participate (see Figure 1). The most common exclusions were the presence of a sleep disorder other than insomnia, a serious nonmalignant medical condition, or shift work. Lack of time and unspecified reasons were among the most common responses for unwillingness to participate. Seventeen women did not complete all the follow-up measures but were included in the intent-to-treat analyses.

Procedures

To assess eligibility, women took part in a scripted telephone screening using the Insomnia Interview Schedule (Morin, 1993) to assess sleep disturbance and rule out disorders other than insomnia. After consent, women completed baseline questionnaires and a daily sleep diary for one week. Qualified women were randomly assigned to CBTI or BPT using an adaptive randomization program, controlling for age, insomnia severity, recruitment site, and breast cancer stage (Matthews, Cook, Terada, & Aloia, 2010). Participants, but not the study therapist, were blind to treatment condition. CBTI and BPT were conducted in parallel; session duration and schedule were the same for each group. Women received an $80 honorarium in three divided amounts and reimbursement for parking or public transportation.

The individual, weekly CBTI sessions consisted of education about sleep restriction, stimulus control, sleep hygiene education, and cognitive therapy derived from existing protocols (Edinger & Carney, 2008; Morin, 1993; Perlis, Jungquist, Smith, & Posner, 2005). An advanced practice nurse with specialized training in CBTI conducted the individual weekly sessions in an office setting. All sessions began by reviewing the participant's sleep diary data, which determined the prescribed sleep schedule. Session 1 included a CBTI overview, conceptual model of insomnia, sleep restriction (Spielman et al., 1987), and stimulus control (Bootzin & Perlis, 1992). Sleep restriction limits the amount of time in bed to the patient's estimated TST. The rationale for the sleep restriction is to consolidate sleep and gradually increase it until an optimal sleep time is achieved (Spielman et al., 1987). Stimulus control provides instructions designed to discourage sleep-incompatible behaviors and reinforce a regular sleep-wake schedule. To help "set" the biologic clock, participants were instructed to adhere within 15 minutes of the prescribed sleep schedule. Sessions 2 and 3 addressed sleep hygiene principles, and cognitive therapy aimed at altering dysfunctional beliefs about sleep and the impact of sleep loss on daytime functioning. Sleep hygiene education promotes good sleep habits such as regular meals and a light bedtime snack; habitual exercise; limited use of caffeine, nicotine, and liquids in the evening; and a sleep-promoting bedroom



BPT—behavioral placebo treatment; CBTI—cognitive behavioral therapy for insomnia

Figure 1. Screening and Enrollment Flow Chart

(quiet, dark, and comfortable) (Edinger & Carney, 2008). Cognitive therapy is designed to alter dysfunctional thoughts and beliefs about sleep and help develop realistic sleep expectations. For example, faulty beliefs include unrealistic sleep expectations and exaggeration of the consequences of sleep loss (Edinger, Wohlgemuth, Radtke, Marsh, & Quillian, 2001b). During sessions 4 and 5, CBTI principles were reinforced and sleep schedules adjusted based on sleep diary data. Session 6 focused on relapse prevention and skills to cope with setbacks.

BPT is based on the concept of desensitization (Steinmark & Borkovec, 1974) and has been used as a placebo treatment in previous insomnia trials (Arnedt, Conroy, Armitage, & Brower, 2011; Edinger, Wohlgemuth, Radtke, Marsh, & Quillian, 2001a; Manber et al., 2008). BPT aims to reduce the conditioned arousal that develops in response to repeated pairings of frustration about not sleeping with difficulties initiating and maintaining sleep. Each individual BPT session began by recording diary data. In the first session, the therapist presented a BPT overview, conceptual model of insomnia, and helped women develop a 10-item arousal hierarchy of behavioral and cognitive activities that occur during poor sleep (e.g., clock watching, worrying about sleep). Each item was ranked from least to most arousing. A five-item neutral hierarchy was developed (e.g., taking a walk, listening to soothing music). Over the course of BPT, each item on the arousal hierarchy was paired with the neutral hierarchy items. Women were instructed to practice the exercise once daily at home, but not within 2–3 hours of bedtime to avoid unintended arousal.

For both groups, sessions 1–3 and 6 were conducted in person (30–60 minutes each) and sessions 4 and 5 were conducted by phone (15–20 minutes each). Treatments were delivered by the first author of the current article. Treatment sessions were audiotaped with participant consent and a portion was reviewed for treatment integrity by an independent consultant certified in behavioral sleep medicine. Fidelity checklists were completed at the conclusion of each session.

Measures

Women completed a sleep diary before and during the intervention and at three- and six-month follow-ups. Measures of insomnia severity, QOL, functioning, fatigue, mood, and attitudes about sleep were assessed at baseline, postintervention, and at three and six months. Sleep knowledge was assessed at baseline and postintervention.

A **sleep-wake diary** is a reliable and sensitive measure of change in daily sleep-wake patterns (Morin, 1993). The diary was completed after morning arousal. Sleep parameters derived from sleep logs have been shown to correlate reasonably with polysomnography (Coates et al., 1982); sensitivity and specificity also were high (92% and 96%, respectively) (Rogers, Caruso, & Aldrich, 1993). Women recorded bedtime, rise time, minutes to sleep onset, minutes awake after sleep onset, number of awakenings, and sleep aid use ("I took ___ mg of medication and/or ___ oz of ___ alcohol as a sleep aid."). Because sleep can be highly variable from night to night, weekly means were calculated for each outcome. Data were considered missing if four or more nights per week were unavailable. Sleep parameters extracted from the diary included SL, SE, WASO, TST, and number of nocturnal awakenings.

The **ISI** (Morin, 1993) is a seven-item measure of perceived insomnia that evaluates global severity of insomnia based on difficulty falling asleep, nocturnal/early morning awakenings, degree of dissatisfaction, and daytime impairment associated with insomnia (0 = none, 4 = very severe). Previously validated in primary insomnia (Bastien, Vallieres, & Morin, 2001) and patients with cancer (Savard, Savard, et al., 2005b), the ISI is a reliable and valid instrument to quantify perceived insomnia severity. Assessed in breast cancer survivors, Cronbach alpha ranged across time from 0.64–0.85 (Dirksen & Epstein, 2008). Scores range from 0–28; total scores are categorized as 0–7, not clinically significant; 8–14, subthreshold insomnia; 15–21, moderate insomnia; and 22–28, severe insomnia. Cronbach alpha was 0.73 in this study.

The **European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire–Core 30 (EORTC QLQ-C30)** is a reliable and validated cancer-specific QOL measure composed of five scales that evaluate functioning (i.e., physical, role, emotional, cognitive, and social functioning), as well as a measure of global health status and QOL. Cronbach alphas have ranged from 0.88–0.84 in fatigued breast cancer survivors (Kluthcovsky et al., 2012). For the current study, the authors focused on the physical function and global health/QOL scales. The five-item physical functioning scale included items such as "Do you have any trouble taking a long walk?" and "Do you need to stay in bed or a chair during the day?" The global health status/QOL scale contains two items regarding overall health and overall QOL during the past week. Raw scores are transformed to a standardized scale ranging from 0–100; higher scores reflect higher levels of physical functioning and global QOL (Fayers et al., 2001). In the current study, Cronbach alpha was 0.73 for the global health/QOL subscale and 0.83 for the physical functioning subscale.

The **Attentional Function Index (AFI)** was designed to measure perceived effectiveness in common activities requiring attention and working memory. Women rated themselves on 14 items ranging from 0 (not at all) to 10 (extremely well) in response to how well they were functioning in key cognitive activities (e.g.,

making decisions, keeping a train of thought). A higher mean score indicates greater cognitive functioning. The AFI has been shown to be consistently reliable with internal consistency coefficients (Cronbach alpha) ranging from 0.84 (Cimprich, 1993) to 0.92 (Cimprich, 1999) in women with breast cancer. Cronbach alpha for the AFI was 0.95 in the current study.

The **Piper Fatigue Scale (PFS)** measures four dimensions of fatigue: behavioral/severity, affective meaning, sensory, and cognitive/mood. Each are assessed in 22 items ranging from 1 (no fatigue) to 10 (extreme fatigue) (Piper et al., 1998). Higher mean scores represent greater fatigue. The revised PFS has been validated in breast cancer survivors (de Jong, Candel, Schouten, bu-Saad, & Courtens, 2006); reported Cronbach alphas have ranged from 0.98 for the total scale and 0.94 for subscales in women with fatigue after breast cancer treatment (Kluthcovsky et al., 2012), indicating good internal consistency. Cronbach alpha for the PFS was 0.96 in this study.

The **Hospital Anxiety and Depression Scale (HADS)** is a 14-item measure of mood and is equally divided into anxiety and depression scales (Zigmond & Snaith, 1983). The internal consistency of the two subscales in patients with cancer, assessed by Cronbach alpha, are 0.93 for anxiety and 0.9 for depression (Moorey et al., 1991). Concurrent validity (compared with psychiatric rating scales) is reported in previous studies (Zigmond & Snaith, 1983). Scores ranged from 0–3, with 21 as the maximum score for each scale. A score of 7 or higher suggests the presence of clinical levels of depression or anxiety. Cronbach alpha was 0.85 for anxiety and 0.81 for depression scales in this study.

Dysfunctional Beliefs and Attitudes About Sleep–16 (DBAS-16) evaluates concerns about the consequences of insomnia, misconceptions about sleep needs and requirements, preoccupations about sleep, and tendency toward medication dependency (Morin, 1993). The DBAS-16 was found to be reliable in adults with insomnia, as evidenced by a Cronbach alpha of 0.77 for clinical and 0.79 for research samples and temporal stability (r = 0.83) (Morin, Vallieres, & Ivers, 2007), including those with insomnia with comorbid medical conditions (Cronbach alpha = 0.82) (Carney et al., 2010). Women indicated how much they agreed with each statement on a 0–10 scale. Higher scores reflect a greater degree of dysfunctional beliefs and attitudes. Cronbach alpha was 0.82 in the current study.

The **Patient Knowledge Test (PKT)** assessed sleep knowledge through a 15-item true or false questionnaire designed by the first author of the current article and was completed at baseline and post-test. The items include facts about sleep and insomnia (e.g., "Because I am getting older, I need less sleep.") and appropriate or inappropriate sleep habits (e.g., "Exercise in the evening helps people fall asleep.") that were addressed in the CBTI condition. Higher scores reflect more correct answers.

Data Analysis

An a priori power analysis using an effect size of 0.65–1.05 from previous studies (Morin, Colecchi, Stone, Sood, & Brink, 1999; Murtagh & Greenwood, 1995; Savard, Simard, et al., 2005), an alpha level of 0.05, and a power of 0.8 indicated that a total sample size of 60 women was required to detect group differences in SE. Data were double-entered and inspected for artifacts, missing or out-of-range values, and nonnormality. Consistent with intent-to-treat analysis, once a participant was randomized, her data were included in the analyses. Full information maximum likelihood estimation was used to address missing data in the analyses. All analyses were performed using SAS®, version 9.3. Sleep diary outcomes included weekly assessments of SL, SE, TST, WASO, and number of nightly awakenings. These outcomes were modeled in a multilevel modeling framework as linear mixed models with random intercepts and unstructured covariance structures using SAS Proc Mixed. The models included a treatment main effect to determine whether an overall difference existed between the groups and a time main effect to determine whether scores changed over time. The main interest, however, was in the treatment-by-time interaction to address the hypothesis that changes over time differed by group. When a significant treatment-by-time interaction was observed,

Table 1. Baseline Sample Characteristics by Group (N = 56)

	CBTI Group (n = 30)		BPT Group (n = 26)	
Characteristic	$\bar{X}$	**SD**	$\bar{X}$	**SD**
Age (years)	52.17	6.86	52.85	7.75
Characteristic	**n**		**n**	
Cancer stage				
• I	9		11	
• II	11		9	
• III	10		6	
Radiation	21		19	
Married	16		14	
Employed full-time	14		12	
Received chemotherapy	22		17	
College educated	19		18	

BPT—behavioral placebo treatment; CBTI—cognitive behavioral therapy for insomnia

Note. All comparisons between treatment groups were nonsignificant (all $p > 0.49$).

two post-hoc tests were conducted to examine treatment differences in changes from baseline (week 1) to the end of the intervention (week 6) and changes from baseline to the follow-up period.

Secondary outcomes were sleep aid use, perceived insomnia severity, QOL, physical function, cognitive function, fatigue, depression, anxiety, sleep attitudes, and knowledge. For sleep aid use, changes in average daily use of sleep aids (prescription and nonprescription) were compared between baseline and the end of intervention using a Wilcoxon rank sum test. The remaining outcomes were measured at baseline, post-treatment, three months, and six months, and as with sleep diary outcomes, were evaluated in terms of the time-by-treatment group interaction in a multilevel modeling framework.

Results

Demographics and Characteristics

Table 1 depicts demographic and characteristics by treatment group. All demographic variables were similar between groups at baseline. On average, women were 52 years old, and most had received radiation and/or chemotherapy. The majority were married and 46% were employed full time. Reported average income levels in the groups were similar. The median annual income in the CBTI group was $60,001–$80,000 and $40,001–$60,000 in the BPT group, which is consistent with the 2011 median household income in Colorado reported in 2011 ($58,629, SE = 2,553) and 2010 ($60,233, SE = 2,481) (U.S. Census Bureau, 2013).

Of the 60 participants enrolled in the study, 17 had missing data. Four women (two CBTI, two BPT) withdrew from the study by the third week, and 13 had data missing for some or all of the follow-up. To examine if missing data affected interpretation of study results, the interaction between attrition and group was estimated for all baseline demographics and sleep variables. Of the 17 tests conducted, no significant interactions were noted between missing data status and group, indicating that no systematic differences existed between those with or without data at follow-up that might influence treatment effects.

Sleep Outcomes

Table 2 depicts the changes in sleep-wake diary outcomes over time by treatment condition. The baseline means for SE of less than 80%, SL of 25–37 minutes, and WASO of greater than 38 minutes suggested substantial onset and maintenance insomnia in both groups. A significant time by treatment interaction was observed for SE, SL, and TST. Figures 2, 3, and 4 illustrate the patterns of change in these three outcomes over time and by group. Means are plotted for baseline (week 1), each week of treatment (weeks 2–6), postintervention (week 7), and the three- and six-month follow-ups. No statistically significant condition effects were noted on scores over time for WASO or number of awakenings.

Formal post-hoc tests were conducted for SE, SL, and TST to interpret the nature of the overall treatment-by-time interaction effect. The CBTI group did not show a

Table 2. Changes in Sleep Diary Outcomes Over Time by Group

Sleep Variable	Baseline $\bar{X}$	$\bar{X}$ Change From Week 1–6	$\bar{X}$ Change From Week 1 to Follow-Up	Time Condition Interaction F	Time Condition Interaction p	Effect Size Comparison of Weeks 1–6[a] d	Effect Size Comparison of Week 1 to Follow-Up[a] d
Sleep efficiency (%)				2	0.046	0.34	0.63
CBTI	79.09	9.39	11.53				
BPT	79.92	5.99	6.34				
Sleep latency (minutes)				3.2	0.002	0.48	0.49
CBTI	36.79	–20.73	–23.22				
BPT	25.46	–7.97	–9.35				
WASO (minutes)				1.42	0.18	0.26	0.09
CBTI	38.25	–20.38	–21.08				
BPT	40.84	–12.12	–18.91				
TST (minutes)				5.55	< 0.0001	0.67	0.03
CBTI	394.16	–0.37	33.46				
BPT	382.7	30.96	35.33				
Awakenings (per night)				0.56	0.81	0.13	0.13
CBTI	2.46	–0.68	–0.85				
BPT	2.84	–0.78	–0.97				

[a] Effect size estimate calculated as Cohen d testing mean change score from week 1 to week 6 follow-ups between CBTI and BPT groups.
BPT—behavioral placebo treatment; CBTI—cognitive behavioral therapy for insomnia; TST—total sleep time; WASO—wake after sleep onset

significantly greater improvement in SE compared to BPT immediately after the intervention (p = 0.1, Cohen d = 0.34), but scores were significantly greater by the follow-up period (p = 0.003) where those in the CBTI group improved SE by 11.53 percentage points and those in the BPT group only increased by 6.34 percentage points, a moderate effect (d = 0.63). The CBTI group reduced the minutes to fall asleep by 20.73 minutes from baseline to week 6, whereas those in the BPT group reduced their sleep onset latency by 7.97 minutes (p = 0.007, d = 0.48), and this improvement was maintained during the follow-up period (p = 0.0005, d = 0.49). Evidence also was found for greater increases in TST during the treatment weeks in the BPT group compared to CBTI (p = 0.012, d = 0.67), although this difference was not maintained at the follow-up period (p = 0.84, d = 0.03).

Sleep Aid Use

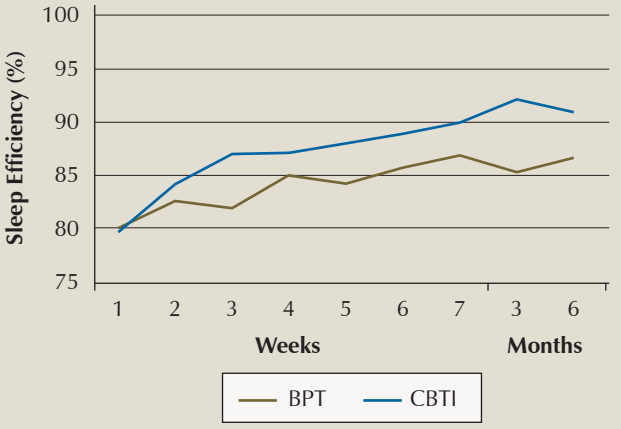
No significant differences were found between the CBTI and BPT groups in terms of change in sleep aid use from week 1 to week 6 (Wilcoxon rank sum test, p = 0.7). At baseline, nine women in the BPT group denied use of prescription sleep aids (sedatives/hypnotics) and nonprescription sleep aids (over-the-counter aids marketed for analgesia, cold/flu, sleep, herbal supplements) compared to 11 in the CBTI group. At the end of treatment, 12 (64%) in the BPT group had no change in their sleep aid use, six (27%) had a reduction, and two (9%) had an increase. In the CBTI group, 12 (41%) had no change in sleep aid use, 12 (41%) had a reduction, and five (10%) had an increase. The median change in both groups was zero.

Secondary Outcome Variables

Table 3 shows the mean scores of the secondary variables over time, by condition, and the results of the modeling of change over time. A significant time by treatment interaction was noted for insomnia severity, physical function, dysfunctional attitudes about sleep, and sleep knowledge, as well as a trend for cognitive function (p = 0.07). Post-hoc tests showed significant improvement from baseline to post-test/follow-up for women in the CBTI group relative to BPT for each of the outcomes with small- to moderate-sized effects observed (Cohen d range = 0.4–0.79). No statistically significant intervention effects were noted on scores over time for QOL, fatigue, depression, or anxiety, with effect sizes ranging from d = 0.12 to d = 0.27.

Discussion

As expected, the primary findings indicate that women who received CBTI demonstrated greater improvements in SE and SL. On average, women in the CBTI group increased SE from 79% to 90% at follow-up.



BPT—behavioral placebo treatment; CBTI—cognitive behavioral therapy for insomnia

Note. Sleep efficiency is the proportion of actual sleep to time spent in bed, based on sleep diary entries. Good sleepers typically have sleep efficiency of 85% or greater.

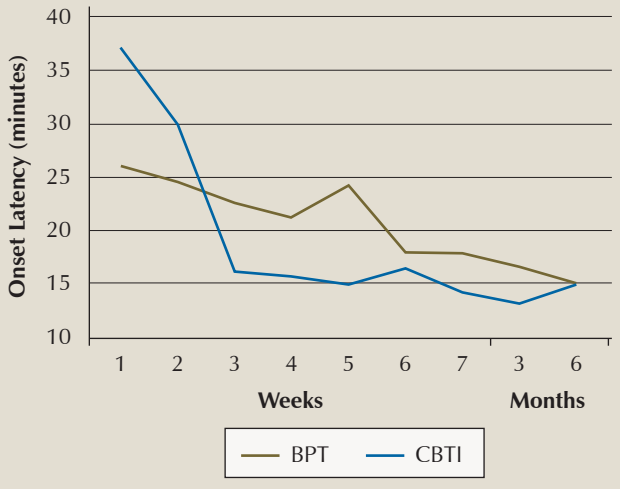
Figure 2. Sleep Efficiency Scores Over Time by Treatment Group

Considering an SE of 85% is used to distinguish clinical insomnia from normal sleep (Savard, Simard, et al., 2005), this finding is clinically meaningful. Similarly, the marked reduction in SL by more than 20 minutes from week 1 to the end of the intervention as well as at follow-up in the CBTI group denotes a striking decrease in time to fall asleep. These findings are consistent with the literature describing outcomes of CBTI and similar sleep interventions in women with breast cancer (Berger, Kuhn, Farr, Lynch, et al., 2009; Berger, Kuhn, Farr, Von Essen, et al., 2009; Epstein & Dirksen, 2007; Savard, Simard, et al., 2005; Tremblay et al., 2009) and other cancer populations (Espie et al., 2008; Rumble, Keefe, Edinger, Porter, & Garst, 2005). These findings suggest CBTI is effective in addressing perpetuating factors of insomnia as outlined in the Behavioral Model of Insomnia (Spielman et al., 1987).

Although the BPT group showed increased TST relative to the CBTI group at week 6, the groups did not differ at follow-up. An initial reduction in TST during the CBTI intervention is expected when participants adhere to a prescribed and restricted sleep schedule, followed by a gradual increase in TST. Contrary to previous studies of women with breast cancer (Berger et al., 2002; Epstein & Dirksen, 2007), the authors did not find a significant differences between groups relative to WASO and number of awakenings over the duration of the study, although both groups improved over time. The improvement in WASO and TST over time in both CBTI and BPT suggests that monitoring sleep via a daily sleep-wake diary and meeting with a supportive healthcare provider may provide the impetus to take

on more positive lifestyle behaviors. Participants in the BPT group may have increased interest in sleep in general and may have sought sleep information elsewhere. BPT is intended to reduce arousal from repeated frustration about not sleeping and, therefore, may be most helpful to those with high anxiety or annoyance related to sleep disturbances. New endocrine treatments used by women in the current study may have caused substantial joint pain in addition to hot flashes (Desai et al., 2013), which were not widely prescribed in previous investigations. With regard to TST, sleep restriction was a component of CBTI. Therefore, decreased TST indicates good adherence, particularly in the beginning weeks (Matthews, Schmiege, Cook, Berger, & Aloia, 2012). TST in women receiving CBTI averaged seven hours nightly by the end of the intervention, suggesting a sustained sleep benefit.

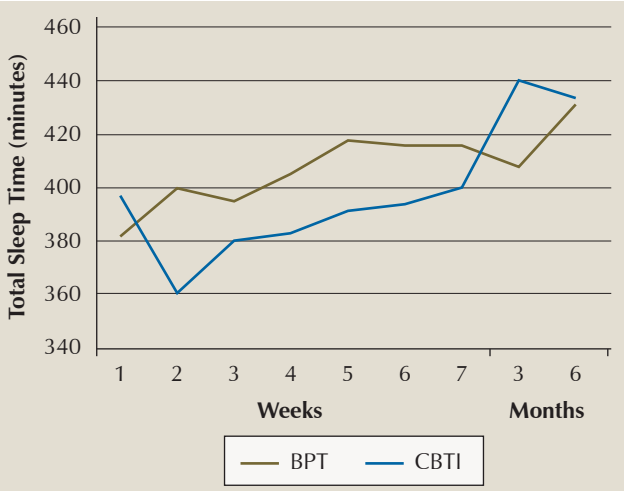
No significant differences were found between groups in terms of change in sleep aid use during the intervention weeks. Neither group received specific recommendations regarding sleep aid withdrawal; however, greater improvement in sleep may reduce the need for sleep aids in the CBTI group. The lack of significant sleep aid reduction is contradictory with other studies of CBTI in breast cancer survivors (Savard, Simard, et al., 2005) and primary insomnia (Espie, Inglis, Tessier, & Harvey, 2001), which suggest that offering alternative nonpharmacologic strategies is sufficient to reduce or stop sleep aid use. The women in this study may have lacked sufficient confidence to give up sleep aids or were psychologically dependent on sleep aids. Although the CBTI group's reductions in sleep aid use were not statistically significantly different compared to the BPT group and interpretation is complicated by baseline differences between groups, the reduction in sleep aid use may be clinically meaningful. Continued study of sleep aid use in larger-scale studies is warranted.



BPT—behavioral placebo treatment; CBTI—cognitive behavioral therapy for insomnia

Note. Sleep latency is the number of minutes to fall asleep after lights out, based on sleep diary entries. Good sleepers typically have sleep latency of less than 20–30 minutes.

Figure 3. Onset Latency Scores Over Time by Treatment Group



BPT—behavioral placebo treatment; CBTI—cognitive behavioral therapy for insomnia

Note. Total sleep time is actual time asleep (does not include sleep latency or minutes awake during the night) based on sleep diary entries. Recommended adult total sleep time is 420–480 minutes.

Figure 4. Total Sleep Time Scores Over Time by Treatment Group

Consistent with other studies of breast cancer survivors, baseline self-report scores of the secondary outcomes suggest moderate severity insomnia (Morin, 1993), good QOL and physical functioning (Minton, Alexander, & Stone, 2012; Zucca, Boyes, Linden, & Girgis, 2012), reduced cognitive functioning (Chen, Miaskowski, Liu, & Chen, 2012), moderate fatigue (Appling, Scarvalone, MacDonald, McBeth, & Helzlsouer, 2012), borderline moderate anxiety, and low depression levels (Trudel-Fitzgerald, Savard, & Ivers, 2013). In the CBTI group, perceived severity of insomnia declined by 8.6 points at postintervention and continued to abate during the follow-up period, during which mean insomnia severity scores dropped to "no clinically significant insomnia" at three and six months. In contrast, women in the BPT group had a 5.9-point reduction in insomnia scores postintervention without further reduction over time, therefore remaining at or above subthreshold insomnia throughout the study. Yang, Morin, Schaefer, and Wallenstein (2009) found that patients with primary insomnia with a six-point ISI score reduction regardless of the baseline score were 48% less likely to report "feeling worn out," 46% less likely to be "unable to think clearly," and 52% less likely to report "feeling fatigued."

They concluded that a six-point reduction in ISI was a clinically meaningful improvement (Yang et al., 2009), which underscores the significant perception of sleep improvement in the current study's CBTI group.

The CBTI group did not report greater improvements in QOL or a reduction in anxiety or depression levels over time. These finding may be caused, in part, by the participants' relatively good QOL and mild dysthymia, providing little room to improve.

In the current study, women did not report lower fatigue despite reductions in insomnia, and this remains a challenging issue for BCSs. Minton and Stone (2013) examined cancer-related fatigue (CRF) and insomnia in women between three months and two years after completion of primary cancer treatment (N = 114). They found that 44% of women with CRF met the criteria for insomnia syndrome, but concluded these symptoms are related but separate entities, and CRF cannot be

Table 3. Secondary Outcomes: Insomnia Severity, QOL, Functioning, Symptoms, and Sleep Knowledge or Attitudes

Variable	Baseline	Postintervention	Three Months	Six Months	Time Condition Interaction and Effect Size[a]		
					f	p	d
Insomnia severity[b]					2.87	0.039	0.67
CBTI	17.6	9.03	7.56	7.43			
BPT	17.29	11.37	10.61	10.84			
Global health/QOL[c]					0.56	0.64	0.12
CBTI	64.03	72.91	72.33	73.32			
BPT	63.14	71.22	65.56	71.44			
Physical function[c]					3.16	0.027	0.79
CBTI	82.44	86.7	88.33	88.27			
BPT	84.04	82.59	80.91	85.06			
Attentional function[d]					2.36	0.07	0.56
CBTI	5.63	6.72	6.7	6.7			
BPT	5.66	5.87	5.89	6.33			
Fatigue[e]					0.39	0.76	0.2
CBTI	5.5	3.98	4.16	3.76			
BPT	5.48	4.25	4.66	4.09			
Depression[f]					0.75	0.52	0.27
CBTI	4.57	3.7	3.43	3.46			
BPT	5.09	4.77	5.03	4.64			
Anxiety[f]					0.42	0.74	0.22
CBTI	6.63	5.99	5.83	5.61			
BPT	8.21	6.89	7.25	6.52			
Sleep attitudes[g]					3.12	0.029	0.4
CBTI	5.44	3.96	3.31	3.46			
BPT	5.66	4.38	4.7	4.45			
Sleep knowledge[h]					9.35	0.004	0.4
CBTI	11.08	12.58	–	–			
BPT	10.81	10.62	–	–			

[a] Effect size estimate calculated as Cohen d testing mean change score from baseline to the average of the follow-up assessments between CBTI and BPT groups.

[b] Insomnia was scored with the Insomnia Severity Index on a scale of 0–28, where higher scores indicate greater insomnia severity.

[c] Global health/QOL and physical function were scored with the European Organisation for the Research and Treatment of Cancer Quality of Life–Core 30 questionnaire on a scale of 0–100, where higher scores indicated greater QOL/health rating or greater physical functioning, respectively.

[d] Attentional function was calculated with the Attentional Function Index on a scale of 0–10, with a higher score indicating greater cognitive function.

[e] Fatigue was determined through the use of the Piper Fatigue Scale, a 0–10 ranking where higher scores indicate greater fatigue and distress.

[f] Depression and anxiety were determined through the use of the Hospital Anxiety and Depression Scale, a 0–21 measure where higher scores indicate greater depression and anxiety, respectively.

[g] Sleep attitudes were examined through the use of Dysfunctional Beliefs and Attitudes About Sleep, a 10-item tool where higher scores indicate greater dysfunctional beliefs.

[h] Sleep knowledge was scored with the Patient Knowledge Test, a 15-item document where higher scores indicate more correct answers.

BPT—behavioral placebo treatment; CBTI—cognitive behavioral therapy for insomnia; QOL—quality of life

Knowledge Translation

Breast cancer survivors (BCSs) spend an excessive time awake while in bed (sleep efficiency) and have difficulty falling asleep (sleep latency) and/or staying asleep, suggesting substantial onset and maintenance insomnia.

BCSs who received cognitive behavioral therapy for insomnia (CBTI) had significantly improved sleep efficiency and sleep latency compared to controls.

CBTI is a promising therapy for insomnia in BCSs with sustained benefits, including less subjective insomnia, greater improvements in physical and cognitive functioning, positive sleep attitudes, and increased sleep hygiene knowledge.

explained by sleep disturbances alone (Minton & Stone, 2013). This finding is supported by data from a CBTI intervention trial that resulted in improved sleep but not fatigue (Savard, Simard, et al., 2005).

Other important findings of this study are the greater improvements in physical functioning and a trend toward improvement in the cognitive functioning in the CBTI group. Many patients with breast cancer develop treatment-related cognitive dysfunction that affects their QOL and can result in diminished functional independence (Wefel & Schagen, 2012). In a study of breast cancer survivors (N = 63), insomnia was associated with worse verbal episodic memory, executive functioning, and subjective cognitive functioning (Caplette-Gingras, Savard, Savard, & Ivers, 2012). Therefore, even a small improvement brought on by effectively managing insomnia appears to have important clinical implications.

As expected, the CBTI group reported greater decreases in dysfunctional beliefs about sleep and increased sleep knowledge from baseline to postintervention. This finding indicates that good fidelity to the content in the CBTI intervention existed, and women understood and assimilated CBTI principles.

Strengths and Limitations

The current study is characterized by several strengths, including randomization, manualized treatment, intervention fidelity verification, and longitudinal data. Women receiving pharmacologic treatment for insomnia and depression were included in the study (under certain conditions), which broadened the generalizability of the findings. However, despite various strategies to enroll a diverse sample, the majority of women were Caucasian and well educated, recruited through referrals, ads, and flyers (reflecting a high level of motivation), limiting the generalization of the findings to diverse groups of women. The study did not control for nonspecific therapeutic ingredients; therefore, determining whether sleep improvements are attributable to the CBTI strategies common to psychotherapeutic approaches such as therapist empathy is not possible. One therapist delivered CBTI and BPT, which could be considered a limitation and a strength. With one therapist, contamination between therapies is possible; however, several strategies were in place to monitor content and maintain high fidelity to the individual therapies. Conversely, having one therapist is a strength in terms of relative consistency of therapeutic alliance

Implications for Nursing Practice

The current study increases awareness of sleep disturbances in patients with cancer and legitimizes impaired sleep as an important concern for patients and the nursing discipline. Nurses can make a substantial difference in the QOL of cancer survivors by recognizing the number of patients with sleep problems and using available measures to accurately evaluate the severity and impact of sleep disturbances. Oncology healthcare providers often fail to ask patients about their sleep, which may lead to unnecessary morbidity. Nurses play a key role in recognition of sleep disturbances at all phases of the cancer care continuum. Through brief questions incorporated in a health history and medication review or specialized sleep assessments, nurses can identify patients with sleep disturbances. For patients with evidence of moderate-to-severe chronic insomnia or suspected of having other sleep disorders, nurses should refer to sleep experts for additional diagnostic testing and treatment. For general sleep disturbances, nurses can provide evidence-based nonpharmacologic and pharmacologic interventions. Nurses can become involved in research studies that build on the science that leads to evidence-based recommendations and policies, and seek specialized education for the delivery of sleep interventions such as CBTI.

Conclusion

The current study contributes to the existing body of research on nonpharmacologic interventions to improve sleep and daytime consequences in breast cancer survivors. Results suggest that CBTI is a promising intervention for insomnia during the six weeks of therapy with sustained benefit in the following months.

Implications for Future Research

Future research replicating these findings would be helpful to increase the generalizability of the results to other cancer types and ethnically diverse groups. Additional studies testing the effectiveness of the intervention are warranted using varying treatment

modalities, including cost analysis. Using the principles of CBTI, interventions to prevent insomnia before it becomes a chronic problem are additional avenues of investigation (Vitiello, McCurry, & Rybarczyk, 2013). Establishing effectiveness of CBTI during other periods in the cancer trajectory will allow healthcare providers to meet individual patients' needs and may contribute to health-related QOL.

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References

Ahn, S.H., Park, B.W., Noh, D.Y., Nam, S.J., Lee, E.S., Lee, M.K., . . . Yun, Y.H. (2006). Health-related quality of life in disease-free survivors of breast cancer with the general population. *Annals of Oncology, 18,* 173–182. doi:10.1093/annonc/mdl333

Ancoli-Israel, S., Liu, L., Marler, M.R., Parker, B.A., Jones, V., Sadler, G.R., . . . Fiorentino, L. (2006). Fatigue, sleep, and circadian rhythms prior to chemotherapy for breast cancer. *Supportive Care in Cancer, 14,* 201–209. doi:10.1007/s00520-005-0861-0

Appling, S.E., Scarvalone, S., MacDonald, R., McBeth, M., & Helzlsouer, K.J. (2012). Fatigue in breast cancer survivors: The impact of a mind-body medicine intervention. *Oncology Nursing Forum, 39,* 278–286. doi:10.1188/12.ONF.278-286

Arndt, V., Merx, H., Stegmaier, C., Ziegler, H., & Brenner, H. (2005). Persistence of restrictions in quality of life from the first to the third year after diagnosis in women with breast cancer. *Journal of Clinical Oncology, 23,* 4945–4953. doi:10.1200/JCO.2005.03.475

Arnedt, J.T., Conroy, D.A., Armitage, R., & Brower, K.J. (2011). Cognitive-behavioral therapy for insomnia in alcohol dependent patients: A randomized controlled pilot trial. *Behavior Research and Therapy, 49,* 227–233. doi:10.1016/j.brat.2011.02.003

Bastien, C.H., Vallieres, A., & Morin, C.M. (2001). Validation of the Insomnia Severity Index as an outcome measure for insomnia research. *Sleep Medicine, 2,* 297–307. doi:10.1016/S1389-9457(00)00065-4

Berger, A.M. (2009). Update on the state of the science: Sleep-wake disturbances in adult patients with cancer [Online exclusive]. *Oncology Nursing Forum, 36,* E165–E177. doi:10.1188/09.ONF.E165-E177

Berger, A.M., Kuhn, B.R., Farr, L.A., Lynch, J.C., Agrawal, S., Chamberlain, J., & Von Essen, S.G. (2009). Behavioral therapy intervention trial to improve sleep quality and cancer-related fatigue. *Psycho-Oncology, 18,* 634–646. doi:10.1002/pon.1438

Berger, A.M., Kuhn, B.R., Farr, L.A., Von Essen, S.G., Chamberlain, J., Lynch, J.C., & Agrawal, S. (2009). One-year outcomes of a behavioral therapy intervention trial on sleep quality and cancer-related fatigue. *Journal of Clinical Oncology, 27,* 6033–6040. doi:10.1200/JCO.2008.20.8306

Berger, A.M., Von Essen, S., Khun, B.R., Piper, B.F., Farr, L., Agrawal, S., . . . Higginbothom, P. (2002). Feasibilty of a sleep intervention during adjuvant breast cancer chemotherapy. *Oncology Nursing Forum, 29,* 1431–1441. doi:10.1188/02.ONF.1431-1441

Blask, D.E., Hill, S.M., Dauchy, R.T., Xiang, S., Yuan, L., Duplessis, T., . . . Sauer, L.A. (2011). Circadian regulation of molecular, dietary, and metabolic signaling mechanisms of human breast cancer growth by the nocturnal melatonin signal and the consequences of its disruption by light at night. *Journal of Pineal Research, 51,* 259–269. doi:10.1111/j.1600-079X.2011.00888.x

Bootzin, R.R., & Perlis, M.L. (1992). Nonpharmacologic treatments of insomnia. *Journal of Clinical Psychiatry, 53*(Suppl.), 37–41.

Bray, F., Ren, J.S., Masuyer, E., & Ferlay, J. (2013). Global estimates of cancer prevalence for 27 sites in the adult population in 2008. *International Journal of Cancer, 132,* 1133–1145. doi:10.1002/ijc.27711

Buysse, D.J. (2013). Insomnia. *JAMA, 309,* 706–716.

Caplette-Gingras, A., Savard, J., Savard, M.H., & Ivers, H. (2012). Is insomnia associated with cognitive impairments in breast cancer patients? *Behavioral Sleep Medicine, 11,* 239–257. doi:10.1080/15402002.2012.672940

Carney, C.E., Edinger, J.D., Morin, C.M., Manber, R., Rybarczyk, B., Stepanski, E.J., & Lack, L. (2010). Examining maladaptive beliefs about sleep across insomnia patient groups. *Journal of Psychosomatic Research, 68,* 57–65. doi:10.1016/j.jpsychores.2009.08.007

Chen, M.L., Miaskowski, C., Liu, L.N., & Chen, S.C. (2012). Changes in perceived attentional function in women following breast cancer surgery. *Breast Cancer Research and Treatment, 131,* 599–606. doi:10.1007/s10549-011-1760-3

Cimprich, B. (1993). Development of an intervention to restore attention in cancer patients. *Cancer Nursing, 16,* 83–92.

Cimprich, B. (1999). Pretreatment symptom distress in women newly diagnosed with breast cancer. *Cancer Nursing, 22,* 185–195.

Coates, T.J., Killen, J.D., George, J., Marchini, E., Silverman, S., & Thoresen, C. (1982). Estimating sleep parameters: A multitrait-multimethod analysis. *Journal of Consulting and Clinical Psychology, 50,* 345–352. doi:10.1037/0022-006X.50.3.345

Cohen, M., & Fried, G. (2007). Comparing relaxation training and cognitive-behavioral group therapy for women with breast cancer. *Research on Social Work Practice, 17,* 313–323.

de Jong, N., Candel, M.J., Schouten, H.C., bu-Saad, H.H., & Courtens, A.M. (2006). Course of the fatigue dimension "activity level" and the interference of fatigue with daily living activities for patients with breast cancer receiving adjuvant chemotherapy. *Cancer Nursing, 29,* E1–E13.

Desai, K., Mao, J.J., Su, I., Demichele, A., Li, Q., Xie, S.X., & Gehrman, P.R. (2013). Prevalence and risk factors for insomnia among breast cancer patients on aromatase inhibitors. *Supportive Care in Cancer, 21,* 43–51. doi:10.1007/s00520-012-1490-z

Dirksen, S.R., Belyea, M.J., & Epstein, D.R. (2009). Fatigue-based subgroups of breast cancer survivors with insomnia. *Cancer Nursing, 32,* 404–411. doi:10.1097/NCC.0b013e3181a5d05e

Dirksen, S.R., & Epstein, D.R. (2008). Efficacy of an insomnia intervention on fatigue, mood and quality of life in breast cancer survivors. *Journal of Advanced Nursing, 61,* 664–675.

Edinger, J., & Carney, C. (2008). *Overcoming insomnia: A cognitive-behavioral therapy approach therapist guide.* New York, NY: Oxford University Press.

Edinger, J.D., Wohlgemuth, W.K., Radtke, R.A., Marsh, G.R., & Quillian, R.E. (2001a). Cognitive behavioral therapy for treatment of chronic primary insomnia: A randomized controlled trial. *JAMA, 285,* 1856–1864. doi:10.1001/jama.285.14.1856

Edinger, J.D., Wohlgemuth, W.K., Radtke, R.A., Marsh, G.R., & Quillian, R.E. (2001b). Does cognitive-behavioral insomnia therapy alter dysfunctional beliefs about sleep? *Sleep, 24,* 591–599.

Epstein, D.R., & Dirksen, S.R. (2007). Randomized trial of a cognitive-behavioral intervention for insomnia in breast cancer survivors [Online exclusive]. *Oncology Nursing Forum, 34,* E51–E59. doi:10.1188/07.ONF.E51-E59

Espie, C.A. (2009). "Stepped care": A health technology solution for delivering cognitive behavioral therapy as a first line insomnia treatment. *Sleep, 32,* 1549–1558.

Espie, C.A., Fleming, L., Cassidy, J., Samuel, L., Taylor, L.M., White, C.A., . . . Paul, J. (2008). Randomized controlled clinical effectiveness trial of cognitive behavior therapy compared with treatment as usual for persistent insomnia in patients with cancer. *Journal of Clinical Oncology, 26,* 4651–4658. doi:10.1200/JCO.2007.13.9006

Espie, C.A., Inglis, S.J., Tessier, S., & Harvey, L. (2001). The clinical effectiveness of cognitive behaviour therapy for chronic insomnia: Implementation and evaluation of a sleep clinic in general medical practice. *Behavior Research and Therapy, 39,* 45–60. doi:10.1016/S0005-7967(99)00157-6

Fayers, P.M., Aaronson, N.K., Bjordal, K., Groenvold, M., Curran, D., & Bottomley, A. (2001). *The EORTC QLQ-C30 scoring manual* (3rd ed.). Brussels, Belgium: European Organisation for the Research and Treatment of Cancer.

Filipski, E., King, V.M., Li, X., Granda, T.G., Mormont, M.C., Claustrat, B., . . . Levi, F. (2003). Disruption of circadian coordination accelerates malignant growth in mice. *Patholgie Biologie, 51,* 216–219. doi:10.1016/S0369-8114(03)00034-8

Filipski, E., King, V.M., Li, X., Granda, T.G., Mormont, M.C., Liu, X., . . . Levi, F. (2002). Host circadian clock as a control point in tumor progression. *Journal of the National Cancer Institute, 94,* 690–697. doi:10.1093/jnci/94.9.690

Fiorentino, L., & Ancoli-Israel, S. (2006). Insomnia and its treatment in women with breast cancer. *Sleep Medicine Reviews, 10,* 419–429. doi:10.1016/j.smrv.2006.03.005

Fortner, B.V., Stepanski, E.J., Wang, S.C., Kasprowicz, S., & Durrence, H.H. (2002). Sleep and quality of life in breast cancer patients. *Journal of Pain and Symptom Management, 24,* 471–480. doi:10.1016/S0885-3924(02)00500-6

Innominato, P.F., Focan, C., Gorlia, T., Moreau, T., Garufi, C., Waterhouse, J., . . . Bjarnason, B.J. (2009). Circadian rhythm in rest and activity: A biological correlate of quality of life and a predictor of survival in patients with metastatic colorectal cancer. *Cancer Research, 69,* 4700–4707. doi:10.1158/0008-5472.CAN-08-4747

Kluthcovsky, A.C., Urbanetz A.A., de Carvalho, D.S., Pereira Maluf, E.M., Schlickmann Sylvestre, G.C., & Bonatto Hatschbach, S.B. (2012). Fatigue after treatment in breast cancer survivors: prevalence, determinants and impact on health-related quality of life. *Supportive Care in Cancer, 20,* 1901–1909.

Manber, R., Edinger, J.D., Gress, J.L., San Pedro-Salcedo, M.G., Kuo, T.F., & Kalista, T. (2008). Cognitive behavioral therapy for insomnia enhances depression outcome in patients with comorbid major depressive disorder and insomnia. *Sleep, 31,* 489–495.

Matthews, E.E., Cook, P.F., Terada, M., & Aloia, M.S. (2010). Randomizing research participants: Promoting balance and concealment in small samples. *Research in Nursing and Health, 33,* 243–253.

Matthews, E.E., Schmiege, S.J., Cook, P.F., Berger, A.M., & Aloia, M.S. (2012). Adherence to cognitive behavioral therapy for insomnia (CBTI) among women following primary breast cancer treatment: A pilot study. *Behavioral Sleep Medicine, 10,* 1–13. doi:10.1080/15402002.2012.666220

Minton, O., Alexander, S., & Stone, P.C. (2012). Identification of factors associated with cancer related fatigue syndrome in disease-free breast cancer patients after completing primary treatment. *Breast Cancer Research and Treatment, 136,* 513–520.

Minton, O., & Stone, P.C. (2013). A comparison of cognitive function, sleep and activity levels in disease-free breast cancer patients with or without cancer-related fatigue syndrome. *BMJ Supportive and Palliative Care, 2,* 231–238. doi:10.1136/bmjspcare-2011-000172

Moore, T.A., Berger, A.M., & Dizona, P. (2011). Sleep aid use during and following breast cancer adjuvant chemotherapy. *Psycho-Oncology, 20,* 321–325. doi:10.1002/pon.1756

Moorey, S., Greer, S., Watson, M., Gorman, C., Rowden, L., Tunmore, R., . . . Bliss, J. (1991). The factor structure and factor stability of the hospital anxiety and depression scale in patients with cancer. *British Journal of Psychiatry, 158,* 255–259. doi:10.1192/bjp.158.2.255

Morin, C.M. (1993). *Insomnia: Psychological assessment and management*. New York, NY: Guilford Press.

Morin, C.M., & Benca, R. (2012). Chronic insomnia. *Lancet, 24,* 1129–1141.

Morin, C.M., Bootzin, R.R., Buysse, D.J., Edinger, J.D., Espie, C.A., & Lichstein, K.L. (2006). Psychological and behavioral treatment of insomnia: Update of the recent evidence (1998–2004). *Sleep, 29,* 1398–1414.

Morin, C.M., Colecchi, C., Stone, J., Sood, R., & Brink, D. (1999). Behavioral and pharmacological therapies for late-life insomnia: A randomized controlled trial. *JAMA, 281,* 991–999. doi:10.1001/jama.281.11.991

Morin, C.M., Vallieres, A., & Ivers, H. (2007). Dysfunctional beliefs and attitudes about sleep (DBAS): Validation of a brief version (DBAS-16). *Sleep, 30,* 1547–1554.

Mormont, M.C., Waterhouse, J., Bleuzen, P., Giacchetti, S., Jami, A., Bogdan, A., & Levi, F. (2000). Marked 24-h rest/activity rhythms are associated with better quality of life, better response, and longer survival in patients with metastatic colorectal cancer and good performance status. *Clinical Cancer Research, 6,* 3038–3045.

Murtagh, D.R., & Greenwood, K.M. (1995). Identifying effective psychological treatments for insomnia: A meta-analysis. *Journal of Consulting and Clinical Psychology, 63,* 79–89. doi:10.1037/0022-006X.63.1.79

Nakaguchi, T., Okuyama, T., Uchida, M., Ito, Y., Komatsu, H., Wada, M., & Akechi, T. (2013). Oncology nurses' recognition of supportive care needs and symptoms of their patients undergoing chemotherapy. *Japanese Journal of Clinical Oncology, 43,* 369–376. doi:10.1093/jjco/hyt003

Okuyama, T., Akechi, T., Yamashita, H., Toyama, T., Nakaguchi, T., Uchida, M., . . . Furukawa, T.A. (2011). Oncologists' recognition of supportive care needs and symptoms of their patients in a breast cancer outpatient consultation. *Japanese Journal of Clinical Oncology, 41,* 1251–1258. doi:10.1093/jjco/hyr146

Page, M., & Berger, A. (2009). Sleep-wake disturbances. In L. Eaton & J. Tipton (Eds.), *Oncology Nursing Society Putting Evidence Into Practice: Improving oncology patient outcomes* (pp. 285–297). Pittsburgh, PA: Oncology Nursing Society.

Palesh, O.G., Roscoe, J.A., Mustian, K.M., Roth, T., Savard, J., Ancoli-Israel, S., . . . Morrow, G.R. (2010). Prevalence, demographics, and psychological associations of sleep disruption in patients with cancer: University of Rochester Cancer Center-Community Clinical Oncology Program. *Journal of Clinical Oncology, 28,* 292–298. doi:10.1200/JCO.2009.22.5011

Payne, J., Piper, B., Rabinowitz, I., & Zimmerman, B. (2006). Biomarkers, fatigue, sleep, and depressive symptoms in women with breast cancer: A pilot study. *Oncology Nursing Forum, 33,* 775–783. doi:10.1188/06.ONF.775-783

Perlis, M.L., Jungquist, C., Smith, M.T., & Posner, D. (2005). *Cognitive behavioral treatment of insomnia: A session-by-session guide*. New York, NY: Springer.

Piper, B.F., Dibble, S.L., Dodd, M.J., Weiss, M.C., Slaughter, R.E., & Paul, S.M. (1998). The revised Piper Fatigue Scale: Psychometric evaluation in women with breast cancer. *Oncology Nursing Forum, 25,* 677–684.

Quesnel, C., Savard, J., Simard, S., Ivers, H., & Morin, C.M. (2003). Efficacy of cognitive-behavioral therapy for insomnia in women treated for nonmetastatic breast cancer. *Journal of Consulting and Clinical Psychology, 71,* 189–200. doi:10.1037/0022-006X.71.1.189

Rogers, A.E., Caruso, C.C., & Aldrich, M.S. (1993). Reliability of sleep diaries for assessment of sleep/wake patterns. *Nursing Research, 42,* 368–372.

Rumble, M.E., Keefe, F.J., Edinger, J.D., Porter, L.S., & Garst, J.L. (2005). A pilot study investigating the utility of the cognitive-behavioral model of insomnia in early-stage lung cancer patients. *Journal of Pain and Symptom Management, 30,* 160–169. doi:10.1016/j.jpainsymman.2005.02.013

Savard, J., Ivers, H., Villa, J., Caplette-Gingras, A., & Morin, C.M. (2011). Natural course of insomnia comorbid with cancer: An 18-month longitudinal study. *Journal of Clinical Oncology, 29,* 3580–3586. doi:10.1200/JCO.2010.33.2247

Savard, J., Simard, S., Blanchet, J., Ivers, H., & Morin, C.M. (2001). Prevalence, clinical characteristics, and risk factors for insomnia in the context of breast cancer. *Sleep, 24,* 583–590.

Savard, J., Simard, S., Ivers, H., & Morin, C.M. (2005). Randomized study on the efficacy of cognitive-behavioral therapy for insomnia secondary to breast cancer, part I: Sleep and psychological effects. *Journal of Clinical Oncology, 23,* 6083–6096. doi:10.1200/JCO.2005.09.548

Savard, J., Villa, J., Ivers, H., Simard, S., & Morin, C.M. (2009). Prevalence, natural course, and risk factors of insomnia comorbid with cancer over a 2-month period. *Journal of Clinical Oncology, 27,* 5233–5239. doi:10.1200/JCO.2008.21.6333

Savard, M., Savard, J., Simard, S., & Ivers, H. (2005). Empirical validation of the Insomnia Severity Index in cancer patients. *Psycho-Oncology, 14,* 429–441. doi:10.1002/pon.860

Schutte-Rodin, S., Broch, L., Buysse, D., Dorsey, C., & Sateia, M. (2008). Clinical guideline for the evaluation and management of chronic insomnia in adults. *Journal of Clinical Sleep Medicine, 4,* 487–504.

Spielman, A.J., Saskin, P., & Thorpy, M.J. (1987). Treatment of chronic insomnia by restriction of time in bed. *Sleep, 10,* 45–56.

Steinmark, S.W., & Borkovec, T.D. (1974). Active and placebo treatment effects on moderate insomnia under counterdemand and positive demand instructions. *Journal of Abnormal Psychology, 83,* 157–163. doi:10.1037/h0036489

Tremblay, V., Savard, J., & Ivers, H. (2009). Predictors of the effect of cognitive behavioral therapy for chronic insomnia comorbid with breast cancer. *Journal of Consulting and Clinical Psychology, 77,* 742–750. doi:10.1037/a0015492

Trudel-Fitzgerald, C., Savard, J., & Ivers, H. (2013). Evolution of cancer-related symptoms over an 18-month period. *Journal of Pain and Symptom Management, 45,* 1007–1018.

U.S. Census Bureau. (2013). Table H-8. Median household income by state: 1984 to 2011. Retrieved from http://www.census.gov/hhes/www/income/data/statemedian

Vitiello, M.V., McCurry, S.M., & Rybarczyk, B.D. (2013). The future of cognitive behavioral therapy for insomnia: What important research remains to be done? *Journal of Clinical Psychology, 69,* 1013–1021. doi:10.1002/jclp.21948

Wefel, J.S., & Schagen, S.B. (2012). Chemotherapy-related cognitive dysfunction. *Current Neurological and Neuroscience Report, 12,* 267–275. doi:10.1007/s11910-012-0264-9

Yang, M., Morin, C.M., Schaefer, K., & Wallenstein, G.V. (2009). Interpreting score differences in the Insomnia Severity Index: Using health-related outcomes to define the minimally important difference. *Current Medical Research and Opinion, 25,* 2487–2494. doi:10.1185/03007990903167415.

Zigmond, A.S., & Snaith, R.P. (1983). The Hospital Anxiety and Depression Scale. *Acta Psychiatrica Scandinavica, 67,* 361–370. doi:10.1111/j.1600-0447.1983.tb09716.x

Zucca, A.C., Boyes, A.W., Linden, W., & Girgis, A. (2012). All's well that ends well? Quality of life and physical symptom clusters in long-term cancer survivors across cancer types. *Journal of Pain and Symptom Management, 43,* 720–731.