ONLINE EXCLUSIVE

Randomized Trial of a Cognitive-Behavioral Intervention for Insomnia in Breast Cancer Survivors

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Purpose/Objectives: To determine the efficacy of a cognitive-behavioral intervention for treating insomnia in breast cancer survivors.

Design: Randomized controlled trial.

Setting: University and medical center settings.

Sample: 72 women at least three months after primary treatment for breast cancer with sleep-onset or sleep maintenance insomnia at least three nights per week for at least three months as determined through daily sleep diaries.

Methods: Random assignment to a multicomponent intervention (stimulus control instructions, sleep restriction, and sleep education and hygiene) or a single-component control group (sleep education and hygiene).

Main Research Variables: Sleep-onset latency, wake after sleep onset, total sleep time, time in bed, sleep efficiency, and sleep quality.

Findings: After the intervention, both groups improved on sleep-onset latency, wake after sleep onset, total sleep time, time in bed, sleep efficiency, and sleep quality based on daily sleep diaries. A between-group difference existed for time in bed. Wrist actigraph data showed significant pre- to postintervention changes for sleep-onset latency, wake after sleep onset, total sleep time, and time in bed. When compared to the control group, the multicomponent intervention group rated overall sleep as more improved.

Conclusions: A nonpharmacologic intervention is effective in the treatment of insomnia in breast cancer survivors.

Implications for Nursing: Breast cancer survivors can benefit from a cognitive-behavioral intervention for chronic insomnia. Sleep education and hygiene, a less complex treatment than a multicomponent intervention, also is effective in treating insomnia.

Key Points . . .

➤ Insomnia is a common problem in women with breast cancer and often is treated with medication.

➤ Although cognitive-behavioral treatment for insomnia demonstrates efficacy in the general population, the use of these treatments for insomnia in patients with cancer is limited.

➤ A short-term, cognitive-behavioral intervention is useful for treating insomnia in breast cancer survivors.

Insomnia is a common sleep disorder in the general population and in patients with cancer (Ohayon, 2002; Yellen & Dyonzak, 1996). Women are predisposed to develop insomnia (Zhang & Wing, 2006), and survivors of breast cancer may be particularly vulnerable to sleep difficulty such as trouble falling asleep or staying asleep. Women with breast cancer have almost twice the prevalence rate of insomnia compared to the general population (Savard, Simard, Blanchet, Ivers, & Morin, 2001). Sleep difficulty is associated with depressive symptoms, medical conditions, decreased quality of life, increased healthcare use, and greater work absenteeism

(Foley, Ancoli-Israel, Britz, & Walsh, 2004; Hatoum, Kong, Kania, Wong, & Mendelson, 1998; Leger, Masseul, Metlaine, & SISPHYE Study Group, 2006).

Nonpharmacologic interventions are effective in managing chronic, primary insomnia (not related to a medical or psychiatric condition) in healthy adults in the general population (Morin, Culbert, & Schwartz, 1994), but more intervention studies are needed to address comorbid insomnia in clinical populations (Morin et al., 2006; National Institutes of Health, 2005) and specifically in patients with cancer. Comorbid insomnia is defined as a symptom or consequence of a preexisting primary medical or psychiatric disorder (Stepanski & Rybarczyk, 2006). The purpose of the present study was to determine the efficacy of a cognitive-behavioral intervention in treating chronic insomnia in breast cancer survivors. Insomnia was defined as difficulty initiating or maintaining sleep.

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Literature Review

Women with breast cancer report sleep difficulty in the pretreatment (Ancoli-Israel et al., 2005), treatment (Sitzia & Huggins, 1998), and post-treatment periods (Northouse et al., 1999). Fatigue is strongly associated with sleep difficulty in breast cancer survivors (Bower et al., 2000) and may play a role in the development of chronic insomnia. Less daytime activity, more daytime napping, and more nighttime awakenings during chemotherapy for breast cancer were associated with higher levels of fatigue and suggest that women may develop a sedentary lifestyle in response to chemotherapy (Berger & Farr, 1999). Healthcare providers' well-meaning recommendations to rest may not only promote fatigue (Corcoran, 1991; Winningham, 1992) but may lay the foundation for the development of a conditioned, persistent insomnia problem. Individuals with insomnia, including those with cancer, often engage in behaviors to manage their sleep difficulty such as resting, napping, going to bed earlier or sleeping later, reading, and watching television (Morin, 1993; Nail, Jones, Greene, Schipper, & Jensen, 1991). Coping behaviors, particularly those that include time spent awake in bed and an irregular sleep-wake schedule, contribute to the development of chronic insomnia for individuals with sleep difficulty (Morin; Spielman & Glovinsky, 1991).

Insomnia in patients with cancer commonly is treated pharmacologically (Savard et al., 2001). The advent of the benzodiazepine receptor agonists and, more recently, a melatonin agonist may offer some flexibility in pharmacologic treatment. However, evidence about long-term use is limited (Krystal et al., 2003; Roth, Walsh, Krystal, Wessel, & Roehrs, 2005). Nonpharmacologic treatments show reliable and durable sleep improvement (Irwin, Cole, & Nicassio, 2006; Morin et al., 1994) and no current evidence of adverse effects from their use (National Institutes of Health, 2005); in addition, individuals with insomnia find those treatments more acceptable and suitable than pharmacologic treatment (Morin, Gaulier, Barry, & Kowatch, 1992).

The literature on nonpharmacologic treatments for comorbid insomnia, including cognitive-behavioral interventions, is limited; in fact, only nine treatment studies were found that addressed patients with cancer. Earlier studies using relaxation found a self-reported decrease in sleep-onset latency (Cannici, Malcolm, & Peek, 1983; Stam & Bultz, 1986). Studies by Berger et al. (2002, 2003) were focused on intervention feasibility factors and did not specify sleep inclusion criteria. Nonrandomized and randomized studies demonstrated significant improvements in outcomes based on the sleep diaries (Davidson, Waisberg, Brundage, & MacLean, 2001; Quesnel, Savard, Simard, Ivers, & Morin, 2003; Savard, Simard, Ivers, & Morin, 2005; Shapiro, Bootzin, Figueredo, Lopez, & Schwartz, 2003), global self-report of sleep (Simeit, Deck, & Conta-Marx, 2004), and polysomnography results (Quesnel et al.; Savard et al., 2005). The treatments in the studies included stimulus control instructions, sleep restriction therapy, cognitive therapy, relaxation, sleep hygiene, and mindfulness-based stress reduction. Although the studies span more than 20 years and vary along several methodologic dimensions, preliminary progress in the nonpharmacologic treatment of insomnia in patients with cancer is evident. The present study addressed some of the conceptual and methodologic limitations of previous studies through the use of a theory-based intervention, treatment manual, randomized design with a comparison group, power analysis, and subjective and objective measures of sleep.

Theoretical Basis of the Intervention

For the present study, the development and maintenance of chronic insomnia are explained within a behavioral framework consisting of predisposing characteristics, precipitating circumstances, and perpetuating factors (Spielman, Saskin, & Thorpy, 1987). Certain predisposing conditions or traits such as arousability, a familial or genetic tendency, and gender may play a role in increasing vulnerability to insomnia (Morin, 1993). Precipitating circumstances such as illness, personal loss, and other stressful life events commonly surround the onset of sleep difficulty. Perpetuating factors such as ineffective strategies to obtain sleep, poor sleep habits, and dysfunctional cognitions maintain insomnia and develop through behavioral conditioning. The perpetuating factors become the target of intervention as the individual with insomnia is taught to reassociate the bed and bedroom with cues for sleepiness, restrict the amount of time spent awake in bed, and establish good sleep practices. The focus on perpetuating factors facilitates the consolidation of sleep and an improvement in insomnia.

Methods

Sample

Women, 18 years of age or older, with a diagnosis of stage I, II, or III breast cancer who completed primary cancer treatment (surgery, chemotherapy, radiation therapy) at least three months before entry into the study and did not have evidence of active disease were included in the present study. Screening eligibility criteria included an insomnia complaint (difficulty falling and/or staying asleep) of at least three months' duration and self-report that insomnia affected daytime functioning. Two consecutive weeks of pretreatment daily sleep diaries were used to establish the sleep eligibility criteria of sleep-onset latency and/or time awake after sleep onset totaling 30 minutes or more for a minimum of three nights per week for two weeks. Exclusion criteria included cognitive impairment as ascertained by the Mini-Mental State Examination (i.e., a score < 27) (Folstein, Folstein, & McHugh, 1975) and suspicion of sleep apnea, restless legs syndrome, or periodic limb movement disorder as determined through the participant interview and a telephone interview with a significant other, if available. Individuals with psychopathology evidenced by a Brief Symptom Inventory global severity index T score greater than 70 (Derogatis & Melisaratos, 1983) were excluded. The inclusion and exclusion sleep criteria were derived from the *Diagnostic and Statistical Manual of Mental Disorders* (American Psychiatric Association, 2000), the *International Classification of Sleep Disorders* (American Sleep Disorders Association, 1997) criteria for disorders relating to initiating and maintaining sleep (psychophysiologic insomnia), and the insomnia intervention research literature's inclusion and exclusion criteria. Primary and comorbid insomnia were determined by identifying the onset of the insomnia and its relationship to the cancer diagnosis, treatment, and post-treatment periods and the woman's perception of whether the insomnia was caused or exacerbated by cancer. Women who

were taking stable dosages of medication for sleep but met the sleep eligibility criteria were not excluded.

Results from previous meta-analyses of the nonpharmacologic treatment of insomnia provided the effect sizes on which to base the power analysis (Morin et al., 1994; Murtagh & Greenwood, 1995). Based on 32 experimental and 32 control cases, with an effect size of 0.70, the power to detect a difference between groups for sleep-onset latency was 0.78 and for wake after sleep onset, with an effect size of 0.65, power was 0.72 (Cohen, 1988).

Design

The data collected in the present study comprised the treatment efficacy component of a pilot test to examine the feasibility of a cognitive-behavioral intervention for breast cancer survivors. The women were assigned using a random numbers table to a multicomponent intervention group (stimulus control, sleep restriction therapy, and sleep education and hygiene) or a component control group (sleep education and hygiene). A randomized controlled trial was used to test the following hypotheses: (a) The multicomponent intervention group would have significantly more improvement after treatment on sleep outcomes (as measured by daily sleep diaries and wrist actigraphy) than the control group, and (b) the multicomponent intervention group would have significantly better subjective evaluation of sleep improvement after treatment than the control group.

Intervention

Stimulus control instructions developed by Bootzin (1972) targeted the perpetuating factors of insomnia. Participants were taught to reassociate the bed and bedroom with rapidly falling asleep or back to sleep through the acquisition of a consistent sleep-wake pattern, strengthening the bed and bedroom as cues for sleep, and weakening them as cues for activities that interfere with sleep (Bootzin, Engle-Friedman, & Hazelwood, 1983). The instructions were designed to shape the development of new permanent sleep habits (Bootzin, Epstein, & Wood, 1991). Details are available in Bootzin and Epstein (2000).

The sleep restriction therapy developed by Spielman et al. (1987) also targeted perpetuating factors. The therapy is based on the observation that people with insomnia spend too much time in bed attempting to sleep (Dement, Miles, & Carskadon, 1982). The aims of sleep restriction therapy are the consolidation of sleep and the limitation of sleep to a specific time by restricting the amount of time spent in bed. An individualized sleep-wake schedule was prescribed that limited participants' amount of time in bed to the estimated mean nightly time spent asleep as determined from a two-week pretreatment daily sleep diary. A wake time, which was adhered to throughout treatment, was agreed on by the therapist and the participant. A bedtime was established that gave the participant an amount of time in bed equivalent to the mean total sleep time before treatment plus about 30 minutes. Each week, the bedtime was made earlier by 15–30 minutes or stayed the same. Participants were never prescribed fewer than five hours of time in bed. Further details and discussion are provided in Epstein and Bootzin (2002) and Wohlgemuth and Edinger (2000).

Sleep education and hygiene are components of the multicomponent intervention and comprised the entire content of

the control treatment. Sleep education provided basic knowledge about sleep processes and functions, sleep architecture, developmental changes in sleep, circadian rhythms, individual sleep needs, sleep deprivation, and supportive information (Bootzin, Epstein, Engle-Friedman, & Salvio, 1996). Sleep education corrected some dysfunctional sleep-related beliefs that may contribute to sleep difficulty. Sleep hygiene consisted of a set of recommendations to improve sleep (e.g., put the bedroom clock where it cannot be seen; avoid coffee, nicotine, and alcohol) (Hauri, 1991). Details of sleep hygiene are provided in Reidel (2000), and a handout can be found in Epstein and Bootzin (2002). The sleep education and hygiene content for the control group provided general information that could benefit participants but was not designed to target the factors that perpetuate their insomnia.

Procedure

Approval for the study was received from the institutional review boards of the two participating sites. Women were recruited from newspaper advertisements and cancer support groups. The potential participants received study information over the phone, answered questions to determine initial eligibility, and were scheduled for a group baseline meeting at the university or medical center classrooms where consent was obtained and a questionnaire packet was completed. The women completed daily sleep diaries every morning and wore a wrist actigraph each night during the two-week pretreatment period. Women who demonstrated the sleep eligibility criteria were randomly assigned to the multicomponent intervention group or control group. The therapist was a master's-level clinical nurse specialist in psychiatric-mental health nursing. She was trained in the delivery of the intervention as part of another study and had four years of experience in delivering the intervention in another study.

The women in both treatment conditions attended four weekly treatment groups at the university or medical center classrooms followed by two weekly individual telephone sessions. The format allowed for learning and discussion as a group and decreased travel time and the length of the sessions. Both treatment groups consisted of four to eight women, were of similar frequency and duration, and followed a treatment manual developed by the first author based on a number of sources (Bootzin & Epstein, 2000; Bootzin et al., 1996; Edinger, 2002; Espie, 2001; Friedman, Bliwise, Yesavage, & Salom, 1991; Glovinsky & Spielman, 1991; Lacks, 1987). The bulk of the treatment was received in the first group session over a two-hour period. In sessions 2–6, the multicomponent intervention group reviewed stimulus control instructions and developed the weekly sleep restriction prescription. The control group reviewed sleep education and focused on the sleep hygiene principles that had been identified in the first session as most troublesome. Both groups focused on reviewing the daily sleep diaries from the previous week, discussing progress to date, shaping awareness of changes in sleep, identifying problems with adherence, troubleshooting, and devising strategies to enhance treatment adherence. Bar graphs of the baseline week and subsequent weeks' daily sleep diary variables were used as teaching tools in sessions 2–4. Group sessions 2–4 lasted about an hour, and the telephone sessions (5 and 6) were 15–30 minutes in length. During the two-week post-treatment phase, all participants wore the wrist actigraph each night, completed the daily sleep diaries each morning, and completed a questionnaire packet similar to

the pretreatment instruments. All meetings and sessions were conducted from 10 am to 3 pm on weekdays.

Measures

Daily sleep: The daily sleep diary, a self-administered record of sleep behaviors, was the self-report measure of sleep. Diaries are a reliable insomnia measure (Coates et al., 1982) and provide a report of sleep from the patient's perspective in the environment in which sleep occurs.

Participants completed the diary on awakening and called the responses to a voice mail service each morning to decrease the possibility of retrospective estimates of sleep. Daily calculations by the research staff during the baseline, treatment, and post-treatment phases included sleep-onset latency (the amount of time to fall asleep), wake after sleep onset (the amount of time spent awake during the night), total sleep time (the amount of time spent asleep during the night), time in bed (the amount of time spent in bed during the night), sleep efficiency (the amount of time in bed that is spent asleep, total sleep time divided by time in bed multiplied by 100), and sleep quality (a Likert-type rating question). Weekly means from before and after treatment were used in the data analysis.

Actigraphy: A wrist actigraph provided the objective measure of sleep for the study during the pretreatment and post-treatment phases. The Actiwatch® AW-64 (Mini Mitter) is a lightweight portable device about the size of a sports watch (1.1 x 1.0 x 0.35 inches) that detects movement and immobility. An interface reader provides a two-way link between the actigraph and a computer for loading the programming and sampling instructions and downloading data. The data were analyzed with Actiware® Sleep software version 3.4 (Mini Mitter).

Actigraphy is a reliable and valid measure to detect sleep in healthy adults (Littner et al., 2003) and has been validated among people with insomnia, including comorbid insomnia (Lichstein et al., 2006). In terms of the sensitivity and specificity of the measure, actigraphy is more likely to detect sleep than wakefulness (Ancoli-Israel et al., 2003). Actigraphy is useful as an outcome measure in patients with medical conditions (Littner et al.) and has been used in studies of clinical populations, including those with cancer (e.g., Berger et al. [2002, 2003]; Miaskowski & Lee [1999]).

The actigraph was worn on the nondominant wrist during nighttime sleep. The women pressed an event-marker button on the watch to indicate when they turned off the lights, intending to go to sleep, and their final awakening in the morning. A low-sensitivity threshold and an epoch length of 0.5 minutes were used in the study for sampling sleep data. The Actiware-Sleep scoring algorithm (Mini Mitter Company, 2003) scores the epochs as either sleep or wake from the time the person turns off the lights intending to go to sleep until the time of the final awakening. An epoch is scored as wake or sleep by comparing activity counts for the epoch and those immediately surrounding it to the threshold sensitivity value. An epoch is scored as wake if the number of counts surpasses the threshold sensitivity. When activity counts fall below or are equal to the threshold sensitivity, the epoch is scored as sleep. The actigraph sleep variables of sleep-onset latency, wake after sleep onset, time in bed, total sleep time, and sleep efficiency were collected and weekly means from pre- and post-treatment points were used in the data analysis.

Sleep evaluation: Four items were used after treatment to evaluate the women's perception of their improvement in sleep over the course of treatment. The items measured improvement in sleep-onset latency, wake after sleep onset, total sleep time, and quality of sleep. Cronbach's alpha for the four items was 0.79.

Statistical Analysis

One-way analysis of variance (ANOVA), Pearson chi-square, Fisher's exact test, and independent t test were used to examine between-group differences at baseline. The efficacy of cognitive-behavioral intervention was tested using repeated measures ANOVA with between- and within-subject factors. Paired or independent t tests were used to examine significant interaction and main effects. Based on the exploratory nature
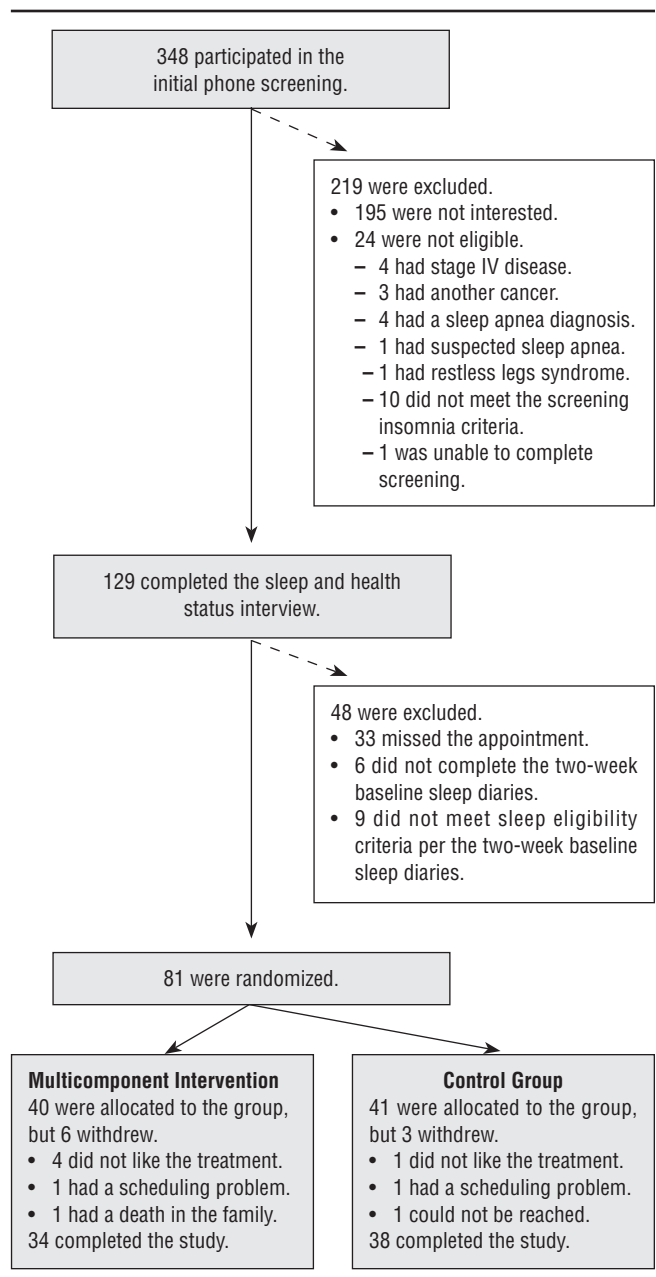

Figure 1. Participant Flow Through the Study

of the study, significant findings ($p \leq 0.05$) and trends toward significance ($p \leq 0.10$) were reported for the sleep outcomes. Independent t tests were used to examine the difference between the groups' evaluation of their sleep after treatment. The data were analyzed with SPSS® version 14.0 (SPSS Inc.). Pre- to post-treatment change in sleep also was examined through percentage improvement rates that were determined by the difference between the post-treatment and pretreatment means divided by the pretreatment mean. Effect sizes were determined by subtracting the mean of the control group from the mean of the multicomponent intervention group and dividing by the pooled standard deviation of the groups. Based on effect sizes reported in behavioral research, an effect size of 0.2 is considered small, 0.5 is medium, and 0.8 is large (Cohen, 1988).

Results

Participant Characteristics

Figure 1 describes the flow of the participants through the study phases. A total of 81 participants were randomly assigned: 40 to the multicomponent intervention group and 41 to the control group. Seventy-two women (89%) completed treatment. No significant differences were found between groups for pretreatment characteristics (see Table 1). At the pretreatment period, women who did and did not take sleeping medications did not differ significantly on daily sleep diary and actigraphy variables.

Self-Report and Objective Sleep Outcomes

The means, standard deviations, percentage rates of improvement, and effect sizes for sleep outcomes are included in Table 2 as are the main effects for time because they comprised the majority of the significant effects. For the sleep diary data, significant time effects were found for sleep-onset latency, wake after sleep onset, total sleep time, time in bed, sleep efficiency, and sleep quality, indicating that both groups improved after treatment. Significant interaction effects were found for time in bed (F[1, 70] = 10.62, p = 0.002) and sleep efficiency (F[1, 70] = 10.64, p = 0.002). After treatment, the multicomponent intervention group spent significantly less time in bed than the control group (t[70] = –2.75, p = 0.008). The post-hoc analysis revealed a trend toward a significant between-group difference for sleep efficiency (t[70] = 1.74, p = 0.08). For the actigraphy outcomes, complete pre- and post-treatment data were available for 31 multicomponent intervention and 30 control participants. Missing actigraph data were related to technical difficulties and subjects who sometimes forgot to wear the actigraph. Significant time effects emerged for sleep-onset latency, wake after sleep onset, total sleep time, and time in bed. No interaction effects were found. For percentage improvement calculations, the multicomponent intervention group had greater percentage improvement in sleep diary and actigraphy outcomes from pre- to post-treatment points compared to the control group except for actigraph-measured sleep-onset latency and total sleep time. The effect sizes obtained were in the small to medium range.

Sleep Evaluation

Means and standard deviations for the four sleep-specific evaluation questions are presented in Table 3. The multicomponent intervention group's post-treatment rating of sleep

Table 1. Sample Demographic and Clinical Characteristics

Characteristic	Multicomponent Intervention (N = 34)			Control Group (N = 38)		
	$\overline{X}$	SD	Range	$\overline{X}$	SD	Range
Age (years)	57.1	9.8	29–74	59.1	10.60	30–86
Education (years)	15.7	3.0	9–24	15.2	2.50	12–20
Years since cancer diagnosis	7.1	7.0	< 1–31	5.3	4.80	< 1–18
Years insomnia experienced	5.8	7.3	< 1–30	4.6	6.07	< 1–30
Characteristic	**n**			**n**		
Marital status						
Single	2			4		
Married	24			25		
Widowed	3			3		
Separated	2			–		
Divorced	2			6		
Significant other	1			–		
Ethnicity						
Native American	1			–		
Black, not Hispanic	1			1		
White	32			37		
Stage at cancer diagnosis[a]						
I	19			17		
II	9			12		
III	4			5		
Primary insomnia	16			11		
Comorbid insomnia	18			27		
Insomnia problem						
Sleep onset	21			21		
Sleep maintenance	31			29		
Mixed	18			13		
Used sleep medication before treatment	13			23		

[a] Although the disease did not spread for six participants, stage was unknown.

improvement over the course of treatment was significantly greater than the control group's for time to fall asleep (t[67] = 2.40, p = 0.02), amount of time spent awake during the night (t[66] = 2.77, p = 0.01), total sleep time (t[67] = 3.48, p = 0.001), and overall sleep quality (t[68] = 3.60, p = 0.001).

Discussion

The cognitive-behavioral intervention and sleep education and hygiene treatment were effective in treating insomnia in breast cancer survivors. The sleep diary results indicated that the multicomponent intervention group spent less time in bed than the control group after treatment, which may reflect the effect of sleep restriction therapy that was received only by the multicomponent intervention group. Sleep restriction therapy focuses on reducing the amount of time spent in bed. The between-group differences for sleep outcomes measured by actigraphy were not significant but were in the expected direction.

The multicomponent intervention and control groups had significant changes after treatment on all sleep diary variables

Table 2. Efficacy of Cognitive-Behavioral Treatment: Daily Sleep Diaries and Actigraphy

Sleep Measure	Multicomponent Intervention			Control Group			Time Effect[a]		Effect Size
	X̄	SD	Improvement (%)	X̄	SD	Improvement (%)	F	p	
Sleep-onset latency (minutes)									
• Daily sleep diaries									
– Pretreatment time point	51.6	55.30		49.0	42.70				
– Post-treatment time point	21.1	17.00	59	27.6	25.30	44	34.61	0.000	0.3
• Actigraphy									
– Pretreatment time point	17.4	12.40		28.2	35.50				
– Post-treatment time point	13.4	10.40	23	19.9	19.90	29	5.28	0.025	0.4
Wake after sleep onset (minutes)									
• Daily sleep diaries									
– Pretreatment time point	57.9	30.60		54.3	34.30				
– Post-treatment time point	28.5	22.45	51	32.6	31.41	40	63.12	0.000	0.2
• Actigraphy									
– Pretreatment time point	33.9	15.60		36.0	24.50				
– Post-treatment time point	28.3	11.80	16	31.1	16.20	14	5.01	0.029	0.2
Total sleep time (minutes)									
• Daily sleep diaries									
– Pretreatment time point	362.8	55.50		373.3	70.30				
– Post-treatment time point	396.0	44.20	9	405.1	52.70	9	46.08	0.000	0.2
• Actigraphy									
– Pretreatment time point	434.7	78.50		426.5	73.00				
– Post-treatment time point	407.0	49.70	7	400.7	54.80	6	5.75	0.02	0.1
Time in bed (minutes)									
• Daily sleep diaries									
– Pretreatment time point	529.6	60.30		519.3	84.20				
– Post-treatment time point	468.8[b]	34.00[b]	11	501.2	62.80	4	36.53	0.000	0.6
• Actigraphy									
– Pretreatment time point	497.9	83.40		495.1	58.40				
– Post-treatment time point	457.6	46.90	8	465.0	51.80	6	11.10	0.001	0.2
Sleep efficiency (%)									
• Daily sleep diaries									
– Pretreatment time point	69.0	10.70		72.2	9.90				
– Post-treatment time point	84.5	7.90	22	81.2	7.70	13	156.69	0.000	0.4
• Actigraphy									
– Pretreatment time point	87.3	5.10		85.5	8.30				
– Post-treatment time point	88.9	4.50	2	86.2	8.10	1	2.33	0.132	0.4
Sleep quality[c]									
• Daily sleep diaries									
– Pretreatment time point	2.6	0.40		2.8	0.50				
– Post-treatment time point	2.8	0.60		3.1	0.50		13.37	0.000	0.4

[a] Daily sleep diaries df = 1, 70; actigraphy df = 1, 59

[b] Significant difference between groups (p = 0.008)

[c] 1 = very restless to 5 = very sound

Note. Thirty-four patients in the multicomponent intervention and 38 patients in the control group completed the daily sleep diaries, whereas 31 in the multicomponent intervention and 30 in the control group completed the actigraphy.

and all actigraphy outcomes except sleep efficiency. Studies of nonpharmacologic treatment of insomnia in patients with cancer have found similar within-group changes on sleep diary outcomes (Cannici et al., 1983; Davidson et al., 2001; Quesnel et al., 2003; Savard et al., 2005; Shapiro et al., 2003). Two feasibility studies used actigraphy but showed no changes in sleep outcomes; perhaps that was a result of a lack of sleep disturbance inclusion criteria (Berger et al., 2002, 2003). The current study's actigraphy outcomes are difficult to compare with other insomnia intervention studies that used the measure. In the comorbid insomnia treatment literature, researchers do not consistently report significant therapeutic gains on actigraphy measures (Currie, Clark, Hodgins, & El-Guebaly, 2004; Currie, Wilson, Pontefract, & deLaplante, 2000; Edinger, Wohlgemuth, Krystal, & Rice, 2005; Rybarczyk, Lopez, Benson, Alsten, & Stepanski, 2002). A recent actigraphy validation study points to a lack of standardization of actigraphy variables, such as wrist placement, activity counts, and sensitivity thresholds, and the use of different algorithms to analyze actigraphy data in insomnia research (Lichstein et al., 2006). Actigraphy appears to underestimate sleep-onset latency and overestimate sleep (Lichstein et al.; Vallieres & Morin, 2003). In the present study, similar discrepancies were apparent between the daily sleep diary and actigraphy

outcomes. Although actigraphy may be a poor measure of sleep in patients with comorbid medical illnesses (Rybarczyk et al.), recent research has found actigraphy to be a satisfactory objective measure in a sample including comorbid insomnia (Lichstein et al.). Actigraphy has clinical utility for assessing insomnia (Vallieres & Morin) and is recommended as a supplement to self-report measures of sleep (Buysse, Ancoli-Israel, Edinger, Lichstein, & Morin, 2006).

High within-group variability existed for diary and actigraphy sleep-onset latency and wake after sleep onset in the control group at the post-test period. It may have reduced the statistical power to find significant between-group differences and may imply that some women benefited more from sleep education and hygiene than others. The high variability in the control group may stem from the construction of the sleep education and hygiene intervention. The goal of using the component control was to include a credible treatment with minimal efficacy (i.e., sleep education and hygiene) (Morin et al., 1994) and nonspecific treatment factors (i.e., elements common to psychotherapy such as therapist contact, treatment frequency, and treatment duration). The sleep education and hygiene treatment may contain recommendations that overlap with the active treatment components (i.e., stimulus control instructions and sleep restriction therapy). The control group was told to establish a regular time to wake up, which is part of the stimulus control instructions. The bar graphs used in the four treatment classes may have demonstrated pictorially to the control participants that they were spending too much time in bed; however, the recommendation to decrease the time in bed, a focus of sleep restriction therapy, was not specifically taught in the control group. The recommendation to set aside some time to wind down (e.g., do something relaxing, make a worry list) before bedtime may have helped to decrease cognitive arousal prior to attempting to sleep. Whether the aspects of the sleep education component that address dysfunctional sleep-related beliefs are responsible for improvement in the control group are difficult to determine because cognitive therapy has never been tested as a single-component intervention for insomnia (Belanger, Savard, & Morin, 2006). Although overlap may exist among sleep education and hygiene treatment, stimulus control instructions, and sleep restriction therapy, a review of sleep hygiene shows that the previously mentioned recommendations, used in the control intervention, all have been included in sleep hygiene treatment in previous intervention studies (Stepanski & Wyatt, 2003), with the exception of the bar graphs. Clearly, careful consideration of the elements included in sleep education and hygiene component control groups is warranted to ensure the exclusion of possible active treatment factors. The role of expectancy (i.e., anticipation that the sleep education and hygiene treatment would be effective) must be considered as contributing to the control group's improvement. The strong camaraderie among the breast cancer survivors, noted in open-ended evaluation questions and anecdotally reported by the research staff and nurse therapist, also may play a role in the change in the control group. Participant follow-up is needed to determine whether sleep education and hygiene are durable treatments that provide the skills necessary to maintain treatment effects in breast cancer survivors.

The percentage of change in daily sleep diary–reported sleep-onset latency and wake after sleep onset for the multicomponent intervention group was higher than that reported for treatment groups in a meta-analysis of nonpharmacologic treatment of primary insomnia (Morin et al., 1994). For the control group, the change was approximately the same as the meta-analysis findings. The effect sizes were small and lower than those reported in the meta-analysis. A medium effect size existed for daily sleep diary–reported time in bed, but this variable was not included in the meta-analysis.

The multicomponent intervention group rated its sleep as significantly more improved than the control group after treatment. The four sleep items provided a more global evaluation of sleep than the discrete outcomes obtained from the daily sleep diaries, which were asked repeatedly over time. The sleep evaluation items, asked after treatment in this study, are referred to as retrospective or transition questions and often ask about the individual perception of the magnitude of change (Fischer et al., 1999). Retrospective estimates of change have been found to be larger than serial measures of change (Aseltine, Carlson, Fowler, & Barry, 1995). The difference in the measures may be that serial items, such as the daily sleep diary questions, focus on the variable at a precise point in time whereas transition questions reflect a broad experience of change over time and therefore are more clinically meaningful to patients (Fischer et al.). The findings point to the need to include both types of measures in the evaluation of sleep outcomes.

In addition to some of the design issues already discussed, the current study has several other limitations. The women were primarily white and well educated and, on average, were diagnosed with cancer six years previously. They were recruited through advertisements and cancer support groups and therefore were motivated to receive treatment. Those factors reflect a selective sample that may limit the generalizability of the findings. Despite the limitations, the findings are promising and have implications for further research. Future directions for the research program will focus on the inclusion of a third treatment condition that incorporates the delivery of sleep education and hygiene in a booklet form, follow-up measurement to ascertain the maintenance of treatment gain, and the identification and measurement of potential mechanisms of change.

Nursing Implications

The significant changes in sleep are encouraging and have clinical implications, if they can be replicated. The multicomponent intervention is more complex than the control

Table 3. Evaluation of Sleep Improvement After Treatment

Variable	Multicomponent Intervention (N = 34)		Control Group (N = 38)	
	X̄	SD	X̄	SD
Time it takes to fall asleep	5.0	1.9	3.9	1.9
Amount of time spent awake during the night	5.8	1.3	4.8	1.6
Total sleep time	5.8	1.3	4.7	1.4
Quality of sleep	5.7	1.2	4.5	1.5

Note. 1 = not at all improved to 7 = very much improved

treatment and requires training and a specialized skill set. The content of the control treatment (i.e., sleep education and hygiene) may be more amenable to delivery by nurses in the clinical setting who are uniquely positioned to affect the sleep of patients with cancer by assessing sleep-wake patterns and intervening early to prevent the onset of sleep difficulty and the development of persistent insomnia.

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