

Feasibility of a Sleep Intervention During Adjuvant Breast Cancer Chemotherapy

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Purpose/Objectives: To evaluate the feasibility of an intervention designed to promote sleep and modify fatigue during four cycles of adjuvant breast cancer chemotherapy.

Design: Prospective, repeated measures, quasi-experimental feasibility study.

Setting: Midwestern urban oncology clinics.

Sample: 25 women between the ages of 40–65 (\bar{X} = 54.3) with stage I–II breast cancer receiving doxorubicin-based chemotherapy.

Methods: Each woman developed, reinforced, and revised an individualized sleep promotion plan (ISPP) with four components: sleep hygiene, relaxation therapy, stimulus control, and sleep restriction techniques. A daily diary, the Pittsburgh Sleep Quality Index, a wrist actigraph, and the Piper Fatigue Scale were used to collect data two days before and seven days after each treatment.

Main Research Variables: Adherence, sleep and wake outcomes, and fatigue.

Findings: Adherence rates with the components of the ISPP varied during treatments one through four: sleep hygiene (68%–78%), relaxation therapy (57%–67%), stimulus control (46%–67%), and sleep restriction (76%–80%). Mean sleep and wake outcomes at baseline, peak, and rebound times were that (a) sleep latency remained brief (less than 30 minutes per night), (b) time awake after sleep onset exceeded the desired less than 30 minutes per night, (c) sleep efficiency scores remained stable at 85%–90%, (d) total rest time remained stable at 8–10 hours per night, (e) subjective ratings of feelings on arising were stable, and (f) nighttime awakenings were 8–10 per night. Fatigue outcomes were that fatigue was stable two days after each treatment and mean daily fatigue intensity was lower at treatment three than at treatment one but rebounded at treatment four.

Conclusions: The intervention was feasible, adherence rates improved over time, and most sleep and wake patterns were consistent with normal values. Revisions will focus on decreasing nighttime awakenings.

Implications for Nursing: Adopting behaviors to promote sleep may assist in maintaining sleep and managing fatigue during chemotherapy.

Key Points . . .

- Recruiting and retaining subjects for a sleep intervention study is feasible.
- Adherence to the intervention is promoted by reinforcement one week after each revision.
- The number and length of nighttime awakenings are above normal during four cycles of chemotherapy.
- Diaries and actigraphs yield different data.

unsatisfactory sleep (Berger & Walker, 2001; Longman, Braden, & Mishel, 1996; Winningham et al., 1994).

In the general population, persistent insomnia is associated with a higher risk of clinical anxiety or depression (Ford & Kamerow, 1989). Studies have shown that unsatisfactory sleep adversely affects daytime performance (Morin, 1993) and contributes to decreasing functional status (Winningham, 1992). Researchers have proposed that sleep disturbances affect fatigue, pain, wound healing, immune function, and mental health in patients with cancer (Lee, 2001).

Despite associations reported between fatigue and insomnia, little is known about their relationship in patients with cancer. Early work by Derogatis et al. (1979) established that during a six-month study period, 44% of 1,500 patients with cancer used prescription drugs to help them sleep. Beszterczey and Lipowski (1977) and Kaye, Kaye, and Madow (1983) substantiated that patients with cancer have more difficulty falling asleep and staying asleep when compared to the general population. Neither one of these studies examined fatigue.

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Digital Object Identifier: 10.1188/02.ONF.1431-1441

Fatigue is the most frequent and distressing side effect reported by patients receiving chemotherapy (Portenoy & Itri, 1999; Richardson, 1995). It presents not only as a primary side effect, but also as a secondary side effect accompanying other effects such as insomnia or the perception of

More recently, Sarna (1993) documented that 31% of patients with lung cancer with fatigue experienced insomnia. Owen, Parker, and McGuire (1999) found that problems falling and staying asleep were accompanied by not feeling rested the next day. Using the basic model of wrist actigraph (Ambulatory Monitoring, Inc., Ardsley, NY), Berger and Farr (1999) and Berger and Higginbotham (2000) documented a relationship between higher numbers of nighttime awakenings and higher daytime fatigue levels at cycle midpoints and at later times following adjuvant breast cancer chemotherapy treatments. Studies are needed to increase the understanding of the linkage between fatigue and insomnia and to test interventions aimed at decreasing fatigue and promoting sleep in patients with cancer.

Since 1985, psychological and behavioral factors increasingly have been recognized as playing an important role in insomnia. The American Academy of Sleep Medicine coordinates the delivery of treatment to people with insomnia. More than a dozen nonpharmacologic interventions have been developed; about half of these have received adequate empirical evaluation of their clinical efficacy. Sleep hygiene counseling, relaxation therapy, sleep restriction, and stimulus control interventions have been shown to produce reliable and durable improvements in sleep patterns in 60%–80% of patients with primary and chronic insomnia (Morin, Culbert, & Schwartz, 1994). Used alone or together, these treatments seek to modify maladaptive sleep habits, reduce arousal from autonomic and cognitive stimuli, and educate about healthy sleep practices. These techniques have helped a majority of people with a long history of poor sleep (Hauri, 1993; Morin, 1993) but have not been tested in patients with cancer (Savard & Morin, 2001).

The overall purpose of this study was to evaluate the feasibility of an intervention designed to promote sleep and modify fatigue in women during (phase I) and after (phase II) doxorubicin-based chemotherapy treatments. Phase II (30, 60, and 90 days after the last treatment and one year after the first treatment) results will be reported in a separate article (Berger et al., in press). The specific aims of phase I (during four cycles of chemotherapy) were to

- Evaluate the feasibility of a four-component intervention consisting of sleep hygiene counseling, relaxation therapy, sleep restriction, and a stimulus control intervention called the individual sleep promotion plan (ISPP).
- Determine patterns of adherence to the four components of the ISPP.
- Examine patterns of sleep and wake variables (e.g., sleep quality, sleep latency, wake after sleep onset [WASO], sleep efficiency, total rest, feelings on arising, nighttime awakenings, daytime naps) and fatigue (daily and peak) in women receiving an ISPP.

Conceptual Framework

Piper's Integrated Fatigue Model® (IFM) identifies 14 factors proposed to influence fatigue in patients with cancer (Piper, Lindsey, & Dodd, 1987). Interventions focused on activity and rest and psychological patterns have been found to decrease fatigue in these patients (Mock et al., 1994, 1997). In descriptive studies, patterns of symptoms, sleeping and waking, and activity and rest have been shown to influence fatigue (Berger & Farr, 1999; Berger & Walker, 2001); how-

ever, interventions have not been evaluated. Selected factors from the IFM guided this intervention that was designed to modify fatigue by promoting healthy sleep and wake patterns in patients during and after cancer chemotherapy.

Literature Review

Sleep Disturbances

Problems sleeping have been reported in patients with cancer during all phases of care (Savard & Morin, 2001). Nocturnal disturbances have a negative effect on sleep quality of hospitalized patients with cancer (Sheely, 1996). Insomnia is one of the most distressing symptoms to patients receiving chemotherapy (Irvine, Vincent, Graydon, Bubela, & Thompson, 1994). Women with breast cancer consistently report difficulty sleeping during the first few months after diagnosis while undergoing treatment (Knobf, 1990; McCorkle & Quint-Benoliel, 1983). Path analyses indicate that symptom distress (e.g., problems with sleeping, nausea, mood) offered the strongest direct explanation for fatigue experienced by women receiving chemotherapy (Berger & Walker, 2001). Higher fatigue is accompanied by lower activity levels, more time spent napping, and increased nighttime restlessness in women receiving chemotherapy (Berger & Higginbotham, 2000). In Piper's (1992) study, the majority of women reported that they were sleeping and napping more by the third treatment of adjuvant breast cancer chemotherapy. Fatigue, aches, pains, and sleep problems persisted after treatment in 294 long-term cancer survivors, 43% of whom had breast cancer (Dow, Ferrell, Leigh, Ly, & Gulasekaram, 1996). Thus, sleep and wake patterns were selected for study as factors influencing fatigue.

Despite the prevalence of sleep disturbances in patients with cancer, no intervention studies to test methods to relieve this troublesome symptom are found in the literature (Ream & Richardson, 1999). Interventions for fatigue have focused on activity without regard for sleep or therapeutic use of rest and naps (Lee, 2001). Interventions to promote quality sleep in patients with cancer are needed. To examine the outcomes of sleep studies in the future, Lee (1997) recommended that sleep researchers collect data that address age, nutritional status, activity level, medications, and the presence of personal and environmental factors, as well as usual bedtime, wake-up time, and bedtime rituals.

The research base is sparse for the use of sleep promotion interventions with clinical populations other than those with chronic insomnia (Floyd, 1999). A meta-analysis of nonpharmacologic interventions indicated that patients with insomnia were better able to initiate sleep after treatment than 81% of untreated control subjects, and 74% were better able to maintain sleep. Stimulus control and sleep restriction are the most effective single therapy components (Morin et al., 1994). Sleep hygiene and relaxation techniques produce desired effects when used with other techniques. Clinical results seen at treatment completion were well maintained for an average of six months, indicating that nonpharmacologic interventions produce reliable and durable changes in the sleep patterns of patients with chronic insomnia (Morin, Colecchi, Stone, Sood, & Brink, 1999). Results from a secondary meta-analysis concur; psychological treatments produce considerable enhancement of sleep patterns and perceptions of sleep quality that are superior to placebo therapies (Murtagh & Greenwood, 1995). The behavioral interventions undergoing evaluation in this

study also have been shown to be highly effective in other populations (e.g., elderly patients, patients with pain), further supporting their selection for this study (Currie, Wilson, Pontefract, & deLaplante, 2000).

Fatigue

Researchers agree that cancer-related fatigue is a multifaceted, subjectively measured phenomenon that fluctuates, but no physiologic measurement that quantifies fatigue has been accepted. Likewise, no single definition of fatigue is widely accepted within nursing science (Tiesinga, Dassen, & Halfens, 1996); the definition used in this study is “a subjective feeling of tiredness that is influenced by circadian rhythm and can vary in unpleasantness, duration, and intensity” (Piper et al., 1987, p. 19).

Fatigue may become chronic and have negative effects (Irvine, Vincent, Bubela, Thompson, & Graydon, 1991). For example, long-term cancer survivors describe their fatigue in relation to decreases in energy, changes in sleep patterns, and decreases in overall functioning (Ferrell, Grant, Dean, Funk, & Ly, 1996). After chemotherapy, heightened fatigue is related to poor sleep quality, more menopausal symptoms, greater use of a catastrophizing coping strategy, and the presence of a psychiatric disorder (Broeckel, Jacobsen, Horton, Balducci, & Lyman, 1998). Intervening during the acute phases of fatigue and insomnia may prevent these chronic effects.

Self-care activities that change activity and rest patterns as well as sleep and wake patterns commonly are adopted by patients but have not often been found to relieve fatigue. Strategies include sleeping or taking naps, resting, or canceling activities (Dodd, 1988); resting or reducing the level of activity (Graydon, Bubela, Irvine, & Vincent, 1995); and going to bed early and sleeping most of the day (Richardson & Ream, 1997). Activities that have been shown to relieve fatigue in patients with cancer include aerobic exercise (MacVicar, Winningham, & Nickel, 1989), self-directed walking combined with a support group (Mock et al., 1994, 1997), and relaxation training and imagery (Decker, Cline-Elsen, & Gallagher, 1992). Interventions designed to modify fatigue by promoting sleep during chemotherapy need to be tested.

Adherence to Medical Advice

The extent to which people’s behavior (e.g., taking medications, following diets, making lifestyle changes) coincides with medical or health advice is termed adherence (Haynes, Taylor, & Sackett, 1979). Several reasons exist for nonadherence: (a) patients experience side effects, (b) they may be unwilling to change their behavior, (c) they may not understand instructions given to them, (d) they may lack family support, or (e) they may change their minds regarding participation (Dunbar-Jacob et al., 2000). When studies involve participants who are living at home, the chances for nonadherence increase. Interventions requiring changes in a habit are particularly susceptible to this hazard (Friedman, Furberg, & DeMets, 1998).

Approximately 50% of patients with a chronic condition have problems following their prescribed regimen (Dunbar-Jacob et al., 2000). Adherence to clinical trials can be enhanced by a more thorough delivery of the intervention (Becker, 1990). Use of nurses to improve adherence by contracting with participants has been shown to be effective. Contracts give participants the opportunity to be involved in decision making, provide them with opportunities to dis-

cuss problems and solutions, and encourage a commitment to the program (Friedman et al., 1998).

In summary, studies conducted on people with insomnia that include behavioral techniques such as sleep hygiene counseling, relaxation therapy, sleep restriction, and stimulus control interventions have been shown to produce reliable and lasting improvements in sleep patterns in the majority of patients. Sleep difficulties have been found to accompany cancer-related fatigue. The feasibility study reported here was designed to deliver the intervention in a manner that promoted adherence and gave women the opportunity to be involved and discuss sleep problems and solutions.

Methods

Design, Sample, and Setting

Three oncology clinics were used in this study. This feasibility study employed a prospective, repeated measures, quasi-experimental design. Eligibility criteria included women who were (a) aged 40–65, (b) diagnosed for the first time with stage I or II breast cancer, (c) treated with modified radical mastectomy or lumpectomy, (d) scheduled to receive doxorubicin-based IV chemotherapy, and (e) English-speaking and able to complete the research tools. The women also had to score greater than 60 on the Karnofsky Performance Scale. Age was restricted because of the natural changes in sleep patterns that occur around age 40 and the possibility that women older than 65 may have fatigue associated with various comorbid diseases that could threaten the validity of the results. Exclusion criteria included comorbidities known to be associated with fatigue: diagnosis of chronic insomnia, congestive heart failure, chronic obstructive pulmonary disease, insulin-dependent diabetes, neuromuscular disease, current steroid therapy, or jobs with rotating or permanent shifts that result in sleep at times other than at night.

Experimental Variables

The independent variable was the sleep intervention. Dependent variables were sleep and wake patterns as well as fatigue patterns. The specific aims of phase I of this study pertain to the times during four cycles of chemotherapy. For the first specific aim (i.e., evaluate the feasibility of a four-component sleep intervention), the variables of interest were willingness to participate in the study and to develop and revise an ISPP. For the second specific aim (i.e., determine patterns of adherence to the ISPP), the variable of interest was the mean adherence rate with each component of the ISPP at each cycle. For the third specific aim (i.e., examine the patterns of sleep and wake variables and fatigue in women in the study), the outcome variables were patterns of sleeping and waking (e.g., sleep latency, WASO, sleep efficiency, total rest, feelings on arising, nighttime awakenings, daytime naps) and fatigue (daily and peak).

Data Collection Schedule and Procedures

Following institutional review board approval, the names of women who had undergone surgery for breast cancer and who were scheduled to begin chemotherapy were obtained from clinic coordinators. A research assistant who was trained by the principal investigator to ensure standardization of delivery of the intervention helped with subject recruitment, intervention delivery, and data entry. Team meetings were held

every other week to review enrollment and schedules and reinforce standardization and revision of the intervention. All eligible women were contacted by phone and invited to participate. Those who agreed to participate made plans to meet the researcher at their homes, doctors' offices, or mutually convenient places, preferably before the first treatment.

Before providing written consent, all women were given an explanation of the study purposes, a description of the instruments and the actigraph, and a review of the data completion schedule. Each instrument packet included an instruction sheet with clear explanations of the instruments and reminders to complete the forms at uninterrupted times on the scheduled days. Plans were made to meet again one week after chemotherapy treatment to return the instruments and reinforce the intervention.

Intervention

Table 1 outlines the intervention schedule. Initial delivery of the sleep intervention generally was scheduled to occur two days before chemotherapy. Because the first visit took one and a half to two hours, delivering the four-component intervention before chemotherapy sometimes was not possible. Researchers, therefore, met with 10 of the women on the first available day during the first week after chemotherapy.

At baseline, the women completed the **Brief Sleep History** (Libbus, Baker, Osgood, Phillips, & Valentine, 1995) to determine sleep patterns before the diagnosis of cancer and the **Pittsburgh Sleep Quality Index (PSQI)** to determine sleep quality and patterns during the past month (Buysse et al., 1989). The researcher reviewed responses to these questionnaires to identify specific areas of sleep difficulty. The women also completed the **Sleep Hygiene Awareness and Practice Scale (SHAPS)** (Lacks & Rotert,

1986) to determine their knowledge and current use of sleep hygiene techniques.

The ISPP was developed and tailored to each woman's specific needs and included four components: (a) sleep hygiene counseling, (b) relaxation therapy, (c) sleep restriction, and (d) stimulus control. Guidelines for pharmacologic management of symptoms during chemotherapy were reviewed. The coscientist model was used when selecting personalized interventions (Hauri, 1993, 1998). This model encourages people with insomnia to become their own sleep scientists by experimenting with various sleep-promoting behaviors in these four components.

Sleep hygiene counseling: This component teaches individuals a variety of health practices and environmental factors that may be of help or hindrance to sleep. Practices that may promote sleep might include reducing sympathetic nervous system stimulation or promoting an environment conducive to sleep by avoiding caffeine, seeking social support, and keeping the bedroom cool, quiet, and relaxing (Richards, 1996). Performing regular activity, a factor from the IFM, may promote sleep and reduce fatigue. Baseline sleep hygiene and caffeine knowledge scores were calculated and discussed, and current sleep hygiene practices were reviewed. The women selected three or four sleep hygiene behaviors they currently were not using from a list derived from a literature review. These behaviors were discussed, and the items were recorded on the ISPP.

Relaxation therapy: This component encompasses strategies such as relaxation exercises or guided imagery aimed at decreasing stress and improving control of the situation in stressed patients with emotional and cognitive arousal (Bootzin & Perlis, 1992; Hu & Silberfarb, 1991). The women served as coscientists by selecting one relaxation therapy technique to use each evening, such as taking a warm bath or shower,

Table 1. Schedule for a Sleep Intervention During Adjuvant Breast Cancer Chemotherapy

Intervention	Treatment 1 Days -2 to +7	Treatment 1 Day +8	Treatment 2 Day -2	Treatment 2 Day +8	Treatment 3 Day -2	Treatment 3 Day +8	Treatment 4 Day -2	Treatment 4 Day +8
Sleep hygiene awareness and practice scale	X	-	-	-	-	-	-	-
Sleep hygiene counseling and selection	X	-	RE	-	RE	-	RE	-
Pharmacology review	X	-	R	-	R	-	R	-
Individual sleep promotion plan components								
• Sleep hygiene techniques	X	-	RE	-	RE	-	RE	-
• Relaxation therapy	X	-	RE	-	RE	-	RE	-
• Sleep restriction	X	-	RE	-	RE	-	RE	-
• Stimulus control	X	-	R	-	R	-	R	-
Continued sleep promotion plan								
• Adherence	-	R	-	R	-	R	-	R
• Problem solving	-	X	-	X	-	X	-	X

R—reinforcement; RE—revision; X—intervention

reading, listening to a relaxation audiotape (provided by the researcher), or viewing a relaxing videotape. Selections were discussed, and they were recorded on the ISPP.

Sleep restriction: To help consolidate sleep, women were instructed to limit the time spent in bed to the number of hours of sleep they normally obtained (Glovinsky & Spielman, 1991). The women could sleep one additional hour if they felt ill or unable to get up at the scheduled time. Although naps typically are not allowed during sleep restriction, up to two naps per day, each less than 60 minutes, were permitted if the women felt drowsy or fatigued following a disturbed night's sleep.

Stimulus control: This component included a set of techniques designed to help individuals establish a consistent sleep and wake pattern, establish the bed and bedroom as cues for sleep, and reduce the association with activities that might interfere with sleep. To help the women's bodies acquire a consistent sleep rhythm, participants were given the following rules (Bootzin, Engle-Friedman, & Wood, 1991).

- Select a time to lie down to sleep each night.
- Use your bed only to sleep. Do not read, watch television, or eat in bed. (Sexual activity is the only exception to this rule.)
- When you intend to go to sleep but are unable to do so within 30 minutes, get up and go into another room. Stay up as long as you wish, and then return to the bedroom to sleep. Watching the clock is not recommended. However, if you are in bed for more than 10 minutes without falling asleep, get up and try again later. The goal is to associate your bed with falling asleep quickly.
- Get up and try again as many times as needed if you remain awake for more than 10 minutes after returning to bed. Once your mind has accepted the association of the bedroom with sleep, repeats will be less necessary.
- Select a time to set your alarm, and get up each day regardless of the amount of sleep you got during the night.

Pharmacology: Recognizing that management of symptoms, a factor from the IFM, influences fatigue, participants were instructed to take medications prescribed for symptom relief and coached to continue to pursue symptom relief until satisfactory results were obtained. The intervention did not attempt to evaluate the effectiveness of sleep medications, but, if used, they were recorded in the daily diary.

Adherence: Adherence was documented for each night during the two baseline days and the first seven days after each chemotherapy treatment. Women completed the ISPP each morning by making a checkmark for items or techniques that were used and placing an "X" next to items that were not used. They left the box blank if the item was "not applicable" the previous night. Adherence was determined by counting the number of times each item was used and dividing by the number of nights at each treatment for a percent adherence rate for each item. When several items were combined to make up one of the four components of the intervention, individual item scores were combined to form a component score in each area at each treatment.

Reinforcements occurred within one week after the ISPP was developed and then one week after the second, third, and fourth chemotherapy treatments. The researcher and the women discussed any difficulties with adherence and problem solved together for about 15–30 minutes to improve adherence. Women were taught to follow the ISPP during the rest of the treatment cycle but were not expected to record adherence.

Revisions were made to the ISPP two days before the second, third, and fourth treatments. The researcher and the women worked each time for about 30 minutes to revise the ISPP. Participants could select the same sleep hygiene or relaxation techniques or make substitutions from the list. Times on the sleep restriction and stimulus control items were kept the same or moved forward or backward by one half-hour.

Measurement of Variables

Attempts were made to minimize participant burden and select measures that had established reliability and validity. Women completed all instruments except the daily diary by circling the number that best answered the questions. The timetable for data collection is shown in Table 2.

Sleep and wake patterns: These patterns were measured with the PSQI, a daily diary, and wrist actigraphs. The PSQI was completed at baseline to measure subjective sleep quality during the previous month (Buysse et al., 1989) and is a subjective, self-rated, paper-and-pencil questionnaire that takes about 10 minutes to complete. Responses to its 19 items are grouped into seven components measuring sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, sleeping medication use, and daytime dysfunction. These components are weighted equally on a 0–3 scale, with a global PSQI score ranging from 0–21. Higher scores indicate more severe complaints and a greater decrease in sleep quality. Cronbach's alpha reliability for the global PSQI was 0.80, and internal consistency reliability and construct validity were demonstrated in women with breast cancer (Carpenter & Andrykowski, 1998). Alpha reliability was 0.77 in this study. A global PSQI score above five has been found to have a sensitivity of 89.6% and specificity of 86.5% in differentiating good from poor sleepers (Buysse et al.). A more appropriate cutoff score of eight was found to indicate poor sleep quality in a variety of clinical populations, so a score of eight was used in this study (Carpenter & Andrykowski).

The **daily diary** was based on Morin's (1993) Sleep Diary. In addition to information about sleep, a record of nausea medications and a single item rating (0–10) of fatigue intensity were added to the diary. The Morin Sleep Diary has been used to examine information on sleep and wake pattern variables related to falling asleep, staying asleep, and total rest (see Table 3). The percentage agreement between the subjective data recorded in sleep diaries and polysomnographic data are acceptable ($\kappa = 0.87$); sensitivity and specificity are also high (92.3% and 95.6%, respectively) (Rogers, Caruso, & Aldrich, 1993). The diary about the previous night's sleep took five minutes to complete each morning. Antinausea or sleeping medications were recorded when they were taken.

Wrist actigraphs enable the continuous monitoring of body movement over time (Brown, Smolensky, D'Alonzo, & Redman, 1990). Wrist actigraphy measures of rest and activity cycles have been developed and validated. Actigraphy offers a useful, noninvasive method of objectively quantifying actual movement and is an important index of sleep, rest, and activity in field studies (Kripke, Mullaney, Messin, & Wyborne, 1978; Redmond & Hegge, 1985). Actigraphy has been used to objectively examine variables concerning the pattern of sleeping and waking in the home and found to be a valuable and valid addition to diary information (Hauri &

Table 2. Data Collection Timetable

Variable	Measurement	Treatment 1 Days -2 to +7	Treatment 2 Days -2 to +7	Treatment 3 Days -2 to +7	Treatment 4 Days -2 to +7
Sleep and wake patterns	Pittsburgh Sleep Quality Index	-2	-	-	-
	Daily diary	-2 to +7	-2 to +7	-2 to +7	-2 to +7
	Wrist actigraph	-2 to +7	-2 to +7	-2 to +7	-2 to +7
Fatigue	Piper Fatigue Scale	3	3	3	3
	Fatigue intensity	-2 to +7	-2 to +7	-2 to +7	-2 to +7

Wisbey, 1992, 1994; Jean-Louis et al., 1997). The actigraph device was worn continuously for nine days on the non-dominant wrist by the women to quantify sleep and wake variables for the two days prior and the seven days after each of the four chemotherapy treatments. Calibrations of the actigraph with polysomnography were reported to be within plus or minus 10% (Brown et al.). Women were instructed to avoid getting the device wet and to push a small marker on the side of the actigraph when turning out the light to go to sleep and arising out of bed in the morning. These markers and the daily diary were used to discriminate day from nighttime when performing the data analyses.

Fatigue: The total **Piper Fatigue Scale (PFS)** (Piper et al., 1998) and a single **fatigue intensity item** (item 7 from the PFS) were used to measure subjective fatigue. The PFS contains 22 items that measure four dimensions of subjective fatigue: behavioral severity (six items), sensory (five items), cognitive/mood (six items), and affective/meaning (five items). Each item is anchored by two words (e.g., strong or weak), and participants circle the number from 0–10 that best

describes the current fatigue experience. Total and subscale mean scores were obtained by summing the individual items of each subscale or total score and dividing by the number of items in the subscale or total score. Five open-ended questions regarding the temporal dimension of fatigue, perceived cause, effect, and additional symptoms complete the PFS. Internal consistency reliability of the scale and four subscales range from alphas of 0.92–0.98 across numerous and diverse studies (Piper et al., 1998) and were 0.94–0.98 in this study. Content and concurrent validity have been estimated in patients with cancer. The PFS takes two to five minutes to complete, and this study's participants completed it at baseline and on day three (i.e., time of peak fatigue) after each treatment.

The fatigue intensity (FI) item—"How would you describe the degree of intensity of the fatigue you are experiencing today?" (0–10)—was added to the daily diary to measure mid-day fatigue intensity. Berger (1996) found the FI item to be correlated with the total score on the PFS ($PFS = 0.86-0.95$, $p < 0.001$). Patients took less than one minute to circle the number from 0–10 that reflected midday (i.e., 2–6 pm) fatigue intensity each day.

Table 3. Definitions of Sleep and Wake Pattern Variables

Variable	Definition
Sleep quality	Subjective assessment of sleep quality over the past month that includes sleep quality, latency, duration, efficiency, disturbances, sleep medication use, and daytime dysfunction
Sleep latency	Number of minutes needed to fall asleep each night
Time awake after sleep onset	Number of minutes awake at night after initially falling asleep
Sleep efficiency	Percent of time in bed spent asleep
Total bed	Number of minutes in bed at night
Total sleep	Number of minutes in bed at night spent asleep
Total rest	Total bed plus daytime naps minus sleep latency and time awake after sleep onset (minutes)
Daytime naps	Number of minutes spent resting during the day
Nighttime awakenings	Number of awakenings per night
Feelings on arising	Subjects' responses to the question: "When I got up this morning, I felt ____." (1 = exhausted to 5 = refreshed)

Data Analysis and Interpretation

Patterns of adherence to the four components of the ISPP were assessed by determining the rate of adherence with each component of the ISPP during four cycles of chemotherapy. Patterns of sleeping and waking (e.g., sleep quality, sleep latency, WASO, sleep efficiency, total rest, feelings on arising, nighttime awakenings, daytime naps) and fatigue (daily and peak) were analyzed by closely examining the descriptive statistics (i.e., frequencies, means, standard deviations, and ranges) at baseline, the peak, and the rebound phases of each treatment. These values then were examined for patterns over time using repeated measures analysis of variance (RM-ANOVA). The EPI-Info, Action3 (Ambulatory Monitoring), and SPSS® (SPSS Inc., Chicago, IL) statistical analysis programs were used for data management.

Results

Sample

Twenty-eight Caucasian women were contacted over a period of six months, and 25 (89%) agreed to participate. No minority women met eligibility criteria during that time. A control group was not used because this was a feasibility study and data were available from preliminary work that described the variables when no intervention was used. The sample description can be found in Table 4. Women were divided between stage I and II disease; most were married, employed full- or part-time, postmenopausal, and high school graduates.

Feasibility

Recruitment procedures were refined from those successfully used in previous studies conducted by the principal investigator. Twenty-five of the 28 women who initially were contacted enrolled in the study. Two women withdrew after the first treatment, and a third woman was dropped from the study when her chemotherapy was stopped after the third treatment. Barriers identified during the study included making contact and scheduling timely appointments with the women, varying levels of interest in participating as coscientists in the ISPP development, variable levels of flexibility in adopting the ISPP behaviors, and incomplete diary and actigraph data.

Adherence

Adherence rates with the data collection procedures and each component of the ISPP varied during four cycles of chemotherapy. One woman did not complete the daily diary in a usable fashion despite efforts to clarify instructions at reinforcement and revision times. Another woman did not wear the actigraph at night after her initial attempts to adapt to it failed. Oversampling resulted in data from 20 participants on written tools. Almost all women were active coscientists in developing and revising the ISPP. Because the instruments were collected one week after each treatment, researchers could not determine whether the women filled out the diary each day or recorded

data for several days just before it was collected. Researchers found it easier to obtain reliable data from the actigraph, but the women sometimes did not wear it continuously.

Self-reported adherence rates with components of the ISPP are shown in Figures 1–4. Rates of adherence to sleep hygiene counseling consistently increased from treatment one to four (68%–78%). Adherence rates for relaxation therapy were lower than for sleep hygiene but highest at treatment four (57%–67%). Adherence rates to the stimulus control instructions were the lowest at most times (46%–67%) and also varied the most. Rates of adherence for sleep restriction techniques were the highest overall (76%–80%); however, these techniques were the only component that showed a slight downward trend over time. This decrease was related to lower adherence rates with getting up at the same time each morning (from 69%–55%) and following the guidelines for naps (range = 53%–63%). Patterns of adherence to each of the four components were analyzed using RM-ANOVA in this small sample and did not detect significant changes over time.

Sleep and Wake and Fatigue Patterns

Baseline sleep quality as measured by the PSQI revealed a mean score of 8.8 (SD = 4.6). Thirteen of the 25 women's scores were greater than eight, indicating that they had experienced poor sleep during the past month.

Means and standard deviations of sleep and wake variables obtained by daily diary and wrist actigraph were determined at baseline, peak, and rebound times at each of the four treatments. For analysis, baseline included the two days before, peak included days one through four after, and rebound included days five through seven after treatment. Because these values were not statistically significant over time, results obtained at treatment three were selected to represent typical values and are shown in Table 5.

Data from the daily diary revealed that mean sleep latency times were consistently within the desired range of less than 30 minutes per night. WASO scores showed a wide range of variability and consistently were longer than the desired 30 minutes per night. Sleep efficiency rates were at or above the

Table 4. Demographic Characteristics of the Sample at Study Entry

Characteristic	n	%
Age (years)		
\bar{X} = 54.3	–	–
Range = 40–65	–	–
SD = 6.8	–	–
Ethnicity		
Caucasian	25	100
Marital status		
Married	21	84
Nonmarried	4	16
Employment		
Full-time	12	48
Part-time	3	12
Not employed	10	40
Education		
High school graduate	17	68
College graduate	7	28
No response	1	4
Stage of breast cancer		
I	11	44
II	14	56
Lymph node status		
Positive	14	56
Negative	10	40
None found	1	4
Surgical procedure		
Breast conservation	11	44
Modified radical mastectomy	7	28
Modified radical mastectomy with reconstruction	7	28
Menopausal status		
Still menstruating (regular or irregular)	6	24
Last cycle more than 12 months ago	19	76

N = 25

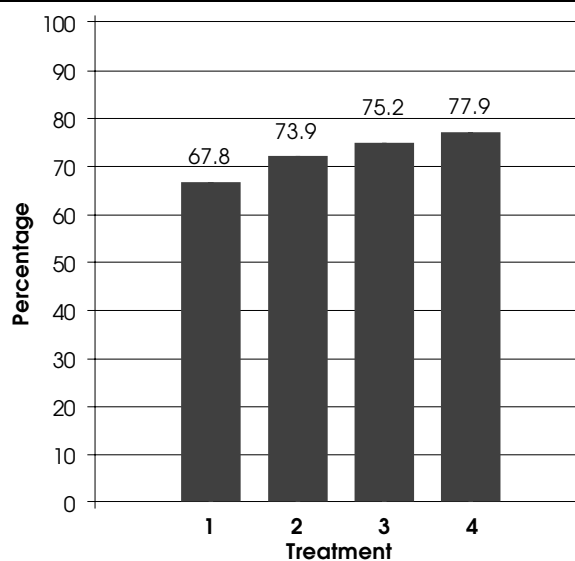


Figure 1. Adherence With Sleep Hygiene Counseling During the First Week After Each Treatment

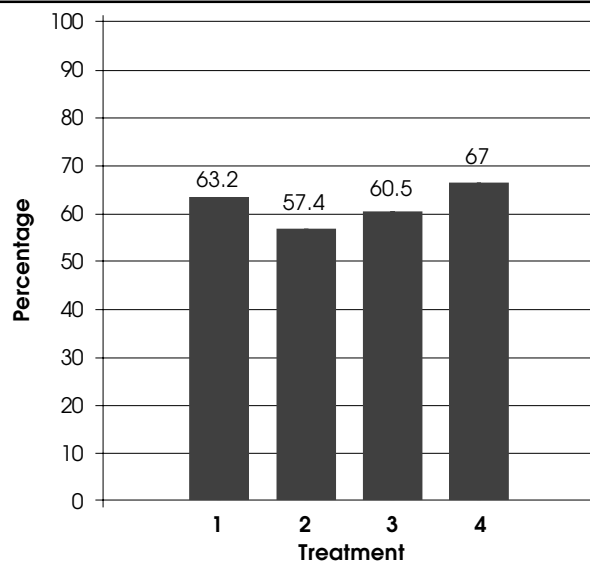


Figure 2. Adherence With Relaxation Therapy During the First Week After Each Treatment

desired 85%, and total rest values were within or close to the upper limit of the desired range of 360–510 minutes per night or six to eight and a half hours. Mean scores for waking up feeling refreshed were at a moderate level and remained stable.

Data from the wrist actigraph revealed that mean sleep latency times were consistently less than 10 minutes per night. WASO scores were consistently more than reported on the diary and ranged from 60–80 minutes per night. Sleep efficiency rates varied greatly, but means were at or above the desired 85% at each time. Total rest scores were consistently longer than those reported on the diary; mean values were approximately 10 hours or 600 minutes per 24 hours at the peak phase and nine hours or 540 minutes per 24 hours during the rebound period. Actigraphic recordings of mean number of nighttime awakenings over time revealed nonsignificant small decreases at peak and rebound times. Women

napped for about 60 minutes at every baseline and for more than 120 minutes at every peak and each rebound after treatments two, three, and four.

RM-ANOVA of all variables revealed no statistically significant changes over time in this small sample. Effect sizes (ES) were estimated to provide information about the strength and integrity of the intervention. Lipsey (1990) recommended that, to detect a small treatment effect, the research study be designed to have adequate power (i.e., $ES = 0.15$). Using actigraph data from this sample, baseline ES for all variables (except daytime naps) ranged from 0.1–0.2. At peak times, only total rest ES was 0.1 or greater. At rebound times, ES for sleep efficiency, total rest, and daytime naps was 0.1 or greater. Total rest had the most consistent ES (range = 0.1–0.15).

Mean daily fatigue intensity scores showed a clinically meaningful but statistically nonsignificant decrease at peak times from treatments one through three (5.7–4.7). Scores rebounded upward to 5.6 at treatment four, as shown in Table 6. Baseline and rebound scores remained stable over time, fluctuating in a narrow range. Peak fatigue scores, obtained 48 hours after each treatment using the PFS, were not significantly different over time in these women, ranging from 5.3–5.9 (0–10).

Discussion

Piper's IFM informed the study design by identifying symptom, sleep and wake, and activity and rest patterns as factors influencing fatigue. Results of the current study are consistent with previous findings (Berger, 1998; Berger & Farr, 1999; Berger & Higginbotham, 2000) that the frequency and duration of nighttime awakenings are above normal limits in women undergoing chemotherapy, further refining the components of sleep and wake pattern disruption.

Findings demonstrate that researchers can feasibly recruit and retain women in a sleep intervention study who are beginning adjuvant breast cancer chemotherapy. Women in this study generally were willing to act as coscientists in developing and revising an ISPP during four cycles of treatment. Higher percentage rates of adherence were found in this

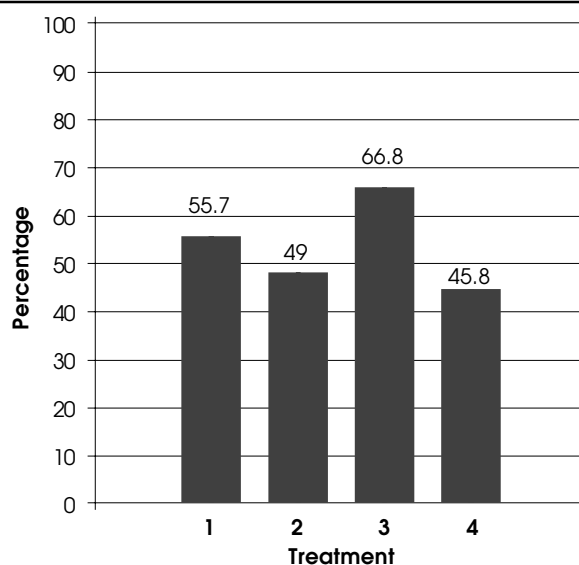


Figure 3. Adherence With Stimulus Control Instructions During the First Week After Each Treatment

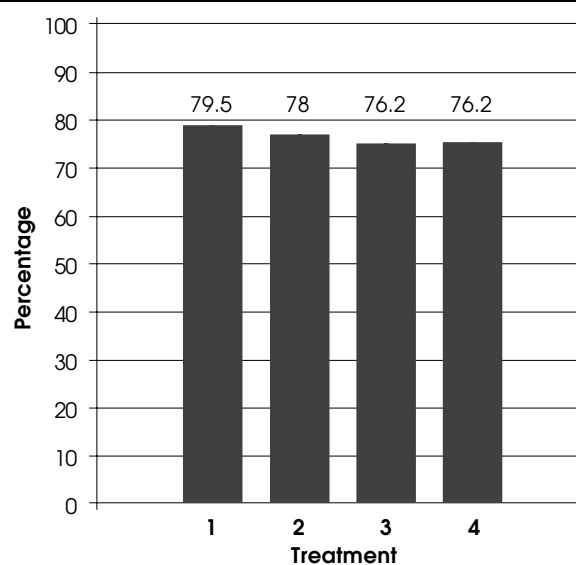


Figure 4. Adherence With Sleep Restriction Techniques During the First Week After Each Treatment

Table 5. Means and Standard Deviations for Sleep and Wake Variables From Diary and Actigraph During Chemotherapy Treatment Three^a

Variable	Baseline ^b				Peak ^c				Rebound ^d			
	Diary		Actigraph		Diary		Actigraph		Diary		Actigraph	
	\bar{X}	SD	\bar{X}	SD	\bar{X}	SD	\bar{X}	SD	\bar{X}	SD	\bar{X}	SD
Sleep latency (minutes)	24.1	47.5	9.8	16.2	25.3	39.2	5.9	6.0	28.3	37.6	5.6	6.7
Wake after sleep onset (minutes)	35.9	39.5	71.0	49.2	53.6	3.8	75.6	54.3	49.0	54.5	66.0	52.1
Sleep efficiency (%)	90.0	47–99	86.0	40–98	85.0	59–99	86.0	57–97	86.0	46–97	87.0	49–97
Total rest (minutes)	516.4	145.5	493.7	79.6	510.3	129.8	587.8	100.4	494.2	122.5	534.5	126.9
Night awakenings (number)	2.0	1.2	9.8	6.3	2.6	0.9	10.7	6.6	2.3	1.2	8.3	6.3
Daytime naps (minutes)	17.1	28.5	66.9	53.2	34.5	26.7	135.8	74.0	17.6	20.6	107.9	91.5
Feelings on arising ^e	3.3	1.1	–	–	3.1	1.1	–	–	3.3	0.9	–	–

^aDoxorubicin-based chemotherapy given every 21 days for four cycles to treat stage I or II breast cancer; ^bBaseline = two days prior to treatment three; ^cPeak = days one through four after treatment three; ^dRebound = days five through seven after treatment three; ^eFeelings on arising (1 = exhausted to 5 = refreshed)

study using the coscientist model than typically have been reported when examining compliance with other components of the medical regimen such as diet or exercise.

Limitations of the study were missing data, recruitment, and the timing of behavioral changes. Determining exact bedtime or wake-up times sometimes was not possible when the diary and actigraph data were missing or did not match. Recruitment of women prior to the first treatment was challenging, and time restrictions delayed the delivery of the intervention in 10 cases to the first week after treatment. Anecdotally, some women spoke about having difficulty trying to change their sleep patterns while they were undergoing chemotherapy, whereas others were more passive and had lower adherence to their plans.

Approximately half of all medically ill patients are estimated to have problems adhering to the medical regimen to the extent that optimal clinical benefits are not obtained (Dunbar-Jacob et al., 2000). Adherence rates in this study may have been higher than in previous studies because of the time and attention given by an RN in a relaxed setting or because

of more thorough delivery of the intervention (Becker, 1990). The most commonly reported reason for poor adherence is forgetting and conflicts with the usual routine (Dunbar-Jacob et al.). During reinforcement sessions in this study, women talked about forgetting to include the selected relaxation therapy technique within two hours of bedtime and not getting out of bed when they could not sleep during the winter months.

Sleep and wake patterns remained stable over time, and means were close to or within normal ranges seen in healthy individuals. During baseline, mean scores reflecting patterns of sleep latency, sleep efficiency, total rest, and feeling refreshed on arising remained stable and within normal limits. These findings reveal maintenance of the sleep and wake cycle despite the insult of chemotherapy. The mean WASO time remained longer than the desired 30 minutes per night using diary and actigraph data, with wide ranges among the women. The number of night awakenings recorded per actigraph was above the normal range of two to six times per night expected in healthy individuals (range = 8.1–9.8). On

Table 6. Means and Standard Deviations for Fatigue Scores During Chemotherapy Treatments^a

Fatigue	Baseline ^b		Peak ^c		Rebound ^d	
	\bar{X}	SD	\bar{X}	SD	\bar{X}	SD
Treatment 1						
Fatigue intensity ^e	2.1	2.0	5.7	2.1	4.9	2.1
Peak fatigue ^f	–	–	5.9	2.1	–	–
Treatment 2						
Fatigue intensity	3.6	2.5	5.4	2.2	5.4	2.3
Peak fatigue	–	–	5.3	2.0	–	–
Treatment 3						
Fatigue intensity	3.4	2.6	4.7	1.4	4.4	2.0
Peak fatigue	–	–	5.5	1.7	–	–
Treatment 4						
Fatigue intensity	3.2	2.6	5.6	1.9	4.7	2.5
Peak fatigue	–	–	5.7	1.5	–	–

^aDoxorubicin-based chemotherapy given every 21 days for four cycles to treat stage I or II breast cancer; ^bBaseline = two days prior to each treatment; ^cPeak = days one through four after each treatment; ^dRebound = days five through seven after each treatment; ^eFatigue intensity = mean of daily fatigue scores (item 7 on Piper Fatigue Scale (PFS)); ^fPeak fatigue total score on PFS 48 hours after treatment

average, women took a one-hour nap each day. Fatigue intensity scores hovered at the upper limit (3.2–3.6) of the desirable mild or low range of fatigue (1–3.9) on the days before the second and later treatments. This range has been shown to be bothersome but has not been found to interfere with the daily activities of most individuals (Piper, 1999).

During the peak period, mean scores of most variables remained stable and within ranges that reflect synchrony of the sleep and wake cycle. Once again, women's WASO time was prolonged beyond the desired 30 minutes per night. This is consistent with the literature that describes the trouble patients with cancer have staying asleep and waking up at night (Berger & Farr, 1999; Berger & Higginbotham, 2000; Beszterczey & Lipowski, 1977; Kaye et al., 1983). These findings indicate that the revised intervention needs to strengthen techniques that are helpful in decreasing nighttime arousal and working toward increasing adherence. Fatigue scores decreased in response to the intervention from treatments one through three but rebounded at treatment four. Possible explanations for this rebound at treatment four are the increased anxiety seen at the end of scheduled treatments or an increased depression over time.

At the rebound period after each treatment, mean scores for most variables remained stable and in the desired ranges. Women were successful in getting close to nine hours (540 minutes) of total rest per 24 hours. Total rest times were lower than at the peak, perhaps reflecting feelings of recovery from the treatment. These women did not desynchronize their sleep and wake cycles by increasing their total rest time as many patients with cancer do (Savard & Morin, 2001). Mean numbers of nighttime awakenings and the numbers of minutes WASO also were lower than at the peak time, suggesting a deeper sleep. This rebound of energy balance is supported

by women's gradually increasing ratings of feeling refreshed on arising and lower ratings of daytime fatigue than observed during the peak period. Some women in the study continued to experience excessive (greater than 30 minutes per night) amounts of time awake after sleep onset.

Implications

Implications for future research include testing the revised intervention in a larger clinical trial. Revisions will focus on promoting adherence and decreasing time awake at night. The intervention will continue to promote daytime activity, limit excess daytime napping, and encourage consistent sleep habits. The program also will include management of symptoms as well as add promotion of psychological adaptation to decrease the multiple factors that promote sleep disturbances and fatigue. Determining ES will inform the power analysis for a full-scale study. Although ES was small, this number appears to be clinically important in maintaining synchronized sleep patterns. If ES were the same or higher in a larger clinical trial, statistically significant outcomes from the intervention would be expected.

Implications for practice are limited because these are feasibility results. Women can be informed that adopting behaviors to promote sleep may assist in maintaining sleep and wake patterns and managing fatigue during chemotherapy. Not only may these techniques help women sleep, but they also may reduce fatigue and allow women to continue to meet their daily energy demands.

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