Adherence, Sleep, and Fatigue Outcomes After Adjuvant Breast Cancer Chemotherapy: Results of a Feasibility Intervention Study

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Purpose/Objectives: To evaluate outcomes of an intervention designed to promote sleep and modify fatigue after adjuvant breast cancer chemotherapy.

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

Setting: Midwestern urban oncology clinics.

Sample: 21 female participants, ages 43–66 years (X = 55.3) with stage I or II breast cancer status post four cycles of doxorubicin chemotherapy. Eight had four additional cycles of paclitaxel, 10 also had radiation, and 18 took tamoxifen.

Methods: Each woman continued to revise her Individualized Sleep Promotion Plan (ISPP), developed during her first cycle of chemotherapy, that included sleep hygiene, relaxation therapy, stimulus control, and sleep restriction components. The daily diary, Pittsburgh Sleep Quality Index, wrist actigraph, and Piper Fatigue Scale were used for seven days 30, 60, and 90 days after the last chemotherapy treatment and one year after the first chemotherapy treatment.

Main Research Variables: Adherence and sleep and wake, fatigue, and ISPP components.

Findings: Adherence to the ISPP components remained high at all times (77%–88%) except for stimulus control (36%–56%). Sleep outcomes means and the actigraph revealed that (a) sleep latency remained less than 30 minutes per night, (b) the time awake after sleep onset exceeded the desired less than 30 minutes per night, (c) sleep efficiency scores ranged from 82%–92%, (d) total rest time ranged from seven to eight hours per night, (e) feelings on arising ranged from 3.7–3.8 (on a 0–5 scale), (f) nighttime awakenings ranged from 10–11 per night, and (g) daytime naps ranged from 10–15 minutes in length. Fatigue remained low, from 2.9–3.5 on a 10–0 scale.

Conclusions: Adherence rates remained high for most components. Sleep and wake patterns were within normal limits except for the number and duration of night awakenings. Fatigue remained low.

Implications for Nursing: Future testing using an experimental design will focus on increasing ISPP adherence and decreasing nighttime awakenings. Adopting behavioral techniques to promote sleep may result in improved sleep and lower fatigue after chemotherapy.

Key Points . . .

➤ Subjects were receptive to continuing their sleep intervention after chemotherapy ended.
➤ Healthy sleep and wake cycles can be maintained after chemotherapy ends.
➤ Sleep maintenance problems persisted throughout the first year after beginning adjuvant breast cancer chemotherapy.
➤ Fatigue levels were in the desired mild range (i.e., less than four); at one-year follow-up, no one reported severe fatigue.

In the general population, persistent sleep disturbances, or insomnia, are associated with a higher risk of clinical anxiety and depression (Hajak, 2000). Studies have shown that insomnia adversely affects daytime performance (Morin, 1993), including driving safety (Dement, 1999). In patients with cancer, sleep disturbances have been linked to fatigue, pain, wound healing, immune function, and mental health (Lee, 2001) and have contributed to decreased functional status (Winningham, 1992). Despite these reported associations, little is known about these relationships in cancer survivors.

Increasing numbers of women are being treated with adjuvant chemotherapy and radiation therapy in an attempt to decrease morbidity and mortality from breast cancer (Bach, 2001). In fact, two to three million of the estimated nine million cancer survivors in the United States are women with a history of breast cancer (American Cancer Society, 2003). Fatigue is the most frequent and distressing symptom reported.
by patients who receive chemotherapy (Portenoy & Itri, 1999). As a symptom, fatigue rarely presents in isolation; more often, it accompanies other symptoms such as depression, pain, and sleep disturbances (Berger & Walker, 2001; Bower et al., 2000).

Researchers have found that breast cancer survivors not only report greater fatigue and weakness and less vitality than healthy women but also differ on subjective measures of sleep quality (Andrykowski, Curran, & Lightner, 1998; Bower et al., 2000). The study results indicated that problems existed with the initiation and maintenance of sleep, a decreased perception of adequate sleep, and greater somnolence during the day. This suggests that poor sleep could underlie cancer-related fatigue. In a study using wrist actigraphs after adjuvant breast cancer chemotherapy treatments, Berger and Farr (1999) documented a relationship between higher numbers of nighttime awakenings and higher daytime fatigue. Lee (2001) suggested that when rest or sleep is inadequate, fatigue may become chronic.

Recognition that psychological and behavioral factors play an important role in insomnia has increased since 1980 (Morin & Wooten, 1996). Many types of treatments for insomnia 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 demonstrated reliable and durable improvements in sleep patterns in 60%–80% of patients with primary and chronic insomnia (Morin, Culbert, & Schwartz, 1994). These techniques have proved helpful to the majority of patients with a chronic history of poor sleep and daytime sleepiness (Hauri, 1993; Morin, 1993); however, until recently, these methods have not been tested in patients with cancer (Savard & Morin, 2001).

Berger et al. (2002) developed an intervention using sleep hygiene counseling, relaxation therapy, sleep restriction, and stimulus control interventions to address sleep disturbances and fatigue in patients with cancer. A two-phase feasibility study was designed to improve sleep and modify fatigue in patients with cancer. The Individualized Sleep Promotion Plan (ISPP) intervention was tested during (phase I) and after (phase II) cancer treatment. Sleep and fatigue outcomes during phase I (i.e., four cycles of adjuvant chemotherapy) have been reported (Berger et al.). This article describes phase II outcomes (i.e., 30, 60, and 90 days after the last treatment and one year after the first treatment). The specific aims of phase II were to

1. Determine the willingness of participants to continue in the feasibility study after completing adjuvant chemotherapy.
2. Determine adherence rates to the four components of the ISPP intervention.
3. Examine sleep and wake patterns (i.e., sleep quality, sleep latency, wake after sleep onset [WASO], sleep efficiency, total rest, feelings on arising, nighttime awakenings, and daytime naps) and fatigue (daily and peak) in women receiving the ISPP intervention.

**Conceptual Framework**

Piper’s Integrated Fatigue Model identified 14 factors believed to influence fatigue in patients with cancer (Piper, Lindsey, & Dodd, 1987). Interventions focused on two of these factors, activity and rest and psychological patterns, have been found to decrease fatigue in patients with cancer (Mock et al., 1994, 1997). In descriptive studies, patterns of symptoms, sleep and wake cycles, and activity and rest have influenced fatigue (Berger & Farr, 1999; Berger & Walker, 2001). The current intervention was designed to modify acute and chronic insomnia and fatigue by promoting healthy sleep and wake patterns in women during and after adjuvant breast cancer chemotherapy.

**Literature Review**

**Adherence to Medical Advice**

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

Approximately 50% of patients with a chronic condition have difficulty following their prescribed regimen (Dunbar-Jacob et al., 2000). However, adherence in clinical trials can be enhanced by more thorough delivery of the intervention (Becker, 1990). Research has found that nurses can improve adherence by contracting with participants. Contracts give participants an opportunity to be involved in decision making, discuss problems and solutions, and convey an expectation of a commitment to the program (Friedman et al., 1998). By using nurses and contracts to promote adherence, self-reported component adherence rates in phase I of this study ranged from a low of 46%–67% for stimulus control to a high of 76%–80% for sleep restriction (Berger et al., 2002).

**Sleep Disturbances**

Sleeping problems have been reported in patients with cancer during all phases of care; however, clinicians have neglected these problems (Savard & Morin, 2001). This is consistent with the public’s lack of awareness of sleep disturbances and their debilitating consequences as a result of sleep alterations (Elliott, 2001). This review focuses on sleep disturbances and particularly insomnia after chemotherapy treatments.

A symptom profile of menstrual cycle changes, hot flashes, insomnia, and vaginal dryness has been described by breast cancer survivors (N = 27) who experience prematurely induced menopause as a result of adjuvant chemotherapy (Knobf, 2001). Berger and Higginbotham (2000) examined sleep and wake patterns after adjuvant breast cancer chemotherapy. Two months following chemotherapy cessation, patients with breast cancer (N = 12) experienced prolonged time awake after sleep onset (X = 73 minutes a night) and below normal sleep efficiency (82%); both correlated with higher fatigue (p < 0.009–0.05).

Despite the prevalence of sleep disturbances in patients with cancer, no intervention studies were found in the literature to relieve this troublesome symptom (Ream & Richard, 1999) until Davidson, Waisberg, Brundage, and...
MacLean (2001) reported on a six-session group program that included stimulus control therapy, relaxation training, and other strategies aimed at consolidating sleep and reducing cognitive emotional arousal. Twelve participants (mean time since diagnosis was 34 months) experienced improved sleep, reduced fatigue, and enhanced ability to perform activities.

Phase I of this study (Berger et al., 2002) evaluated the feasibility of the ISPP intervention in promoting sleep and modifying fatigue during adjuvant chemotherapy treatments. The intervention was found to be feasible, with adherence rates near 70%. Sleep and wake patterns were maintained within normal ranges except for the number and duration of nighttime awakenings.

Interventions for fatigue have focused on activity without regard for sleep or the therapeutic use of rest and naps (Lee, 2001). Interventions to promote quality sleep and modify fatigue in patients with cancer are needed. To examine the outcomes of future sleep studies, 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.

**Fatigue After Cancer Treatment**

The definition of fatigue used in this study was “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). Researchers agree that cancer-related fatigue is a multifaceted, subjective phenomenon that fluctuates (Winninngham et al., 1994). However, no physiologic measurement that quantifies fatigue has been accepted.

Fatigue may become chronic and have negative effects in cancer survivors (Irvine, Vincent, Bubela, Thompson, & Graydon, 1991). Approximately one-third of a large sample (N = 1,957) of breast cancer survivors reported more severe fatigue than the other two-thirds. This fatigue was associated with higher levels of depression, pain, and sleep disturbance (Bower et al., 2000). These findings are consistent with those of Lindley, Vasa, Sawyer, and Winer (1998) who reported that approximately 30% of patients had moderate to severe fatigue two years after breast cancer treatment ended.

Long-term cancer survivors describe their fatigue in relation to pain, decreased energy, changes in sleep patterns, and decreased overall functioning (Ferrell, Grant, Dean, Funk, & Ly 1996; Ferrell, Grant, Funk, Otis-Green, & Garcia, 1997). According to data from 294 long-term cancer survivors, of which 43% were breast cancer survivors, fatigue, aches, pains, and sleep problems persist after treatment (Dow, Ferrell, Leigh, Ly, & Gulasekaram, 1996). Heightened fatigue after chemotherapy is related to poor sleep quality, increased menopausal symptoms, greater use of a catastrophizing coping strategy, and the presence of a psychiatric disorder (Broeckel, Jacobsen, Horton, Balducci, & Lyman, 1998). However, these studies were not prospective designs; therefore, information regarding baseline data, timing, and etiologies of fatigue cannot be determined.

Interventions during the acute phases of fatigue and insomnia will yield important baseline information and may prevent chronic effects of therapy. Phase I of this study initiated the ISPP intervention during the first cycle of chemotherapy and documented significantly lower (p < 0.05) mean daily fatigue intensity scores for the first seven days after the third treatment than fatigue scores from a prior descriptive study when no intervention occurred (Berger et al., 2002; Berger & Higginbotham, 2000). Interventions designed to modify fatigue by promoting sleep during and after chemotherapy offer promise because these symptoms often occur simultaneously (Dodd, Miaskowski, & Paul, 2001).

Cancer-related fatigue remains a problem after treatment ends and is accompanied by other symptoms, including sleep disturbances. These sleep disturbances generally have been ignored in cancer survivors because interventions for fatigue after treatment primarily have focused on activity. This feasibility study was designed to deliver the sleep intervention in such a way as to promote long-term adherence and the favorable adherence and sleep and fatigue outcomes achieved during phase I of this study.

**Methods**

This study’s methods are described in detail in the article describing phase I outcomes (Berger et al., 2002). A basic review of the study methods follows.

**Design**

This feasibility study employed a prospective, repeated-measures, quasi-experimental design. No control group was used because of limited funding and the availability of data regarding these variables from studies conducted without an intervention.

**Sample and Setting**

Participants for this one-year study were recruited prior to or within one week after the women’s first adjuvant chemotherapy treatment. Eligibility criteria included women who (a) were 40–65 years of age, (b) were diagnosed for the first time with stage I or II breast cancer, (c) were treated with modified radical mastectomy or lumpectomy, (d) were scheduled to receive doxorubicin-based IV chemotherapy, (e) spoke English and were able to complete the research tools, and (f) had a Karnofsky Performance Scale score greater than 60 (Karnofsky, Abelmann, Craver, & Burchenal, 1948). Exclusion criteria included comorbidities associated with fatigue, such as chronic heart or lung disease. Three oncology clinics were used to recruit subjects.

**Data Collection Procedures During Phase I and Phase II**

Following institutional review board approval, all eligible subjects were contacted by phone and invited to participate. Before obtaining written consent, all women were given an explanation of the study purposes, a description of the instruments and wrist actigraph, and a review of the data completion schedule. Each instrument packet included an instruction sheet with clear explanations of the instruments and reminders for completing the forms. The same instruments were used to collect data on sleep, wake, and fatigue variables during phases I (during four cycles of adjuvant chemotherapy) and II of the study (30, 60, and 90 days after the last treatment and one year after the first treatment).

**Measurement of Variables**

**Adherence:** Adherence was documented each night during the seven days of data collection. Women filled in the ISPP...
each morning by making a checkmark for items from each component that were used, placing an “X” next to items that were not used, or leaving the box blank if it was “not applicable” the previous night. Adherence was determined by counting the number of times each item was used and dividing it by seven (days of data collection) to yield a percent adherence rate for each item at each time. As 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.

Sleep and wake patterns: The Pittsburgh Sleep Quality Index (PSQI), a daily diary, and wrist actigraphs were used to track sleep and wake patterns. The PSQI takes less than 10 minutes to fill out and was completed 60 days after the last treatment and again one year after the first treatment. This paper-and-pencil questionnaire measures subjective sleep quality during the previous month (Buysse et al., 1989). Responses to the 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. In women with breast cancer, Cronbach’s alpha reliability estimates for the global PSQI was 0.80 and evidence for construct validity was demonstrated (Carpenter & Andrykowski, 1998). A global PSQI score above 5 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 8 was found to indicate poor sleep quality in a variety of clinic patients (Carpenter & Andrykowski). Therefore, a score of 8 was used in this study.

The daily diary was based on Morin’s Sleep Diary (Morin, 1993). The diary about the previous night’s sleep took five minutes to complete each morning during each of the seven days of data collection. A record of nausea medications and a single item of fatigue intensity (on a 0–10 scale) were added. 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. One item asks how the subject felt on arising this morning (1 = exhausted to 5 = refreshed). The percent agreement between the subjective data recorded in sleep diaries and polysomnographic data were acceptable (kappa = 0.87); sensitivity and specificity also were high (92.3% and 95.6%, respectively) (Rogers, Caruso, & Aldrich, 1993).

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 patterns of sleeping and waking in the home and is a valuable and valid addition to diary information (Hauri & Wisbey, 1992, 1994; Jean-Louis et al., 1997). The Mini-Motionlogger® Actigraph (Ambulatory Monitoring, Inc., Ardsley, NY) was worn continuously for seven days for each data collection period on the nondominant wrist to quantify sleep and wake variables. Calibrations of the actigraph with polysomnography were within plus or minus 10% (Brown et al.). Participants were instructed to avoid getting the device wet and 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 bedtime from nighttime when performing the data analyses.

Fatigue: The total Piper Fatigue Scale (PFS) (Piper et al., 1998) and the single fatigue intensity 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 or mood (six items), and affective meaning (five items). Each item is anchored by two words (e.g., strong versus weak), and subjects circle a number from 0–10 that best describes their 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, but these results are not reported in this article. 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 0.97–0.98 in this phase of the study. Content and concurrent validity estimates have been documented in patients with cancer (Piper et al., 1998). The PFS takes two to five minutes to fill in, and the women completed it at each data collection period.

The fatigue intensity item, “How would you describe the degree of intensity of the fatigue you are experiencing today?”, was added to the daily diary to measure midday fatigue intensity each day. This item was correlated (r = 0.93–0.94, p < 0.001) with the total score on the PFS in this study and takes less than one minute to circle a number (0–10) that reflects midday (i.e., 2–6 pm) fatigue intensity each day.

Intervention During Phase I

The first visit in each patient’s home lasted 1.5–2 hours. At baseline, the women completed the Brief Sleep History (Libbus, Baker, Osgood, Phillips, & Valentine, 1995) to determine sleep patterns prior to the diagnosis of cancer and the PSQI to determine sleep quality and patterns during the prior month (Buysse et al., 1989). The researcher reviewed responses to these questionnaires to identify specific areas of sleep difficulty. Women also completed the Sleep Hygiene Awareness and Practice Scale (Lacks & Rotert, 1986) to determine their knowledge and current usage of sleep hygiene techniques.

An ISPP was developed and tailored to the women’s specific needs and included four components: (a) sleep hygiene counseling, (b) relaxation therapy, (c) sleep restriction, and (d) stimulus control. The sleep hygiene counseling component teaches a constellation of health practices and environmental factors that may be a 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). The relaxation therapy component encompasses strategies such as relaxation exercises or guided imagery aimed at decreasing
stress and improving control of the situation (Bootzin & Perlis, 1992; Hu & Silberfarb, 1991). The sleep restriction component helps to consolidate sleep by limiting the time spent in bed (Glovinsky & Spielman, 1991). The stimulus control component includes a set of techniques designed to help an individual develop a consistent sleep and wake pattern, establish the bed and bedroom as cues for sleep, and reduce the association with activities that may interfere with sleep (Bootzin, Engle-Friedman, & Wood, 1991). Guidelines for the pharmacologic management of symptoms during chemotherapy also were reviewed. The coscientist model was used when selecting personalized interventions (Hauri, 1993, 1998). This model encourages patients with insomnia to become their own sleep scientists by experimenting with various sleep-promoting behaviors in these four components. A more extensive description of the intervention can be found in Berger et al. (2002).

The researcher and the women revised the ISPP two days before the second, third, and fourth treatments; they worked each time for about 30 minutes. The ISPP intervention was revised according to the coscientist model and tailored to the women’s needs using sleep hygiene counseling, relaxation therapy, sleep restriction, and stimulus control. Participants could select the same sleep hygiene or relaxation techniques or make substitutions from the list. Times on sleep restriction and stimulus control items were kept the same or moved earlier or later by a half hour. Symptom management was reviewed, and women were urged 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.

Intervention 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 each woman 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.

Following training from the principal investigator to ensure standardization of delivery of the intervention, the research assistant helped with subject recruitment, delivery of the intervention, and data entry. Team meetings were held every other week to review enrollment and schedules and reinforce standardization and revision of the intervention.

**Intervention During Phase II**

Revisions were made to the ISPP 30, 60, and 90 days after the participants’ last treatment. The researcher and each participant discussed current fatigue levels and identified specific areas of sleep difficulty. They then reviewed current usage of the ISPP intervention techniques and worked each time for about 30 minutes to revise the ISPP for use during the next seven days and nights according to the same procedure described previously. Intervention reinforcements occurred when the instruments were picked up at the end of the seven-day data collection periods. At that time, the researcher and each woman discussed any difficulties with adherence and problem-solved together to improve adherence for about 15–30 minutes. Women were taught to follow the ISPP until the next appointment but were not expected to record adherence.

**Data Analysis**

Patterns of adherence to the four ISPP components were assessed by determining the rate of adherence with each component at selected times after chemotherapy. Patterns of sleep and wake (sleep quality, sleep latency, WASO, sleep efficiency, total rest, feelings on arising, nighttime awakenings, daytime naps) and fatigue (daily and peak) were analyzed by examining descriptive statistics (i.e., frequencies, means, standard deviations, and ranges) at each point in time. Values were examined for patterns over time using repeated measures analysis of variance (RM-ANOVA). The EPI-Info, Action3, and SPSS® (SPSS Inc., Chicago, IL) statistical analysis programs were used for data management and analysis.

### Table 1. Demographic Characteristics of the Sample at Study Entry

<table>
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<th>Characteristic</th>
<th>Treatment 1 (N = 25)</th>
<th>One Year After Treatment 1 (N = 21)</th>
</tr>
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<td>Age (years)</td>
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</tr>
<tr>
<td>Range</td>
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<tr>
<td>X</td>
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<td>3 14</td>
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<tr>
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</tr>
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<td>II</td>
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<td>1 5</td>
</tr>
<tr>
<td>Last cycle more than 12 months ago</td>
<td>19 76</td>
<td>20 95</td>
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*Note. Because of rounding, percentages may not total 100.*
Results

Feasibility

The first aim was to determine the willingness of participants to continue in the feasibility study after completing chemotherapy treatments. Twenty-eight Caucasian women who were about to begin adjuvant chemotherapy were contacted during a six-month period, and 25 (89%) agreed to participate. Twenty-one of the 25 women who enrolled in the study completed all eight data collection times, with no withdrawals after chemotherapy ended. These 21 women were divided almost evenly between stage I and II disease; most were married, employed full- or part-time, postmenopausal, and high school graduates with some college education (see Table 1). Barriers identified during phase I of the study that continued during phase II included making contact and scheduling timely appointments with the women, varying levels of enthusiasm for participating as coscientists in the ISPP development, variable levels of flexibility in adopting the ISPP behaviors, and incomplete diary and actigraph data.

Adherence

The second aim of phase II was to determine adherence rates to the four components of the ISPP intervention. Adherence rates varied during this phase (see Figures 1–4). The one-year measurement was intended to determine the long-term outcomes of the sleep intervention. Almost all women were active coscientists in developing and revising the ISPP. Because the instruments were collected one week after dropping them off at the women’s homes, whether the women actually completed the diary each day or recorded data for several days immediately before it was scheduled to be retrieved cannot be determined. Although collecting reliable data from the actigraph was easier, participants did not always wear them continuously, resulting in about 5% missing data.

Rates of adherence to ISPP components were 77%–88% for sleep hygiene counseling, 83%–88% for relaxation therapy, 36%–56% for stimulus control instructions, and 83%–88% for sleep restriction techniques. Patterns of adherence were stable over time, with stimulus control showing the most fluctuation.

Sleep, Wake, and Fatigue Patterns

The third aim of the study was to examine sleep and wake patterns (sleep quality, sleep latency, WASO, sleep efficiency, total rest, feelings on arising, nighttime awakenings, daytime naps) and fatigue (daily and peak) in women receiving the ISPP intervention 30, 60, and 90 days after their last treatment and one year after the first treatment. Mean sleep quality as measured by the PSQI 60 days after the final treatment was 7.0 (SD = 3.16), including 15 women who scored in the “good” range (less than eight) and six who scored in the “poor” range (above eight). One year after the first treatment, mean sleep quality was 7.2 (SD = 3.84), with 12 women scoring in the “good” range and nine scoring in the “poor” sleep quality range during the prior month.

Means and standard deviations of sleep and wake variables obtained by daily diary and wrist actigraph at selected times after treatments are shown in Table 2. Data from the daily diary revealed that mean sleep latency times were regularly within the desired range of less than 30 minutes a night. WASO scores showed a wide range of variability and were longer than the desired 30 minutes per night at three of the four measurements. Sleep efficiency rates were at or above the desired 85%, and total rest values were within or close to the upper limit of the desired range of 360–510 minutes a night, or 6–8.5 hours. Nighttime awakenings were at the desired level (less than six per night) and the length of daytime napping was less than 20 minutes per day. Scores for feeling refreshed on awakening were consistently at a moderately high level (3.7–3.8 on a 0–5 scale).

In comparison, data from the wrist actigraph revealed that mean sleep latency times regularly were less than 10 minutes per night. Mean WASO scores were consistently more than reported on the diary, ranging from 56–73 minutes per night, with 74%–88% of women’s WASO scores greater than 30 minutes at each time. Mean sleep efficiency rates varied from 85%–89% at all later times except 60 days after chemotherapy (82%). Approximately 80% of women had sleep efficiency greater than 85% at all later times, except 90 days after chemotherapy, when only 68% of women scored more than 85%. Total rest times were regularly lower than those reported on the diary, with mean values approximately seven hours, or 420 minutes every 24 hours. Nighttime awakenings were more frequent than the desired less than six per night and women napped, on average, for 10–15 minutes each day.

RM-ANOVA of all variables revealed few statistically significant changes over time in this small sample. Both the number of nighttime awakenings per actigraph and length of daytime naps per diary decreased over time (p < 0.01–0.03). Effect sizes were estimated to provide information about the strength and integrity of the intervention. Lipsey (1990) recommended...
that the research study must be designed to have adequate power for an effect size of 0.15 to detect a small treatment effect. Using data from this sample, the length of daytime naps (recorded in the diary) effect size was significant at 0.175.

Means, ranges, and standard deviations of fatigue measures are shown in Table 3. Fatigue scores were not significantly different over time, ranging from 2.9–3.3 (on a 0–10 scale) on the PFS and 2.9–3.5 (on a 0–10 scale) on the daily fatigue intensity scores. Of concern was the number of women (n = 6–9, 29%–43%) experiencing moderate to severe fatigue after receiving chemotherapy, further refining and clarifying the components of the sleep and wake pattern disruption (Berger, 1998; Berger & Farr, 1999; Berger & Higginbotham, 2000; Berger et al., 2002).

In regard to the study’s feasibility, the findings demonstrate that retaining women in a study that promotes adherence to a tailored sleep intervention for one year is possible. Women generally were willing to act as coscientists in developing and revising an ISPP at regular intervals after completing adjuvant chemotherapy.

Discussion

Piper’s Integrated Fatigue Model informed the study design by identifying the sleep and wake patterns that influenced fatigue. Results of the current study are consistent with previous findings that indicated that the frequency and duration of nighttime awakenings are higher than normal in women after receiving chemotherapy, further refining and clarifying the components of the sleep and wake pattern disruption (Berger, 1998; Berger & Farr, 1999; Berger & Higginbotham, 2000; Berger et al., 2002).

In regard to the study’s feasibility, the findings demonstrate that retaining women in a study that promotes adherence to a tailored sleep intervention for one year is possible. Women generally were willing to act as coscientists in developing and revising an ISPP at regular intervals after completing chemotherapy treatments.

Higher adherence rates were found in this study using the coscientist model than typically have been reported when examining compliance with other components of a medical regimen, such as diet or exercise. Throughout phase II, adherence to all components of the ISPP, except for the stimulus control component, was greater than 75%. Women stated that they found it easier to follow the ISPP after chemotherapy treatments were over. Adherence rates for getting out of bed during the night when unable to fall back to sleep ranged from 36%–56%. Problems were found with scoring this component (did not use versus did not need to use) if women did not think they had remained awake during the night for more than 20–30 minutes. Adherence rates are important data when considering the effect of an intervention.

Examination of sleep, wake, and fatigue patterns revealed important findings in regard to sleep disturbances and fatigue in patients with cancer. Sleep and wake patterns remained stable over time, and means were close to or within normal ranges seen in healthy subjects. The mean WASO remained longer than the desired 30 minutes per night, using both diary and actigraph data, with wide ranges among the women. The number of nighttime awakenings recorded per actigraph was above the normal expectation in healthy subjects of less than six times per night (range = 2–22). About half of the women took daytime naps 30 and 60 days after chemotherapy treatments were completed, one woman took naps at the 90-day measurement, and one-third of the women were napping at the last measurement. This may reflect return to a prediagnosis lifestyle. Only two to three women exceeded the suggested upper limit of 60 minutes per nap at one or more times.

These findings are consistent with the literature describing sleep maintenance problems among patients with cancer (Berger & Farr, 1999; Berger & Higginbotham, 2000; Besztercsey & Lipowski, 1977; Kaye, Kaye, & Madow, 1983). The results imply that the revised intervention needs to strengthen the components that are helpful in decreasing the number and duration of nighttime arousals and increase adherence with the intervention.

The participants 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 number of WASO minutes by actigraph were lower than during treatment, suggesting increased sleep consolidation after chemotherapy ended. However, the majority of women continued to experience more than 30 minutes of WASO per night, perhaps associated with the tamoxifen therapy that was initiated shortly after completing chemotherapy (Knobf, 2001).

Mean fatigue intensity scores remained in the desirable mild range (less than four) (National Comprehensive Cancer Network, 2002). At this intensity, fatigue has been shown to be bothersome, but it does not interfere with the daily activities of most individuals (Piper et al., 1999). However, half of the women’s scores were in the moderate (4–6.9) to severe (7–10) range at each time. One explanation for this finding is that almost half of the sample received radiation therapy at these times. No participants reported severe fatigue at one year.

Limitations of the phase II study included a lack of a control group, missing data, and timing of behavioral changes. Determining the exact bedtime or wake-up time was sometimes impossible when the diary or actigraph data were missing or the
diary entry did not coincide with changes in activity on the actigraph recording. 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. Symptom management and promotion of psychological adaptation to decrease the multiple factors that promote sleep disturbances and fatigue will be added.

The implications for practice are limited at this time because the researchers have reported primarily on the feasibility results. Women can be informed that adopting behavioral techniques to promote sleep may assist in maintaining sleep and wake patterns and managing fatigue after chemotherapy. This type of intervention may assist in managing sleep disturbances and fatigue in patients with other tumor types. Not only may these techniques help patients sleep, but they also may reduce fatigue and allow them to continue to meet their daily energy demands.

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### Table 2. Sleep and Wake Variables From the Daily Diary and Actigraph After Chemotherapy

<table>
<thead>
<tr>
<th>Variable</th>
<th>30 Days After Last Treatment</th>
<th>60 Days After Last Treatment</th>
<th>90 Days After Last Treatment</th>
<th>One Year After First Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Diary</td>
<td>Actigraph</td>
<td>Diary</td>
<td>Actigraph</td>
</tr>
<tr>
<td></td>
<td>X</td>
<td>SD</td>
<td>X</td>
<td>SD</td>
</tr>
<tr>
<td>Sleep latency (minutes)</td>
<td>18.6</td>
<td>13.60</td>
<td>8.2</td>
<td>6.5</td>
</tr>
<tr>
<td>Wake after sleep onset (minutes)</td>
<td>34.9</td>
<td>33.20</td>
<td>69.3</td>
<td>50.5</td>
</tr>
<tr>
<td>Sleep efficiency (%)</td>
<td>91.0</td>
<td>77–99</td>
<td>87.0</td>
<td>56–96</td>
</tr>
<tr>
<td>Total rest (minutes)</td>
<td>484.0</td>
<td>66.10</td>
<td>428.0</td>
<td>60.9</td>
</tr>
<tr>
<td>Night awakenings (number)</td>
<td>1.9</td>
<td>1.00</td>
<td>10.2</td>
<td>6.0</td>
</tr>
<tr>
<td>Daytime naps (minutes)</td>
<td>12.5</td>
<td>21.30</td>
<td>11.2</td>
<td>8.8</td>
</tr>
<tr>
<td>Feelings on arising</td>
<td>3.7</td>
<td>0.71</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

a Doxorubicin-based chemotherapy was administered to 21 women for four 21-day cycles. Eight women had four additional 21-day cycles of paclitaxel to treat stage I or II breast cancer.

b Feelings on arising (1 = exhausted to 5 = refreshed)

c Fatigue is the mean total score on the Piper Fatigue Scale.

### Table 3. Fatigue Scores After Chemotherapy

<table>
<thead>
<tr>
<th>Fatigue Rating</th>
<th>X</th>
<th>Range</th>
<th>SD</th>
<th>Mild (0–3.9)</th>
<th>Moderate (4–6.9)</th>
<th>Severe (7–10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue intensity (n = 19)</td>
<td>2.9</td>
<td>0.00–7.6</td>
<td>2.4</td>
<td>14</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Fatigue (n = 19)</td>
<td>3.3</td>
<td>0.45–7.2</td>
<td>2.2</td>
<td>12</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>60 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue intensity (n = 20)</td>
<td>3.5</td>
<td>0.00–8.7</td>
<td>2.8</td>
<td>12</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Fatigue (n = 20)</td>
<td>3.2</td>
<td>0.18–7.9</td>
<td>2.7</td>
<td>12</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>90 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue intensity (n = 21)</td>
<td>3.3</td>
<td>0.00–8.1</td>
<td>2.4</td>
<td>12</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Fatigue (n = 18)</td>
<td>3.4</td>
<td>0.09–8.5</td>
<td>2.8</td>
<td>10</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>One year</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue intensity (n = 21)</td>
<td>3.4</td>
<td>1.00–6.0</td>
<td>1.6</td>
<td>12</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>Fatigue (n = 18)</td>
<td>2.9</td>
<td>0.05–6.3</td>
<td>2.2</td>
<td>12</td>
<td>6</td>
<td>0</td>
</tr>
</tbody>
</table>

a Doxorubicin-based chemotherapy given to 21 women for four 21-day cycles. Eight women had four additional 21-day cycles of paclitaxel to treat stage I or II breast cancer.

b Fatigue intensity is the mean (0–10) of daily fatigue scores (item 7 on the Piper Fatigue Scale).

c Fatigue is the mean total score on the Piper Fatigue Scale (0–10) on day one at each time.


References


For more information . . .

- Susan G. Komen Breast Cancer Foundation
  www.komen.org
- National Breast Cancer Coalition
  www.natlbc.org
- Breast Cancer Action
  www.bcaction.org

Links can be found using ONS Online at www.ons.org.