Symptom management is a vital aspect of the practice of oncology nursing. The Oncology Nursing Society has identified outcomes sensitive to nursing intervention, known as nursing-sensitive patient outcomes. This article presents information about sleep-wake disturbances that occur in patients with cancer and makes recommendations for evidence-based interventions to improve sleep for patients.

Sleep-wake disturbances occur in 30%–75% of people with cancer and have a negative impact on other symptoms and quality of life. Despite the frequency and severity of sleep-wake disturbances, limited research has tested interventions to improve sleep-wake outcomes. Although no interventions currently receive the highest recommendations for implementation into practice, several nonpharmacologic interventions show initial positive findings in promoting high-quality sleep and daytime functioning. Oncology nurses can screen for sleep-wake disturbances and suggest tailored interventions. Four categories of promising interventions are cognitive-behavioral therapy, complementary therapies, psychoeducation and information, and exercise. Clinicians can use the Putting Evidence Into Practice (PEP) card and PEP resources at www.ons.org/outcomes to improve sleep-wake outcomes.

Editor’s note. This article is the second in a series on the Putting Evidence Into Practice project, in which best practices for patient care are presented.

Changes in health policy have mandated cost-effective, high-quality care for which healthcare providers are held accountable. The Oncology Nursing Society (ONS) has identified nursing-sensitive patient outcomes (NSPOs) for patients with cancer. NSPOs are outcomes that are attained through or are significantly impacted by nursing interventions. The interventions must be within the scope of nursing practice and integral to the processes of nursing care (Given & Sherwood, 2005). The Putting Evidence Into Practice (PEP) weight-of-evidence classification model provides guidance for nursing interventions based on the evidence in each practice area (Gobel, Beck, & O’Leary, 2006).

Sleep-Wake Disturbances

Cancer and treatment-related symptoms are patient-centered outcomes influenced by nursing care (Given & Sherwood, 2005). In 2004, an ONS state-of-the-science conference about sleep-wake disturbances in patients with cancer and their caregivers was held. A group of experts in the field of sleep-wake disturbances in patients with cancer defined the outcome, reviewed the literature regarding tools with which it could be measured, and presented current studies on interventions to improve the outcome (Berger et al., 2005). Sleep-wake disturbances then was added to the list of outcomes to be developed in the PEP project. Sleep-wake disturbances are patient-centered outcomes that can be improved with nursing care. The disturbances are perceived
Disturbed sleep may impact daytime sleepiness, functional ability, immune function, and quality of life. Evidence suggests that a variety of nursing interventions may affect sleep-wake disturbances positively in people with cancer.

**Figure 1. Definitions, Incidence and Prevalence, Etiology and Risk Factors, and Prognosis for Sleep-Wake Disturbances**

Highlights of the Reviewed Literature

At the present time, no nursing intervention can be categorized as “recommended for nursing practice” to assist patients with cancer with sleep-wake disturbances. For an intervention to meet criteria in that ONS PEP weight-of-evidence category, it needs to have demonstrated effectiveness by strong evidence from rigorously designed studies, meta-analyses, or systematic reviews and demonstrate that the risk of harm is small compared with the benefit. Also, no nursing intervention can be classified as “likely to be effective” at this time. Interventions in that ONS PEP weight-of-evidence category must show evidence that is less well established than would be expected for interventions that meet the criteria to be included in the “recommended for practice” category, such as supportive evidence from a single, well-conducted, randomized, controlled trial that included fewer than 100 subjects. Studies are needed that test pharmacologic and nonpharmacologic interventions in patients with cancer to identify those that meet the rigorous criteria to be listed in those PEP weight-of-evidence categories. See inset for the Sleep Team’s PEP process.

Pharmacologic Interventions

Despite widespread use of such interventions, the finding that no published meta-analysis or experimental design study has examined the efficacy of using sedative-hypnotic drugs, such as benzodiazepines, in patients with cancer was surprising. Pharmacologic interventions have been assigned to the ONS PEP weight-of-evidence category “benefits balanced with harms,” which infers that clinicians and patients should weigh the beneficial and harmful effects according to individual circumstances and priorities.

Although the drugs have not been studied in patients with cancer, sedative-hypnotics are prescribed commonly for...
A group of three nurses came to be identified as the Sleep Team; one advanced practice nurse, one doctorally prepared nurse researcher with expertise in the topical area, and one staff nurse, who in this case was master’s prepared. The team developed the Oncology Nursing Society (ONS) Sleep-Wake Disturbances Putting Evidence Into Practice (PEP) card and Web site resources. The collaboration across skill levels and educational backgrounds provided an opportunity and encouragement for the advanced practice nurse and staff nurse to become familiar with and involved in outcomes research. It also provided an opportunity for translation from research to the bedside by mixing skill levels, points of view, and, in this case, a variety of prior nursing experiences in roles and patient populations.

The Process of Putting Evidence Into Practice

A group of three nurses came to be identified as the Sleep Team; one advanced practice nurse, one doctorally prepared nurse researcher with expertise in the topical area, and one staff nurse, who in this case was master’s prepared. The team developed the Oncology Nursing Society (ONS) Sleep-Wake Disturbances Putting Evidence Into Practice (PEP) card and Web site resources. The collaboration across skill levels and educational backgrounds provided an opportunity and encouragement for the advanced practice nurse and staff nurse to become familiar with and involved in outcomes research. It also provided an opportunity for translation from research to the bedside by mixing skill levels, points of view, and, in this case, a variety of prior nursing experiences in roles and patient populations.

Using the state-of-the-science sleep-wake disturbances work as a basis for reference, the team developed the ONS PEP resources. The state-of-the-science group had conducted several computerized literature searches on the major search engines (MEDLINE®, CINAHL®, and PsychINFO) during 2004 and early 2005. Key words used for primary and secondary searches included sleep, sleep disturbance, sleep-wake disturbance, cancer, intervention, insomnia, sleep restriction, sleep hygiene, relaxation therapy, massage, and yoga. The searches were run in an attempt to identify all pharmacologic and nonpharmacologic intervention studies that examined sleep disturbances or sleep quality outcomes in adults with cancer. As of March 2005, no pharmacologic studies and 20 nonpharmacologic studies were identified. The literature was reviewed again for new articles using the same search technique prior to the initial ONS PEP meeting in June 2005 and again prior to submission of PEP resources in December 2005.

Twenty-four studies met inclusion criteria, which were reports in the English language of studies examining pharmacologic or nonpharmacologic interventions for sleep-wake disturbances, measurement of sleep by using either an instrument designed to measure sleep or an item or a subscale from another instrument, scores on the sleep measure reported in the results, and study participants including people diagnosed with cancer at any time point since diagnosis.

Similar to many projects, the present project had inherent difficulties and problems. One problem in the ONS PEP development was defining the final product. The initial PEP teams were the first ones to formulate a vision of the scope of the process and the resources that would be developed. The project took more time and required more revisions than anticipated because of its evolving nature and scope. A second issue was trying to fit the nursing intervention studies into the classification systems currently in use for evaluating the levels of evidence of medical and nursing research studies (Hadorn, Baker, Hodges, & Hicks, 1996; Ropka & Spencer-Cisek, 2001). Working collaboratively, the advanced practice nurse, nurse researcher, and staff nurse teams from each of the four outcome groups helped make evidence-based interventions accessible to clinical nurses. This was done by reaching consensus about who the user was and the scope of the project, as well as developing the ONS PEP weight-of-evidence classification model (Gobel, Beck, & O’Leary, 2006).

The model for synthesis of evidence-based literature described by Rutledge, DePalma, and Cunningham (2004) guided the review process. Phase I included organizing and searching the literature and gathering the original articles. A medical librarian was used to ensure that all literature that met the search criteria was found. Much of this work had been completed prior to the formation of the Sleep Team by those involved with the ONS sleep-wake disturbances state-of-the-science conference in 2004. That work is available in an associated article that was published in 2005 (Berger et al., 2005). In phase II, the Sleep Team critiqued the selected literature and developed the evidence table for sleep-wake disturbances (see Table 1). Information was retrieved from the intervention, sample, setting, study design, measurement, and results categories. All of the current article’s authors participated in the process. In phase III, the team classified the level of evidence of the studies using the ONS PEP Classification Schema that had been developed as part of the overall PEP process. Phase IV was the dissemination phase, and this article serves to present and disseminate conclusions and clinical implications of that process to clinical nurses.

Throughout, the research team used the ONS PEP Classification Schema to classify studies. The assignment of classifications is based on the level and quality of the evidence. The level of evidence is determined by the methodological rigor of the study. The classification is presented in a flowchart figure (see Figure 1) and in four categories: evidence-based (sufficient quality evidence); effectiveness not established (insufficient quality evidence); inadequate quality; and no evidence. The ONS PEP Classification Schema includes a color code to identify studies in the four categories: blue for the evidence-based category, green for the effectiveness not established category, yellow for the inadequate quality category, and white for no evidence.

Based on the evidence, herbal supplements also have been assigned to the ONS PEP weight-of-evidence category “benefits balanced with harms.” Studies have described potential interactions among herbal agents and chemotherapy and other common drugs, making herbal agents potentially dangerous for use in patients with cancer. Herbal supplements are not recommended for patients receiving chemotherapy unless they consult and receive approval from the oncology team. Oncology clinicians are advised to review a patient’s use of herbal agents at regular intervals, dependent on the treatment plan. Review of herbal agent use should be integrated into oncology clinical practice. For more information, refer to the ONS PEP card (see Appendix) and the online PEP resources (www.ons.org/outcomes).

Nonpharmacologic Interventions

All nonpharmacologic interventions for sleep-wake disturbances that have been tested in patients with cancer currently are classified in the “effectiveness not established” category. Interventions for which data currently are insufficient or of inadequate quality are included in this category, and it contains reports of pilot or small studies. All but one of the studies (N = 24) presented in the sleep-wake intervention evidence table (see Table 1) were published since 2000, which is an indication of the infancy of the research on the symptom. Two short- and long-term use. In making a decision about which, if any, pharmacologic agents to use, nurses need to consider the sleep-wake disturbances that patients report (e.g., sleep latency, maintenance disturbances). Other factors should be considered, including patients’ current medication profiles, comorbidities, and lifestyles. The drugs most commonly prescribed are in the benzodiazepine and nonbenzodiazepine groups and vary considerably in their half-lives. All nonbenzodiazepines list the benefit of reduced sleep latency. Two agents (eszopiclone and zolpidem controlled release) have been approved to improve sleep maintenance. Harmful and less desirable effects include daytime sleepiness and impaired daytime functioning from drugs with longer half-lives as well as problems staying asleep during the second half of the night from drugs with shorter half-lives. Benzodiazepines and nonbenzodiazepines are recommended for intermittent use (7–10 days). Besides benzodiazepines and nonbenzodiazepines, tricyclic antidepressants, second-generation antidepressants, antihistamines, chloral derivatives and neuroleptic agents may be considered when attempting to improve sleep. The National Cancer Institute (2005) Physician Data Query Sleep Disorders Web site and other drug information resources are available to assist in the selection of a sedative-hypnotic agent. Potential interactions with over-the-counter and prescription medications patients are taking also must be considered carefully.
Table 1. Sleep-Wake Intervention Evidence Table

<table>
<thead>
<tr>
<th>STUDY</th>
<th>INTERVENTION CHARACTERISTICS AND PRIMARY OUTCOME(S)</th>
<th>SAMPLE CHARACTERISTICS</th>
<th>SETTING CHARACTERISTICS</th>
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<th>SLEEP-WAKE DISTURBANCES MEASURES</th>
<th>RESULTS AND CONCLUSIONS</th>
<th>LEVELS OF EVIDENCE AND COMMENTS</th>
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<tr>
<td>Allison, Edgar, et al., 2004; Allison, Nicolau, et al., 2004; Berger et al., 2002</td>
<td>NuCare coping strategies program: self-study book and audiotape designed to enhance personal control and teach emotional and instrumental coping responses</td>
<td>N = 66; 59 completed program and 50 gave outcome data; no age, gender, race, or ethnicity given; head and neck cancer diagnoses; treatment phase = 1 and 2</td>
<td>Participants choose among small group (n = 3), one-on-one with therapist (n = 33), or home format without a therapist (n = 23); in Canada</td>
<td>Prospective, feasibility, repeated measures, nonrandomized, one group</td>
<td>European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C-30 (EORTC QLQ-C30) item for sleep disturbance</td>
<td>Improvement in sleep</td>
<td>Oncology Nursing Society (ONS) level of evidence: II (6)</td>
</tr>
<tr>
<td>Berger et al., 2002</td>
<td>Multicomponent CBT, individual sleep promotion plan: sleep hygiene, relaxation, stimulus control, sleep restriction</td>
<td>N = 25 female Caucasians, X age = 54.3 years (40–65), stage I or II breast cancer during adjuvant chemotherapy, treatment phase = 1</td>
<td>Urban oncology clinics and patient homes in the mid-western United States</td>
<td>Prospective, quasi-experimental, feasibility, repeated measures, one group</td>
<td>Pittsburgh Sleep Quality Index (PSQI), daily diary, wrist actigraph</td>
<td>Sleep latency, efficiency, total rest, and rating of feeling refreshed on awakening were stable; time awake after sleep onset and night awakenings exceeded desired levels.</td>
<td>ONS level of evidence: II (6)</td>
</tr>
<tr>
<td>Berger et al., 2003</td>
<td>Multicomponent CBT, individual sleep promotion plan: sleep hygiene, relaxation, stimulus control, sleep restriction</td>
<td>N = 21 female Caucasians, X age = 55.3 years (43–66), stage I or II breast cancer following adjuvant chemotherapy, treatment phase = 2</td>
<td>Patient homes in the mid-western United States</td>
<td>Prospective, quasi-experimental, feasibility, repeated measures, one group</td>
<td>PSQI, daily diary, wrist actigraph</td>
<td>High adherence except for stimulus control; sleep latency remained stable; sleep efficiency ranged from 82%–92%; total rest ranged from seven to eight hours per night; night awakenings ranged from 10–11 per night.</td>
<td>ONS level of evidence: II (6)</td>
</tr>
<tr>
<td>Dalton, 2004</td>
<td>Patients received standard CBT, profile-tailored CBT (PTCT), or usual care; PTCT matched patients’ scores on the Biobehavioral Pain Profile to specific CBT modules</td>
<td>N = 131; X age = 52 years; 72% female; patients were experiencing cancer-related chronic pain for more than six weeks; mixed cancer diagnoses, most common were breast, colon, lung, lymphoma; treatment phase = 1</td>
<td>One inpatient and three outpatient cancer centers in the southeastern United States</td>
<td>Randomized, controlled trial (RCT)</td>
<td>One sleep item on the Brief Pain Inventory</td>
<td>Immediately pre- to immediately postintervention, the PTCT group had less interference of pain with sleep; response to the intervention decreased with time.</td>
<td>ONS level of evidence: II (6)</td>
</tr>
<tr>
<td>Davidson et al., 2001</td>
<td>Multimodal CBT: group therapy included stimulus control therapy, relaxation training, sleep consolidation strategies,</td>
<td>N = 14 (12 completed), X age = 54.7 years, mixed cancer diagnoses, X time since diagnosis =</td>
<td>Outpatient clinics at a major cancer center in central and midwestern Canada and the community serving the</td>
<td>Prospective, quasi-experimental, repeated measures, one</td>
<td>Sleep diary, Sleep Impairment Index</td>
<td>Sleep improved from baseline to four weeks to eight weeks after intervention.</td>
<td>ONS level of evidence: II (6)</td>
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<tr>
<td>Quesnel et al., 2003</td>
<td>Multimodal CBT combined strategies; establish treatment objectives, stimulus control, sleep restriction, coping strategies for fatigue, and reframing maladaptive cognitions. Outcomes: sleep, mood, fatigue, global and cognitive QOL.</td>
<td>N = 10 women with nonmetastatic breast cancer (stages I–III), X age = 54.3 years, completed chemotherapy and/or radiation therapy, all had a diagnosis of chronic insomnia disorder per Diagnostic and Statistical Manual-IV (DSM-IV), all had completed high school, treatment phase = 2.</td>
<td>One site; subjects were recruited from the community sleep laboratory and subjects’ homes in Quebec, Canada.</td>
<td>Prospective, quasi-experimental, repeated measures, randomized, one group</td>
<td>Insomnia Severity Index, Insomnia Interview Schedule, sleep diary, self-report scales, breathing parameters, polysomnography (electromyography and electroencephalography).</td>
<td>Most had statistically significant improvement in sleep efficiency and decreased total wake time pre- and post-treatment. Sleep efficiency continued to improve at the six-month follow-up, but total wake time did not. Findings on sleep diaries were corroborated by objective measures.</td>
<td>ONS level of evidence: II (6)</td>
</tr>
<tr>
<td>Savard et al., 2005</td>
<td>Eight weekly 90-minute group sessions combined behavioral (stimulus control, sleep restriction), cognitive (cognitive restructuring), and educational (sleep hygiene, fatigue, stress management) strategies. Outcomes: sleep, medication use, psychological distress, QOL.</td>
<td>N = 57 women who had completed radiation and chemotherapy for stage I–III breast cancer who met DSM-IV criteria for a chronic insomnia syndrome, treatment phase = 2.</td>
<td>Subjects were recruited from the community by advertisement; in Canada.</td>
<td>RCT</td>
<td>Insomnia Interview Schedule, Structured Clinical Interview for DSM-IV, sleep diary, polysomnography, Insomnia Severity Index.</td>
<td>Treated patients showed a significantly greater improvement in sleep post-treatment as assessed by self-report instruments. However, polysomnography data were not significantly more improved in treated patients. Treated patients had reduced use of sleep medication.</td>
<td>ONS level of evidence: II (6)</td>
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**Complementary Therapies—PEP Weight-of-Evidence Category: Effectiveness Not Established**

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<tr>
<td>Cannici et al., 1983</td>
<td>Individual muscle relaxation training over three sessions plus instructions for home practice twice daily. Outcomes: sleep.</td>
<td>N = 30; X age = 56 years (21–80); 11 men and 19 women with a variety of cancers; groups: relaxation (n = 15), usual care (n = 15); treatment phase = 1 and 2.</td>
<td>Quiet office in the hospital, patients’ homes, or patients’ hospital rooms; in the southeastern United States.</td>
<td>RCT</td>
<td>Daily diary questionnaire pertaining to patients’ sleep behavior the previous night for a total of nine nights</td>
<td>Sleep onset latency was reduced in the relaxation group compared with the usual care group; at the three-month follow-up, differences in sleep latency were maintained and no differences existed in other sleep variables.</td>
<td>ONS level of evidence: II (5)</td>
</tr>
<tr>
<td>Carlson &amp; Garland, 2005</td>
<td>Mindfulness-based stress reduction meditation (MBSR):</td>
<td>N = 63, X age = 54 years (32–78), 49 women and</td>
<td>Outpatient setting in Canada.</td>
<td>Prospective, quasi-experimental</td>
<td>PSQI</td>
<td>Pretreatment, 91% had PSQI scores of 5 or more and 51%</td>
<td>ONS level of evidence: II (6)</td>
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Table 1. Sleep-Wake Intervention Evidence Table (Continued)

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<tr>
<td>Carlson et al., 2003</td>
<td>Relaxation, meditation, gentle yoga, and daily practice plus audiotape of meditations. Outcomes: sleep, mood, stress, fatigue.</td>
<td>14 men, with mixed cancer diagnoses and stages, treatment phase = 2</td>
<td>Mental, feasibility, repeated measures, one group</td>
<td>Prospective, quasi-experimental, repeated measures, one group</td>
<td>PSQI</td>
<td>had scores of 10 or more; post-treatment, 27% had PSQI scores of more than 10. Sleep disturbances were significantly reduced, and subjective sleep quality improved.</td>
<td>ONS level of evidence: II (6)</td>
</tr>
<tr>
<td>Carlson et al., 2004</td>
<td>MBSR: relaxation, meditation, gentle yoga, and daily practice plus audiotape of meditations. Outcomes: QOL, mood, symptoms of stress, immune and hormone parameters.</td>
<td>Pretest: N = 59; 49 patients with stage 0, I, or II breast cancer and 10 with early-stage prostate cancer; post-test: N = 42 patients; treatment phase = 2</td>
<td>Outpatient setting in Canada; eight weekly, 90-minute group sessions plus three-hour silent retreat on Saturday between weeks six and seven</td>
<td>Prospective, quasi-experimental, feasibility, repeated measures, one group</td>
<td>PSQI</td>
<td>Significant improvements in sleep.</td>
<td>ONS level of evidence: II (6)</td>
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<tr>
<td>Cohen et al., 2004</td>
<td>Tibetan yoga: seven weekly sessions with a yoga instructor, imagery and exercise; four aspects: controlled breathing and visualization, mindfulness, two types of postures, daily practice. Outcomes: psychological adjustment, sleep, fatigue.</td>
<td>N = 39 (final = 38), lymphoma diagnoses, X age = 51 years in both groups, treatment phase = 1 and 2</td>
<td>Community outpatient setting affiliated with a comprehensive cancer center in the southern United States</td>
<td>Prospective, quasi-experimental, repeated measures, nonrandomized, two groups</td>
<td>PSQI</td>
<td>Significantly lower sleep disturbances (total PSQI) during follow-up; scores were 5.8 for intervention group versus 8.1 for wait-list control group; better sleep quality, shorter latency, longer duration, and fewer medications.</td>
<td>ONS level of evidence: II (6)</td>
</tr>
<tr>
<td>de Moor et al., 2002</td>
<td>Expressive writing sessions; random assignment to neutral health issues writing or expressive writing groups. Outcomes: psychological and behavioral adjustment, symptoms of distress, perceived stress, mood, sleep.</td>
<td>N = 42, X age = 56.4 years, 85% male, newly diagnosed with stage IV metastatic renal cell carcinoma, four to six weeks postoperative, treatment phase = 1</td>
<td>Outpatient setting in the southwestern United States</td>
<td>Prospective, feasibility, repeated measures, two groups</td>
<td>PSQI</td>
<td>Statistically significant improvements in the expressive writing group were found for four of the sleep disturbance measures on the PSQI (total score and subscales of sleep quality, sleep duration, and daytime dysfunction).</td>
<td>ONS level of evidence: II (6)</td>
</tr>
<tr>
<td>Fobair et al., 2002</td>
<td>Supportive-expressive group therapy: discussed problems, coping, treatment, mood, self-efficacy, relationships, pain, sleep, body image, and sexuality. Outcomes: emotional distress, mood, self-efficacy.</td>
<td>N = 20, X age = 47 years, stage I–IIA breast cancer, status post-surgery with no extensive disease at time of intervention, treatment phase = 1</td>
<td>Three community settings in northern California</td>
<td>Prospective, quasi-experimental, nonrandomized, one group</td>
<td>Quality and quantity of sleep and daytime sleepiness using a brief questionnaire based on the Structured Insomnia Interview</td>
<td>Patients undergoing 12 weeks of supportive group therapy showed statistically significant improvement in sleep (less waking during night).</td>
<td>ONS level of evidence: II (6)</td>
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<td>Shapiro et al., 2003</td>
<td>Multiple sessions and one-hour silent treatment; training in meditative practices (Kabat-Zinn), sitting meditation, body scan, Hatha yoga, and “loving kindness” meditation; didactic material on physical and psychological effects of stress and tools to cope with stress. Control group chose a stress management technique.</td>
<td>N = 63 women; free choice control group (n = 32), MBSR (n = 31); subjects were aged 18–80 years (X age = 57), with a history of stage II breast cancer; women were currently working, retired, or on disability; treatment phase = 2</td>
<td>Subjects’ homes in the western United States</td>
<td>RCT</td>
<td>Sleep diary, daily diary recording activities patients engaged in for stress management</td>
<td>Hypothesis 1: Sleep function is associated with psychological distress. (Confirmed) Hypothesis 2: Sleep efficiency would be improved after controlling for baseline distress. (Not confirmed) Hypothesis 3: Sleep efficiency and sleep quality would improve with MBSR. (Partially confirmed)</td>
<td>ONS level of evidence: II (6)</td>
</tr>
<tr>
<td>Simeit et al., 2004</td>
<td>Multimodal psychological sleep management program combining relaxation techniques (progressive muscle relaxation [PMR] or autogenic training [AT]), sleep hygiene, cognitive techniques, and advice in stimulus control techniques.</td>
<td>N = 80 in PMR group, N = 71 in AT group, and N = 78 in control group; mixed sample of adults; X age = 58 years; predominantly breast, kidney, or prostate cancer diagnoses; treatment phase = 2</td>
<td>Three to four weeks’ stay in an oncology rehabilitation clinic in Germany</td>
<td>Prospective, quasi-experimental, repeated measures, nonrandomized, two groups</td>
<td>PSQI (German translation)</td>
<td>No statistically significant difference existed between the PMR and AT groups. Improvement was noted in intervention groups with sleep latency, sleep duration, sleep efficiency, sleep medication (less), and daytime dysfunction.</td>
<td>ONS level of evidence: II (6)</td>
</tr>
<tr>
<td>Smith et al., 2002</td>
<td>Swedish technique of effleurage and petrissage; control group received deliberate focused communication.</td>
<td>N = 41; all patients (men and women) had cancer diagnoses, including lymph, lung, gastrointestinal, genitourinary, head and neck, leukemia, breast, and skin; treatment phase = 1</td>
<td>Inpatients in a Veterans Affairs hospital in the midwestern United States</td>
<td>Prospective, quasi-experimental, repeated measures, nonrandomized, two groups</td>
<td>Verran and Snyder-Halpern (VSH) Sleep Scale</td>
<td>Sleep quality remained the same.</td>
<td>ONS level of evidence: II (6)</td>
</tr>
<tr>
<td>Soden et al., 2004</td>
<td>Weekly massage with lavender essential oil and inert carrier oil (larnotherapy group), massage with and inert carrier oil only (massage group) and a control group</td>
<td>N = 42; X age = 73 years (44–85); 10 men and 32 women; all had advanced cancer diagnosis including breast, lung, gastrointestinal,</td>
<td>Three specialist palliative care units in the south Thames region of West Sussex, United Kingdom</td>
<td>Prospective, feasibility, repeated measures, nonrandomized, three groups</td>
<td>VSH Sleep Scale</td>
<td>No significant change occurred in mean VSH sleep quality scores from baseline to final assessment in any group. When combined, a statistically significant difference existed</td>
<td>ONS level of evidence: II (6)</td>
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<td>Weze et al., 2004</td>
<td>Healing touch method was a noninvasive, non–condition-specific method involving placing of hands on various parts of the body for about 40 minutes, giving particular attention to areas of pain or discomfort. <strong>Outcomes</strong>: symptoms, QOL</td>
<td>N = 35, X age = 57 years (24–80), 11 men and 23 women, approximately 50% had cancer less than one year and 50% had cancer one to five years; patients had mixed cancer types, 40% had advanced disease, treatment phase = 1 and 2</td>
<td>Outpatient Centre for Complementary Care in Eskdale, United Kingdom</td>
<td>Prospective, feasibility, repeated measures, nonrandomized, one group</td>
<td>EuroQoL EQ-5D and visual analog scales; sleep disturbances item: 0–3 = sleeping too much, 4–7 = sleeping well, and 8–10 = sleeping poorly</td>
<td>Statistically significant improvement was found pre- to post-test on sleep disturbances.</td>
<td>ONS level of evidence: II (6)</td>
</tr>
<tr>
<td>Wright et al., 2002</td>
<td>AT to revert from arousal of the autonomic nervous system to one of profound relaxation associated with the parasympathetic activity. <strong>Outcomes</strong>: anxiety, depression, coping, sleep</td>
<td>N = 18, age = 40–80 years, all had cancer diagnoses and were either pain free or had pain controlled with nonopioids or mild opioids, treatment phase = 1 or 2</td>
<td>Outpatient cancer center and subjects’ homes in Ireland</td>
<td>Prospective, quasi-experimental, repeated measures, one group</td>
<td>Qualitative interview</td>
<td>Qualitative remarks indicated that AT was very helpful for sleep induction.</td>
<td>ONS level of evidence: III (8)</td>
</tr>
<tr>
<td><strong>Psychoeducation and Information—PEP Weight-of-Evidence Category: Effectiveness Not Established</strong></td>
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<tr>
<td>Kim et al., 2002</td>
<td>Tape-recorded educational message (informational intervention versus standard of care) at treatment 1 and different message at treatment 5; side effects of radiation therapy for prostate cancer. <strong>Outcomes</strong>: seventy of side effects from radiation</td>
<td>N = 152, X age = 70.8 years; 96% Caucasian; receiving radiation for curative, localized prostate cancer; stage A (13%), stage B (66%), and stage C (21%); treatment phase = 1</td>
<td>Eight cancer centers in the eastern United States</td>
<td>RCT</td>
<td>Single-item measure of sleep was obtained at week 2 and the end of treatment.</td>
<td>A brief educational intervention is helpful in reducing sleep problems resulting from radiation therapy and cancer.</td>
<td>ONS level of evidence: II (6)</td>
</tr>
<tr>
<td>Williams &amp; Schreier, 2005</td>
<td>Audiorecording included education about the self-care behaviors</td>
<td>N = 71, X age = 50.4 years (30–74), 85% had Tertiary medical center and a satellite cancer treatment</td>
<td>RCT</td>
<td>Modified self-care diary measured the</td>
<td>More women in the control group reported difficulty</td>
<td>ONS level of evidence: II (6)</td>
<td>(Continued on next page)</td>
</tr>
</tbody>
</table>
Table 1. Sleep-Wake Intervention Evidence Table (Continued)

<table>
<thead>
<tr>
<th>STUDY</th>
<th>INTERVENTION CHARACTERISTICS AND PRIMARY OUTCOME(S)</th>
<th>SAMPLE CHARACTERISTICS</th>
<th>SETTING CHARACTERISTICS</th>
<th>STUDY DESIGN</th>
<th>SLEEP-WAKE DISTURBANCES MEASURES</th>
<th>RESULTS AND CONCLUSIONS</th>
<th>LEVELS OF EVIDENCE AND COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coleman et al., 2003</td>
<td>of exercise and relaxation to manage anxiety, fatigue and sleep problems; self-care diary mirrored the audiotape; control group received education about side effects. <strong>Outcomes:</strong> fatigue, anxiety, sleep</td>
<td>N = 24, X age = 55 years, 10 women and 14 men, Caucasian, receiving high-dose chemotherapy and peripheral blood stem cell transplantation for multiple myeloma (with bone involvement), treatment phase = 1</td>
<td>Outpatients at a cancer research center in the midwestern United States</td>
<td>Pilot feasibility, RCT</td>
<td>Wrist actigraphy latency, minutes of sleep at night, percentage of time asleep at night, number of nighttime awakenings, frequency of daytime naps, minutes of sleep in daytime, and total minutes of sleep during each 24-hour period; Epworth Sleepiness Scale</td>
<td>Feasibility was supported for individualized exercise programs for patients receiving aggressive treatment for multiple myeloma.</td>
<td>ONS level of evidence: II (6)</td>
</tr>
<tr>
<td>Mock et al., 1997</td>
<td>Self-paced, progressive, home-based exercise program; walking exercise versus usual care; individualized walking based on age, level of fitness, and history of exercise <strong>Outcomes:</strong> exercise, fatigue, physical functioning, emotional distress, sleep</td>
<td>N = 46 women, X age = 49 years, 87% Caucasian, predominately stage I (72%) breast cancer, undergoing radiation therapy, treatment phase = 1</td>
<td>Two university teaching hospitals in the southeastern United States; instruction given at the institution; intervention carried out at home</td>
<td>Two-group pretest/post-test, quasi-experimental design</td>
<td>Symptom Assessment Scale, Piper Fatigue Scale, 12-minute walk test</td>
<td>Women who exercised regularly reported less difficulty sleeping than the control group.</td>
<td>ONS level of evidence: II (6)</td>
</tr>
<tr>
<td>Young-McCaughan et al., 2003</td>
<td>Subjects met twice per week for 12 weeks for exercise and education <strong>Outcomes:</strong> exercise tolerance, activity, sleep, QOL.</td>
<td>N = 62; 50% men and 50% women; X age = 55 years; mixed ethnicity; all with varying cancer diagnoses and stages; therapy included surgery, chemotherapy, radiation therapy, immunotherapy, endocrine therapy, and hormonal therapy; treatment phase = 1 or 2</td>
<td>Two major military medical centers in the southwestern United States; inpatient and outpatient setting</td>
<td>Prospective feasibility study with repeated measures</td>
<td>Wrist actigraphy to measure duration of sleep, percentage of night spent asleep, average length of a sleep episode, number of awakenings; Cancer Rehabilitation Evaluation System—Short Form sleep item</td>
<td>No improvement in sleep patterns per actigraphy; improved subjective rating</td>
<td>ONS level of evidence: II (6)</td>
</tr>
</tbody>
</table>
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publications from the same data sets by two authors (Allison, Edgar, et al., 2004, and Allison, Nicolau, et al., 2004; Carlson, Speca, Patel, & Goodey, 2003 and 2004) were counted as one study for the evidence table. Evidence indicates that several nonpharmacologic interventions show initial positive findings in promoting quality sleep and daytime functioning in patients with cancer. The Sleep Team organized the interventions into CBTs, CTs, psychoeducation and information, and exercise categories for the evidence table. Definitions of these strategies can be found in the definitions table in the online ONS PEP resources (www.ons.org/outcomes). CBTs and CTs have been the most frequently tested interventions to improve sleep in patients with cancer. Results of large randomized, controlled trials are needed to confirm the mostly positive results from these small, nonrandomized studies.

Several issues regarding the strength of evidence of the studies were reviewed. Sleep was a primary outcome variable in only 42% of the studies. The samples represented a variety of cancers, but the groups were relatively small and had a predominance of Caucasian subjects who were undergoing active treatment in outpatient settings. Most of the studies were quasi-experimental designs with no control groups. Six were randomized, controlled trials, although sample sizes usually were fewer than 100. No consistency existed across studies regarding tools used to measure the outcomes, making the results difficult to compare. Most of the studies were conducted in the United States or Canada, with a few using a sample of Western Europeans. The development of the knowledge base on this topic will be indicated when results are reported from several large randomized, controlled trials that have used sleep measurements with established psychometric properties and whose primary outcome variable has been sleep-wake disturbances. More information about measurement of sleep-wake disturbances can be found on the ONS Web site at www.ons.org/evidence.

CBTs involve a variety of psychological and behavioral treatments that can be used alone or in combination. They can change negative thought processes, attitudes, and behaviors related to a person's ability to fall asleep, stay asleep, get enough sleep, and function during the day. More than 20 CBTs have been developed since 1985 for use in acute and chronic insomnia; among the most effective interventions are stimulus control, sleep restriction, relaxation therapy, and sleep hygiene (Morin, Culbert, & Schwartz, 1994). Interventions have been tested in patients with cancer using the following CBTs: NuCare, stimulus control, sleep restriction, relaxation therapy, sleep hygiene, profile-tailored CBT, and cognitive restructuring strategies. For more information about the strategies, view the ONS PEP resources online at www.ons.org/outcomes. As a group, results show that several sleep disturbance variables have been improved with CBTs, including higher sleep quality (Savard, Simard, Ivers, & Morin, 2005), longer duration (Allison, Edgar, et al., 2004; Allison, Nicolau, et al., 2004; Davidson, Waisberg, Brundage, & MacLean, 2001; Quesnel, Savard, Simard, Ivers, & Morin, 2003), and higher sleep efficiency (Davidson et al.; Quesnel et al.). Berger et al. (2002, 2003) demonstrated that the individual sleep propensity plan intervention maintained normal ranges of sleep variables except the number and length of nighttime awakenings.

CTs are a group of diverse medical and healthcare practices and products that presently are not considered to be part of conventional medicine. The following CT interventions have been tested in patients with cancer: aromatherapy, expressive therapy, expressive writing, healing, autogenic training, massage, muscle relaxation, mindfulness-based stress reduction, and yoga. Results indicate that when specific CTs were employed, several sleep-wake disturbance variables improved, including higher sleep quality (Carlson & Garland, 2005; Carlson et al., 2003, 2004; Cohen, Warnerke, Fouladi, Rodriguez, & Chaoul-Reich, 2004; de Moor et al., 2002; Shapiro, Bootzin, Figueredo, Lopez, & Schwartz, 2003; Soden, Vincent, Craske, Lucas, & Ashley, 2004), shorter latency (Cannici, Malcolm, & Peek, 1983; Cohen et al.; Simeit, Deck, & Conta-Marx, 2004; Wright, Courtney, & Crowther, 2002), longer duration (Cohen et al.; de Moor et al.; Fobair et al., 2002; Simeit et al.; Weze, Leathard, Grange, Tiplady, & Stevens, 2004), higher sleep efficiency (Simeit et al.), less daytime dysfunction (de Moor et al.), and use of fewer medications (Cohen et al.; Simeit et al.). Swedish techniques of therapeutic massage resulted in sleep quality remaining the same but not improving (Smith, Kemp, Hemphill, & Vojir, 2002).

Psychoeducation and information interventions include the use of structured education via a variety of media to provide patients with specific information regarding treatment and side effects. One randomized, controlled trial, using a single-item measure of sleep, increased sleep duration using an educational informational tape in men receiving radiation for localized prostate cancer (Kim, Roscoe, & Morrow, 2002). Another randomized, controlled trial, using a modified self-care diary to measure the severity of sleep disturbances, showed no change in sleep disturbances after using informational audiotapes in women with breast cancer undergoing chemotherapy (Williams & Schreier, 2005).

Exercise interventions involve any planned, structured, and repetitive bodily movement that is performed with the intent of improving or maintaining one or more components of physical fitness, performance, or health. Three aerobic, strength, and resistance training exercise interventions have been conducted for the primary purpose of improving exercise tolerance and decreasing fatigue; a secondary outcome was improving sleep. One quasi-experimental study reported that patients in the experimental group who used a self-paced, progressive, home-based exercise program had less difficulty sleeping (Mock et al., 1997). Another quasi-experimental study revealed that self-reported sleep patterns were improved in subjects who met twice per week for exercise and education (Young-McCaughan et al., 2003). A third study found that conducting a home-based aerobic and resistance-training exercise program for patients who were receiving high-dose chemotherapy and peripheral blood stem cell transplantation for multiple myeloma was feasible; the intervention is being tested now in a larger sample using a randomized, controlled trial design (Coleman et al., 2005). View the original articles that are included in Table 1, the Appendix, and the online ONS PEP resources to learn more about the interventions designed to improve sleep-wake disturbances in patients with cancer (ONS, 2005, 2006).

Summary

Sleep-wake disturbances have been identified as common and distressing symptoms in patients with cancer. No evidence-
based nursing interventions for sleep-wake disturbances can be given the highest recommendation at this time. The reasons relate primarily to the infancy of research in the topic area and the many gaps in knowledge.

The current study designs frequently are descriptive or quasi-experimental. Few instruments have established psychometric properties in patients with cancer, and they have been used inconsistently. Sleep rarely has been selected as the primary outcome of cancer symptom management studies. When sleep is not the primary outcome, instruments by which sleep and day functioning and sleepiness are measured are more likely to be brief and unidimensional. Because of the inconsistency in selecting instruments to date, few comparisons can be made among results of the studies. The development of the knowledge base on this topic will be indicated when results of several large randomized, controlled trials are reported in which the primary outcome variable is sleep-wake disturbances.

A need also exists to expand samples to include a wider scope of cancer diagnoses, stages of disease, and treatments. Samples of patients with breast cancer and mixed diagnoses have been included most frequently in studies to date. Most studies have examined patients’ sleep during active cancer treatment, with fewer examining sleep during long-term follow-up and none examining sleep at the end of life. Studies have been conducted most frequently in the outpatient setting and less often in hospitals and rehabilitation settings in the United States or Canada, with a few in Western Europe.

Nursing educators need to include sufficient content about sleep to students at the graduate and undergraduate levels (Lee, Landis, et al., 2004). Educators also need to teach students to develop care plans that use the highest levels of evidence-based interventions for patients with cancer.

Clinical nurses can use the PEP card and online resources to become familiar with several types of interventions that show promise and have shown efficacy in smaller studies, including CBTs, a variety of CTs, psychoeducational strategies, and exercise techniques. The Clinical Sleep Assessment for Adults and Children (Lee & Ward, 2005) has been selected by the state-of-the-science conference participants as an ideal tool to use to screen for sleep-wake disturbances in the clinical setting (Berger et al., 2005). Clinicians can use assessment data to design and implement a tailored intervention to increase patients’ ability to fall asleep, stay asleep, and wake up refreshed and without excessive daytime sleepiness. Clinical nurses gradually will become more comfortable teaching patients about interventions to improve sleep in one or more of the categories. The PEP card provides clinical nurses with resources to access current evidence-based interventions for specific NSPOS. The recommendations for practice enable nurses to provide high-quality, evidence-based care to patients with cancer experiencing sleep-wake disturbances.

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**References**


Learn More About Putting Evidence Into Practice

For more information about evidence-based interventions for sleep-wake disturbances, including different versions of the Putting Evidence Into Practice card, definitions, evidence tables, and a complete list of references, visit www.ons.org/outcomes/sleep.shtml.

Putting Evidence Into Practice information on three other nursing-sensitive patient outcomes—fatigue, nausea and vomiting, and prevention of infection—also is available online at www.ons.org/outcomes.
Appendix. Putting Evidence Into Practice Card on Sleep-Wake Disturbances

What Can Nurses Do to Assist People With Cancer With Sleep-Wake Disturbances?

**RECOMMENDED FOR PRACTICE**

Interventions for which effectiveness has been demonstrated by strong evidence from rigorously designed studies, meta-analyses, or systematic reviews and for which the expectation of harms is small compared to the benefits

There is no intervention that can be recommended for nursing practice as of 12/1/2005.

**LIKELY TO BE EFFECTIVE**

Interventions for which the evidence is less well established than for those listed under “Recommended for Practice”

There is no intervention that is likely to be effective for nursing practice as of 12/1/05.

**BENEFITS BALANCED WITH HARMs**

Interventions for which clinicians and patients should weigh the beneficial and harmful effects according to individual circumstances and priorities

Pharmacologic

In spite of widespread use, no published meta-analyses or experimental design studies examining the efficacy of hypnotic drugs in patients with cancer were found. Nurses must systematically evaluate how patients with cancer respond to a pharmacologic intervention, particularly the efficacy, side effects, and potential interactions with other over-the-counter and prescription medications they are taking.1,2

Although the drugs have not been studied in patients with cancer, hypnotics are commonly prescribed for short-term use. Benzodiazepines and nonbenzodiazepine drugs vary in their half-lives. Those with longer half-lives can cause daytime sleepiness and impair functioning; those with shorter half-lives may wear off in the middle of the night. Agents included in the National Cancer Institute’s PDQ Sleep Disorders Web site1 that are commonly prescribed but must be individually evaluated for side-effect profile include

- Benzodiazepines: diazepam 5–10 mg, triazolam 0.125–0.5 mg, and clonazepam 0.5–2 mg
- Nonbenzodiazepine hypnotics: zolpidem tartrate 5–20 mg, zaleplon 10–20 mg, and eszopiclone 1–3 mg
- Other classes of drugs: Tricyclic antidepressants, second-generation antidepressants, antihistamines, chloral derivatives, and neuroleptics are less commonly used but may be considered to improve sleep.

Herbal supplements

No published meta-analyses or experimental design studies were found specific to the efficacy of herbal therapy in patients with cancer. Studies describe potential interactions between herbal agents with chemotheraphy and other common drugs, making herbal agents potentially dangerous for use in people with cancer.4

**EFFECTIVENESS NOT ESTABLISHED**

Interventions for which insufficient data or data of inadequate quality currently exist

Cognitive behavioral therapy

Therapy that involves changing negative thought processes and attitudes about one’s ability to fall asleep, stay asleep, get enough sleep, and function during the day5

Instruct patients in the following stimulus control and sleep restriction techniques.

- Go to bed only when sleepy and at approximately the same time each night.
- Get out of bed and go to another room whenever unable to fall asleep; return to bed only when sleepy again.
- Use the bedroom for sleep and sex only.
- Maintain a regular rising time each day.
- Avoid daytime napping. If needed, limit to 30–45 minutes.

Sleep hygiene techniques include behaviors to promote a good night’s sleep and optimal functioning the next day.5

- Use a preferred relaxation technique within two hours of going to bed, such as taking a warm bath or shower, reading, listening to soft music, receiving a massage, etc.
- Avoid caffeine after noon; complete dinner three hours before bedtime; do not go to bed hungry.
- Replace mattress every 10–12 years and pillows more frequently; keep the bedroom cool and use light covers; do not watch television in the bedroom, etc.

Two randomized controlled trials and four quasi-experimental studies have tested cognitive-behavioral therapy, primarily with patients with breast cancer and also with patients with a variety of other cancer diagnoses.6–11 Results included favorable sleep outcomes, except that the number and length of night awakenings were greater than normal limits.

Complementary therapies, including expressive therapy, expressive writing, healing, autogenic training, massage, muscle relaxation, mindfulness-based stress reduction (MBRS), yoga

- Encourage patients to decrease stress by selecting relaxation techniques that suit them, including massage, individual muscle relaxation, meditation, MBSR, yoga, and autogenic training.
- Encourage patients to keep a journal in which they document their deepest thoughts and feelings about their illness and treatment.
- Encourage patients to decrease stress by focusing on isolating various muscle groups while moving progressively up and down the body. Encourage focused breathing, with all attention centered on the sensations of breathing, including the rhythm and rise and fall of the chest.
- Provide referral to appropriate practitioners as needed.

One randomized controlled trial and two quasi-experimental trials looked at MBSR, a combination therapy of relaxation techniques, meditative techniques, and yoga, in breast cancer, early prostate cancer, and a mixed group of cancer populations and found improved sleep quality with the therapy.14–17

Two studies using mixed cancer populations found autogenic training to have favorable sleep outcomes.14,15 Patients with lymphoma showed significant decreases in sleep disturbances with Tibetan yoga.16 Supportive-expressive group therapy intervention resulted in decreased wake-after-sleep-onset time in patients with breast cancer.11 One randomized controlled trial with subjects with newly diagnosed stage IV metastatic renal cell cancer showed improvement in four measured areas of sleep disturbance when using expressive writing.13 One randomized controlled trial with a variety of cancer populations showed a reduction in sleep latency when using progressive muscle relaxation.19 Patients with a variety of cancer diagnoses showed improvement on self-reported sleep disturbances with the use of healing touch.20 One study that looked at the use of massage on a group of patients with a variety of cancers undergoing therapy showed unknown benefit.21

...
Education/information
• Provide patients with information regarding specifics of treatment and expected side effects, including sleep-wake disturbances.
• Repeat this information throughout the treatment.
• Teach patients basic information about sleep hygiene (see "Cognitive behavioral therapy").

One randomized controlled trial showed favorable sleep outcomes using an informational tape as an educational intervention with men receiving radiation for localized prostate cancer. Another randomized controlled trial using informational audiotapes with women with breast cancer undergoing chemotherapy showed no change in sleep disturbances.27

Exercise
• Rule out bone metastasis or exercise contraindications.
• Have patients complete moderate exercise (e.g., brisk walking 20–30 minutes four to five times per week) at least three hours before bedtime.
• Encourage patients to perform strength and resistance training.

Two quasi-experimental studies showed favorable sleep outcomes using aerobic exercise, one with patients with breast cancer and another with patients with a variety of cancers.28,29 A third study looking at exercise and sleep in subjects with multiple myeloma was inconclusive because of a high (42%) attrition rate.10

References


