



Sleep/Wake Disturbances

Evidence Table

(Literature search completed through May 2008)

Author and Year	Characteristics of the Intervention	Sample Characteristics, Setting Characteristics, Study Design, and Conceptual Model	Measures	Results and Conclusions	Limitations, Major and Minor Flaws, Cautions and/or Contraindications, Special Training Needs, and Costs
<b>Pharmacological Therapies- PEP Weight of Evidence Category: Benefits Balanced with Harm</b>					
Carpenter et al., 2007b	<p>Trial examined the efficacy of two doses of venlafaxine: 37.5 mg of venlafaxine (low-dose study) or 75 mg of venlafaxine (high-dose study) to treat hot flashes after breast cancer</p> <p>Women were scheduled for 14 weekly visits. Weeks 1 and 2 provided baseline information, and weeks 3-14 included six weeks of treatment and six weeks of placebo.</p> <p>Outcomes: hot flash (frequency, severity, and bother), hot flash impact on daily life, negative effect, fatigue, sleep, and QOL</p>	<p>N = 57 (breast cancer survivors in low-dose study) N = 20 (breast cancer survivors in high-dose study)</p> <p>Treatment phase: long-term follow-up</p> <p>University cancer clinics in the southeastern and midwestern United States.</p> <p>Two randomized, double-blind, placebo-controlled crossover trials</p> <p>Conceptual model not identified</p>	<p>Adherence measured by capsule counts and weekly written verification: Sternal skin conductance monitor Electronic event markers and written diaries used for self-reporting hot flashes POMS-SF, Positive and Negative Affect Scale, CES-D, Diagnostic and Statistical Manual of Mental Disorders and Hamilton Rating Scale-Depression, PSQI, Medical Outcomes Survey(MOS).</p>	<p>Venlafaxine resulted in modest decreases in hot flashes, but only hot flash interference improved differentially at the higher dose. The timing of venlafaxine's effects on hot flashes varied by dose. Only women with a greater to or equal to 50% decrease in physiologic hot flashes experienced significant improvement in fatigue, sleep quality, and QOL. Although side effects were mild, most patients discontinued venlafaxine long term.</p>	<p>Racially and ethnically homogeneous samples, small sample sizes, limited treatment time, and lack of pharmacogenetic data</p> <p>Limitations involved in assessing hot flashes: subjective hot flash measures are prone to placebo effects and subjective hot flash measure and secondary outcome measures may both be subject to a positive reporting bias.</p> <p>Study psychologist used to verify the absence of depressive symptoms, which could confound data if present</p> <p>Trained study nurses are required.</p>
<b>Cognitive Behavioral Therapy—PEP Weight of Evidence Category: Effectiveness Not Established</b>					
Allison et al., 2004	<p>NuCare coping strategies program: self-study book and audiocassette designed to enhance personal control and teach emotional and instrumental coping responses</p> <p>Training in problem solving, relaxation, coping skills, goal</p>	<p>N = 66 patients with head and neck cancer; 59 completed the program and 50 gave outcome data. No age, gender, race, or ethnicity was given.</p> <p>Treatment phase: active treatment and long-term follow-up</p>	<p>The European Organization for Research and Treatment of Cancer QOL Questionnaire C-30 (EORTC QLQ C-30) was used to measure QOL and sleep.</p>	<p>Improvement reported in physical and social functioning and global QOL, sleep disturbance, fatigue, and depressive symptoms.</p>	<p>Patients able to choose format used.</p> <p>Pilot study was not designed to test the effectiveness of the intervention.</p> <p>Special training of research nurse is required.</p>



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	<p>setting, communication, social support, and lifestyle factors</p> <p>Outcomes: quality of life (QOL), anxiety, and depression</p>	<p>Participants chose among a small group format (n = 3), one-on-one sessions with a therapist (n = 33), or a home format without a therapist (n = 23)</p> <p>Canada</p> <p>Prospective, nonrandomized one-group feasibility design</p> <p>McGill Model of Nursing was used; it stresses a partnership between the patient and family where situation-responsive learning about healthy behaviors and coping can occur.</p>			<p>No cost to patients</p>
<p>Arving et al., 2007</p>	<p>Individualized psychosocial support intervention using cognitive behavioral techniques, including relaxation, distraction, activity scheduling, and ways to improve communication</p> <p>Frequency varied based on patient perception of need.</p> <p>Outcomes: QOL, fatigue, nausea, pain, dyspnea, insomnia, appetite loss,</p>	<p>N = 179 consecutive primary patients with breast cancer</p> <p>Treatment phase was active treatment.</p> <p>Participants were randomized in blocks of nine into one of three alternatives: individual psychosocial support by (a) a specially trained oncology nurse (n = 60), (b) a psychologist (n = 60), or (c) standard care (n = 59)</p>	<p>EORTC QLQ C-30, EORTC QOL Questionnaire Breast Cancer Module, The Hospital Anxiety and Depression Scale (HADS), the Impact of Event Scale, and the State Trait Anxiety Inventory (STAI)-State</p>	<p>The results revealed statistically significant group by time interactions on global QOL and health status, nausea and vomiting, and systemic therapy side effects subscales. Intervention groups showed statistical differences on the insomnia, dyspnea, and financial difficulties EORTC subscales, in favor of one or both of the interventions.</p>	<p>Dose was not controlled but varied by number of sessions and driven by "patient need".</p> <p>Need for special training to deliver intervention</p>



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	constipation, diarrhea, and financial difficulties	Sweden  Prospective, randomized, quasi-experimental study using repeated measures at baseline, one, three, and six months  Conceptual model was not identified			
Berger et al., 2002	Multicomponent cognitive-behavioral therapy  Individual sleep promotion plan: sleep hygiene, relaxation treatment, stimulus control, and sleep restriction  Plan starts two days before the first treatment, is revised before each treatment, and is reinforced seven days after each treatment. Four doses and reinforcements administered.  Restrictions are delivered by RNs.  Outcomes: sleep and fatigue	N = 25 female Caucasians (mean age = 54.3 years, range = 40–65 years) with stage I or II breast cancer during adjuvant chemotherapy  Treatment phase: active treatment  Urban oncology clinics and patient homes  Midwestern United States Prospective, repeated measures, quasi-experimental feasibility study, one group  Piper's Integrated Fatigue Model	Pittsburgh Sleep Quality Index (PSQI), daily diary, and wrist actigraph	Sleep latency, efficiency, total rest, and rating of feeling refreshed on awakening were stable; time awake after sleep onset and nighttime awakenings exceeded desired levels.	The pilot study was not designed to test the effectiveness of the intervention.  Research RN training is required.  Actigraphs incur cost.
Berger et al., 2003	Multicomponent cognitive-behavioral therapy	N = 21 female Caucasians (mean age = 55.3 years, range = 43–66 years) with	PSQI, daily diary, and wrist actigraph	High adherence was found except for stimulus control. Sleep latency remained stable.	The pilot study was not designed to test the effectiveness of the

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	<p>Individual sleep promotion plan: sleep hygiene, relaxation, stimulus control and sleep restriction was delivered by an RN. The plan starts two days before the first treatment, continues during chemo treatment, is revised 30, 60, and 90 days after the last treatment, and is reinforced seven days later. Three doses administered.</p> <p>Outcomes: sleep, fatigue</p>	<p>stage I or II breast cancer following adjuvant chemotherapy</p> <p>Treatment phase: long-term follow-up</p> <p>Patients' homes</p> <p>Midwestern United States</p> <p>Prospective, repeated measures, quasi-experimental feasibility study, one group</p> <p>Piper's Integrated Fatigue Model</p>		<p>Sleep efficiency ranged from 82%–92%; total rest ranged from seven to eight hours per night. Night awakenings ranged from 10–11 per night.</p>	<p>intervention.</p> <p>Research RN training is required.</p> <p>Actigraphs incur cost.</p>
<p>Carpenter et al., 2007a</p>	<p>Cognitive-behavioral intervention to determine acceptability of a DVD delivery platform for intervention and pilot test the efficacy of the intervention</p> <p>Participants viewed DVD and were asked to practice intervention for one week.</p> <p>Outcomes: hot flash occurrences, severity, bother, mood disturbance, affect, hot flash disruption, and sleep disturbances</p>	<p>N = 49 (26 at site 1 and 23 at site 2), with 40 completing all aspects of the study. Women with any stage breast cancer or high risk for disease were included. Women were aged 21 or older and experiencing hot flashes (75% Caucasian, average age of 54.42 years, 93% post-menopausal)</p> <p>Treatment phase: long term follow up</p> <p>Outpatient cancer clinics serving rural and urban areas,</p>	<p>Center for Epidemiological Studies-Depression scale (CES-D), Profile of Mood States- Short Form (POMS-SF), Positive and Negative Affect Scale, objective hot flash monitoring, Biolog3991, hot flash severity and bother, Hot Flash-Related Daily Interference Scale, PSQI, and wrist actigraphy (Actiwatch-Mini Mitter, Bend, OR)</p>	<p>DVD was an accepted and feasible intervention delivery method. Although statistically significant improvement in hot flash parameters was observed, changes were equal to about a 10% change. The 10% reduction in hot flashes did affect related outcomes, with Hot Flash-Related Daily Interference Scale improving in all participants and CES-D scores improving in the subset that reported the worst hot flash severity.</p> <p>No change in affect or sleep</p>	<p>Unblinded, single-group design Allows for placebo effect</p> <p>Small sample size</p> <p>Difficulty quantifying frequency of intervention use and, therefore, the variable was not included in the analyses.</p> <p>Drawbacks to using DVD include the one-way nature of instruction and limited opportunity for participants to ask questions.</p>



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		<p>in the midwestern and southeastern United States</p> <p>Nonrandomized pretest, post-test design pilot study</p> <p>Carpenter's Conceptual Model First premise is that hot flashes are physiologic events as well as reported events. Second premise is that hot flashes can have a negative impact on mood, affect, daily activities and sleep. The cognitive-behavioral intervention is aimed at reported hot flash severity and bother.</p>		was noted.	
Cohen & Fried, 2007	<p>Comparison of cognitive-behavioral group intervention versus a relaxation and guided imagery group training intervention.</p> <p>Intervention groups received nine weekly sessions of 90 minutes each. Control group received standard of care</p> <p>Outcomes: psychological distress, sleep, fatigue, and health locus of control</p>	**** See complementary medicine section for further description of study ****			
Dalton et al., 2004	Patients received standard cognitive-based therapy,	N = 131 patients (mean age = 52 years) who were	Brief Pain Inventory, Profile of Mood States, Karnofsky	Short-term outcome: Based on the Brief Pain	Poor retention was noted, with only 28 patients completing



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	<p>profile-tailored cognitive-based therapy, or usual care. The therapy group sessions ranged from 5–50 minutes in length.</p> <p>Standard cognitive-based therapy is comprehensive cognitive and behavioral therapy that evaluates thoughts, feelings, and behaviors. It uses six to eight treatment strategies to teach patients to understand the relationship among pain, suffering, and emotions; to use symptom-coping skills, problem solving, relaxation, and self-control; and to modify cognitive distortions associated with emotional distress.</p> <p>Profile-tailored cognitive-behavioral therapy matched patients' scores on the Biobehavioral Pain Profile to specific cognitive-behavioral treatment modules, environmental influences, loss of control, healthcare avoidance, past and current experience, physiologic responsivity, and thoughts of disease progression.</p>	<p>experiencing cancer-related chronic pain for more than six weeks that was associated with disease progression, adjuvant therapy, or surgical exploration; 72% were female. 63% were Caucasian, and 35% were African American. Patients had at least one elevated score on the Biobehavioral Pain Profile.</p> <p>The most common diagnoses were lymphoma and breast, colon, and lung cancers.</p> <p>Treatment phase: active treatment One inpatient and three outpatient cancer centers in the southeastern United States</p> <p>Randomized, controlled trial</p>	<p>Performance Status, Medical Outcomes Study–Short Form Health Survey, Katz Index of Independence in Activities of Daily Living</p>	<p>Inventory, interference with sleep improved immediately pre- to immediately post-intervention for the profile-tailored cognitive-behavioral therapy group.</p> <p>Between-group comparison of the treatment effect over the entire study found treatment effects for interference of pain with mood and sleep. Response to the intervention decreased with time.</p>	<p>the study. The final sample size was very small.</p> <p>Other concepts: fatigue, pain, bowel patterns, symptom distress, QOL, better Karnofsky Performance Status</p> <p>RNs received a two-day training course to deliver the intervention.</p> <p>Space is needed to provide the intervention.</p>



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Davidson et al., 2001	<p>Multimodal cognitive-behavioral therapy: group therapy, six 1–1.5 hour sessions weekly X 5 and repeated in four weeks; stimulus control therapy, relaxation training, sleep consolidation strategies, and strategies to reduce cognitive-emotional arousal were included.</p> <p>Outcomes: sleep, quality-of-life role function and insomnia, fatigue</p>	<p>N = 14, but 12 completed the study; participants' mean age was 54.7 years. Subjects had mixed cancer diagnoses, and the mean time from diagnosis was 33.6 months.</p> <p>Treatment phase: long-term follow-up</p> <p>Outpatient clinics at a major cancer center in Central Canada and the community serving the cancer center</p> <p>Midwestern Canada</p> <p>Repeated measure, quasi-experimental; no control group</p> <p>Conceptual model was not identified.</p>	Sleep diary and Sleep Impairment Index	Sleep improved from baseline to four weeks and to eight weeks after the intervention. Improved sleep measures: number of awakenings, wake after sleep onset, and sleep efficiency	<p>Limitations included a small sample size, relatively healthy participants, use of self-report only, and lack of a placebo control group. Also, the duration of effects after eight weeks was unknown.</p> <p>Space to provide intervention is needed.</p>
Dirksen & Epstein, 2008	Determine the efficacy of intervention for insomnia on fatigue, mood, and QOL in breast cancer survivors who were randomized to a multicomponent intervention: stimulus control, sleep restriction, sleep education, and hygiene or control intervention: sleep education and hygiene.	<p>N = 34 (multicomponent intervention:) N = 38 (control group) Women aged 18 years or older with a diagnosis of stage I, II, or III breast cancer with an insomnia complaint of at least three months duration</p> <p>Treatment phase: follow up (not really long term)</p>	POM Fatigue/Inertia Subscale(SF/I) STAI CES-D FACT-Breast, ISI	The intervention group statistically improved on fatigue, trait anxiety and depression. The control intervention showed trends toward significance in improvement in fatigue, trait anxiety and depression as well. Both groups showed improvement in QOL. A significant correlation was found between insomnia	<p>Selective sample: women were primarily white, well educated, and, on average, were diagnosed with cancer six years previously Recruitment via ad and support groups and therefore more motivated to receive treatment</p> <p>Space for group meetings</p>



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	<p>Four weekly treatment group sessions, session 1 being two hours and sessions 2–4 being one hour, followed by two weekly individual telephone sessions (15-30 minutes).</p> <p>Outcomes: fatigue, mood, and QOL</p>	<p>University or Medical Center Classrooms</p> <p>Randomized controlled trial</p> <p>Conceptual Model: Three P's (predisposing, precipitating, and perpetuating factors)</p>		<p>severity and fatigue for both groups. It also correlated significantly with trait and state anxiety and QOL for the control intervention group.</p>	<p>Master's level CNS in psych, trained in the delivery of the intervention</p> <p>Long-term sustainability of intervention is unknown</p>
<p>Epstein &amp; Dirksen, 2007</p>	<p>Interventions tested included multicomponent intervention: stimulus control, sleep restriction, sleep education, and hygiene and a control intervention: sleep education and hygiene</p> <p>Four weekly treatment group sessions, session 1 = 2 hours, session 2-4 = 1 hour, followed by two weekly individual telephone sessions (15-30 minutes).</p> <p>Outcomes: Sleep-onset latency, wake-after-sleep onset, total sleep time, time in bed, sleep efficiency, and sleep quality</p>	<p>N = 34 (multicomponent intervention:) N = 38 (Control Group)</p> <p>Women age &gt;18 with a diagnosis of stage I, II, or III breast CA with an insomnia complaint of at least 3 months duration</p> <p>Treatment phase: follow up</p> <p>University or Medical Center Classrooms</p> <p>Randomized controlled trial</p> <p>Conceptual Model: 3-P's (predisposing, precipitating, and perpetuating factors)</p> <p>Spielman, Saskin, &amp; Thorpy, 1987</p>	<p>Daily Sleep Diary, sleep-onset latency, wake-after-sleep onset, total sleep time, time in bed, sleep efficiency, and sleep quality.</p> <p>Actigraphy</p> <p>Sleep evaluation</p> <p>Perception of sleep-onset latency, wake-after-sleep onset, total sleep time, and quality of sleep</p>	<p>After the intervention, both groups improved on sleep-onset latency, wake-after-sleep onset, total sleep time, time in bed, sleep efficiency, and sleep quality based on daily sleep diaries. A between-group difference existed for time in bed. Wrist actigraph data showed significant pre- to post-intervention changes for sleep-onset latency, wake-after-sleep onset, total sleep time, and time in bed. When compared to the control group, the multicomponent intervention group rated overall sleep as more improved.</p> <p>A nonpharmacologic intervention is effective in the treatment of insomnia in</p>	<p>Selective sample: the women were primarily white, well educated and, on average, were diagnosed with cancer six years previously. Recruitment via ad and support groups and therefore more motivated to receive treatment.</p> <p>Space for group meetings</p> <p>Actigraph cost</p> <p>Master's level CNS in psych, trained in the delivery of the intervention</p>

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Espie et al., 2008	<p>5-50 minute, small group (four to six) sessions delivered across five consecutive weeks, following a manualized protocol. Sessions included, sleep information, sleep hygiene and relaxation, sleep scheduling, cognitive approaches, developing a strong and natural sleep pattern.</p> <p>Outcomes: Sleep, health-related QOL, psychopathology, and fatigue</p>	<p>N = 100 (Cognitive Behavioral Therapy [CBT] intervention) N = 50 (Treatment as Usual [TAU])</p> <p>103 females; mean age 61 years</p> <p>Completed active therapy for breast, prostate, colorectal, or gynecologic cancer more than one month prior, with a diagnosis of chronic insomnia</p> <p>Treatment phase: follow-up Two oncology clinics in Glasgow and Aberdeen, Scotland</p> <p>Study design: randomized clinical trial two-group CBT versus TAU</p> <p>Cognitive Behavior Model</p>	<p>HADS, Fatigue Symptom Inventory (FSI), FACT-General, PSQI, Epworth Sleepiness Scale-ESS, sleep diary, Actigraphy</p>	<p>breast cancer survivors.</p> <p>CBT associated with mean reductions in wakefulness of 55 minutes per night compared with no change in TAU group. Outcomes sustained six months after the intervention. Statistically significant improvement in wake-after-sleep onset-, sleep onset latency, and sleep efficiency, not total sleep time. Actigraphy did not show statistically significant changes in sleep outcomes. CBT patients had reduced symptoms of fatigue, anxiety, and depression and increased physical and functional QOL compared to TAU.</p>	<p>Training required to deliver CBT Space for group meeting Actigraph cost</p>
Quesnel et al., 2003	<p>Two-phase multimodal cognitive-behavioral therapy combined strategy: (a) over 3–10 weeks and (b) over eight weeks; eight weekly sessions lasted 90 minutes.</p> <p>Establish treatment objectives, stimulus control, sleep</p>	<p>N = 10 women with nonmetastatic breast cancer (stages I–III), mean age = 54.3 years; women completed chemotherapy and/or radiation therapy. All had a diagnosis of chronic insomnia disorder per the <i>Diagnostic and Statistical Manual of Mental Disorders</i></p>	<p>ISI, Insomnia Interview Schedule, sleep diary, self-report scales, polysomnography and breathing parameters</p>	<p>Most women experienced a statistically significant improvement in sleep efficiency and decreased total wake time pre- and post-treatment. Sleep efficiency continued at the six-month follow-up, but total wake time did not.</p>	<p>Limitations included the small sample size and incomplete sleep diaries.</p> <p>Potential existed for influence factors, such as intragroup alliance and empathy.</p> <p>Sleep improvement may be an</p>



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	<p>restriction, coping strategies for fatigue, and reframing maladaptive cognitions.</p> <p>Outcomes: sleep, mood, fatigue, and global and cognitive QOL</p>	<p>(4th ed.). All had completed high school.</p> <p>Treatment phase: long-term follow-up</p> <p>One site; subjects were recruited from the community sleep laboratory and subjects' homes.</p> <p>Quebec, Canada</p> <p>Prospective nonrandomized, repeated measures; quasi-experimental; single-case design comparing each individual over time</p> <p>Cognitive Behavioral Model</p>		<p>Findings on sleep diaries were corroborated by objective measures.</p>	<p>effect of time away from cancer therapy.</p> <p>A trained psychologist must administer the tests; in addition, cost is incurred by using a sleep laboratory for polysomnography.</p>
<p>Savard et al., 2005</p>	<p>Eight weekly, 90-minute group sessions combined behavioral (stimulus control, sleep restriction), cognitive (cognitive restructuring), and educational (sleep hygiene, fatigue, and stress management) strategies.</p> <p>Outcomes: sleep, medication use, psychological distress, QOL</p>	<p>N = 57 women who had completed radiation and chemotherapy for stage I–III breast cancer and met <i>Diagnostic and Statistical Manual of Mental Disorders</i> (4th ed.) criteria for a chronic insomnia syndrome.</p> <p>Treatment phase: long-term follow-up</p> <p>Subjects were recruited from the community by advertisement.</p>	<p>Insomnia Interview Schedule, Structured Clinical Interview for <i>Diagnostic and Statistical Manual of Mental Disorders</i> (4th ed.), sleep diary, polysomnography and ISI</p>	<p>Treated patients showed a significantly greater improvement in sleep post-treatment as assessed by self-reported instruments. However, data from polysomnography were not significantly more improved. Treated patients reduced use of sleep medication.</p>	<p>Limitations included a homogeneous sample (i.e., all white), with most being highly educated, and a self-selected study group.</p> <p>Use of a wait-list control</p> <p>A master's-level psychologist who has experience in the administration of this treatment protocol must be included.</p>

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		Canada 2 group clinical trial with wait list control  Cognitive Behavioral Model			
Savard, 2006	8-(60-90 minute) weekly sessions of cognitive therapy followed by 3 booster sessions given at 3 week intervals. The focus of the therapy was aimed at developing an optimistic but realistic attitude toward their situation as opposed to a negative or overly positive attitude.  Outcomes: depression anxiety, insomnia, fatigue, QOL, and immunological measures	N= 45 Caucasian women with metastatic breast disease (stage IV) with depressive symptoms determined by HADS-D scores.  Treatment phase- active treatment  3 Canadian cancer clinics  2 group clinical trial using wait list control Randomly assigned either to the (1) cognitive therapy (CT) or (2) waiting list control (WLC) condition  Model- Cognitive theory of emotions	Structured Clinical Interview for DSM-IV Scale for Suicide Ideation HADS Beck Depression Inventory Hamilton Depression Rating Scale(HRDS) ISI Multidimensional Fatigue Inventory (MFI) The European Organization for Research and treatment of Cancer QOL Questionnaire( EORTC QLQ-C33) The European Organization for Research and treatment of Cancer Breast Cancer Specific QOL Questionnaire Module (EORTC QLQ-BR23) Health Behavior Questionnaire( HBQ) List of Life Events (LLE) Immunologic Measures included lymphocyte subpopulations, NK cell activity, cytokine secretion	Although the group comparison was statistically significant on the HDRS measure only, comparison of means of other measures BDI, HADS-D revealed a reduction in depression scores in the treatment group vs. control group. In pooled group analysis these gains were sustained. Also, when using pooled data set only found decreased anxiety, fatigue, and insomnia symptoms No treatment effect found on the immune variables  Study supports the efficacy of using cognitive therapy for treating depressive symptoms in women with metastatic breast cancer	Small homogenous sample  Patients not severely depressed, leave less room for improvement.  Licensed psychologist trained in Cognitive Therapy required to deliver treatment.



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Vilela et al., 2006	<p>The Nucare program, a short-term psychoeducational coping strategies intervention.</p> <p>Three delivery formats offered: (1) small group (2) one-to-one (3) home format with didactic material</p> <p>The didactic material comprises a workbook, cassette or CD containing spoken instruction to guide individual through the workbook and music to accompany the relaxation training component.</p> <p>Outcomes: QOL and depressive symptoms</p>	<p>N = 101 Patients with head and neck primary cancer, up to 36 months following diagnosis, who had finished their cancer treatment and were able to understand and complete the study questionnaires.</p> <p>Treatment phase: long-term follow-up</p> <p>Outpatient oncology clinic at the Jewish General Hospital Montreal, Canada</p> <p>Feasibility study, prospective, nonrandomized design, two groups, repeated measures at baseline and at three and four months,</p> <p>Conceptual model was not identified.</p>	<p>European Organization for Research and Treatment of Cancer Core QOL to measure health-related QOL</p> <p>HADS to measure depression and anxiety</p>	<p>Compared with their baseline scores, the intervention group had improved physical and social functioning, global QOL, fatigue, sleep disturbance, and depressive symptoms; the control group showed no changes in QOL or depressive symptoms.</p>	<p>Sample make-up and size</p> <p>The sample was a convenience one and a significant number of who people refused to participate, thereby reducing generalizability.</p> <p>Sample size was not based on any calculation or hypothesis; rather, it was determined by logistical and financial constraints, so some differences may have been missed owing to insufficient power.</p> <p>Loss to follow-up, which was greater in the test group than in the control group</p>
<p><b>Complementary Therapies— PEP Weight of Evidence Category: Effectiveness Not Established</b></p>					
Bozcuk et al., 2006	<p>Non-preferred music intervention at the time of chemotherapy administration</p> <p>Music intervention consisted of instrumental pieces of</p>	<p>N = 18 (median age of 45.5 years) mainly with stage II breast cancer receiving chemotherapy after modified radical mastectomies</p>	<p>EORTC QLQ-C-30</p>	<p>Brief, non-preferred music exposure at the time of chemotherapy administration does not improve QOL in patients with early stage breast cancer. However, there</p>	<p>Small sample size/pilot study</p> <p>Does not account for any other confounding variables except age</p>

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	<p>international classical music played during administration of chemotherapy</p> <p>Outcomes: QOL</p>	<p>Treatment phase: active treatment</p> <p>Outpatient clinics of the medical oncology department in Turkey</p> <p>A prospective quasi-experimental, pilot study</p> <p>Conceptual model was not identified</p>		<p>is still a possibility that a subgroup (age &gt; 45) will benefit from this approach as suggested by the interaction with patient age being highly significant for the insomnia and appetite loss scales.</p>	
Cannici et al., 1983	<p>Individual muscle relaxation training over three sessions plus instructions for home practice twice daily</p> <p>Outcomes: sleep</p>	<p>N = 30 patients (11 men and 19 women) with a mean age of 56 years (range = 21–80 years) and a variety of cancers</p> <p>Groups: relaxation (n = 15) and usual care (n = 15)</p> <p>Treatment phase: active treatment and long-term follow-up</p> <p>Quiet office in the hospital, patient's home, or patient's hospital room</p> <p>Southeastern United States</p> <p>Randomized, controlled trial</p> <p>No conceptual model was</p>	<p>Daily diary and questionnaire pertaining to sleep behavior the previous night for a total of nine nights</p>	<p>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. No differences were found in other sleep variables.</p>	<p>Sleep was measured by self-report.</p> <p>Training is needed in delivering muscle relaxation.</p> <p>No cost issues existed.</p>

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Carlson & Garland, 2005	<p>Mindfulness-based stress reduction meditation program: relaxation, meditation, gentle yoga, and daily practice; eight sessions and a 52-page booklet with weekly instructions plus an audiotape of the meditations</p> <p>Outcomes: sleep, mood, stress, fatigue</p>	<p>used.</p> <p>N = 63 patients (49 women and 14 men) with a mean age of 54 years (range = 32–78 years) and mixed cancer diagnoses and stages</p> <p>Treatment phase: long-term follow-up</p> <p>Outpatient setting Canada</p> <p>Prospective, repeated measures, quasi-experimental feasibility study; one group</p> <p>Mindfulness conceptual model was used.</p>	PSQI	At pretreatment, 91% of the sample had a PSQI of 5 or more and 51% had a score of 10 or more. At post-treatment, 27% reported a PSQI of more than 10. Sleep disturbance was significantly reduced, and subjective sleep quality was improved.	<p>Limitations included a lack of control or comparison group; also, only a subjective sleep measurement was used. The relative importance of different components of the intervention is not known.</p> <p>Training in delivering the intervention is needed.</p> <p>Cost is incurred for a space for the class and an instructor.</p>
Carlson et al., 2003; Carlson et al., 2004	<p>Mindfulness-based stress reduction meditation program: relaxation, meditation, gentle yoga, and daily practice; eight sessions and a 52-page booklet with weekly instructions plus an audiotape of the meditations</p> <p>Outcomes: QOL, mood, symptoms of stress, immune and hormone parameters</p>	<p>Pretest: N = 59 (49 patients with stage 0, I or II breast cancer and 10 with early-stage prostate cancer) Post-test: N = 42</p> <p>Treatment phase: long-term follow-up</p> <p>Outpatient setting; eight weekly, 90-minute group sessions plus a three-hour silent retreat on Saturdays on weeks 6 and 7</p>	EORTC QLQ C-30 subscale for sleep disturbance	Significant improvements were reported in sleep quality.	<p>Lack of control of the comparison group was a limitation.</p> <p>The relative importance of different components of the intervention is not known. Improvement in sleep was not correlated with the degree of program attendance or minutes of home practice.</p> <p>Training in delivering the intervention is needed.</p>



Sleep/Wake Disturbances

Evidence Table

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		Canada  One group, pre- and post-test design  Mindfulness conceptual model was used.			Cost incurred for a space for the class and an instructor.
Cohen et al., 2004	Tibetan yoga: seven weekly sessions with a yoga instructor who used imagery and exercise; four aspects: controlled breathing and visualization, mindfulness, two types of posture, and daily practice  Outcomes: psychological adjustment, sleep, fatigue	N = 39 (final N = 38) patients with lymphoma who had a mean age of 51 years in both groups  Treatment phase: active treatment and long-term follow-up  Community outpatient setting affiliated with a comprehensive cancer center  Southern United States  Prospective, quasi-experimental; two groups (wait-list control)  Mindfulness conceptual model was used.	PSQI	Tibetan Yoga (TY) group reported significantly lower sleep disturbances scores (total PSQI) at follow up; The TY group scores were 5.8 versus 8.1 for the wait list control group. At follow up the TY group reported better subjective sleep quality, shorter latency, longer duration, and use of fewer sleep medications	The small sample was a limitation; in addition, the study did not control for time since diagnosis.  Methods of yoga taught may vary with instructor.  Training in yoga is required.  Costs are incurred for a space for the class and an instructor.
Cohen & Fried, 2007	Comparison of cognitive-behavioral group intervention versus a relaxation and guided imagery group training intervention.	N = 170 stage I and II patients with breast cancer 2-12 months since surgery and receiving treatment (chemotherapy or radiotherapy)	Brief Symptom Inventory (BSI) FSI Perceived Stress Scale Mini Sleep Questionnaire (MSQ) Multidimensional Health Locus	General Stress Index and perceived stress dropped in both intervention groups but not in the control group. Means of fatigue symptoms and sleep difficulties fell in	Fairly high dropout rate N = 170, but only 114 completed the evaluation  Need for therapist trained in CBT and RGI

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	<p>Intervention groups received 9 weekly sessions of 90 minutes each. Control group received standard of care</p> <p>Outcomes: psychological distress, sleep, fatigue, and health locus of control.</p>	<p>Oncology center in northern Israel</p> <p>Active treatment</p> <p>Randomized control trial, three groups, CBT relaxation and guided imagery (RGI), and control group</p>	<p>of Control (MHLC) Adherence Questionnaire</p>	<p>both intervention groups but only significantly in the RGI group.</p> <p>External health locus of control dropped more in the CBT group.</p> <p>No differences were observed among groups in internal locus of control.</p> <p>Participants in the RGI group reported significantly higher adherence to self-practice at home than did those in the CBT group.</p>	<p>Meeting space</p> <p>Method of recruiting participants</p> <p>Group design: A model with four groups, CBT, RGI, combined CBT and RGI, and control, could shed light on whether the combined model is more advantageous than each of the interventions singly.</p> <p>Follow-up should be for longer periods and with more assessment points.</p> <p>Adherence</p>
<p>de Moor et al., 2002</p>	<p>Four weekly sessions of expressive writing associated with the first four cancer vaccines</p> <p>Random assignment to neutral health issues writing or expressive writing of the group's deepest thoughts and feelings</p> <p>Outcomes: psychological and behavioral adjustment, symptoms of distress,</p>	<p>N = 42 patients (85% male) with newly diagnosed stage IV metastatic renal cell carcinoma who were four to six week postoperative; mean age was 56.4 years.</p> <p>Treatment phase: active treatment</p> <p>Outpatient setting</p> <p>Southwestern United States</p>	<p>PSQI</p>	<p>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).</p>	<p>The small sample size was a limitation.</p> <p>Generalizability was questionable because of the nature of the illness.</p> <p>Space is needed for the writing to occur, prior to the injection.</p>



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	perceived stress, mood, sleep	Pilot study Randomized, controlled trial  Conceptual model was not identified.			
Fobair et al., 2002	Twelve 90-minute meetings of a supportive-expressive group therapy led by a licensed clinical social worker; participants discussed problems, coping, treatment, mood, self-efficacy, relationships, pain, sleep, body image, and sexuality.  Outcomes: emotional distress, mood, self-efficacy, body image, sexuality, social support, QOL, pain, sleep	N = 20 patients with stage I–IIIA breast cancer who had a mean age of 47 years  Status post surgery  Treatment phase: active treatment  Three community settings in Northern California  One group, pre- and post-test  Conceptual model was not identified.	Quality and quantity of sleep and daytime sleepiness using a brief questionnaire based on the Structured Insomnia Interview	Patients undergoing 12 weeks of supportive group therapy showed statistically significant improvement in sleep (less waking during night).	Limitations included a small sample and lack of a control group.  Training required to observe for unstable emotional status.  Lesbian licensed clinical social worker familiar with supportive-expressive group therapy is needed; cost incurred for a space for the class and the instructor.
Rabin et al., 2008	12-week theoretically grounded physical activity intervention and relaxation intervention delivered via telephone; the physical activity intervention was based on the Moving Forward Intervention (individuals pass through five stages of readiness when changing a health behavior), and the relaxation component included instructions in progressive muscle relaxation.	**** See exercise section for further description of study *****			



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	Outcomes: intervention feasibility and acceptability, physical activity, mood, fatigue, and sleep quality				
Shapiro et al., 2003	<p>Six weekly, two-hour sessions and one-hour silent treatment session; training in meditative practices (Kabat-Zinn), sitting meditation, body scan, Hatha yoga, and "Loving Kindness" meditation</p> <p>Didactic material on physical and psychological effects of stress and tools to cope with stress; control group chose a stress management technique to engage in each week and used a workbook and diary.</p> <p>Outcomes: sleep</p>	<p>N = 63 women with a history of stage II breast cancer who had a mean age of 57 years (range = 18–80 years); women were working, retired, or on disability</p> <p>Free-choice control group N = 32 Mindfulness-based stress reduction group N = 31</p> <p>Treatment phase: long-term follow-up</p> <p>Subjects' homes</p> <p>Western United States</p> <p>Randomized, controlled trial</p> <p>Mindfulness conceptual model was used.</p>	Sleep diary and a daily diary to record the activities they engaged in for stress management	<p>Hypothesis: Sleep function is associated with psychological distress. (confirmed)</p> <p>Hypothesis: Sleep efficiency would be improved after controlling for baseline distress. (not confirmed)</p> <p>Hypothesis: Sleep efficiency and sleep quality would improve with mindfulness-based stress reduction. (partially confirmed)</p>	<p>Lack of compliance with the practice of mindfulness techniques existed; the control group was given too much leeway in their choice of activities to reduce stress.</p> <p>Self-report from sleep diary was a limitation.</p> <p>Personnel trained in Kabat-Zinn and Hatha yoga are needed.</p>
Simeit et al., 2004	Multi-modal psychological sleep management program combining relaxation techniques (progressive muscle relaxation (PMR), or autogenic training (AT), sleep	<p>N = 80 in progressive muscle relaxation group N = 71 in autogenic training group N = 78 in control Mixed sample of adults with a</p>	Pittsburgh Sleep Quality Index (German Translation)	No statistically significant difference was found between the progressive muscle relaxation and autogenic training groups. Improvement was noted in the intervention	<p>Covariates such as hormone therapy and their effects on various sleep variables</p> <p>Use of a validated tool validity of German translation was not</p>



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	<p>hygiene, cognitive techniques and advice in stimulus control techniques Outcomes: sleep, QOL</p>	<p>mean age of 58 who predominantly had breast, kidney, or prostate cancer</p> <p>Treatment phase: long-term follow-up</p> <p>Three to four weeks' length of stay in an oncology rehabilitation clinic</p> <p>Germany</p> <p>Quasi-experimental design; sequential recruitment of groups, patient choice for progressive muscle relaxation or autogenic training Conceptual model was not identified.</p>		<p>groups regarding sleep latency, sleep duration, sleep efficiency, sleep medication (decreased), and daytime dysfunction.</p>	<p>addressed.</p> <p>The design was not randomized.</p> <p>Staff must be trained in autogenic training, progressive muscle relaxation, and other intervention techniques.</p>
<p>Smith et al., 2002</p>	<p>A trained RN provided 15–30 minutes of the light Swedish technique of effleurage and petrissage three times per week in the patient's hospital bed; sessions were 24 hours apart and at different times of the day and evening. The control group received 20 minutes of deliberate focused communication.</p> <p>Outcomes: pain, sleep, symptom distress, anxiety</p>	<p>N = 41</p> <p>All patients (both men and women) had a cancer diagnosis, including leukemia and lymph, lung, gastrointestinal genitourinary, head and neck, breast, and skin cancers.</p> <p>Treatment phase: active treatment</p> <p>Inpatients in a veteran's</p>	<p>Verran and Snyder-Halpern Sleep Scale</p>	<p>Sleep quality remained the same.</p>	<p>Limitations included a small sample size and a lack of random assignment to groups. Cohorts were treated sequentially.</p> <p>The sleep scale was not tested for validity and reliability with polysomnography.</p> <p>The RN must be trained in massage techniques.</p>

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		<p>administration hospital</p> <p>Midwestern United States</p> <p>Quasi-experimental; pre- and post- intervention comparison groups (One group received massage, and the other was the control arm.)</p> <p>Rogers' Science of Unitary Human Beings and Watson's Theory of Transpersonal Caring were used.</p>			
Soden et al., 2004	<p>Patients were randomly allocated to one of three groups (a) massage with lavender essential oil and an inert carrier oil, (b) massage with inert carrier oil, (c) control group without massage. Those patients receiving weekly massages were not told which oils were used. The two massage groups received a standardized 30-minute back massage weekly for four weeks. Patients in the control group completed the assessment scales weekly during the study period but did not receive any massage.</p> <p>Outcomes: anxiety,</p>	<p>N = 42, patients with cancer, median age 73 yrs old</p> <p>Patients recruited from three specialist palliative care units in South Thames region, UK</p> <p>Randomized controlled trial</p> <p>No conceptual model was used.</p>	<p>VAS of pain intensity, Modified Tursky Pain Descriptors Scale, Verran and Snyder-Halpern Sleep Scale, HADS, Rotterdam Symptom Checklist</p>	<p>Unable to demonstrate any significant long-term benefits of aromatherapy or massage in terms of improving pain control, anxiety, or QOL. Sleep scores improved significantly in both the massage and the combined massage groups.</p>	<p>Recruitment to the study was slow and the sample sizes were smaller than planned.</p> <p>The poor performance status and fatigue experienced by many patients made it difficult for them to complete the questionnaires and attend weekly for treatment sessions.</p> <p>Relatively high attrition rate (14%)</p> <p>Massage therapists were unable to tailor the treatment to individual patients, which may have undermined its true effect.</p>



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	aromatherapy, massage, pain, palliative care, and sleep				
van den Berg et al., 2006	<p>Five haptotherapy intervention sessions were given during the period of chemotherapy, according to the wishes of the patient.</p> <p>Outcomes: QOL, mood, meaning in life, general functioning, physical and psychological symptoms, sleep quality, and body awareness</p>	<p>N = 31 (intervention group): Patients with cancer aged 18 or older treated with chemotherapy for the first time between April 2000 and November 2002</p> <p>N = 26 (control group): Patients with cancer who started first chemotherapy treatment between September 2002 and March 2003</p> <p>Treatment phase: active treatment</p> <p>Day clinic of the Diaconssenhuis Zeist (intervention group) and three hospitals in the Utrecht region (control group)</p> <p>Exploratory study with a quasi-experimental design with an intervention and matched control group, which were both studied pre- and post-test. Non-randomized design</p> <p>No conceptual model was used.</p>	<p>Questionnaire that measured a broad scale of physical, emotional, and psychological aspects of well-being of the patients</p> <p>EORTC (dimensions of QOL)</p> <p>Questionnaires taken from Helen Dowling Institute</p> <p>Meaning of life</p> <p>General functioning</p> <p>Satisfaction with care</p> <p>QOL (VAS)</p> <p>Symptoms (RSCL [write out])</p> <p>POMS</p>	<p>The haptotherapy treatment improved the perceived general QOL and the perceived cognitive and social functioning of patients. No improvement was found for mood, meaning in life, general functioning, physical symptoms, sleep quality, or body awareness.</p>	<p>Small sample size</p> <p>No long term follow-up</p> <p>The period between sessions varied because of patient wishes.</p> <p>Nonrandomized design may have contributed to selection bias. Amount of time between first patient receiving intervention and the control group being started was two-and-a-half years.</p> <p>Post-test given to the patient by the haptotherapist.</p> <p>Haptotherapist required for intervention</p> <p>38% drop out in intervention group</p>
Weze et al., 2004	Healing touch method: a noninvasive, noncondition-	N = 35 (11 men, 23 women) with a mean age of 57 years	EuroQoL (EQ-5D) & visual analog scales; sleep	A statistically significant improvement was found from	Limitations included the small sample.



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	<p>specific method where hands are placed on various parts of the body for about 40 minutes; particular attention is given to areas of pain or discomfort. Four one-hour sessions were conducted over four to six weeks (or withdrawn).</p> <p>Outcomes: symptoms, QOL</p>	<p>(range = 24–80 years); approximately half of the sample had cancer for less than a year, and approximately half had cancer for one to five years. Cancer types were mixed, but 40% had advanced disease.</p> <p>Treatment phase: active treatment and long-term follow-up</p> <p>Outpatient center for complementary care</p> <p>Eskdale, Cumbria</p> <p>One group; pre- and post-test feasibility design</p> <p>The therapeutic touch conceptual model was used.</p>	<p>disturbance 0–3 = sleeping too much, 4–7 sleeping well, and 8–10 = sleeping badly</p>	<p>pre- to post-test on sleep disturbances.</p>	<p>Providers must be trained in gentle touch.</p> <p>Limitations included the small sample; in addition, subjects' baseline served as their own control.</p> <p>Providers must be trained in gentle touch.</p>
<p>Wright et al., 2002</p>	<p>A 10-week autogenic training to revert from arousal of the autonomic nervous system to one of profound relaxation associated with the parasympathetic activity; patients were told to practice three times per week.</p> <p>Outcomes: anxiety, depression, coping, sleep</p>	<p>N = 18 patients with a cancer diagnosis who were pain free or had pain controlled with nonopioids or mild opioids; ages ranged from 40–80 years.</p> <p>Treatment phase: active treatment or long-term follow-up</p>	<p>Qualitative interview</p>	<p>Qualitative remarks indicated that autogenic training was very helpful for sleep induction.</p>	<p>Staff must have autogenic training.</p> <p>Training was not well defined.</p>



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		Outpatient cancer center; subjects' homes  Ireland  One-group quantitative and qualitative pre- and post-test design  A coping conceptual model was used.			
<b>Psychoeducational Intervention— PEP Weight of Evidence Category: Effectiveness Not Established</b>					
Kim et al., 2002	Educational intervention on the side effects of radiation therapy for prostate cancer; a four-minute followed by an eight-minute tape-recorded message (informational intervention vs. standard of care information) was used at treatment 1, and a different message was used at treatment 5.  Outcomes: severity of side effects from radiation	N = 152 patients receiving radiation for curative, localized prostate cancer who had a mean age of 70.8 years; 96% were Caucasian. 13% were in stage A, 66% were in stage B, and 21% were in stage C.  Treatment phase: active treatment  Eight cancer centers  Eastern United States  Randomized, controlled trial  Self-Regulation Theory and negative affectivity perspective were used.	A single-item measure of sleep was obtained at week 2 and the end of treatment.	A brief educational intervention is helpful in reducing sleep problems resulting from radiation therapy and cancer.	Baseline symptom severity was not measured.  No training is required.  Cost is incurred when developing the tape-recorded messages.
Williams & Schreier,	A 20-minute audiotape was used that included education	N = 71 patients with a mean age of 50.4 years (range =	A modified self-care diary measured the number of side	More women in the control group reported difficulty	Control was lacking regarding how much and what kind of



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2005	<p>about the self-care behaviors of exercise and relaxation to manage anxiety, fatigue, and sleep problems. A self-care diary mirrored the audiotape; the control group received education about side effects.</p> <p>Outcomes: fatigue, anxiety, sleep</p>	<p>30–74 years); 85% had stage I or II breast cancer and were receiving chemotherapy regimens with cyclophosphamide.</p> <p>Treatment phase: active treatment</p> <p>Tertiary medical center and a satellite cancer treatment clinic</p> <p>Southeastern United States</p> <p>Randomized, controlled trial</p> <p>Orem’s Self-Care Deficit was used.</p>	<p>effects, severity of each side effect, number of self-care behaviors performed for each side effect, and the effectiveness of each self-care behavior.</p>	<p>sleeping at baseline; both groups experienced increased severity of sleep disturbance between the first and second self-care diary.</p>	<p>information was given to women at the time of treatment; the use of the self-care audiotapes may have been insufficient.</p> <p>In addition, the trial had a small sample size.</p>
<p><b>Exercise— PEP Weight of Evidence Category: Effectiveness Not Established</b></p>					
Coleman et al., 2003	<p>A home-based exercise program was used that included aerobic and resistance training. The exercise group received an individualized exercise prescription, with strength levels and aerobic capacity at first testing. The control group received usual care.</p> <p>Outcomes: exercise, fatigue, mood, sleep</p>	<p>N = 24 Caucasian patients (10 women, 14 men) who had a mean age of 55 years; patients were on high-dose chemotherapy and were receiving peripheral blood stem cell transplant for multiple myeloma (with bone involvement).</p> <p>Treatment phase: active treatment</p> <p>Outpatients at a cancer research center</p>	<p>A wrist actigraph was used to measure latency, minutes of sleep at night, percent time asleep at night, number of nighttime awakenings, frequency of daytime naps, minutes of sleep during the daytime, and total minutes of sleep during each 24-hour period. The Epworth Sleepiness Scale also was used.</p>	<p>Feasibility of individualized exercise program for patients receiving aggressive treatment for multiple myeloma was determined.</p>	<p>The small sample size was a limitation.</p> <p>The study had a 42% attrition rate; equal attrition was noted in both groups.</p> <p>Valid and reliable sleep latency is difficult to determine from actigraphy.</p> <p>The test is time consuming and a burden to patients.</p> <p>An exercise testing facility is</p>



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		<p>Midwestern United States</p> <p>Pilot feasibility; randomized, controlled trial</p> <p>Cardiovascular training conceptual model was used.</p>			<p>needed.</p>
<p>Mock et al., 1997</p>	<p>A self-paced progressive home-based exercise program (walking exercise versus usual care) was used. Individualized walking was based on age, level of fitness, and history of exercise. The program was a brisk, incremental, 20–30—minute walk, followed by a 5-minute slow walking cool down, four to five times per week for six weeks.</p> <p>Outcomes: exercise, fatigue, physical functioning, emotional distress, sleep</p>	<p>N = 46 females who had a mean age of 49 years; 87% were Caucasian, and 72% had stage I breast cancer and were undergoing radiation therapy.</p> <p>Treatment phase: active treatment</p> <p>Two university teaching hospitals</p> <p>Instructions were given at the institution, but the intervention was carried out at home.</p> <p>Southeastern United States</p> <p>Two group, controlled trial; pre- and post-test experimental design</p> <p>The Roy Adaptation Model was used.</p>	<p>Symptom Assessment Scale, Piper Fatigue Scale, 12-minute walk test, and sociodemographic information</p>	<p>Women who exercised regularly reported less difficulty sleeping than the control group.</p>	<p>Only first subject received random assignment. Subsequent subjects were alternately assigned to usual care or exercise group.</p> <p>A diffusion effect was possible for exercisers in usual care group. The small sample size and lack of control over the intervention in the home were limitations; in addition, patients had to adhere to a five-day-a-week regimen.</p> <p>Caution: Maintain safety while exercising</p> <p>Exercise physiologist consultation is needed. RNs must be trained in delivering the intervention. The study should be supervised by a principal investigator.</p>



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Rabin et al., 2008	<p>12-week theoretically grounded physical activity intervention and relaxation intervention delivered via telephone; the physical activity intervention was based on the Moving Forward Intervention (individuals pass through five stages of readiness when changing a health behavior), and the relaxation component included instructions in progressive muscle relaxation.</p> <p>Outcomes: intervention feasibility and acceptability, physical activity, mood, fatigue, and sleep quality</p>	<p>N = 23 enrolled and 19 early stage breast cancer survivors completed who had a mean age of 52.5 years old</p> <p>Treatment phase: long term follow-up</p> <p>Outpatient oncology clinics</p> <p>United States</p> <p>Single-arm, pre- and post-experimental, pilot feasibility study</p> <p>Transtheoretical Model and the Social Cognitive Theory were used.</p>	<p>Medical and demographic form, acceptability and feasibility form, Seven Day Physical Activity Recall, Stage of Motivational Readiness, IM Systems-3 dimensional accelerometers, POMS, and PSQI</p>	<p>This pilot study suggests that the intervention is feasible and acceptable and produces promising effects on mood, sleep, and fatigue.</p> <p>When comparing 12- and 24-week follow-up data to baseline data, participants demonstrated significantly increased physical activity, improved mood and sleep quality, and reduced fatigue. The significant increase effect found for objective accelerometer data from baseline to 12 weeks was not maintained at 24 weeks.</p>	<p>Absence of a control group and small sample size were both limitations.</p> <p>The socio-economic and racial homogeneity and conservative eligibility criteria also were limitations.</p> <p>Minimal resources are needed to provide two theoretically grounded interventions.</p>
Young-McCaughan et al., 2003	<p>Subjects met twice a week for 12 weeks for exercise and education.</p> <p>Outcomes: exercise tolerance, activity, sleep, and QOL</p>	<p>N = 62 patients (31 men, 31 women) who had a mean age of 55 years; subjects had mixed ethnicity and varying cancer diagnosis and stages. Therapy included surgery, chemotherapy, radiation therapy, immunotherapy, and endocrine and hormonal therapy.</p> <p>Treatment phase: active</p>	<p>Wrist actigraphy was used to measure the duration of sleep, percentage of night spent asleep, average length of a sleep episode, number of awakenings. Cancer Rehabilitation Evaluation System-short form (CARES-SF) sleep item also was used.</p>	<p>No improvement was found in sleep patterns per actigraphy; improved subjective rating was noted.</p>	<p>This was a feasibility study; therefore, no control group was used.</p> <p>The small sample size and missing actigraphy data were limitations.</p> <p>Cost is incurred for actigraphs, and staff must be trained in the exercise measurement.</p>



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		<p>treatment or long-term follow-up</p> <p>Two major military medical centers Inpatient and outpatient settings</p> <p>Southwestern United States</p> <p>Prospective feasibility study with repeated measures</p> <p>The Roy Adaptation Model and Cardiac Rehabilitation Model were used.</p>			