

**Depression
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
ONS PEP Weight-of-Evidence Category: Recommended for Practice					
Psychoeducational Interventions					
Antoni et al., 2001	<p>Participants were randomly assigned to the intervention or control. The intervention was a closed, structured group that met weekly for 10 two-hour sessions. It included didactic material, experiential exercises, and homework assignments (practicing relaxation exercises) and focused on learning to cope better. The control group participants received a condensed version of the intervention during a five–six hour seminar; it provided information but lacked the therapeutic group environment and support.</p> <p>Participants were assessed initially, post-treatment, at three months, and at nine months.</p>	<p>N = 100 women with stage 0, I, or II breast cancer; patients were recruited from several hospitals and medical practices in Miami, FL. The study was advertised by letters and posters, and participants phoned for eligibility screening.</p> <p>Recent research has found that in the absence of prior psychiatric history, severe psychiatric symptoms are rare among patients with early-stage breast cancer. This crisis has diverse ramifications, some of which are positive.</p>	<p>Outcomes measured: distress (mood disturbance, depressive symptoms, and thought intrusion and avoidance), perceptions of benefit from having breast cancer, and general optimism regarding the future.</p> <p>Scales:</p> <p>Profile of Mood States (POMS), Center for Epidemiological Studies-Depression (CES-D), Impact of Events Scale (IES), Life Orientation Test-Revised (LOT-R), and a 17-item measure of perceived benefits.</p>	<p>The intervention group showed reduced prevalence of moderate depression per the CES-D. The intervention also influenced two measures of positive well-being—increasing reports of experiencing benefit from having had breast cancer and increasing general optimism about the future. Thus, an implication here is that it is important to collect information on positive experiences as well as negative. Responding to adversity presents an opportunity to experience growth and positive change.</p>	<p>Although this is a well-designed RCT, several flaws exist. The sample is made up of volunteers, relatively educated, affluent, and motivated. Only 26% identified themselves as an ethnic minority. The participants had non-metastatic cancers and were free from physical and mental health comorbidities at the time of recruitment so generalizability is constrained. The measure of benefit finding is new; more information is needed regarding its validity.</p> <p>Levels of distress reported in this sample were generally low.</p>
Given et al., 2004	<p>Patients were provided with a focused assessment that corresponded with a specific symptom management treatment intervention. The interventions recommended were based on a cognitive-behavioral approach.</p>	<p>A total of 237 patients and their family caregivers participated in the study of 609 eligible patients in this randomized control trial. Patients were diagnosed with a solid tumor and were within two months of the first cycle of chemotherapy. Patients who were receiving radiation or had previous chemotherapy were not eligible.</p> <p>Men and women were included in the study who were diagnosed with a variety of tumor types in various cancer stages. The</p>	<p>Data analysis included two-sample t tests, a chi-square test, and a general linear model. The Center for Epidemiological Studies Depression Scale was used.</p>	<p>The use of cognitive-behavioral interventions helped to lower depression at 10 weeks over those receiving usual care among those with higher levels of baseline symptoms. In patients with a higher level of depression at baseline, the cognitive-behavioral interventions were less effective. Thus, cognitive-behavioral interventions may indirectly lower depression by managing symptoms with less of an affective component.</p> <p>Symptoms with a physiologic and</p>	<p>Limitations: Medications used to treat depression were not standardized. A variety of medications were used at various doses. The article did not describe in detail how the intervention sessions were completed, only that phone interviews and in-person sessions were conducted varying in time from 30–60 minutes. The background and training for the nurses who provided interventions were not identified. The specific symptom</p>

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		<p>underlying concept used is that self-management strategies are learned. A cognitive-behavioral approach would then assist patients in controlling symptoms. The control arm received usual care.</p> <p>Patients were assessed for symptoms such as nausea, vomiting, insomnia, dyspnea, anorexia, fever, cough, dry mouth, constipation, mouth sores, pain, and fatigue. Symptoms that have been identified with depression were placed in a subindex and included fatigue, insomnia, anorexia, and poor concentration.</p>		<p>psychological component may be more difficult to modify and require longer term intervention.</p>	<p>management interventions were not provided. It would have been helpful to know the symptom management strategies that were utilized and if specific guidelines were established.</p>
<p>Gotay et al., 2007</p>	<p>The purpose of the study was to evaluate the effectiveness of a brief telephone intervention. Women were randomly assigned either to telephone intervention group (TG) or control group (CG). TG received 4–8 counseling/information sessions by telephone at weekly intervals. Content reflected primary patient concerns and common domains from a quality of life (QOL) model. After the first session, an information packet was sent consisting primarily of National Cancer</p>	<p>Three hundred five women experiencing a 1st recurrence of breast cancer; random assignment to TG or CG; both groups were well balanced except more TG patients received chemotherapy and more CG patients received hormone therapy for recurrence. Assessments were completed at baseline, three months, and six months. Statistically significant—more CG patients progressed during the six months on study.</p> <p>Multiple site representation</p>	<p>Emotional well-being was measured by Cancer Rehabilitation Evaluation System-Short Form (CARES-SF).</p> <p>Depressive Symptoms were assessed with CES-D.</p> <p>Secondary Outcomes: Social support: Reynolds et al's four-item scale</p> <p>Optimism/pessimism: Life Orientation test</p> <p>Surprise of the recurrence:</p>	<p>The telephone intervention was feasible and well-accepted, but there were no benefits associated with the intervention for either emotional well-being or depressive symptoms. Patient distress started and remained very high in this sample.</p>	<p>This is a well-designed RCT with adequate sample size; however, the study's generalizability is unclear given that the patients came from multiple institutions across the United States; the catchment area cannot be precisely described and characteristics of refusing patients were not monitored.</p> <p>This sample included high levels of psychological and disease-related disability, and telephone calls from a nonprofessional may not have been appropriate for</p>

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	<p>Institute pamphlets. Counselors were breast cancer recurrence survivors <u>at least</u> one year post recurrence.</p>	<p>(SWOG conducted)</p>	<p>three point question posed</p> <p>Sense of coherence: Sense of Coherence scale (Antonovsky)</p> <p>Support services utilized and satisfaction with the telephone intervention also were requested.</p>		<p>modifying patient distress. Significant findings were lacking.</p>
<p>Helgeson, Lepore, & Eton, 2006</p>	<p>A psychoeducational approach to determine if self-esteem, self-efficacy, and baseline depressive symptoms moderated the effects on QOL of the psychoeducational interventions for men with prostate cancer</p> <p>The initial interview was conducted by a male at the subject's home approximately two months after treatment. Follow-up assessments were completed via phone at 2 weeks, 6 months, and 12 months after the interventions. Each intervention had eight groups of 10–12 men. The educational intervention included six weekly lectures on topics revolving around prostate cancer, side effects,</p>	<p>Two hundred fifty men with localized prostate cancer randomized to one of three groups: group education, group education plus peer discussion, or standard care.</p> <p>Eleven radiation and oncology groups were represented.</p> <p>Emerging evidence suggests some people are more likely than others to benefit from psychosocial and educational interventions. This study examines characteristics that distinguish those who are most and least likely to benefit.</p>	<p>Data analyses test moderation at two waves of data: the first and last follow-ups. The study utilized the Short-Form General Health Survey (SF-36), the 15-item modified version of CES-D, quality control interviews, survey of positive health behaviors, the University of California Los Angeles Prostate Cancer Index (PCI), the 10-item Rosenberg Global Self-Esteem Scale, and a nine-item inventory to measure self-efficacy based on a previous study.</p>	<p>Regarding depressive symptoms—at two weeks lower self-esteem was associated with greater depressive symptoms in the control group but not the intervention groups. At 12 months, lower self-esteem was associated with greater depressive symptoms among controls but not among combined or education intervention participants. Self-efficacy did not interact with either intervention to predict depressive symptoms at either data point.</p> <p>It must be remembered that this study was not measuring depressive symptoms following intervention but was determining whether self-esteem, self-efficacy, and baseline depressive</p>	<p>RCT with adequate sample size; limitations: Findings not unique to one intervention, Caucasian and middle-class preponderance of sample limited generalizability, large number of analyses conducted-increasing the potential for chance findings.</p>

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	treatment, and coping. The education plus discussion group had the same lectures plus an additional 45 minute discussion after each lecture. The control group received standard care.			symptoms moderated the effects of the psychoeducational interventions. A subset of men, mostly those with low self-esteem, benefited psychologically from the interventions.	
Lewis, Casey, Brandt, Shands, & Zahlis, 2006	This is a five, one-hour scripted and multi-component cognitive behavioral educational counseling intervention delivered in two week intervals. Components include five home-based mother sessions of interactive didactics, experiential exercises, skilled efficacy enhancing rehearsals with a patient educator, mother-child booklets about cancer, mother and child's workbooks and between session phone page access to patient educator.	13 mothers with stage 0, I, and II breast cancer and 13 school-age children participated. Study took place in the Pacific Northwest of the United States. Study design was a single group pretest and post-test design. Enhancing Connection Program (EC is derived from previous research and three theories; a developmental-contextual model of parenting, coping theory, and social cognitive theory.	Maternal measures: CES-D, state anxiety by the STAI-Y scale, and cancer self-efficacy scale. Mother-Child measures: Relatedness scale and Family Peer Relationship Scale. Child measures: Illness- Related Pressures scale, Cancer Worries Scale, Disenfranchised Grief Scale, revised Child Manifest Anxiety Scale, Child's Depression Inventory, and the Child's Behavioral Problem Checklist.	Suggestive evidence that the EC resulted in improved functioning for mothers and children Significant improvements between baseline and post-test in mother's depressed mood, state anxiety, and self-efficacy in caring for self and her family with the impact of cancer; for children there were significant improvements in behavioral-emotional functioning, cancer worries, and anxiety/depressed mood.	Single group design with very small sample. Results do not generalize to mother-child dyads involving children with clinically-elevated anxiety or depressive symptoms or to mother-child dyads in which the quality of the mother-child relationship is poor. Results should be viewed with caution.
Manne et al., 2007	Efficacy of two psychological interventions was compared to usual care. The coping and communication-enhancing intervention (CCI) involved challenging assumptions and talking about thoughts and feelings with others. Six-hour-long individual sessions	Three hundred fifty-three women with primary gynecologic cancer, in active treatment, from 2 comprehensive cancer centers and 8 hospitals representing 3 states. Participants were randomly assigned to CCI, SC or usual	Beck Depression Inventory, Impact of Events Scale, Emotional Expressiveness Questionnaire, Cancer Rehabilitation Evaluation System-subscale, modified Expectancy Rating Form, and a version of Borkovec and Nau's treatment evaluation	For all patients depressive symptoms first dropped: for patients in CCI and SC, depressive symptoms remained relatively flat after six months, but in UC they began to increase. There was no significant difference between the interventions'	Poorly designed RCT; a high rate of refusal and survey incompleteness existed. Sample was primarily Caucasian, young, and had ovarian cancer; this lack of diversity limits generalizability. Participants were reimbursed at \$25 for each survey or

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	<p>were held with a final telephone booster session. Session content focused on enhancing coping, educating, and practicing skills; home practice assignments were included.</p> <p>Supportive counseling (SC) also involved two-hour long sessions and a telephone booster. Rather than topic discussion, reactions to cancer, support of existing coping behaviors and autonomy were stressed.</p> <p>Usual care included routine social work consultations.</p> <p>Nineteen experienced therapists provided intervention.</p>	<p>care and were assessed preintervention and at three, six, and nine months.</p> <p>Rates of psychological distress are known to be high in gynecologic cancers, which are often advanced at initial diagnosis. This intervention is based on the cognitive-affective-social processing theory. Assumptions about an experience are challenged, comfort is increased with negative emotional aspects of the experience, and talking with others about thoughts and feelings is promoted.</p>		<p>effects and no impact of either intervention on cancer-specific distress.</p>	<p>session, which is relatively high. Different therapists were used for SC and CCI.</p>
<p>Pugliese et al., 2006</p>	<p>This describes an integrated approach with a qualified psychotherapist as an active part of the oncology team. A PhD specialist was introduced at first consultation; there, the oncologist asked the patient for both medical and psychological treatment consent. The psychologist performs psychological</p>	<p>Ninety-eight participants with metastatic or locally advanced colorectal cancer were recruited from a single cancer institute in Rome, Italy.</p> <p>A prospective, nonrandomized design was used.</p>	<p>Outcomes measured: anxiety and depression, adaptation and awareness, and subjective perception of medical treatment quality. Scales were the HADS and the EORTC QLQ C30.</p>	<p>The results do show feasibility and provide some evidence showing the benefit of the inclusion of the integrated approach to oncology care. Patients seemed to have a positive inner experience regarding their physician-patient relationship. Prior to treatment 30% (29 patients) were found to have psychopathologic disorders.</p>	<p>Prospective, nonrandomized, small sample size, no control group, one site</p> <p>The exact actions of the psychologist are not clear.</p>

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	<p>evaluations, conducts structured interviews, and measurements, observes, and supports patients.</p> <p>The second study aim is to evaluate feasibility of this integrated approach.</p>	<p>The underlying concept is the team approach to oncology care by incorporation of psychological assessment and support to improve patients' health related quality of life (HRQOL). Outcome data were collected before and after 18 weeks of chemotherapy.</p>		<p>With the total of 294 psychodynamic interviews conducted, the McNemar test showed a significant improvement in terms of adaptation and awareness between pretreatment and 18 weeks. The mean HADS score initially was 4.9±2.9 for anxiety and 5.5±3.4 for depression, showing no abnormal depression or anxiety. After the 18 weeks, the scores for anxiety decreased ($p < 0.02$). No significant change occurred with depression.</p> <p>At the completion of 18 weeks of therapy, there was a significant increase in the number of patients having a positive experience on HRQOL (53% versus 70%), anxiety (49% versus 63%), depression (54% versus 69%), interpersonal relationships (61% versus 79%), free-time (61% vs. 73%), and positive perception of treatment quality .</p>	
Scheier et al., 2005	<p>Women with breast cancer were assigned to a three-arm clinical trial. In the two active arms, the women received</p>	<p>N = 252</p> <p>Women aged 50 and younger within two months of</p>	<p>Outcomes measured: depressive symptoms assessed using a 10-item version of the CESDS.</p>	<p>At the 13th-month assessment, participants in the nutrition arm reported significantly fewer depressive</p>	<p>Compliance with treatment sessions was higher in the nutrition arm than in the education arm. Trial focused</p>

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	<p>either an educational intervention, which provided information about their disease and treatment, or information about nutrition, featuring a low-fat, high-fruit-and-vegetable-eating pattern. Both active treatment arms received four group sessions meeting once per month for four consecutive months. Sessions were led by professionals, and interactions between participants were kept to a minimum. The control arm was standard medical care.</p>	<p>completing nonhormonal adjuvant therapy, with a diagnosis of stage 0, I, or II breast cancer with <u>no more than 10</u> positive lymph nodes; random assignment; recruited from oncology clinics and MD offices in a single state.</p> <p>Assessments occurred at baseline, then 4, and 13 later (corresponding to immediate post-intervention and nine months post-intervention.)</p> <p>This study was designed to evaluate interventions targeted to occur at the point when treatment is ending—a time when distress and concerns are known to increase. It also targets younger women; as some studies report younger women are at greater risk for psychological distress and face different challenges than do older women.</p>	<p>Health-related QOL was assessed using the SF-36 from the Medical Outcome Studies.</p> <p>Mediating measures also were assessed including intrusive thoughts, self-efficacy, cancer concerns, self-concept, and coping.</p>	<p>symptoms and in the education arm, marginally fewer depressive symptoms than those in the control arm. The difference between the two active treatment arms was not significant. The mediating factors also were identified as contributing by enhancing self-efficacy expectations, reducing some concerns regarding morbidity and mortality, lessening intrusive thoughts about illness, and buffering self-concept perceptions.</p>	<p>on early-stage disease; it is not known if generalizability exists in patients with advanced disease. Sample composed largely of Caucasian, middle-class women in one state.</p> <p>RCT; adequate sample size but little diversity of sample limits generalizability, difference between two treatment arms was not significant.</p>
<p>Sharpe et al., 2004</p>	<p>Patients with major depressive disorder were recruited from consecutive attendees at cancer clinics and provided an intervention (problem-solving therapy) to evaluate whether the outcome of major depression was affected.</p>	<p>This study was nonrandomized and compared the outcomes of two sequentially recruited cohorts. All of the participants were female (N = 30 per group).</p>	<p>Patients were evaluated for the presence of major depression using the Structured Clinical Interview for DSM-IV, the Hospital Anxiety and Depression Scale (HADS), and the Manchester Concerns Checklist.</p>	<p>The authors concluded that patients who received the intervention had less depression than those receiving usual care.</p>	<p>Major flaws:</p> <ol style="list-style-type: none"> 1. No standard number of problem-solving sessions was used. Patients were provided 1–13 weeks of interventional sessions. 2. All patients were female. 3. No control was provided for the use of medications. More patients

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					<p>in the interventional group were on antidepressants compared to those receiving usual care. 4. The study was not randomized. Limitations: Only one nurse provided the intervention, making it difficult to reproduce.</p>
<p>Thastum, Munch-Hansen, Wiell, & Romer, 2006</p>	<p>Focused on illness-related problems and well-defined goals to enable family to care for children.</p>	<p>24 mothers, 17 fathers, and 34 children Mixed methods; single group; comparison group were those who refused counseling; qualitative interviews Danish sample</p>	<p>Beck Depression Inventory, McMaster Family Assessment Device, Beck's Youth Inventories of Emotional and Social Impairment; Inventory of Parent and Peer Attachment; Health-related quality of life (HRQOL) Counseling was evaluated by the Questionnaire on the Opinion of Counseling Interviews</p>	<p>Improved depression scores of parents; improvement in family general functioning, communication, affective responsiveness Children reported decreased depression. Qualitative findings were that the counseling had benefits; more open communication and sharing of illness-related emotions</p>	<p>Lack of randomization, small sample; results must be interpreted with caution. Interpreter bias in qualitative results.</p>
<p>Vilela, et al., 2006</p>	<p>The NuCare program is a short-term psychoeducational intervention with the aim of teaching individuals with cancer how to cope with the disease. Three different delivery means were available and participants</p>	<p>N = 101. N consisted of a convenience sample of patients with head and neck cancer from the outpatient clinic in one hospital in Montreal, Canada. Participants had completed their cancer treatment.</p>	<p>Outcomes were QOL and depressive symptoms. European Organization for Research and Treatment of Cancer Core Quality of Life (EORTC QLQ-C30) and the HADS</p>	<p>Intervention delivery is feasible. From baseline to follow-up, in test group there was improvement on most QOL scores and statistically significant improvement in</p>	<p>Prospective, quasiexperimental design without randomization, and baseline characteristics of test and control groups were significantly different. Therefore, it cannot be assured that any changes in</p>

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	<p>chose their method. These methods were small group format, one-to-one format, or home format. Outcomes were evaluated at baseline and three to four months later. A control group received no intervention.</p>	<p>Control group was matched by the amount of time since diagnosis and stage of cancer.</p> <p>This was a feasibility study using a prospective, nonrandomized design.</p> <p>Head and neck cancer is particularly traumatic because of the high levels of symptomatic, functional, and psychological problems faced with treatment. Psychosocial and educational interventions have been found to help patients with cancer, but few have involved patients with head and neck cancer. The Nuicare psychoeducational program provided a workbook describing good coping, ways of thinking, communication, effective uses of social support, problem-solving techniques, goal setting, healthy lifestyle, and relaxation training.</p>		<p>depression (1.2 points, $p < .05$). Control group showed deterioration in most of the EORTC QLQ-C30 and HADS scores at follow-up. However, none of the changes were statistically significant at the 5% level.</p>	<p>outcomes were because of the intervention.</p> <p>Convenience sample with many refusals in participation reduce generalizability</p> <p>The three delivery formats were not compared.</p>
Pharmacologic Interventions					
Antidepressant Medications					
Musselman et al., 2001	<p>Patients with malignant melanoma received paroxetine or placebo two weeks prior to initiation of interferon alfa, continuing for the first 12 weeks</p>	<p>40 adult patients with malignant melanoma that had been resected but was estimated to have a greater than 50% chance of recurrence</p>	<p>Patients were evaluated at baseline and at regularly scheduled intervals for the first 12 weeks of therapy. Tools included the Hamilton</p>	<p>Major depression symptoms developed in 2 of 18 patients in the paroxetine group (11%) and 9 of 20 (45%) in the placebo group. Paroxetine treatment also</p>	<p>The sample size was small. One disease group and one site were involved in the study.</p>

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	of therapy. Study tablets contained 10 mg of paroxetine; both groups took one tablet daily for a week, followed by 2 tablets daily for a week. Two weeks after the initiation of interferon alfa (four weeks after beginning paroxetine or placebo), the dosage of the study medication could be increased up to four tablets per day at the discretion of the study psychiatrist. The average number of tablets at the maximal dose for each group was 3.1.	Randomized, double-blind study Single site	Depression and Carroll Depression rating scales, the Hamilton Anxiety Scale, and the Neurotoxicity Rating Scale.	significantly decreased the likelihood that interferon alfa therapy would have to be discontinued because of severe depression.	

ONS PEP Weight-of-Evidence Category: Likely to Be Effective

Pharmacologic Interventions

Methylphenidate

Homsí et al., 2001	A phase II study of methylphenidate for depression in patients with advanced cancer. Patients who were identified as being depressed by a palliative medicine attending physician were treated with methylphenidate twice daily. Doses were titrated per regimen until response was obtained. Patients were assessed during a telephone call or bedside interview.	15 women and 15 men with the following primary cancer sites: breast (5), esophagus (4), head and neck (4), lung (4), pancreas (4), colorectal (2), and other (7) [N = 30]. One center was included, and inpatients and outpatients were enrolled in the palliative care program. Inclusion criterion was the answer of "yes" to the question, "Are you depressed?" with no current or previous antidepressant use. The study timeframe was seven days.	Question, "Are you depressed?" Other symptoms (anorexia, concentration problems, fatigue, and sedation) were assessed by a categorical rating (none, mild, moderate, or severe) before starting methylphenidate and daily thereafter. Pain was assessed using a 0-10 scale. Known side effects of methylphenidate also were assessed. Satisfaction question, "Are you satisfied with the way the drug affected your mood?" was asked at the end of the study on day 7.	Depression resolved in all patients, most on day 3. Maximum daily dose needed was 20 mg. Other symptoms also improved, mean pain scores significantly decreased, and all who responded to treatment were satisfied with therapy.	Small sample, with no randomization Long-term efficacy and side effect data are needed. Single site data are less transferable than multisite data.
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Nonpharmacologic Interventions

Relaxation

Sloman, 2002 ²⁰	Patients were assigned to one of four treatment conditions: (a)	26 men and 30 women with advanced cancer who were being	The HADS measured anxiety and depression, and the Functional	All three treatments showed significant reductions in	The sample size of 56 is small; a clear description of the PMR and
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	<p>progressive muscle relaxation (PMR) training, (b) guided imagery training, (c) both a and b, and (d) control group. In the control group, the nurse spent an equal amount of time with subjects discussing general health and treatment concerns.</p>	<p>cared for at home in Sydney, Australia; all were receiving palliative care. Patients were randomly assigned to one of four groups to determine the efficacy of relaxation and imagery for control of depression and anxiety. A trained nurse taught patients the techniques in their homes, left a tape recorder and cassette, and asked subjects to practice the technique twice daily. The nurse visited twice weekly to repeat the sessions.</p>	<p>Living Index—Cancer scale measured quality of life. Pretesting was done, and post-testing was conducted in all subjects three weeks after the initial session.</p>	<p>depression over the control group. No one treatment proved to be significantly superior, and none of the three treatments produced a significant reduction in anxiety.</p>	<p>guided imagery techniques was not provided, so replication would be difficult. The study occurred in one site, with one nurse conducting the interventions. Post-testing at three weeks showed a short-term benefit; long-term benefits were not addressed.</p>

ONS PEP Weight-of-Evidence Category: Effectiveness Not Established

Nonpharmacologic Interventions: Complementary Methods

Aromatherapy and Massage

<p>Soden, Vincent, Craske, & Ashley, 2004</p>	<p>Participants were randomly allocated to receive weekly massages with either lavender (aromatherapy group), an inert carrier oil (massage group), or no intervention. The two massage groups received a 30-minute back massage weekly for four weeks. Scales were completed the week before the first treatment and in the week after the last massage.</p>	<p>Forty-two patients with advanced cancer were recruited from three palliative care units in the United Kingdom.</p> <p>Patients with cancer are increasing their use of complementary therapies. Anecdotal evidence suggests that aromatherapy and massage may benefit physical and psychological symptoms, but studies of good methodological quality are few.</p>	<p>A visual analogue scale (VAS) of pain intensity; a Modified Tursky Pain Descriptors Scale; the Verran and Snyder-Halpern sleep scale; the Hospital Anxiety and Depression scale; and the Rotterdam Symptom Checklist</p>	<p>Significant long-term benefits of aromatherapy or massage were not demonstrated for pain, anxiety, or QOL. A statistically significant reduction in depression scores was present in the massage group.</p>	<p>RCT but small sample size; predominance of women and older age group limit ability to generalize</p> <p>The measurement interval allows other variables to affect the scores in this population of low performance and fatigued patients.</p> <p>Study recruitment took two years.</p>
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Massage					
Cassileth & Vickers, 2004	Patients received one of three types of massage therapy and were asked to report on their symptoms post-therapy. Massages were provided by 12 licensed massage therapists.	1,290 inpatients and outpatients participated in the study. Patients were referred by physicians, nurses, or self for the therapy. Patients received Swedish massage, light touch massage, or foot massage according to their preference. Sessions lasted, on average, 20 minutes for inpatients and 60 minutes for outpatients. Conceptual model: Tactile stimulation is essential to survival and massage therapy can be used to reduce symptoms.	Patients reported the level of symptom distress (0-10) on a card prior to and following massage therapy. Comparisons were analyzed by analysis of covariance, with the baseline score as the covariate.	The effect of massage on symptom relief was demonstrated as a positive response with respect to depression.	Limitations: 1. Not randomized 2. The information about the study demographics or participants did not include enough detail. 3. There was no standard procedure for length of massage or specific type of session. Patients had a choice of three techniques. 4. Patients were referred to massage therapy, including self-referral. Self-referral may skew the post-therapy reports because patients expect a benefit. 5. No standardized assessment tool was used to measure results because symptoms were rated on a card. 6. No way to differentiate which of the massage techniques was the most beneficial
Hernandez-Reif et al., 2004	Patients were randomized to receive massage therapy or standard treatment. The massage therapy group received 15 massages that were 3-30 minutes long per week by a trained massage therapist for four weeks. The control group received standard medical care alone.	This was a randomized study that consisted of 34 women who had stage I or II breast cancer and were at least three months post treatment.	Participants were assessed for anxiety and mood scales utilizing three standardized assessment tools: State-Trait Anxiety Inventory (STAI), Profile of Mood States (POMS), and Symptom Checklists-90-R (SCL-90-R). Immune and neuroendocrine functions were monitored using blood levels of specific immune system markers.	Massage did show some benefit in patient mood scale assessment tools and immune system function. Specifically, reduced anxiety was found on the STAI after the first and last sessions. Reduced depression was found on the POMS depression score after the first and last sessions and from the first to the last day of the study. The SCL-90-R confirmed a reduction in depression from the first to the last day.	Limitations: The study only looked at the short-term benefit to patients. Long-term effectiveness was not demonstrated. Sample size was small; participants had early-stage breast cancer diagnoses. Patients were randomized based on a coin toss.

**Depression
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
				<p>Wilcoxon's matched pairs signed ranks tests revealed an increase in dopamine and serotonin levels in the massage group; the control group showed a significant increase in norepinephrine. Natural killer cell cytotoxicity did not attain significance.</p>	
<p>Nonpharmacologic Intervention: Exercise</p>					
<p>Berglund, et al., 2007</p>	<p>Aim of study was evaluation of effect of psychosocial rehabilitation on newly diagnosed patients with prostate cancer.</p> <p>Patients enrolled in the "Between Men" program and randomized to one of four groups. Each intervention group met for seven sessions. The physical training consisted of 60-minute sessions of light physical training, including movement, fitness training, relaxation, and breathing exercises; the information group contained 60 minutes of information about prostate cancer, treatment, side effects, etc.; the combination group</p>	<p>N = 158 newly diagnosed patients with prostate cancer</p> <p>Single site (Uppsala, Sweden)</p> <p>Extended treatment side effects including erectile dysfunction and urinary incontinence persist in patients with prostate cancer. Research suggests that physical activity and exercise is associated with improvements in HRQOL.</p>	<p>HADS depression and anxiety subscales; EORTC QLQ-C30; a cancer-specific multidimensional tool with subscales of functioning and symptoms</p>	<p>This RCT did not find any differences in depression or anxiety symptoms among participants at the pre, Six-month, and 12-month assessments. The physical training group appeared to have the most improvement in depressive symptoms between baseline and 12 months, but the confidence intervals were too overlapping.</p>	<p>Possible ineffective intervention diminished control over activity and information in the control group; 20% dropout rate after 12 months; lack of heterogeneity among participants ; small sample in each group; limited generalizability</p>

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	<p>combined exercise and information for a total of 135 minutes; and the control group received standard care.</p> <p>Four research questions were asked, including whether physical training reduces depression among men with prostate cancer.</p>				
<p>Hanna, Avila, Meter, Nicholas, & Kaminsky, 2008</p>	<p>The Cancer Exercise Program (CEP) is based on exercise, education, and support. Patients attended twice a week as able until they completed 16 exercise sessions. Exercise mode was based on patients' fitness level; individualized heart rate target ranges were supplied. The education component focused on symptom management, coping, survivorship, resources, spirituality, stress management, treatment, and others. Education was an optional and encouraged component of the CEP. Peer support was encouraged, and the exercise specialist also provided support.</p>	<p>N = 39; 13 different cancers represented; most patients had finished cancer treatment within six months of beginning the program.</p> <p>Study took place in a 350-bed teaching hospital in a Midwestern city.</p> <p>The design was a retrospective analysis of archived data; nonrandomized; no control group; small sample size.</p>	<p>Fatigue was measured by the revised Piper Fatigue Scale, and mood was measured by the Profile of Mood States. These were completed before the first exercise session and again after the conclusion of all the sessions. Physical function also was measured.</p>	<p>Patients reported a significant decrease in their total mood disturbance after participation in the CEP as compared to before. Eighty percent of the sample improved, and 20% stayed the same or decreased.</p> <p>Fatigue and physical function also improved.</p>	<p>Retrospective analysis; very small sample size; lack of a control group; patients only were compared against themselves; educational sessions were optional; it is unknown whether the number of sessions attended or which topics had any effect.</p> <p>Various types of cancer in one study.</p>

**Depression
Evidence Table**

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Midtgaard, et al., 2005	Patients with cancer undergoing chemotherapy volunteered to participate in a six-week (nine hours weekly) structured exercise program. Fitness training, relaxation, body awareness training, and high or low intensity programs were offered, and safety measures were incorporated. Participants were assessed for depression and anxiety at baseline and after the six-week intervention.	<p>N = 91 men and women receiving chemotherapy (various cancers represented); 70% female; participants self-referred after seeing posters and pamphlets in the clinics</p> <p>Study took place in Denmark, Sweden. Prospective, pretest, post-test one group design</p> <p>Based on longstanding evidence that physical activity improves physical performance in patients with cancer. "Body and Cancer" is a five-year research project designed to determine the effectiveness of structured exercise intervention in patients undergoing chemotherapy.</p>	<p>HADS-Anxiety subscale; HADS-Depression subscale</p> <p>Aerobic capacity also was estimated using the VO2Max Test.</p>	<p>Anxiety and depression scores were reduced from baseline to six weeks. Depression's decrease was more moderate, but both were significant.</p> <p>Low levels of both depression and anxiety were reported at baseline.</p> <p>VO2max significantly increased over time. Improvements in VO2max were associated with improvements in depression but not anxiety.</p>	<p>Small sample size; disproportionate number of women; self-referred sample may represent more motivated and psychologically intact group; no control group; unequal number of cancers with different cancer diagnoses; no information collected about psychopharmacologic drug use which could have influenced results; sample demonstrated little anxiety or depression at baseline.</p>