Complementary and alternative medicine in the management of pain, dyspnea, and nausea and vomiting near the end of life: a systematic review


Authors' objectives
To assess the efficacy of complementary and alternative medicine (CAM) modalities in treating pain, dyspnoea, and nausea and vomiting in patients near the end of life.

Searching
The databases searched were MEDLINE (from 1966 to 1998), CINAHL (from 1982 to 1997), Cancerlit (from 1993 to 1998), AIDSLINE (from 1980 to 1998), Social Work Abstracts (from 1977 to 1997) and PsycLIT (from 1967 to 1998). Full details of the search terms used for each database were given. The bibliographies of identified studies and reviews were examined and experts were consulted for additional references. No language restrictions were applied. Unpublished studies and abstracts were not included.

Study selection
Study designs of evaluations included in the review
Original clinical reports or reviews were eligible. Laboratory reports, case reports, anecdotes, surveys and commentaries were excluded. Randomised controlled trials (RCTs; single-blinded and unblinded), non-randomised controlled trials, and case series were included.

Specific interventions included in the review
CAM modalities to treat pain, dyspnoea, and nausea and vomiting were eligible. Studies that focused on central nervous stimulation techniques were excluded. The CAM modalities included transcutaneous electrical nerve stimulation (TENS), acupuncture, massage therapy, aromatherapy, psychotherapy, behaviour therapy, hypnosis, imagery, cognitive coping strategies, relaxation techniques, and music therapy. Definitions of all these modalities were given.

Participants included in the review
Adult patients with incurable conditions, who were near the end of their life, were eligible. Studies involving primarily patients with chronic conditions that were not fatal or not characteristic of dying patients were excluded. The actual participants included comprised the following groups: hospice and out-patient cancer patients; cancer patients with intractable cancer pain, abdominal pain due to invasive or metastatic cancer, breast cancer, lung cancer, and oral mucositis; HIV-positive patients with painful peripheral neuropathy; and patients with chronic obstructive pulmonary disease (COPD).

Outcomes assessed in the review
The inclusion criteria were not defined a priori in terms of outcomes. Studies that focused primarily upon biological mechanisms, risk factors, predictors or prognosis were excluded. The following outcomes were included: symptoms assessed using the European Organisation for the Research and Treatment of Cancer Quality-of Life Questionnaire; fatigue; quality of life; pain relief; reduced analgesic requirements; pain, as assessed using the World of Health Organisation grading system, visual analogue scale, graphic rating scale; feelings of relaxation; anxiety; breathlessness, as measured on a 5-point shortness of breath scale, a modified Borg visual analogue scale, Fletcher scale, visual analogue scale, and as walking distance in 6 minutes; pain sensation and pain suffering; and nausea.

How were decisions on the relevance of primary studies made?
Two authors independently reviewed studies meeting the initial inclusion criteria, and any disagreements were resolved by discussion or by consensus with two other authors. A 'best evidence' approach was used to identify studies for final inclusion in the review.

Assessment of study quality

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No formal validity assessment was undertaken, though some aspects of validity (blinding and statistical power) were mentioned in the text.

**Data extraction**
Two authors independently extracted and tabulated the following data: study design, inclusion and exclusion criteria, setting, sample size, CAM modality, specifics of CAM treatment, outcomes assessed and methods of assessment.

**Methods of synthesis**
**How were the studies combined?**
The studies were grouped according to symptom targeted, intervention, and study design, and combined in a narrative review.

**How were differences between studies investigated?**
Evidence was discussed in relation to study design.

**Results of the review**
Twenty-one studies (1,175 patients) were included: 11 RCTs (603 patients), 2 non-randomised controlled trials (69 patients) and 8 case series (503 patients).

Only results from the RCTs are reported here.

**Pain (7 CAM therapies).**

TENS: there was one double-blind RCT with 15 patients, one non-randomised controlled study with 60 patients, and 2 case series with 38 patients. The RCT lacked the power to detect any effect on pain and reported that, compared with the control, fatigue was reduced in the treatment group.

Acupuncture: there was one single-blind RCT with 239 HIV patients, and 2 case series with 275 patients. The RCT found no statistically-significant difference in peripheral neuropathy between real and sham acupuncture in HIV patients.

Massage: there was one RCT with 28 patients and one case series with 9 patients. The RCT found that men had immediate short-term pain relief (p=0.01).

Massage plus aromatherapy: there was one case series with 103 patients; no RCTs were identified.

Psychological therapies: there were 2 RCTs with 152 patients, and one case series with 58 patients. In one RCT, women with breast cancer who were enrolled in a support group reported a statistically-significant difference in pain sensation and pain suffering over 10 months follow-up (p<0.01), but no difference in the number and duration of episodes of pain was reported. This RCT also reported on hypnosis (see below). In the other RCT, bone marrow transplant patients receiving relaxation/imaging or a package of cognitive behavioural skills reported significantly less pain than patients receiving usual treatment or usual treatment plus therapist support (p<0.01).

Music therapy: there was one multiple crossover RCT with 9 patients (very small sample size). No statistically-significant difference between the treatment groups was observed (p<0.07).

Hypnosis: there was one RCT with 58 patients. Self-hypnosis significantly reduced the pain sensation in breast cancer patients receiving group support (p<0.05).

**Dyspnoea (5 RCTs with 160 patients, and one case series with 20 patients).**

The following studies reported a significant benefit from the intervention: acupuncture (1 RCT with 24 COPD patients and 1 case series with 20 patients); acupressure (1 RCT with 31 COPD patients); progressive muscle
relaxation/breathing retraining (1 RCT with 20 COPD patients); psychoanalysis (1 RCT with 65 COPD patients), and nausea and vomiting (1 non-randomised controlled trial with 6 patients). The study of breathing/coping/counselling (1 RCT with 20 lung cancer patients) found no significant difference between the treatment groups.

No large-scale trials in terminally ill patients were identified that were not associated with chemotherapy.

**Authors' conclusions**

Despite the paucity of controlled trials, there are data to support the use of some CAM modalities in terminally ill patients. Trials of CAM may not be readily identified on routine literature searches.

**CRD commentary**

The aims were stated and the inclusion criteria were defined in terms of the participants and interventions. Several relevant databases were extensively searched, experts were contacted and no language restrictions were applied. Some information was given on the methods used to select the studies and extract the data. A formal validity assessment was not undertaken, although aspects of validity were commented upon in the text. Some relevant information was clearly presented in tabular format, but the methods used to assess validity were not described. A narrative review was appropriate given the small number of studies of variable design, and the studies were correctly grouped by study design. The validity of the controlled trials was not assessed, in particular, no comment was made on the validity of the methods used to assess the outcomes. Thus, the quality of the evidence could not be evaluated. The number of outcomes assessed in the included studies was not reported, and it is not clear whether the positive outcomes reported were the primary outcomes of the included studies or one of many reported outcomes.

Given the small number of controlled trials of unknown validity on which to base conclusions, caution must be advised when interpreting the results of this review.

**Implications of the review for practice and research**

Practice: The authors made the following recommendations (only grade 2 evidence from RCTs and grade 3 evidence from controlled trials is reported here). TENS and acupuncture may provide short-term pain relief in terminally-ill cancer patients (grade 3); acupuncture does not appear to reduce peripheral neuropathy pain in patients with HIV (grade 2); relaxation with imagery and cognitive coping skills can improve pain in patients with oral mucositis (grade 2); support group therapy can improve pain in advanced cancer patients and hypnosis can enhance pain relief (grade 2); acupuncture may provide relief in patients with malignancy-related breathlessness (grade 3); acupuncture/acupressure and breathing retraining with progressive muscle relaxation improve dyspnoea in severe COPD patients (grade 2); psychoanalytic therapy does not appear to relieve dyspnoea in COPD patients (grade 2); acupressure does not appear to relieve cancer-related nausea (grade 3).

Research: The authors state that future studies in CAM require sound designs, larger sample size, reliable blinding, and specific and clinically relevant outcomes.

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