
Complementary and alternative therapies for the management of menopause-related symptoms: a systematic evidence review

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CRD summary

This review assessed randomised evidence for the use of complementary and alternative therapies in the treatment of menopausal symptoms. The review included a wide range of interventions but concluded that there was insufficient evidence to demonstrate that any of the included therapies was effective. Given concerns about aspects of the review methods, it is not clear how reliable these conclusions are.

Authors' objectives

To evaluate the efficacy of complementary and alternative therapies for the management of menopausal symptoms.

Searching

MEDLINE, PsycINFO, the Cochrane Library, MANTIS and AMED were searched from inception to March 2005; the search terms were not reported. In addition, known systematic reviews, reference lists and websites were searched. Experts were also contacted for additional studies. Only trials published in the English language were eligible for inclusion.

Study selection

Study designs of evaluations included in the review

Randomised controlled trials (RCTs) and systematic reviews were eligible for inclusion in the review. All of the included studies were RCTs.

Specific interventions included in the review

Trials of alternative therapies categorised by the National Center for Complementary and Alternative Medicine versus placebo-controlled trials were regarded as eligible for inclusion; however, some included trials used control groups given other therapy. The interventions included in the review were biologically based therapies (including phytoestrogens), mind-body and behavioural therapies, manipulative or body-based therapies, energy therapies and whole medical systems.

Participants included in the review

Studies of women who were menopausal, including those diagnosed with breast cancer, were eligible for inclusion. Women with and without a diagnosis of breast cancer were included in the review.

Outcomes assessed in the review

The inclusion criteria for the outcomes were not defined. Studies reporting the following outcomes were included in the review: hot flash frequency and severity, sleep disturbance, vaginal dryness, vaginal bleeding, urinary frequency or incontinence, quality of life, depression, anxiety, sexual dysfunction and cognitive function. Most of the included studies assessed these outcomes using the Kupperman Index and the Greene Climacteric Scale.

How were decisions on the relevance of primary studies made?

The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality

The validity of the studies was assessed using criteria developed by the U.S. Preventive Services Task Force. Two reviewers independently assessed the validity of the studies. Any disagreements were resolved by consensus.

Data extraction

Data were extracted into evidence tables, but the authors did not state how many reviewers performed the extraction.

Methods of synthesis

How were the studies combined?

The studies were combined in a narrative.

How were differences between studies investigated?

The studies were grouped by the type of intervention assessed. Further differences were discussed in the narrative synthesis.

Results of the review

Seventy RCTs were included in the review; 48 assessed biologically based therapies including phytoestrogens, nine assessed mind-body therapies, one assessed a manipulative or body-based therapy, two assessed energy therapies and ten assessed whole medical systems.

Biologically based therapies (48 studies).

Phytoestrogens, including soy isoflavones extract (8 studies) and red clover (6 studies).

There were mixed results from trials examining biologically based therapies including phytoestrogens. One good-quality study in women with breast cancer (n=175) found no difference between treatment and placebo groups, but improvements in both groups. The largest reasonable quality trial of phytoestrogens in women without breast cancer (n=241) found no differences between groups given two doses of isoflavones or placebo on any outcome. Nine other trials found no differences between the groups, mixed results, or were considered to be of a poor quality.

Two fair-quality trials of soy isoflavone supplements in women with breast cancer (n=182 and n=177) showed evidence of improvement in either hot flash severity or frequency in the treatment groups. One fair-quality trial in women without breast cancer (n=75) showed evidence of improvement only in hot flash frequency. The other studies were of a poor quality and showed mixed results.

None of the good- or fair-quality trials of red clover reported any between-group differences in hot flashes.

Other phytoestrogen preparations.

Two studies assessed women with breast cancer (one fair-quality trial, n=12; one poor-quality trial, n=52) and neither found between-group differences. One poor-quality study (n=70) compared genistein with placebo or estrogen over one year and found a significant and persistent reduction in hot flash incidence in both treatment groups; the effect was significantly greater in the estrogen group than in the genistein group. Two poor-quality studies (n=30 and n=50) found no treatment effects with phytoestrogen creams.

Black cohosh (4 studies).

One large (n=304) fair-quality study showed improvements in menopausal symptoms in the treatment group. However, no differences were observed in a smaller (n=62) fair-quality trial. One poor-quality study (n=136) and one fair-quality study (n=85) of breast cancer survivors showed no improvement in hot flashes with treatment.

Dehydroepiandrosterone (2 studies).

One fair-quality study (n=60) found no differences between the treatment and placebo groups. One small poor-quality study (n=22) did not report between-group comparisons.

Other therapies (11 studies).

One fair-quality study (n=125) assessed vitamin E in women with breast cancer and found no between-group differences. One fair-quality study (n=80) assessed kava and found greater improvement in anxiety compared with placebo, while another fair-quality study (n=64) assessed phospholipids liposome injections and found greater improvement in anxiety and menopausal symptoms compared with placebo. The remaining studies were considered to be of a poor quality and were not discussed in detail.

Mind-body and behavioural therapies (9 studies).

Two fair-quality (n=173 and n=81) and one poor-quality (n=30) trial examined exercise. Both of the fair-quality trials reported improvements (one in quality of life and one in menopausal symptoms) with treatment. Two poor-quality trials examined relaxation breathing, but neither reported between-group differences. One small poor-quality study (n=14) assessed progressive muscle relaxation and found an improved time for the onset of hot flashes for the intervention group ($p < 0.1$). No between-group differences were found for audiotape relaxation versus usual care in one poor-quality trial (n=40). One fair-quality trial of stress management versus usual care (n=86) and one fair-quality trial of counselling support for women with breast cancer versus usual care (n=76) found no between-group differences in menopausal symptoms. However, women in the usual care group were more likely to experience aches and pains than those in the stress management group ($p < 0.1$).

Manipulative or body-based therapies (1 study).

One small fair-quality study (n=30) evaluated low-force osteopathic manipulation of the pelvis, spine and cranium compared with sham treatment and reported improvements in hot flashes, night sweats, urinary frequency, depression and insomnia in the treatment group.

Energy therapies (2 studies).

One poor-quality study (n=80) found no difference between reflexology and routine foot massage on any outcome. Another poor-quality study (n=15) found a greater improvement in hot flashes in a placebo group than in a group treated with magnets at acupressure points ($p = 0.02$).

Whole medical systems (10 studies).

Four studies assessed acupuncture, three comparing it with sham acupuncture and one with acupuncture intended for general well-being. No trial found any difference between these groups in hot flashes, although one poor-quality trial (n=30) reported improved mood in the treatment group. One of the fairer quality trials (n=45) also contained a group treated with conjugated oestrogen; this group showed significant improvement in self-reported symptoms compared with acupuncture and sham acupuncture ($p < 0.001$).

Six studies assessed traditional Chinese medicinal herbs; three of these used combination therapies. Only one fair-quality trial (n=384), which used a standardised dose of ginseng compared with placebo, showed greater improvement in the treatment group: there were between-group differences in depression, well-being and health scores, but not hot flashes.

Authors' conclusions

There are insufficient data to support the effectiveness of any complementary and alternative therapy for the management of menopausal symptoms.

CRD commentary

The review question and the inclusion criteria were clear although broad. The authors searched a number of relevant databases. However, as only trials published in English were eligible for inclusion, it is possible that publication and/or language bias might have been introduced into the review; this may have increased the likelihood that trials with positive outcomes were over-represented in the evidence found by the review. In addition, the authors did not report whether they employed methods designed to reduce bias and error in the study selection and data extraction processes. The authors appear to have conducted an appropriate validity assessment and to have used this to inform their synthesis

of the results. The decision to employ a narrative synthesis was reasonable given the broad scope of the review and the considerable heterogeneity between the included studies. However, a clearer indication of the effect sizes, and thus the clinical relevance of the results, would have been helpful. The authors' conclusions are an accurate reflection of the inconclusive results of the review, although concerns with review methodology may mean that these conclusions did not fully reflect the evidence base.

Implications of the review for practice and research

Practice: The authors did not state any implications for practice.

Research: The authors stated that many of the therapies included in the review should be examined in trials with rigorous methodology in order to determine the benefits and safety of them.

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Bibliographic details

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Other publications of related interest

1. Nelson HD, Haney E, Humphrey L, Miller J, Nedrow A, Nicolaidis C et al. Management of menopause-related symptoms. Evidence Report/Technology Assessment. Rockville (MD): Agency of Healthcare Research and Quality; 2005. Report No.: 120. 2. Nelson HD. Menopause. *Lancet* 2008;371:760-70.

These additional published commentaries may also be of interest.

Libbus MK. Review: sparse good quality evidence supports the use of alternative therapies for menopausal symptoms. *Evid Based Nurs* 2007;10:14.

Soy, black cohosh may have some benefit for menopause symptoms. *POEMs* 2006;55:939.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.