Complementary and alternative medicine (CAM) in reproductive-age women: a review of randomized controlled trials

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CRD summary
This review assessed the effects of complementary and alternative medicine therapies relevant to obstetrics and gynaecology. This review provides an overview of the field, showing some limited evidence for some therapies and pointing to the need for further trials. Although no formal assessment of study quality appears to have been performed, issues of methodological quality were discussed in the review.

Authors' objectives
To review complementary and alternative medicine (CAM) therapies relevant to obstetrics and gynaecology, and to identify exposures to these therapies in women of reproductive age.

Searching
MEDLINE (from 1966 to 2002), AMED (from 1985 to 2000) and the authors' own files were searched; the search terms were provided.

Study selection
Study designs of evaluations included in the review
To be included, the studies had to be randomised controlled trials (RCTs).

Specific interventions included in the review
The inclusion criteria for CAM interventions were not stated.

Participants included in the review
The participants were women of reproductive age (not specified). Of the included trials, 45 were for pregnancy-related conditions, 33 for premenstrual syndrome (PMS) and 13 for dysmenorrhoea.

Outcomes assessed in the review
The outcomes were not pre-specified. Those included in the review were relief of premenstrual symptoms and pain, infertility outcomes, relief of pregnancy-related symptoms, and labour induction and outcomes.

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 authors did not state that they assessed validity.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction.

Methods of synthesis
How were the studies combined?
The trials were tabulated and combined in a narrative format according to the medical condition.
How were differences between studies investigated?
Differences between the studies were identified in the tables and text of the report.

Results of the review
Ninety-three trials with a total of 13,997 participants were included.

PMS.
Vitamin B6 was the subject of the most trials in this area and the majority of these demonstrated some benefit. The doses ranged from 50 to 600 mg/day, but no dose-response effects were seen. Due to inadequacies in the methodology of many studies and inconsistencies in the dose or outcome measure, it was not possible to make specific clinical recommendations. Reducing dietary fat or increasing exercise may benefit PMS and there was also some evidence for the benefits of calcium and magnesium supplements. Two studies of chaste-tree berry (Vitex agnus-castus) reported a benefit but only relative to baseline. Evening primrose (Oenothera biennis) oil did not appear to be effective in two of the three trials. Trials of manual therapies and mind-body treatments were few and had small sample sizes, high dropout rates and a lack of placebo controls, but showed some beneficial outcomes.

Dysmenorrhea.
Consumption of fish oil supplements showed promising results, as did exercise programmes and acupuncture (based on one trial).

Infertility.
There was little evidence that CAM therapies were effective for infertility. In one trial a significantly higher viable pregnancy rate was demonstrated in both the cognitive-behavioural and support group treatment arms. A trial of chaste-tree berry found no significant differences between the groups in terms of spontaneous menstruation, pregnancy, or take-home baby rates during treatment or 6 months later.

Nausea and vomiting in pregnancy.
In 10 of the 14 studies acupuncture point stimulation for nausea and vomiting showed significant benefit on at least one measure. Three trials used needles, nine acupressure bracelets, one self-applied finger pressure and one transcutaneous electric nerve stimulation. Two small studies found significant benefits with ginger at doses of 500 mg/day and 1 g/day. Vitamin B6 lessened nausea in two trials.

Other pregnancy symptoms.
One trial supported acupuncture for back or pelvic pain, while massage improved both back pain and mood in another. Positive benefits were seen for plant-derived rutosides, magnesium and immersion in water.

Labour induction and outcomes.
No major effects were observed for acupuncture point stimulation for inducing labour. One trial of moxibustion for turning breech babies showed promising results. Mind-body therapies and massage might reduce anxiety and pain during labour but more research is needed. The benefits of perineal massage were inconsistent. Neither aromatherapy nor homeopathy reduced perineal discomfort. Listening to a relaxation or imagery tape increased the volume of milk in mothers of premature infants. The application of cabbage leaves or cabbage extract failed to help breast engorgement in four controlled trials.

Authors’ conclusions
There was some limited evidence for selected CAM therapies. It is necessary to clarify safety issues as these therapies are popular among women of reproductive age.
CRD commentary
This review had defined inclusion criteria for the participants and study design; the inclusion criteria for the interventions and outcomes were less clear. Two databases were searched, including one specifically related to complementary medicine. This was supplemented by searching the authors’ own files. No formal validity assessment appears to have been performed, although issues of methodological quality were discussed in the report. Details of the studies were provided and the authors’ conclusions appear to have been based on their results. However, more weight could have been given to larger, more robust trials. Furthermore, it was unclear whether more than one reviewer was involved in each stage of the review process, which would help to minimise bias. This review provides an overview of the field, showing the promise of several therapies and pointing to the need for further trials. Such trials, if appropriately powered, would allow a closer examination of the efficacy and safety profile of these CAM therapies in women of reproductive age.

Implications of the review for practice and research
Practice: The authors stated that acupuncture point stimulation should be considered a proven treatment. They added that health care practitioners should familiarise themselves with the P6 point to be able to instruct patients in this procedure.

Research: The authors highlighted the need for larger clinical trials to determine the groups of women for whom particular treatments might be most appropriate. More specifically, they commented that additional studies of vitamin B6 would help to clarify optimal dosing; further research is indicated on the promising effects of diet and exercise on dysmenorrhea; and there is a need to determine the safety of newly formulated herbal products and food supplements. The authors stated that future studies of CAM therapies should enrol an adequate number of participants, use blinding and placebo controls appropriately, use standard outcome measures, and present all data and analyses. Finally, the authors commented that, as industrial funding for CAM therapies is likely to remain limited, other sources of funding will be needed if both the safety and efficacy of these therapies are to be evaluated.

Funding
NIH NCCAM, grant number P50 AT00090.

Bibliographic details
Fugh-Berman A, Kronenberg F. Complementary and alternative medicine (CAM) in reproductive-age women: a review of randomized controlled trials. Reproductive Toxicology 2003; 17(2): 137-152

PubMedID
12642146

Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Complementary Therapies; Dysmenorrhea /therapy; Endometriosis /therapy; Female; Humans; Infertility, Female /therapy; Leiomyoma /therapy; Pelvic Pain /therapy; Pregnancy; Pregnancy Complications /therapy; Premenstrual Syndrome /therapy; Randomized Controlled Trials as Topic

AccessionNumber
12003009375

Date bibliographic record published
30/06/2004

Date abstract record published
30/06/2004
Record Status
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.