Dietary supplements and herbal remedies for premenstrual syndrome (PMS): a systematic research review of the evidence for their efficacy

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CRD summary
The authors concluded that there is evidence of benefit for calcium and vitamin B6 in women with premenstrual syndrome, mixed findings for magnesium and evening primrose oil and insufficient data about St. John's Wort, agnus castus or ginkgo biloba. There was insufficient information about the included studies to assess the reliability of the authors' conclusions.

Authors' objectives
To evaluate the effectiveness of dietary and herbal treatments for premenstrual syndrome (PMS).

Searching
MEDLINE, EMBASE, AMED, CINAHL, PsycINFO and the Cochrane Controlled Trials Register were searched from inception to 2006 using the reported search terms. One additional study was identified from the reference lists of review articles.

Study selection
Study designs of evaluations included in the review
Crossover and parallel-group randomised controlled trials (RCTs) were eligible for inclusion in the review.

Specific interventions included in the review
Studies that compared an active treatment with a placebo or comparison treatment taken continuously or premenstrually over at least a 1-month cycle were eligible for inclusion. Studies that evaluated combinations of treatments were excluded. The included studies evaluated calcium, vitamin B6, magnesium, evening primrose oil, Vitex agnus castus, St. John's Wort and ginkgo biloba, and compared these treatments with placebo. The duration of treatment ranged from one cycle to 12 months.

Participants included in the review
Studies of women of reproductive age with a retrospective or prospective diagnosis of PMS or premenstrual dysphoric disorder were eligible for inclusion. The participants had to be without other pre-existing psychiatric conditions but they could have depression or anxiety that was only present premenstrually. Women taking the oral contraceptive pill were eligible.

Outcomes assessed in the review
Studies that assessed combined PMS symptoms, global scores or specific symptoms were eligible for inclusion. Where specified, the included studies measured outcomes using symptom change, symptom complex scores, the Mental Health Questionnaire, Menstrual Distress Questionnaire, congestive symptoms and visual analogue scales. The outcomes were measured by patients or assessed by medical practitioners.

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 a formal validity assessment was conducted. However, the following methodological features were discussed in the results: sample size, study design (including blinding), dose and duration of treatment, screening and assessment tools used. The authors did not state how the validity assessment was performed.
Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction.

Each study was apparently classified as showing a positive (indicated by a tick in the data extraction tables) or nonpositive (indicated by a cross) effect of the treatment of interest. The methods used to classify the studies as showing positive or nonpositive effects were not described.

Methods of synthesis
How were the studies combined?
The authors grouped the studies by type of treatment and summarised the evidence.

How were differences between studies investigated?
Some differences between the studies were apparent from the tables. The reasons for differing results among studies of similar treatments were not discussed.

Results of the review
Twenty-six RCTs (n=3,239) were included. In addition, the results from one systematic review were also reported.

Two 'well-designed' studies showed that calcium for at least three cycles may be of benefit.

The results were mixed for vitamin B6 (10 studies). Five studies showed positive results for vitamin B6 and 5 studies showed nonpositive effects. A systematic review of 25 studies reported a pooled odds ratio of 2.32 (95% confidence interval: 1.95, 2.54).

The results were mixed for magnesium (4 studies). Two studies showed positive results and 2 studies showed nonpositive effects. The authors stated that the studies had methodological problems.

Three of the 4 studies of agnus castus showed a positive effect. The authors stated that many studies had methodological problems.

Two of the 4 studies of evening primrose oil showed positive results. The authors stated that the best quality study showed no benefit.

One study of St. John's Wort did not show any positive effect on any symptom subgroup.

One study of gingko biloba showed a positive effect on congestive PMS symptoms.

Authors' conclusions
There was evidence of benefit for calcium and vitamin B6 and mixed findings for magnesium and evening primrose oil. There were insufficient data to support the use of St. John's Wort, agnus castus or ginkgo biloba. Further research is required.

CRD commentary
The review addressed a clear question that was defined in terms of the participants, intervention, outcomes and study design. Several relevant sources were searched, but it was not clear if unpublished studies were eligible or whether any language restrictions were applied. The methods used to select the studies, assess validity and extract the data were not described, thus it is not known whether efforts were made to reduce reviewer error and bias. A formal validity assessment was not conducted; some methodological features were discussed in the text but this was not done systematically. Drop-out rates were high in some studies (64% in one study) but no comment was made about the effect of this on the results. The findings for individual studies were reported without supporting data or levels of statistical significance, and this means it is not possible to verify the findings reported in the review. Additional information about
the statistical analysis would have been more informative. There was insufficient information about the review methods and the included studies to assess the reliability of the authors' conclusions.

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

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

Research: The authors stated that there is a need for larger, double-blind, placebo-controlled RCTs to evaluate treatments used for PMS. Future studies should use strict criteria to prospectively diagnose PMS and enrol representative populations. Diagnostic methods, outcome measures and assessment measures should be standardised.

**Bibliographic details**


**Indexing Status**

Subject indexing assigned by CRD

**MeSH**

Calcium /administration & dosage /therapeutic use; Dietary Fats, Unsaturated /therapeutic use; Evidence-Based Medicine; Fatty Acids, Essential /therapeutic use; Female; gamma-Linolenic Acid; Ginkgo biloba /therapeutic use; Hypericum /therapeutic use; Linoleic Acids; Magnesium /administration & dosage /therapeutic use; Phytotherapy; Placebos; Plant Oils; Plants, Medicinal; Premenstrual Syndrome /drug therapy /prevention & control; Pyridoxine /administration & dosage /therapeutic use; Vitex

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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.