Herbs, vitamins and minerals in the treatment of premenstrual syndrome: a systematic review

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CRD summary
The review found that among herbs, vitamins and minerals used to treat premenstrual syndrome, only calcium had good evidence of effectiveness. The authors noted that more research was required. In view of a suboptimal literature search, limited evidence base and questionable quality of the included studies, the authors’ conclusions require cautious interpretation.

Authors' objectives
To assess the efficacy of herbs, vitamins and minerals for premenstrual syndrome (PMS).

Searching
Clinical Evidence, The Cochrane Library, Mayo Clinic, Medscape, MEDLINE, Natural Medicines Comprehensive Database, EMBASE, IPA and IBIDS were searched from inception to April 2008. Search terms were reported. Internet searches were carried out using Google. Reference lists of articles retrieved were checked. The search was restricted to published articles in English or French.

Study selection
Randomised controlled trials (RCTs) that compared therapies that contained a single herb, vitamin or mineral to treat premenstrual syndrome or premenstrual dysphoric disorder (PMDD) were eligible for inclusion. Studies were required to include controls that received a recognised therapy or placebo and to report changes in symptom severity as outcomes. Studies with patient satisfaction as the sole outcome were excluded.

Participants in the included studies had differing types and severity of premenstrual syndrome. Interventions included chasteberry, evening primrose oil, ginkgo, saffron, St John’s wort, soy, vitamin B6, vitamin E, calcium and magnesium. Doses and types of preparation varied across studies. Most studies were placebo controlled, but interventions were also compared with each other or with other comparators such as fluoxetine. Changes in a wide range of physical and psychological symptoms were reported (such as anxiety, breast pain, cramps, total symptoms), in most cases symptom scales (such as Moos Menstrual Distress questionnaire, Premenstrual Tension Syndrome Scale, visual analogue scales) were used. Few studies used a predetermined definition of clinical response. In addition to symptom changes, the review reported adverse events. Study duration varied from three to 12 months (where stated).

Two reviewers independently selected the studies. Disagreements were resolved by a third reviewer.

Assessment of study quality
A reviewer-designed tool was used to assess components of study quality such as randomisation, allocation concealment, reporting of withdrawals and detailed description of the intervention. Studies were rated as good, average or poor quality. The overall quality of a study was determined according to whether the study was considered of sufficient quality to apply the results to practice (fully, partially or not at all).

Two reviewers independently conducted the assessment.

Data extraction
Descriptive data were extracted from each study, with p values for differences in scores between the groups and/or for changes from baseline.

Two reviewers independently extracted the data.
Methods of synthesis
Studies were combined in a narrative synthesis organised by intervention. The effectiveness of each intervention was assessed according to the number, quality and proportion of relevant studies that reported evidence of statistically significant benefit (or trend to benefit).

Results of the review
Twenty-nine RCTs were included in the review (n=3,576, range one to 617). Twenty-eight studies were double blinded. Eleven were crossover studies. Twenty-one percent of studies described methods of randomisation, 7% described allocation concealment, 50% reported reasons for withdrawals and 62% described the intervention in detail. Only 40% were considered of adequate overall quality to be applicable to practice.

There was statistically significant evidence that calcium was effective for reducing premenstrual syndrome symptoms (two good-quality RCTs). There was evidence of possible effectiveness for chasteberry (two good-quality RCTs) and vitamin B6 (one good, three average and two poor-quality RCTs). There was limited evidence of effectiveness for saffron (one good-quality RCT), vitamin E, ginkgo and magnesium (one average-quality RCT each).

Adverse events (where reported) included perceived weight gain and difficulty swallowing (in a study of evening primrose oil), nausea and headache (with calcium), diarrhoea (with magnesium) and unspecified adverse events, usually described as mild (with chasteberry, ginkgo, saffron and St John's wort).

There was no statistically significant evidence of effectiveness for evening primrose oil (three RCTs, two good quality), St John's Wort or soy (one good-quality RCT each).

Authors' conclusions
Among herbs, vitamins and minerals used to treat premenstrual syndrome, only calcium has good evidence of effectiveness. More research was required.

CRD commentary
The objectives and inclusion criteria of the review were clear. Relevant sources were searched for studies. The search was restricted by language and publication status, which meant that the review was subject to language and publication biases. Steps were taken to minimise the risk of reviewer bias and error by having more than one reviewer select studies, assess validity and extract data. The decision to combine the studies by narrative synthesis was appropriate given the heterogeneity between them. Study quality was assessed and this assessment was incorporated into the synthesis. However, the quality rating was not reported for all studies and it appeared that in some studies designated good quality a high proportion of participants were not included in analysis. In view of the suboptimal literature search, limited evidence base and questionable quality of the included studies, the authors' conclusions require cautious interpretation.

Implications of the review for practice and research
Practice: The authors stated that there was good evidence to support use of elemental calcium 100mg to 1,200mg daily for premenstrual syndrome symptoms of negative affect, water retention, food cravings and pain. Women with high dietary calcium may need a lower supplemental dose.

Research: The authors stated that well-powered RCTs of adequate duration should investigate natural products for treatment of premenstrual syndrome. Investigation of effects on individual premenstrual syndrome symptoms would be useful. Studies should report their diagnostic criteria for premenstrual syndrome and define in detail the intervention, baseline participant characteristics and outcome measures. Adverse events should be systematically reported.

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