CRD summary
This review assessed the effectiveness and safety of soy products for the treatment of perimenopausal symptoms such as hot flushes. The authors concluded that soy products are safe to use in the short-term and that there was some evidence that they were effective, though definitive conclusions were not possible. The authors' conclusions are appropriate, but it should be noted that many of the studies found no evidence of effectiveness.

Authors' objectives
To investigate the efficacy of soy preparations for the treatment of physical and psychological perimenopausal symptoms.

Searching
MEDLINE, EMBASE, Phytodok and the Cochrane Library were searched from inception to March 2003 with no language restrictions; the search terms were provided. Over 90 suppliers of isoflavone products were contacted for data, and the authors' files were searched. The bibliographies of retrieved articles were also checked.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials that scored three or above on the Jadad quality scale were included.

Specific interventions included in the review
Studies evaluating soy or soy isoflavones as monotherapy were eligible for inclusion. Studies of soy as part of a phytoestrogen-rich diet, or in combination with other sources of phytoestrogens, were excluded. In the included studies soy was provided as flour, in capsules, as a beverage or extract, and as soy protein. Where reported, the isoflavone content ranged from 34 to 134.4 mg daily. Comparisons were made with non-soy supplements (e.g. wheat flour), complex carbohydrates, or placebo capsules. The duration of treatment ranged from 6 to 24 weeks.

Participants included in the review
Healthy women with perimenopausal symptoms and no major diseases were eligible. Studies of participants with artificially induced menopause were excluded. The perimenopausal symptoms of women varied between the included studies. In the majority of studies the participants had amenorrhoea; this ranged from 3 to 12 months' duration. In less than half of the included studies the participants also had elevated follicle stimulating hormone levels. Where reported, the frequency of hot flushes ranged from at least one per day to at least seven per day. Where reported, the mean or median age of the women ranged from 50 to 55 years.

Outcomes assessed in the review
Studies assessing physical and/or psychological outcomes were eligible for inclusion. Studies assessing only blood hormonal data, vaginal cytology, or non-clinical end points were excluded. The included studies mainly assessed the frequency and/or severity of hot flushes. General menopausal symptoms were also assessed and one study investigated quality of life.

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
Studies were assessed for description of randomisation, blinding and withdrawals using the Jadad scale. The minimum possible quality score was 0 and the maximum was 5. The authors did not state how the papers were assessed for...
quality, or how many reviewers performed the quality assessment.

**Data extraction**
The data were extracted by one reviewer and checked by a second. Effect sizes were not calculated.

**Methods of synthesis**

How were the studies combined?
The studies were combined in a narrative.

How were differences between studies investigated?
Differences between the studies were reported in the text and tables.

**Results of the review**

Ten RCTs were included (n=784).

Four studies had a Jadad score of 3, 5 studies scored 4, and the remaining study scored 5. All 10 RCTs were double-blind. The majority of the included studies did not independently assess the quality or bioavailability of the isoflavone content of the soy product used.

In six of the 10 studies there was no statistically significant difference between the treatment and control groups in the primary outcome measures. In the remaining studies there was a statistically significant difference in outcomes, in favour of the soy supplement, between the two groups: 2 studies reported a reduction in the frequency of hot flushes; one reported an improvement in oestrogenic symptom score and hot flush severity score; and one reported a decrease on a menopause symptom index. Seven studies reported adverse events and one of these stated there were none. The most common adverse events were gastrointestinal, such as nausea and constipation, but these were similar in both the soy and the control groups.

**Authors’ conclusions**

There was some evidence for the efficacy of soy preparations for perimenopausal symptoms, though the diversity of the studies included in the review meant it was difficult to draw a definitive conclusion. There were no serious concerns about safety in short-term use.

**CRD commentary**
The review addressed a clear research question using defined inclusion criteria. A number of relevant electronic databases were searched and the search terms used were provided. Unpublished data were also sought. The review methodology was not well described and only the data extraction appeared to use measures to reduce error and bias. The methodological quality of the included studies was assessed and aspects of quality were discussed in the synthesis. Appropriate details on the study populations were reported. Given the diversity of the studies it was appropriate to conduct a narrative synthesis. The authors’ conclusions are appropriate.

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

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

Research: The authors stated that the use of soy products for perimenopausal symptoms merits further investigation. Stricter inclusion criteria for symptom severity and frequency are required, as well as the standardisation of isoflavone content to determine the most effective dose.

**Bibliographic details**

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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.