Psychological intervention for premenstrual syndrome: a meta-analysis of randomized controlled trials
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CRD summary
This review concluded that evidence from low-quality randomised trials suggested cognitive behavioural therapy may have beneficial effects in managing symptoms associated with premenstrual syndrome (PMS) and that further studies of rigorous methodological quality were necessary. This review was generally well-conducted and the authors' cautious conclusions are likely to be reliable.

Authors' objectives
To evaluate the effectiveness of psychological interventions for premenstrual syndrome.

Searching
AMED, CINAHL, EMBASE, MEDLINE and PsycINFO from inception to October 2007 were searched; search terms were reported. Cochrane Central Register of Controlled Trials, PapersFirst and ProceedingsFirst were searched. References of retrieved studies and other relevant articles were also searched. No language restrictions were applied. Two reviewers independently conducted the literature search.

Study selection
Randomised controlled trials (RCTs) that compared psychological interventions to no active intervention in women who presented with premenstrual syndrome were eligible for inclusion. Psychological intervention was defined as any non-pharmaceutical intervention that could influence behaviour or symptom perception.

The participants in the included trials had moderate to severe symptoms of premenstrual syndrome. The diagnostic criteria for premenstrual syndrome varied between studies, as did the comparators that were used (wait list, placebo pill, no treatment and symptom monitoring by spouse). Included interventions were categorised into three domains: cognitive behavioural therapy (undefined, relaxation techniques, positive reframing), education therapy (premenstrual syndrome symptom management program, premenstrual educational program) and monitoring (self monitoring of symptoms).

The individual interventional sessions lasted 15 to 120 minutes. Frequency of sessions ranged from twice daily to one per week. The duration of intervention ranged from two days to four months. Outcomes reported in the trials included anxiety, behavioural changes, depression, effect on daily living, sexual relations and water retention and edema.

Two reviewers independently assessed the studies for relevance and disagreements were resolved by discussion.

Assessment of study quality
The study validity was assessed using the criteria of method of randomisation, concealment of allocation, blinding, intention to treat analysis, compliance, similarity of co-interventions in both groups, similarity of timing of outcome assessment and handling of withdrawals. Two reviewers independently assessed the study quality and resolved any discrepancies by discussion.

Data extraction
Two reviewers independently extracted the data regarding the scores at baseline and after completion of intervention. For each study, effect size was calculated for all outcome measures of interest.

Methods of synthesis
Pooled effect sizes were calculated with 95% confidence intervals (CIs) using a random-effects model. Number needed to treat was calculated for the statistically significant results. Statistical heterogeneity was assessed using $\chi^2$ and the $I^2$ squared statistic. A priori sub group analysis was performed based on the type of psychological intervention. Sensitivity
analysis was carried out using post-treatment scores instead of change scores to calculate the effect size.

**Results of the review**

Nine RCTs (n=at least 435) were included in the review. All trials were considered to be of poor methodological quality: only one trial reported method of randomisation; no trials reported method of allocation concealment; most trials were not or did not appear to be blinded; and loss to follow up ranged from 10 to 67%.

**Anxiety:** The pooled results from four RCTs found no significant impact of psychological interventions on anxiety (effect size -0.36, 95% CI: -0.82 to 0.10, $I^2=48.1\%$). However, subgroup analysis showed cognitive behavioural therapy (effect size -0.58; 95% CI: -1.15, -0.01, number needed to treat was five; two RCTs) and self monitoring (effect size -0.63, 95% CI: -1.17 to -0.09, number needed to treat was five; one RCT) to be effective in reducing anxiety symptoms.

**Behavioural change:** The pooled results from two trials found no significant beneficial effect of cognitive behavioural therapy (effect size -0.47, 95% CI: -1.05 to 0.12), but re-analysis using the 18-month outcomes from one of the studies showed cognitive behavioural therapy improved behavioural symptoms (effect size -0.70, 95% CI: -1.29 to -0.10, number needed to treat was four). No evidence of significant statistical heterogeneity was found.

**Depression:** The pooled results from six RCTs found no significant impact of psychological intervention on depression scores (effect size -0.07, 95% CI: -0.41 to 0.27, $I^2=44.8\%$), but subgroup analysis showed a beneficial effect of cognitive behavioural therapy (effect size -0.55, 95% CI: -1.15 to -0.05, number needed to treat was five). Neither education (two trials) nor monitoring (one trial) demonstrated beneficial effects.

**Interference of symptoms on daily living:** Pooled results from two trials showed a significant benefit of cognitive behavioural therapy on interference with activities of daily living (effect size -1.10, 95% CI: -1.81 to -0.39). Substantial statistical heterogeneity was found ($I^2=73.9\%$).

**Sexual relationship:** Pooled results from two studies found a significant benefit of psychological intervention on improvement in sexual relationship (effect size -0.67, 95% CI: -1.22 to -0.11, number needed to treat was four). No evidence of significant statistical heterogeneity was found.

**Water retention and edema:** Pooled results from two studies found a significant benefit of psychological intervention on reducing the impact of water retention and edema (effect size -0.56, 95% CI: -1.06 to -0.05; number needed to treat was five). No evidence of significant statistical heterogeneity was found.

Use of post-treatment scores instead of change scores to calculate the effect size did not significantly alter the results.

**Authors’ conclusions**

Evidence from low-quality randomised trials suggested that cognitive behavioural therapy may have beneficial effects in managing symptoms associated with premenstrual syndrome.

**CRD commentary**

The review addressed a well-defined question in terms of study designs, participants and interventions. Outcomes of interest were not defined a priori. Several databases were searched without language restriction and some attempt was made to identify unpublished data. The review process was conducted with sufficient measures to minimise error and bias throughout. Appropriate criteria were used to assess study validity and the results summarised in the text. The overall quality of the included studies was considered poor. The statistical techniques used appeared to be appropriate and statistical heterogeneity was assessed. Possible sources of heterogeneity were explored by a priori subgroup analyses. The paucity of good-quality evidence supported the authors’ suitably cautious conclusion and this overall conclusion appeared reliable. However, the recommendation of cognitive behavioural therapy for practice may have been overstated in view of poor quality of the studies and the small sample size.

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

**Practice:** The authors stated that experts should not dismiss the role of psychological therapies and particularly cognitive behavioural therapy in treating symptoms associated with premenstrual syndrome.
Research: The authors stated the need for clinical trials of higher methodological quality that compared cognitive behavioural therapy with no psychological interventions in women who received selective serotonin reuptake inhibitors (SSRIs) and trials that compared cognitive behavioural therapy to pharmacological therapy.

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