Reviewers report

Title: Effects and Treatment methods of Acupuncture and Herbal Medicine for Premenstrual syndrome/Premenstrual Dysphoric Disorder: Systematic Review

Version: 2 Date: 28 January 2013

Reviewer: Margaret Diana van Die

Reviewers report:

The authors are to be commended for such an ambitious undertaking, covering both acupuncture and herbal interventions for PMS and PMDD. However, the main limitation of this review is that it does not include sufficient information to fully inform future research or clinical practice.

Lack of clarity is evident in some sections regarding structure of the manuscript inclusion requirements. The authors are referred to other reviews to clarify these points:


Oral ginseng formulae for stable chronic obstructive pulmonary disease: a systematic review.


Major Compulsory Revisions:

1. It is not customary for inclusion criteria to combine RCTs and a former systematic review/met-analysis. The authors have two choices in addressing this:
   i. They can source the original studies included from the previous systematic review/met-analysis, and include the full data (i.e. including baseline data and end-of-treatment means/SD's), citing these studies, or
   ii. They can omit these studies (if there is nothing to add) and refer to this review
in their introduction/methods. In this case, the Methods (abstract and body of manuscript) should state that, “Studies included in the 2011 meta-analysis of acupuncture by Kim et al are not included in this review”.

2. Inclusion/Exclusion criteria: It needs to be clarified whether multi-component herbal formulations were included. It would appear that they were included, as the two Chinese herbal decoctions contain eight herbs each.

3. Data extraction: i. Further information should be mentioned/extracted: condition (whether PMS or PMDD), sample size, study duration, herbal extract and dosage regimen.

ii. The omission of adverse events is a serious omission. If possible, it should be added.

iii. It is also of relevance in PMS-PMDD studies whether or not two cycles of prospective ratings were recorded prior to study entry.

Results:

4. The names of all the herbal ingredients in the two herbal formulations mentioned (Xiaoyaosan and DanZhi xiaoyaosan) need to be listed (common and Latin binomials), as well as quantities of each herb per dose/tablet.

5. The herbal extracts and the form of administration need to be stated consistently (for each study). This could be indicated in the text and/or the tables.

6. There appears to be some misunderstanding of the requirements of the Risk of Bias assessment.

This should include selection bias; blinding of outcome assessment; blinding of participants and personnel; attrition bias; reporting bias. The authors are referred to the Cochrane risk of bias tool available in RevMan: ms.cochrane.org/revman/download

No attempt has been made to assess the quality of the trials included.

7. Discussion:

This should follow the format:

i. Restatement of principal findings

ii. Comparison with other reviews

iii. Possible Explanation/s for findings

iv. Implications

v. Limitations

8. Limitations:

This refers to the limitations of the RCTs evaluated, and of the current review. Eg The points raised in the abstract regarding different endpoints, inclusion criteria, degree of symptom severity, diagnoses, etc.

Also please mention the limitations of this review. Eg much research has been conducted on phytotherapy prior to these inclusion dates.

9. Conclusion:
i. The conclusion and recommendations included within the body of the discussion are overstated, and ignore the research conducted prior to these inclusion dates (eg “No other previous evidence supports the results.” And “This study shows that alternative medicine is as much effective as mainstream medicine with the advantage of fewer major side effects”. The adverse events were not addressed in this review.) This should be re-worked.

ii. The authors need to clarify the implication of the equivalence of Vitex to fluoxetine.

10. The final conclusion does not really follow from the findings, since the study did not focus on Korean herbal interventions. It should therefore be amended to reflect the study findings.

Minor Essential Revisions:

11. Figure 1 (flowchart) requires further information for greater clarity. Also it does not concur with the number of tables indicated in the tables (– ie 12 studies on herbal interventions, and four on acupuncture.) Specifically, please elaborate the reasons for exclusion of the 24 studies, and give a breakdown of the 14 RCTs included, in terms of the number that were acupuncture studies, and the number of herbal medicine studies. Please refer to the systematic review on-line by Jong-In Kim et al for guidelines:

Acupuncture for the treatment of tinnitus: a systematic review of randomized clinical trials
Jong-In Kim, Jun-Yong Choi, Dong-Hyo Lee, Tae-Young Choi, Myeong Lee, Edzard Ernst BMC Complementary and Alternative Medicine 2012, 12:97 (17 July 2012)

12. Results:
There is a lot of data to report. So sub-headings should be employed to facilitate reading.

13. The number of studies reporting on each intervention should be included (in brackets after the intervention, or in text).

14. References need to be included after every mention of a result. Again the authors are directed to the on-line review for an example of this:

Acupuncture for the treatment of tinnitus: a systematic review of randomized clinical trials
Jong-In Kim, Jun-Yong Choi, Dong-Hyo Lee, Tae-Young Choi, Myeong Lee, Edzard Ernst BMC Complementary and Alternative Medicine 2012, 12:97 (17 July 2012)

15. The authors state that, “The percentage reduction was defined as difference in symptom score between the final score after treatment and symptom score at baseline” i. Do the authors mean this was divided by the baseline score? ii. If this was calculated by the authors it belongs in METHODS section.

16. The outcomes could be further sub-divided to assist the reader: For example,
as well as the broad headings of acupuncture and herbal medicine already employed, each section could be further sub-divided into overall symptoms, physical symptoms, and psychological symptoms.

17. The range of improvement should be included, and ii. It should be specified unambiguously how this compares to the comparator/s.

18. References:

In the reference list, please be consistent with listing under surname.

19. Table 2:
i. Please include sample size and duration of treatment for each study. The control should be included for Ref 15.
ii. The heading ‘Time’ should be altered to ‘Frequency’
iii. Abbreviations used in the table should be expanded underneath the table.
iv. It appears that study 12 the analysis of a sub-population of study 12. This needs to be stated within the manuscript as well as highlighted in the table.

20. Table 3 i. need to be more clearly labelled. Eg Percentage reduction in symptoms by intervention.
ii. Further information is needed for the reader to determine whether a result was non-significant or not reported. Eg NS or NR.
iii. Abbreviations used should be clarified underneath the table.
iv. The presentation of results in Table 3 suggest that many symptoms demonstrated the same percentage reduction. If this is due to the RCTs reporting results for symptom clusters, it would be clearer if the results were presented to reflect that, or if it were stated in the text.

21. Use of English:
Please refer to the returned manuscript for corrections to use of English in track changes mode.

Level of interest
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An article whose findings are important to those with closely related research interests

Quality of written English
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Needs some language corrections before being published (iahve made many corrections in-text using track-changes mode)

Statistical review
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No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests
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I declare that I have no competing interests

Decision
Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Open peer review
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**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**
I declare that I have no competing interests