Reviewer’s report

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

Version: 3 Date: 1 April 2013

Reviewer: Margaret Diana van Die

Reviewer’s report:

The amendments made by the authors have considerably improved the quality of this review. However, some of the points were not addressed, and further changes are still required:

1. ABSTRACT

i) It is stated in the last sentence of the Methods section that ‘study outcomes were presented as mean differences’. Yet this is not made clear in the tables. It would appear that data are end-of-treatment scores. This needs to be clarified both in the tables and the abstract.

ii) Under ‘Results’, it is stated that herbal medicine significantly improved PMS/PMDD symptoms. However it is not clear if this refers to all the herbal interventions reviewed.

iii) The ‘Conclusions’ section needs to give more of an overview of the study findings (before discussing limitations), implications of findings as well as recommendations.

2. Background. Several other reviews have been conducted of these interventions. It is not clear why only the review by Kim et al is referenced. (See below)

3. Data extraction: As recommended previously, the ingredients of the formulations Xiao Yao San (ie Radix Bupleuri (Chai Hu), 3g, Radix Glycyrrhizae (Gan Cao), 3g, Rhizoma Atractyloides Macrocephalae (Bai Zhu), 1.5g, Radix Albus Paeoniae Lactiflorae (Bai Shao), 6g, Tuber Curcumae (Yu Jin), 6g, Bulbus Fritillariae Cirrhosae (Chuan Bei Mu), 6g, Rhizoma Acori Graminei (Shi Chang Pu), 6g, Rhizoma Cyperi Rotundi (Xiang Fu), 6g, Pericarpium Citri Reticulatae Viride (Qing Pi), 6g, Fructus Citri Aurantii (Zhi Ke), 6g, Radix Angelicae Sinensis (Dang Gui), 10g, Sclerotium Poriae Cocos (Fu Ling), 10g, Rhizoma Gastrodiae Elatae (Tian Ma), 5g) and Dan Zhi Xiao Yao San (Dan Pi (Cortex Moutan) 68.2 mg, Zhi Zi (Fructus Gardeniae) 68.2 mg, Chai Hu (Radix Bupleuri) 68.2 mg, Dang Gui (Radix Angelicae Sinensis) 68.2 mg, Bai Shao (Radix Alba Paeoniae) 68.2 mg, Bai Zhu (Rhizoma Atractylodis Macrocephalae) 68.2 mg, Fu Ling (Poria) 68.2 mg.

Gan Cao (Radix Glycyrrhizae) 22.6 mg.

The authors of these articles could be contacted if there is uncertainty regarding the exact formulations used. If they cannot be contacted, it should be stated what
the normal ingredients are, but that this could not be verified as no response was forthcoming from the study authors.

RESULTS

4. The information under the headings ‘Synthesis of Results (two places) belongs in the Methods section.

5. The number of studies and different interventions could be written as the first sentence of the respective paragraphs.

6. FLOWCHART

“6 citations identified form other sources” should be defined – were these identified as a result of hand-searching reference lists of journal articles?

7. TABLE 2

i) It is not clear why there are two rows for reference 10 (studies 3 -4), and what the different data represent (under the heading ‘Outcome’). Outcomes need to be specified as they are reported in table 3 for greater clarity.

ii) It is not clear whether the sample size is for the treatment arm only. The column heading needs to reflect this.

iii) Were the data available for studies 5 – 9 in this table? If so, this should be included. If not, ‘n/a’ should be included.

iv) What were the medications used as comparators in studies 6 – 9?

8. TABLE 3

Please clarify whether ‘Outcome’ refers to ‘end-of-treatment scores unless otherwise stated’, or mean differences, as stated in your abstract.

9. TABLE 4. The heading is confusing. “Significant result (%)… The results are non-significant”

10. DISCUSSION: The discussion should be a synthesis of the results rather than a restatement of findings. For example, the strength of the evidence for the different interventions should be made apparent to the reader, and:

i) The first paragraph and sentence 1 of the second paragraph belongs to the introduction.

ii) The findings of this study should be compared with comparable reviews on these interventions – including (but not restricted to) the following:


4. van Die MD, Burger HG, Teede HJ, Bone KM. Vitex agnus-castus Extracts for Female Reproductive Disorders: A Systematic Review of Clinical Trials. Planta
Med 2012.


iii) the studies with which findings are compared should be referenced.

iv) The authors should include the strengths of the current study (and what it contributes to the literature that the other reviews did not include).

v) The sentence “In acupuncture studies, more than five studies have been excluded…” should be deleted. This is covered by flowchart and search limits in results section. The following sentence may be relevant if rewritten: eg “Our findings were consistent with case studies examining herbal interventions and acupuncture. (refs)”

vi) Findings should be explained with reference to known mechanisms of action of the herb/s. ie Based on current knowledge of mechanisms of Vitex, Hypericum, Ginkgo etc, why might these be effective in PMS/PMDD (1 sentence each). The indications for the multi-component formulations could be given (eg liver chi stagnation causing psychological dysphoria etc/ liver-spleen dishormony, which manifests as symptoms such as…..). With regard to the TCM understanding, a further sentence could be added at the end of the paragraph, such as “Hence, treatment targetings these meridians/points/syndromes, may exert their benefits in PMS and PMDD by correcting underlying dysfunctions.”

vi) The implications of the equivalence to fluoxetine need to be explained. ie Is fluoxetine of proven efficacy in PMS/PMDD? If so, then equivalence to fluoxetine is actually a positive finding. (The also implies the the word ‘However’ should be removed from the sentence relating to this finding in the results section, as it does not contrast with other positive findings).

vii) the quality of the studies should be commented on (by referring back to the risk of bias assessment, as well as power, sample sizes, etc).

ix) The meaning of the sentence, “On the contrary, at least 4 trials…… a limitation on such wider experience in literature” is unclear.

x) The clause, “therefore conclusions about their efficacy many not speak for all alternative therapies” is self-evident and should be deleted.

11. CONCLUSION: Bearing in mind what clinicians and future researchers will want to know,

i) Can you draw any conclusions regarding the overall findings? Was the evidence for any intervention more convincing that for others? (ie greater number of studies, better methodological quality, larger sample sizes, longer treatment duration?)

ii) Summarize the main limitations of these studies. As mentioned by Reviewer 2, the main limitation appears to be that most interventions had only one study conducted on them.

ii) Can you make specific recommendations for future research based on the limitations of these studies?
12. REFERENCES:

i) Authors should be listed by surname, initial.

ii) According to the requirements of the journal, either all authors should be listed, or the first three followed by et al. Referencing style should be followed consistently.

13. Points not addressed from previous review:

i) “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.” This refers to the extract such as is given in the Ma and He studies, for example (VAC BNO 1095), as well as the mg/day and any information given regarding standardization. (Eg the Canning study on Hypericum states “900 mg/day (standardized to 0.18% hypericin; 3.38% hyperforin)”) Sufficient information should be provided to allow clinicians and other researchers to establish phytoequivalence with a different product.

ii) Results section: 17. The range of improvement should be included, and ii. It should be specified unambiguously how this compares to the comparator/s. (ie were all the interventions significantly superior to the controls?)

iii) 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. The authors are directed to: van Die MD, Burger HG, Teede HJ, Bone KM. Vitex agnus-castus Extracts for Female Reproductive Disorders: A Systematic Review of Clinical Trials. Planta Med 2012. (Free on PubMed)

iv) As previously noted, the standard of English expression obscures the meaning. The recommended changes from the previous review should be implemented, or the services of a proof editor sought.

Spelling of the herbs should be checked throughout and corrected where necessary. Consistency with use of Latin binomials or common names is recommended.

v) ‘PMS’ should be changed to read ‘PMS/PMDD’ throughout the document.

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’