Reviewer’s report

Title: Manual acupuncture for the infertile female with polycystic ovary syndrome (PCOS): study protocol for a randomized sham-controlled trial

Version: 0 Date: 23 Dec 2018

Reviewer: Parvin Abedi

Reviewer's report:

1. Title: I recommend the term of infertile female instead of sterile female.
2. This study has some grammatical and typographical errors and should be revised by a native English linguistic. Example: Our study intends to explore the effect of manual acupuncture in infertility female with PCOS. That should be in infertile female.
3. It is not clear that women in the control group, that receive Sham acupuncture and herb therapy, do they receive placebo for the herb therapy or real treatment?
4. Please change all terms of sterility to the infertility.
5. What is the standard treatment for PCOS. In my opinion, only considering herb therapy and then acupuncture for infertile women with PCOS is not ethical. At least one group with the standard treatment should present in the study.
6. Introduction: line 53: please the year for prevalence.
7. Introduction: page 4, line 1-3. What is the current standard care (please name it).
8. Please write every word in full for the first time and then use its abbreviation (OHSS).
9. Please provide reference for following sentence: meanwhile, it also has other impact effects like reversible ovarian enlargement (>10%), visual symptoms, headaches, and so on.
10. Method: there is need for more information about allocation concealment. How authors conceal the process of assignment (using sealed envelope etc…).
11. Inclusion/exclusion criteria: do authors exclude women with secondary infertility (those who had a pregnancy and then affected with PCOS and infertility)
12. Method: please mention which types of pregnancy test will be used (urine or β HCG)?
13. Do the Sham group receive acupuncture or only are the placebo (acupuncture with the false points). This matter is not clear in the manuscript.
14. In terms of laboratory tests, please explain all special methods and kits that will be used by authors.
15. Please explain what you do with the adverse effects and blinding. You need to break the blinding to treat the adverse effects. In the case for remaining blind to the rest of the study, I recommend that you use the unique code in time of randomization.
16. In the method, please explain the follow-up and how and when do you do them.
17. Please explain what method for analyzing data will be chosen by authors (intention to treat or per protocol). Because in this study authors have two follow ups, they need to use the repeated measure test.
18.
**Level of interest**  
Please indicate how interesting you found the manuscript:

An article of importance in its field

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Please indicate the quality of language in the manuscript:

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Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.

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