**Reviewer's report**

**Title:** Danggwijagyaksan for climacteric syndrome in peri- and postmenopausal women with a blood-deficiency dominant pattern: study protocol for a randomized, double-blind, placebo-controlled pilot trial

**Version:** 0  **Date:** 21 Oct 2017

**Reviewer:** Jitendra Singh

**Reviewer's report:**

This study is the study protocol dealing with important issues of women health. The trial will be aimed to explore the safety, efficacy and feasibility of Danggwijagyaksan (DJS) for improving climacteric syndrome in peri-and postmenopausal women with a blood-deficiency dominant pattern. The authors have presented a good description of the trial, its process and the expected outcomes and appears to be high quality study. However, some of the questions still remain unanswered and need revision for improvement in reporting of the protocol.

**METHODS/DESIGN**

1. **Recruitment:** The authors explained recruitment process of study participants but it seems not very clear to the readers. To recruit the participants, which step will be done first? Screening then recruitment or recruitment then screening. Pls mention it step by step (and also revise Fig 1, if needed).

2. It is better to insert a heading "Participants" before inclusion criteria.

3. **Inclusion criteria:** The authors mentioned in third point: an MRS score of 9 or higher will be included. But Menopause Rating Scale (MRS) categorized climacteric syndrome as mild, if scored 5-8 [24]. So, why participants having mild level of climacteric syndrome is not included in this study as this trial is designed for climacteric syndrome. This need clarification.

4. **Exclusion criteria:** The authors mentioned in 12th point: other cases considered inappropriate for this trial by the investigator. So, meaning of inappropriate cases should be specify.

5. **Intervention:** Who will perform intervention? Is there any role of Pharmaceutical company in conduction of this Trial? It should be clearly mention.
6. Outcome measures: Authors described very well for the tools used to assess primary and secondary outcomes? However, its reliability and validity is lacking. Also, authors need to talk about methods to handle biological specimen for laboratory test.

7. It is appropriate to insert a heading "Data collection" before statistical analysis and it should consists: Methods of data collection? How will reliability be ascertained? What is the trustworthiness plan to deal with data from intervention and control group?

8. Ethical consideration: In case of any adverse events, will participants receive any compensation? If not, what is the justification? If yes, what form of compensation?

The structure of the protocol can be improved.

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