Author's response to reviews

Title: Effects of acupuncture on serum metabolic parameters in premenopausal obese women: study protocol for a randomized, patient-assessor blind, sham-controlled clinical trial

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Author's response to reviews: see over
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Re: Manuscript #1749053864162667 Effects of acupuncture on serum metabolic parameters in premenopausal obese women: study protocol for a randomized, patient-assessor blind, sham-controlled clinical trial

Dear Dr. Doug Altman, Curt Furberg and Jeremy Grimshaw

My colleagues and I greatly appreciate the comments and critiques of the reviewers and have incorporated their suggestions and recommendations into the manuscript. We wish to acknowledge the reviewers contributions.

Reviewer #1

1. Authors should explain the relation between obesity and premenopausal women.

We agree with the reviewer that it could be better to explain the relation between obesity and premenopausal women. In this study, we wanted to exclude the effect of menopause on obesity and other possible metabolic conditions. Therefore, we just added the following sentence in the Inclusion criteria of Participants part under Methods/design section: “To avoid the effect of menopause on obesity and serum metabolic parameters [19], we decided to include only premenopausal women”. (line 7-9, page 6)

2. Please report detailed information of the allocation concealment.

We tried to report detailed information of the allocation concealment in the Randomization part under Methods/design section as following: “Randomization will be conducted using a computer-generated random allocation sequence by a statistician with no clinical involvement in this trial and the random code will be kept by a clinician who will not contact patients. Randomization code will be released after the participants are recruited for the trial and all baseline measures are taken to ensure allocation concealment”. (line 9-12,15-17, page 7)

We used centralized randomization and sealed envelope for allocation concealment.
to prevent selection bias.

3. Authors focused on serum metabolic parameters in premenopausal obese women. But in inclusion criteria, 19 years of age will be included. Authors should understand the definition of premenopausal women.

We agree with the reviewer that it could be confused when we say three characteristics in a time, such as “premenopausal adult obese women”. So we changed the sentence in Inclusion criteria of Participants part under Methods/design section as following: “The eligibility criteria for the study include adult women (19 years of age or older) in premenopausal state with regular menstruation, clinical diagnosis of obesity (body mass index of 25 kg/m² or more)”.

(line 5-7, page 6)

We used the term “premenopausal” to express the state of having normal menstrual cycles with monthly periods, against “perimenopausal or menopausal”.

4. There are too many parameters regarded as primary outcome. It is difficult to evaluate the effect of acupuncture.

We agree with the reviewer that too many parameters could make it difficult to evaluate the effect of acupuncture. Therefore, we decided to reduce parameters for primary outcome measurement. As you see under Discussion section, we determined serum cholesterol and TG levels as the primary outcome measure and other metabolic profiles as secondary outcome measures as following: “So far, one clinical trial has examined the effect of acupuncture on metabolic parameters in obese patients [18], which used serum cholesterol and TG levels. Referring to the previous study, we will use serum cholesterol levels including LDL, HDL and TG levels among serum metabolic parameters as the primary outcome measurement. And we will also determine other serum metabolic profiles as secondary outcome measurements because the main purpose of this study is to assess the efficacy of acupuncture on obesity from the perspective of metabolomics and therefore better understand the pathophysiological mechanism of obesity and acupuncture”. (line 10-17, page 15)

We also changed the Primary outcome measurement and Secondary outcome measurement part under Outcome section as mentioned above. (line 12-13, page 10, line 12-17, page 11)

5. Some grammatical errors and textual problems should be improved in this article. It is important to get a native writer to check the paper.

As recommended, the paper was edited and proofread by a native writer. Please refer to the attached document of “certificate of proofreading”.

We thank you for your consideration and look forward to hearing from you.

Sincerely yours,

Mi-Yeon Song, KMD, Ph. D.
Hi-Joon Park, KMD, Ph. D.