Author’s response to reviews

Title: Acupuncture for postprandial distress syndrome (APDS): study protocol for a randomized controlled trial

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Author’s response to reviews:

Dear Dr. Scherer

Thanks again for your letter and for the Reviewer’s comments concerning our manuscript. We have detailed our responses to Reviewer’s concerns and comments. Following are point-by-point responses to the Reviewers’ comments and suggestions.
Reviewer reports:

The manuscript is much improved, but there are a few minor corrections/explanations still needed.

1. The justification for the sample size is inadequate. Typically sample size calculations include some indication of previous data obtained along with some measure of variance and the clinically meaningful difference that is the goal of the trial. Please provide some information on "clinical experience" - either references that show the expected rate of improvement and the expected difference you expect to see. Include that specific information in your description of how the sample size was determined. Right now, with only 21 persons in each group, it is not clear if the trial is protected against a type II error (not seeing difference between treatment groups when there is one). Also you should provide information on the 'clinically meaningful difference between groups.

Response: We thank the Reviewer for the question. As we said, this trial is a pilot study. Therefore, we estimate the sample size just based on the feasibility. Since this trial consists of three centers, the sample size for this pilot trial is 42 subjects, 14 in each center. Before we recruited, we have registered (ISRCTN18135146). After this study is completed, the outcomes will aid in the calculation of the appropriate sample size for our further randomized clinical trials. We have explained it in the manuscript (highlighted in red).

2. The statistical plan says 'All data will be presented as means..." but the primary outcome is a rate (or proportion) and cannot be a mean. Please update the statistical plan to say specifically how the primary outcome will be analyzed.

Response: We thank the Reviewer for the suggestion. We have updated this part. The categorical data will be described as percentage (n %), and continuous data using mean ± standard deviations. The primary outcome will be analyzed using Chi-square ($\chi^2$) test (highlighted in red).
3. Page 6 - lines 54-57: extra space between ran and dom; participates should be participaNts; and the tense needs to be past tense (have MET all inclusion criteria and completeD baseline assessment)

Response: We are sorry about these wrong types. We have revised them (highlighted in red).

4. You have indicated in your response that the sponsor had no role in the design or conduct of the trial, but this needs to be stated in the manuscript. Simply add a sentence such as "The funding has no role in the design or conduct of the trial.

Response: We thank the Reviewer for the suggestion. We have added this sentence (highlighted in red).