Author's response to reviews

Title: The effects of two Chinese herbal medicinal formulae vs. Placebo controls for treatment of allergic rhinitis: A randomised controlled trial

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Responses to reviewers’ comments
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We have made the following changes in the revised manuscript according to the reviewers’ comments and suggestions:

Reviewer 1
1. The whole manuscript needs re-written. The whole text is redundant, for example, the introduction of CS text is repeated at least 3 times, in both methods part and discussion part.

Response:
We have restructured and edited the whole manuscript, especially the redundant parts or sentences in the introduction, methods and discussion on the description of the CS and its functions. We have also tightened these main sections (introduction, methods and discussion) of the manuscript to make precisely and clearly presented.

2. The author spent a lot of writing to explain Chinese medicine theory in both background and discussion part, such as diagnosis methods, treatment principles, formula properties, and Yin/Yang concept, yet it is difficult to understand the rationale and the explanation, also there are some sentences seem very assertive (as an example: Yin is associated with physical form of an object with less energetic qualities such as stillness, deficiency, weak, and cold and ‘Yang’, related to functioning of an object or a human being with more energetic qualities such as moving, excess, strong, and heat.)

Response:
We agree with the reviewer’s suggestions and have shortened the explanation of the Chinese medicine theory in the introduction and discussion. The importance of ‘Zheng’ or pattern differentiation has been highlighted and the rationale for the use and testing of the YS and CS has also been explained on pp.5-7. Those assertive sentences have been modified accordingly, for example, the sentences relation to ‘Yin’ and ‘Yang’ on p. 5 have been changed to “Body constitution and
current health status of an individual can be considered in term of the balance between co-existing ‘Yin’ and ‘Yang’ (i.e., believed to be the physical form and functioning of a human being with low or deficient and high or excessive energetic qualities, respectively)…”

3. The title “Herbal medicinal formula vs. alternative herbal formula and Placebo control’ is confusing. There are a lack of background introduction on the objective of the study. Why the author concentrate on the comparable effect of the two formulae rather than the effect evaluation of the two formulae? Is there any logistic correlation between the comparative effect (the objective and hypothesis) and the clinical challenge delivered in the background part?

Response:
We agree with the reviewer’s suggestions. The title has been amended and now is written as “The effects of two Chinese herbal medicinal formulae vs. Placebo controls for treatment of allergic rhinitis: A randomised controlled trial”. We have also added information about the rationale for the use and examination of the effects of the YS and CS on p. 8 and the hypotheses of this clinical trial by the end of the introduction (p. 9). We have clarified that the main purpose of this study was to examine the effects of two herbal formulae for people with AR, while the comparison of the effects between the CS and YS in treatment of AR is the secondary objective/hypothesis in this study.

4. There is a lack of description on whether the patients received the same comprehensive health assessment by the researchers, including vital signs and oxygen saturation, peak flow rates to detect respiratory functioning before treatment. If not, why should the patients receive this examination only once after treatment?

Response:
We have made changes and clarified that the comprehensive health assessment had been conducted during each outcome measurement and the interim assessment on p. 20. This is described as “During each outcome measurement and interim assessment, they also received a comprehensive health assessment by the researchers, including their vital signs and oxygen saturation, peak flow rates to detect respiratory functioning and possible adverse effects of the treatment received.”

5. There is spicy taste food such as ginger in placebo, yet ginger is also a “hot” herb according to Chinese medicine theory, thus how to avoid the treatment effect of the placebo? And how to assure the similar taste of the three different formulae, especially of the two different herbal formulae although the application of the syrup?

Response:
The reviewer is correct to point out that the ginger used in the placebo medication is ‘hot’ in nature. It had been used for producing similar spicy taste as the other two medicines (CS and YS) in this study. The fresh ginger had been used in very small amount (3g) for which it would not be able to exert therapeutic
but rather reasoning effect. In addition, cold food is contra-indicated and at risk of harmful effect for those participants with AR in the placebo group who presented with a ‘Cold’ nature of body condition. Hence, a small amount of fresh ginger could serve as a placebo with very similar taste and smell as the two herbal medicines used in this study, and prevent any ‘cold’ food or ingredient to be added with potential harm for the participants in the placebo group.

In addition, the methods to ensure similar taste, colour and texture of the medications among the three study groups were described in more details in the interventions section on pp. 13-14.

6. In the conclusion part, it is difficult conclude that “As allergic rhinitis and other chronic illnesses are highly prevalent and distressing to the sufferers, Chinese medicine can be an effective alternative approach to Western medicine in reducing their enduring symptoms and possible curing the illness” from this study.

Response:

We agree with the reviewer’s comments on the sentence. The sentence has been deleted and the conclusion on p. 33-34 has also been edited to summarise the main findings and implications.

7. There are still some spelling errors in the text, please read the text again and revise them.

Response:

The revised manuscript has been edited carefully and spelling mistakes were corrected by the second author who has published prolifically and finally by a native English speaking editor.

Reviewer 2

1. Authors were not able to identify “Zheng” such as Yang deficiency and Qi deficiency and Yin deficiency.

Response:

The importance of pattern differentiation or ‘Zheng’ identification such as Yang-deficiency and Qi-deficiency has been described on pp.4-5 and the potential effects of the CS and YS in relation to the ‘Zheng’ regarding AR have also been described on p. 8. The importance of pattern or ‘Zheng’ differentiation in the treatment of AR as demonstrated by the results of this trial has also been made in the discussion section.

2. The production method of placebo is incredible.

Response:

We appreciate that the reviewer highly appraised our high quality and standard of production for the medications used in this study. Therefore, the internal validity of the study contributed by the high consistency and integrity of the interventions used could be enhanced.
3. T-test was used among three arms in this manuscript. It is not suitable obviously.

Response:
We are sorry to make such careless typo. error on the use of statistical tests for comparison of characteristics and baseline outcome scores between three groups. We have amended the sentences in the data analysis section on p. 22. The statistical tests used for examining the homogeneity of sample in terms of their characteristics (mainly nominal data) and baseline mean outcome scores (interval or ratio data) were Goodness of Fit Chi-square test and one-way analysis of variance test, respectively.

4. Writing in this paper need be concise than before.

Response:
As responded to the first item of Reviewer 1’s comments, we have re-written the introduction, methods and discussion sections to make the manuscript be more concise and clear. In addition, the manuscript has been edited by the second author who has published prolifically and then an English editor.

Thank you very much for your time and effort on the first review, as well as this second review and reconsideration.