

Peer Review File

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Major Revision

Comment 1: In the “2.2 Study design and setting” section, authors stated that “Sample size of our study was calculated by computational formula”, please provide the formula and parameters for sample size calculation.

Reply 1: Thank you for comment on this important concern. The computational formula and parameters have been added in our new manuscript.

Changes in the text: Sample size of our study was calculated by computational formula. The computational formula is as follows:

$$N = [(Z_{\alpha} + Z_{\beta}) \sigma / \delta]^2 (Q_1^{-1} + Q_2^{-1})$$
. The parameters is as follows: $\alpha = 0.05$, $\beta = 0.20$, $Q_1 = Q_2 = 0.5$.

Page 4, line 80-82

Comment 2: Please describe how to do the randomization allocation concealment.

Reply 2: Thank you for comment on this important concern. The randomization allocation concealment has been added in our new manuscript.

Changes in the text:

The random allocation sequence will be produced by an independent researcher who is not involved in the recruitment, evaluation and intervention of participants. Before intervention commencement, the research staff will inform eligible participants of their intervention allocation by telephone.

Page 5-6, Line 99-103

Comment 3: The trial use single-blind method, while, for the placebo control, we suggest this trial use double-blind method, to blind researchers and patients.

Reply 3: Thank you for the important comment. We will optimize our clinical trial according to your comments.

Comment 4: We suggest this trial add the diagnosis of TCM syndrome type, and include the special TCM syndrome type for MSDG.

Reply 4: Thank you for comment on this important concern. The diagnosis of TCM syndrome type for MSDG section has been added in our manuscript.

Changes in the text:

TCM syndrome type of all participants should be deficiency of spleen and kidney with blood stasis. The diagnostic standards of deficiency of spleen and kidney with blood stasis include primary symptoms and secondary symptoms. Primary symptoms include Lumbago, edema, weakness, gloomy complexion, and dyspepsia. Secondary symptoms include limb numbness, scaly dry skin, frequent micturition at night, and diarrhea.

Page 7-8, line 124-13.