Author’s response to reviews

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

Authors:

Jing-Wen Yang (yangjw0626@126.com)
Li-Wen Zhang (zhangliwen0929@126.com)
Guang-Xia Shi (shiguangxia2008@126.com)
Yi Du (dodo_8110@aliyun.com)
Jun Wang (wangjunee@yeah.com)
Jing-Jie Zhao (13466376389@139.com)
Yan Cao (caoyan92cy@163.com)
Jian-Feng Tu (tujianfeng1@126.com)
Shuai Zhang (15010541329@163.com)
Cheng Tan (tancheng206@126.com)
San-San Chen (1187140763@qq.com)
Cun-Zhi Liu (lcz623780@126.com)

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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 are sorry about our grammar, spelling errors. 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:

Please see attached document - manuscript is conceptually ok, but there are many grammar, spelling errors, and a few places where additional explanations are needed

Response: We thank the Reviewer for the careful revision. We are very sorry about the wrong types and grammar, spelling errors in the manuscript. We have revised all of them (highlighted in red). Furthermore, we response point-by-point about a few places where need additional explanations.

Abstract

Secondary endpoints including global assessment, symptoms, disease-specific quality of life (QoL) and depression and anxiety will be assessed at baseline, 4, (something measured at baseline cannot be an outcome – and the 4 week measurement is the primary outcome time point)8, 16 weeks after randomization

Response: We thank the Reviewer for the suggestion. Baseline is not an outcome, we have deleted this time point. The global assessment at 4 weeks after randomization is our primary outcome. Global assessment at 8 and 16 weeks after randomization is one of the secondary outcomes. The other secondary outcomes including symptoms, disease-specific quality of life (QoL) and depression and anxiety will be assessed at 4, 8, 16 weeks after randomization. We have revised it (highlight in red).

Intervention

Acupuncturists will be required to achieve the typical acupuncture sensation of De qi, and needles will be stimulated manually at least 30 seconds at every acupoint with retained (not clear exactly what you mean because there is no noun - do you mean needles are retained - may be say ‘acupoint and retained in place for’ ?) for 20 minutes.

Response: We thank the Reviewer for the suggestion. The needles are retained 20 minutes. We have revised them (highlighted in red).
Adverse events

Any adverse events related to acupuncture will be monitored and recorded by participants or acupuncturists using a questionnaire designed. (not clear what you mean here – do you mean a questionnaire with pre-specified adverse events?)

Response: We thank the Reviewer for the question. We have a questionnaire with pre-specified adverse events, such as local bleeding, redness, itching at the sites of needle insertion and dizziness.

Statistical analysis

The per-protocol analysis that will include only those participants who will have completed more than 10 acupuncture treatments > 10 and have no major protocol violations performed for the primary and secondary outcomes. (what do you mean by this? are the protocol violations related to ‘performed for the primary and secondary outcomes – or do you meant the per protocol analysis is ‘performed for the primary and secondary outcomes? Also, define what you mean by ‘major’ protocol violations - )

Response: We thank the Reviewer for the question. The protocol violations mainly include taking other drugs during the trial, not completing the CRF as required and so on. It is not directly related with “performed for the primary and secondary outcomes”. We have revised this part (highlight in red).