Author’s response to reviews

Title: Effectiveness of strengthened stimulation during acupuncture for the treatment of allergic rhinitis study protocol for a randomized controlled trial

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Author’s response to reviews: see over
1. P(age) 1, p(aragraph) 2, l(ine) 2. Define [PER] and [IAR] here as well as P 16  
Answer: PER (persistent allergic rhinitis), IAR (intermittent allergic rhinitis)

2. P 3, p 1, l 8. Replace [significantly] by [dramatically] or some or similar word.  
Answer: It dramatically impacts quality of life (QOL) and creates an economic burden.

4. P 3, p 1, l 15. Insert [incur additional] between [and] and [healthcare].  
Answer: A remarkable numbers of patients with AR are not satisfied with conventional medical treatment for they repeatedly experience side effects and incur additional healthcare costs.

5. P 4, p 1, 5 and 6. Replace [trails] by [trials].  
6. P 4, p 1, l 6. Replace [fail to] by [do not].  
7. P 4, p 1, l 7. Insert [and] between [acupuncture] and [didn’t].  
Answer: … At the same time, a number of trials have the same situation in migraine [11,12], low back pain [13,14] and some other diseases. All the trials do not find verum acupuncture more effective than sham acupuncture and didn’t emphasize…

8. P 4, p 1, l 14. Replace [significance] by [importance] or some similar word.  
Answer: The importance of De qi was first mentioned circa 100 B.C.,

9. P 4, p 1, l 17 and 21. Which is correct: [qizhi] or [qizhi]?  
Answer: the correct one is [qi zhi].

10. P 4, p 1, l 22. Insert [theory] between [the] and [of].  
Answer: …belief in the theory of acupuncture that the intensity of the stimulus must…

11. P 5, p 1, l 4. Replace [Bell] by [Bell’s] and either add additional items or delete [etc.].  
Answer: … such as the Bell’s palsy, knee osteoarthritis, etc [17-18].

Answer: Chengdu University of TCM, China. The study will be sequentially
13. P 6, p 1, l 1. Add an [s] to read [twelve-weeks].
**Answer:** … follow-up period of twelve-weeks. The total study period will be 18…

**Answer:** … concealed in light-proof and sealed sequentially numbered envelopes…

15. P 6, p 2, l 8. Replace [had] by [will have].
**Answer:** acupuncturists will have access to the treatment allocation.

16. P 6, p 3, l 5. Rewrite as [...] they will be asked not to communicate [...].
**Answer:** … nature of the intervention, but they will be asked not to communicate with…

17. P 7, p 1, l 1. Add [ed] to read [linked].
**Answer:** ...and the case report forms are not directly linked to the treatment…

18. P 7, p 2, I tem) 2, l 3. Rewrite as [...] a space between each one.
**Answer:** …These symptoms should last > 1 h on most days…

**Answer:** (5) No current participation in any other clinical trials

20. P 8, p 1, I 6, l 2. Add a [.] to read [lactating].
**Answer:** the last 6 months, or women who are lactating.

**Answer:** ...assigned treatment for various reasons at any of the stages of the trial

22. P 8, p 2, I 3. Add a [.] to read [follow-up]. Also See Little RJ et al in NEJM 2012 Oct 4 as to how to avoid missing data in clinical trials.
**Answer:** (3) They do not fully participate in treatment or follow-up.

23. P 9, p 2, l 6. Replace [were] by [will be].
**Answer:** ...will be used for...

24. P 9, p 2, l 12. Replace [were] by [are].
Answer: ... which could affect the allergic rhinitis symptoms, are not permitted.

25. P 9, p 3, l 2. Rewrite as [10-30 mm]; insert a space.
Answer: ...selected with 10–30 mm in...

26. P 10, p 1, l 2 and 5. Replace [were] by [will be].
Answer: ... The needles will be left...
... the needles will be inserted...

27. P 10, p 1, l 7. Replace [opposite] by [other].
Answer: Patients in the other treatment group...

28. P 10, p 2, l 3 and 10. Provide R(eference)s to these points.
Answer: We choose these acupoints according to 'WHO Standard Acupuncture Point Location'[1]. These acupoints were commonly reported to be useful in traditional Chinese medicine journals. In Hu’s research[2], Yingxiang(LI20), Hegu(LI4) and Yintang (EX-HN3) are the most common used acupoints in treatment of allergic rhinitis. While in Mao’s[3] thesis, L120, EX—HN3, LI4 and ST36 are the most widely used acupoints.


29. P 10, p 2, l 7 and 8. Since [or] logically includes [and], delete [and/]
Answer: ... to the imbalance of the Large Intestine or Stomach meridian or Governor ...

30. P 11, p 1, l 3 and 4. Explain how this happens
Answer:
In Suwen (Plain Questions), the 24th, described it as: YangMing is always full of qi and blood.
According to the TCM theory, Zusanli(ST36) is considered as the he-point (combined-point) on stomach meridian, Quchi(LI4) is the he-point (combined-point) of Yangming’s large intestine meridian. In Chinese theory, “He” means convergence, sufficient Qi of the meridian, which converge to the zangfu organs, just as rivers converge into the sea. Chinese classics Spiritual Pivot (Ling shu) describe that the combined point can treat the viscera’s disease (He zhi nei fu). In SuWen, it was said that the spleen meridian and the stomach meridian have the internal-external relation. The qi is exchanged in the two meridians. So stimulate ST36 can fortify the stomach qi and spleen qi. As the same, the internal-external relation is also between lung meridian and large intestine, so stimulate LI4 can replenish lung qi.

31. P 11, p 2, l 2. Rewrite as [The trial ...].
Answer: The trial protocol has been approved ...

32. P 11, p 2, l 3 and 4. Rewrite as [Written informed consent will be requested for all participants ...].
Answer: Written informed consent will be requested for all participants before registration.

33. P 12, p 2, heading. Rewrite as [Primary Outcomes].
Answer: Primary Outcome

34. P 12, p 4. Provide more detail about RQLQ, as to number of questions, scoring and how the questions are answered. Is there a Chinese validation for this questionnaire? Cite it.
Answer: add this to my manuscript

“The RQLQ evaluates impairment of everyday life (activity, sleep, everyday life problems, condition of health) caused by symptoms of the eyes and nose. It contains 28 questions related to these dimensions. Each question can be divided into seven degrees: 0-not trouble, 1-hardly trouble at all, 2-somewhat trouble, 3-moderaely trouble, 4-quite a bit trouble, 5-very trouble, 6-extremely trouble.”

The Chinese version of RQLQ was consented by Professor Elizabeth Juniper, and provided by the MAPI Research Center. (Qiulan L, JiYan X; on Clinical Application and Assessment of Rhinoconjunctivitis Quality of Life Questionnaire (Chinese Version ). Guangzhou University of Chinese Medicine. 2008).

The Chinese version of RQLQ has been attached in the mail.

35. P 13, p 2 heading. Rewrite as [Secondary Outcomes].
Answer: Secondary Outcome

36. P 13, p 3, l 1. Rewrite as [To test ...] since [In order] is redundant in English.
Answer: To test the effectiveness of blinding ...

Answer: ... 3rd acupuncture session to assess ...

38. P 14, p 1, l 5. Were drop outs accommodated in the sample size justification?
Answer: The drop-out rate is 20%.

Answer: ... and ranges for rank data; and frequencies and percentages for discrete data.

Answer: I found the article Altman D G, Dore C J. Randomisation and baseline comparisons in clinical trials [J]. The Lancet, 1990, 335(8682):
149-153. Thank you very much by giving me this suggestion. It reemphasized that randomization integrity is more important. We’ll adhere to this principle in our trial. And it had been deleted from my manuscript.

41. P 15, p 1, l 1, 3, 5, Replace [population] by [group].
   Answer: l 1: The intention-to-treat (ITT) group...
             L3: (PP) group      l 5: ... the ITT group and PP group.

42. P 15, p 1, l 5. Either define [PP] or provide a R. Add [PP] and [ITT] to P 16
   Answer:
   The intention-to-treat (ITT) group is defined as the patients who are randomized and received at least one treatment session.
   The per-protocol (PP) group is defined as the patients who completed the study and do not have major protocol violations

43. P 15, p 1, l 6 and 7. How will the comparison be made?
   Answer: All analyses were based on the ITT group and PP group. And the result of the ITT analysis will be compared with that of the PP analysis to check whether the results are consistent.

44. P 15, p 2, l 5. Replace [trail] by [trial].
   Answer: The main objective of this trial...

45. P 16, p 1, l 5. Rewrite as [To ensure ...].
   Answer: ... To ensure the efficacy and safety of...

46. P 16, p 5, l 1 and 2. Insert a space after the numbers 1 and 2.
   Answer: 1 Chengdu University of Traditional Chinese Medicine, Chengdu, Sichuan Province... 2 Department of Otorhinolaryngology...

47. P 17, R 10. Delete [-] in [Gunnarsson].

**Answer:**


Replaced with


49. P 18, R 16. Provide the first 30 authors before using [et al], just like R 2.

**Answer:**


Replaced with


50. P 21, column 2, make the word [baseline] be on a single line and in column 3, rewrite as [12 sessions].

**Answer:**

<table>
<thead>
<tr>
<th>week</th>
<th>-2 0 1 2 3 4 6 8 1 1 1 1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
</tr>
</tbody>
</table>

51. P 22, Appendices 3 and 4. Some parts look strange with inverted questions marks.

**Answer:** For this item, I failed to find out the strange questions marks. Could you make it more clearly? I’ve recalibrated the format. I hope there will not be any parts look strange.