Author’s response to reviews

Title: Efficacy and safety of Acupuncture for chronic dizziness: a randomized, controlled clinical trial

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Author’s response to reviews: see over
Dear editor,

Thank you for your time and efforts. According to the reviewers’ comments on our manuscript, we have finished revisions. The main amendments have been highlighted in red in the revised manuscript. We hope that the revised version is acceptable for publication in your journal. For details of the revisions please see the Response to Editors and Reviews attached.

Thank you again for your cooperation.

Sincerely yours,

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Editorial requests:

1) Please ensure the title conforms to journal style for study protocol articles. The title should follow the format ‘_________: study protocol for a randomized controlled trial’.

**Author response:**

Thanks for your very careful review of our paper. According to your comments, we modified the title 'Efficacy and safety of Acupuncture for chronic dizziness: a randomized, controlled clinical trial' to 'Efficacy and safety of Acupuncture for chronic dizziness: study protocol for a randomized controlled trial'.

2) Please mention each author individually in your Authors' Contributions section. At present Yan Liu is missing. We suggest the following kind of format (please use initials to refer to each author's contribution): AB carried out the molecular genetic studies, participated in the sequence alignment and drafted the manuscript. JY carried out the immunoassays. MT participated in the sequence alignment. ES participated in the design of the study and performed the statistical analysis. FG conceived of the study, and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

**Author response:**

We mistook XL for YL (Yan Liu). According to your comments, we modified the sentence 'XL was in charge of coordination and directed implementation' to 'YL was in charge of coordination and directed implementation'.
Response to Reviewer
Reviewer: Fan-Rong Liang
Reviewer's report:
Discretionary revisions
The study protocol 'Efficacy and safety of Acupuncture for chronic dizziness: a randomized, controlled clinical trial' submitted by Z. Xue focused on the RCT evaluating acupuncture's effect on dizziness. It is a well-drafted manuscript, the logic is clear, the trial design is sound and reasonable. However, there are certain issues for the authors to concern to make the protocol suitable for further publication.

Major Issues:
1. Population

as to this part, I think the author should state in their manuscript about how the participant was enrolled, namely the procedure of propagation by advertisement, introduction of all interests and benefits as well as risks along with this trial, signing a written consent form, etc. These are essential to assure the common rights for participant, which therefore must be supplemented lately.

Author response:

Thanks for your very careful review of our paper. According to your comments, we stated in our manuscript about how the participant was enrolled.

The propagation of our trial will be carried out by poster at this Hospital. All candidates will go through a standardized interview and receive more information about the study and the treatments. Patients will be informed in a manner suggesting that two different types of acupuncture treatment were compared. One type is traditional, another is new, and both of the efficacies is uncertain, not mentioning terms such as ‘placebo’ or ‘sham’. The participants’ written consents will be obtained. They will also thoroughly be explained on the purpose and procedures, and potential risks and benefits of the study. They could withdraw from the study at any time without any consequences.

We have added this content in the ‘Population’ section.
2. Exclusion criteria

how about excluding ‘patient receiving or received acupuncture treatment in past 3 month’?

**Author response:**

According to your comments, we have added ‘patients receiving or received acupuncture treatment in past 3 month’ in the ‘Exclusion criteria’ section.

3. Interventions

what kind of needle will be used? which brand? how long, the size and type, etc. It should be fully elaborated in the manuscript. Secondly, Is there manipulation of needles inserted? The manuscript should introduce all procedures clearly and adequately no matter what approach the manipulation modality is, namely manual, or electrical, as this is a protocol article.

**Author response:**

According to your comments, we introduced what kind of needle we used and the manipulation of needles inserted.

Single-use, sterile, 40 mm×0.25 mm or 25mm ×0.25 mm (depending on the area to be treated), silver-handle needles (HanYi disposable acupuncture needle, made in Tianjin HuaHong Medical Co., Ltd., Tianjin, China) without guide tubes are used in group A. Needles are correctly inserted and manually stimulated until the ‘De Qi’ sensation is elicited. The needles will stay in place for 30 min and manually stimulate every 10 min. Only needle acupuncture is allowed, whereas other forms of acupuncture treatment (e.g. laser acupuncture, electro-acupuncture, moxibustion) are not permitted. The same type of needles will be used as group A, but the insertion is superficial and physicians are not instructed to achieve ‘De Qi’. We has added this content in the ‘Interventions’ section.

4. Randomization and blinding

'..., another research coordinator who is uninvolved with data collection randomly
assigns them to one of two treatment groups by using a computer-generated, blocked random-allocation sequence.’ the description of randomization is far more insufficient. I am assuming that the 2nd researcher coordinator or data collector will take part in the process of randomization, and moreover he/she just assign the included participant according to a random-allocation sequence, so is there any measures to guarantee allocation concealment? If there is, will it be done by a opaque envelope, or somewhat. It should be stated.

Author response:

According to your advice, we stated the concealment in our study. The allocation of the randomization sequence will concealed centrally by telephone. We have added this content in the ‘Randomization and blinding’ section.

5. Randomization and blinding
'The patients, data collection staff, and data analysts are blinded during the study period.’ according to last paragraph, it stated that 'evaluation, another research coordinator who is uninvolved with data collection randomly assigns them to one of two treatment groups...', there will be a researcher getting involved in both data collection and randomization procedure. Thus, it is quite a paradox here. The author should regroup it.

Author response:

'Another research coordinator who is uninvolved with data collection randomly assigns them to one of two treatment groups...'. This researcher does not getting involved in both data collection, he/she will only participate in randomization procedure.

1. Abstract-background
'Nontraditional remedies'
Usually, the 'acupuncture' therapy is called a manner of traditional Chinese medicine, the diction 'nontraditional' seems quite inappropriate here. I would like to suggest the
authors replace this word by 'non-conventional' to make it reasonable. This comment is still suitable to the rest part of the manuscript.

Author response:

Thanks for your very careful review of our paper. According to your comments, we replaced 'nontraditional ' by 'non-conventional' to make it reasonable.

2. Abstract-Methods

'one of two treatment groups receiving acupuncture treatment for 4 weeks.' in order to avoid misunderstanding, I would prefer to modifying the sentence 'two treatment groups receiving acupuncture treatment....4 weeks' to 'two treatment groups receiving verum and sham acupuncture treatment respectively, for 4 weeks'.

Author response:

Thanks for your very careful review of our paper. According to your comments, we modified the sentence 'two treatment groups receiving acupuncture treatment....4 weeks' to 'two treatment groups receiving verum and sham acupuncture treatment respectively, for 4 weeks'.

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare that I have no competing interests.