Author’s response to reviews

Title: A Prospective Randomized Controlled Study of Auricular Point Acupressure to Manage Chronic Low Back Pain in Older Adults: Study Protocol

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Title: A Prospective Randomized Controlled Study of Auricular Point Acupressure to Manage Chronic Low Back Pain in Older Adults: Study Protocol

We would like to thank the reviewers for their thoughtful comments and clear suggestions. We believe the manuscript is now stronger because of the changes made as a result of the reviewers’ feedback. We appreciate the opportunity to revise and resubmit this manuscript. We have
responded to each reviewer’s comments below and indicate the line number with red font in the manuscript where the change has been made and can be easily found.

1. Page 2, line 38 "The ecological momentary assessment (EMA) smartphone app…" the phrasing needs to be explained - what does this mean? Unless you are working in this field many readers will be unfamiliar with the term. E.g "Ecological momentary assessment (EMA) involves repeated sampling of subjects' current behaviors and experiences in real time, in subjects' natural environments. EMA aims to minimize recall bias, maximize ecological validity, and allow study of microprocesses that influence behavior in real-world contexts."

Response: Thanks so much for your comments. The explanation of EMA has been added (lines 219-223).

2. SPIRIT checklist - It is not acceptable for Trials journal for the authors leave any items blank or with N/A in the SPIRIT checklist. Further information is required. Please either edit the protocol and insert page numbers in the checklist or insert relevant information in the SPIRIT checklist.

1) Item 2b: All items from the World Health Organization Trial Registration Data Set. Please state: Please refer to Item 2a and registration in ClinicalTrials.gov NCT03589703

Response: Item 2b has been revised (line 50).

2) Item 5c: role of sponsors’ etc. information needs to be inserted into the protocol. An example of what has been written is: "The sponsor played no part in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication"

Response: The role of funders have been inserted in the protocol (lines 405-407).

3) Item 5d: This cannot be N/A. Perhaps you could give information on the composition, roles and responsibilities of the coordinating centre and trial steering committee and all groups providing day to day support for the trial. We also need information on who is responsible for all aspects of local organisation including identifying potential recruits and taking consent. Who is supervising the trial and how often they will meet, plus information on the Trial Steering Committee (TSC), and how often they will meet over the course of the trial to oversee conduct and progress. Plus, information and how often the Stakeholder and Public Involvement Group (SPIG) if there is one, and their specific role.

Response: The roles of all the group have been added in the protocol (lines 361-362).
4) Item 11d: relevant concomitant care field needs completing and ensure information in the protocol. Perhaps you could state that Implementing X or X will not require alteration to usual care pathways (including use of any medication) and these will continue for both trial arms.

Response: Relevant treatment requirements have been added in the protocol (lines 179-182).

5) Item 25: protocol amendments - please details plans for notifying of any changes to the protocol i.e. notifying sponsor and funder first then the PI will notify the centres and that a copy of the revised protocol will be sent to the PI to add to the Investigator Site File. You may also want to state that any deviations from the Protocol will be fully documented using a breach report form. You can also include you will update the protocol in the clinical trial registry.

Response: The information has been inserted in the protocol (lines 364)

6) Item 26b: Can suggest something like this: "On the consent form, participants will be asked if they agree to use of their data and blood samples should they choose to withdraw from the trial. Participants will also be asked for permission for the research team to share relevant data and blood samples with people from the Universities taking part in the research or from regulatory authorities, where relevant."

Response: The information has been added in the protocol (lines 398-400).

7) Item 31a: This item cannot be N/A in the SPIRIT checklist and there does not appear to be information in the manuscript. Please document dissemination in the protocol and in the checklist. Perhaps you could state how results will be communicated to X and X and other relevant groups via publications, reporting results in databases, data sharing arrangements, twitter - social media or through the sponsor etc.

Response: The information has been added in the protocol (lines 379-381).

8) Item 31b: page 18 you state the author contributions please insert page number into checklist or you could also state "All named authors adhere to the authorship guidelines of Trials. All authors have agreed to publication." Or All authors have contributed to writing the manuscript as detailed p18, no professional writers have been involved.

Response: Item 31b has been revised (lines 410-413).

9) Item 31 c: Access to data cannot be N/A - it is really important so complete information on page 18. Consider stating "The datasets analysed [1] during the current study are available from the corresponding author on reasonable request."

Response: The information has been inserted in the protocol (lines 408-409).
10) Item 32: This item is referred to in Item 26a and cannot be left blank. Where can the reader obtain the Informed consent form? If not in appendix then please state where it can be obtained or perhaps state "These are available from the corresponding author on request."

Response: Model consent form and other related documentation are available upon request.

3. References: You have chosen to use a large number of references, please check all are necessary. I note there are 8 self-citations for Yeh. There were 17 articles that could not be checked, please check format for websites, include date checked and ensure sufficient information as in guidelines below. Seven articles was not validated (https://trialsjournal.biomedcentral.com/submission-guidelines/preparing-your-manuscript/study-protocol/#references).

Thanks for your suggestions, the number of reference has been decreased to 66. Our team have done a lot of work in this area, so there are 8 self-citations, but 2 of the self-citation have been deleted.

1) 2. BY THE NUMBERS: Musculoskeletal Back Pain is sourced from The Burden of Musculoskeletal Diseases in the United States (BMUS).

Response: The reference has been deleted.


Response: The reference has been revised (lines 420-423).


Response: The reference has been deleted.


Response: The reference has been revised (lines 426-428).


Response: The reference has been revised (lines 429-431).


Response: The reference has been deleted.


Response: The reference has been revised (lines 436-438).


Response: The reference has been deleted.


Response: The reference has been deleted.


Response: The reference has been deleted.


Response: The reference has been deleted.


Response: The reference has been deleted.

Response: The reference has been revised (lines 534-537).


Response: The reference has been revised, and it is available through https://apps.who.int/iris/handle/10665/60870 (lines 460-463).


Response: The reference has been revised (lines 566-568).


Response: The reference has been revised (lines 477-479).


Response: The reference has been deleted.

18) 84. Epic at Johns Hopkins. Johns Hopkins Medicine, Editor. 2016. (Not Checked)

Response: The reference has been deleted.


Response: The reference has been revised. (Lines 559-562)


22) Wertz R. Intention to treat: Once randomized, always analyzed. Clinical Aphasiology. 1995;23:57-64. (Not Validated)


Response: The reference has been revised (lines 580-581).

24) Joinpoint Regression Program, Statistical Methodology and Applications Branch, Surveillance Research Program. 2019, National Cancer Institute. (Not Checked)

Response: The reference has been revised. The book cannot be accessed through PubMed, but it is available through https://surveillance.cancer.gov/joinpoint/ (lines 585-587).