Reviewer's report

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

Version: 0  Date: 20 Nov 2019

Reviewer: Kirsty Loudon

Reviewer's report:

This is the editorial comment.

This is a well written comprehensive protocol on a potentially important intervention to address low back pain in older adults.

I had a few comments and have mainly used the SPIRIT checklist to structure my questions.

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."


* 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.

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,

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"

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.

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.

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.

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."

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.

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.

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

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."

* 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).

Level of interest
Please indicate how interesting you found the manuscript:

An article whose findings are important to those with closely related research interests

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

Quality of figures
All images and figures within the manuscript should be genuine i.e. without evidence of manipulation. No specific feature within an image may be enhanced, obscured, moved, removed, or introduced. If you have concerns about the veracity of the figures you should choose the first option below.

Statistical review
Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.

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Please complete a declaration of competing interests, considering the following questions:

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Were you mentored through this peer review?

No