Reviewer’s report

Title: Acupuncture Treatment for Carotid Atherosclerotic Plaques: Study Protocol for a Pilot Randomized, Single Blinded, Controlled Clinical Trial

Version: 1 Date: 10 Aug 2020

Reviewer: Kirsty Loudon

Reviewer's report:

This is a review by the SPIRIT protocol editor for Trials.

This is a well written protocol for a randomised controlled trial to study the Safety and Efficacy Assessment of Acupuncture Treatment for Carotid Atherosclerotic Plaques.

Thank you for submitting a SPIRIT checklist. It is, however, not possible to leave any item blank - a rationale needs to be given why N/A.

I have structured my comments using the SPIRIT items.

*Item 1: The title should include Pilot as you clearly indicate in your sample size calculations that this is a pilot study to guide a future definitive RCT. "Study Protocol for a Pilot Randomized, Single Blinded, Controlled Clinical Trial. There appears to have been some previous feedback on the title so it was changed to emphasise "Safety and Efficacy…" However you have not used the usual outcomes of recruitment and retention for pilot studies but 2 3D ultrasound indicators as the primary outcomes: the total plaque volume (PV) of the carotid artery on each side and the grey-scale median (GSM) so this study may be under powered for the outcome being assessed. I am also not sure this primary outcome correspond to the title "safety and efficacy". Your discussion also does not mention using the results to guide a future trial instead you state "Therefore, we hope to compare the efficacy of acupuncture, western medicine and placebo to verify the effectiveness and safety of acupuncture for carotid atherosclerotic plaques, and we hope to provide an effective treatment for arteriosclerotic plaques." Suggest you edit this sentence to include the intention, if the pilot is a success to undertake an adequately powered RCT.


*Item 17b: / is not acceptable please write in the SPIRIT checklist "patients, outcome assessors and data analysts are blinded but as acupuncturists administering treatment are not blinded unblinding will not occur".

*Item 20b: please complete methods for any additional analyses (e.g. subgroup and adjusted analyses), if not please state this.

*Item 21b. Please state if there will be any interim analyses and formal stopping rules for the trial. Perhaps there are no anticipated problems that are detrimental to the participant but please include this information in the protocol and insert the line number into the SPIRIT checklist.
*Item 31a: This item is blank 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: lines 584-592 you state the author contributions please insert this information 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 lines 584-592, no professional writers have been involved.

*Item 31 c: Access to data cannot be left blank in the checklist. The following information is in line 568-70: "The data will be available after the study is complete by asking for the consent or approval of Wenbin Fu (principal investigator)."

*Item 32: This item is referred to in Item 26a and cannot be left blank. You have uploaded the Informed consent form so please write in the SPIRIT checklist - see appendix.

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