Author’s response to reviews

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

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* 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 emphasis "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.
Combined with the editor’s comments, we believe that the evaluation of effectiveness and safety requires a large sample multi-center study. This study is a pilot study, and the evaluation indicators of the study are not focused on safety assessment. The purpose of the study is to provide data basis for subsequent large-sample multi-center studies. After discussion, we think that the title should be revised to “Acupuncture treatment for carotid atherosclerotic plaques: Study Protocol for a Pilot Randomized, Single Blinded, Controlled Clinical Trial”.

The part in discussion “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.” is changed to ” Therefore, we hope this pilot study could provide an effective data basis for subsequent large-sample studies of acupuncture treatment for atherosclerotic plaque.”(Line 440-442).

* Item 2b. All items from the World Health Organization Trial Registration Data Set. Please state: Please refer to Item 2a and Retrospectively registered 1st November 2018, http://www.chictr.org.cn/index.aspx ChiCTR1800019259. The relevant content has been added to the SPIRIT checklist.

* 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". The relevant content has been added to the SPIRIT checklist.

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

The relevant content has been added to the SPIRIT checklist.

* 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.

The relevant content has been added to 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.

The relevant content has been added to the manuscript (line554-556: The results will be communicated to main investigators and sponsors and other relevant groups via publications, reporting results will be saved in ResMan Research Manager of the Clinical Trial Management Public Platform.) and SPIRIT checklist.
* 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.

The relevant content has been added to the SPIRIT checklist.

* Item 31c: 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 570 approval of Wenbin Fu (principal investigator)."

The relevant content has been added to the SPIRIT checklist.

* 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.

The relevant content has been added to the SPIRIT checklist.