Reviewer's report

Title: Acupuncture treatment on the motor area of the scalp for motor dysfunction in children with cerebral palsy: study protocol for a multicenter randomized controlled trial

Version: 0 Date: 07 Nov 2019

Reviewer: Kirsty Loudon

Reviewer's report:

This is the editorial comment.

1. I am a little unclear why the authors are undertaking this RCT. I am not sure if the reason is that they are specifically focussing on the treatment for CP in children using Jiao's scalp acupuncture, perhaps scalp acupuncture using Jiao's motor area and Si shencong (EX-HN1) acupoint. I would strongly suggest they put this in the title to highlight the intervention being tested.

So I suggest the authors improve their introduction to justify why they are undertaking this RCT - this could then connect with the Discussion. The references mentioned in the introduction do include several meta-analyses of this subject area eg #20. Relevant to the reader would be of the 22 included studies in this review with a total of 1718 participants - how many were using Jiao's scalp acupuncture? The authors of this 2018 review concluded "More high-quality and large-scale studies are needed."

I think on page 4 line 17 the authors should state that they are planning on undertaking a HIGH QUALITY study. While it has 4 hospitals involved, they are all in China and it has only 100 participants so it is unfortunately not a large scale study and will be a limitation of this RCT. Clearly CP in children is a world-wide problem.

2. Page 3 (line 7) A reference of 2004 is used to state: "In 2004, the lifetime cost of health care for cerebral palsy in the USA was estimated at $921,000" This is nearly SIXTEEN years old and a lot has changed time so up-to-date references are needed.

3. The English in this protocol needs checked by a native English speaker. I have indicated 5 points below which can be addressed but I am unable to edit the whole manuscript so it is important the English is checked before Trials will consider accepting for publication.

4. The title should not have a capital "T" for trial (see above editing title to clearly indicate the type of acupuncture being tested)

5. the opening sentence of the abstract does not make sense "Scalp acupuncture has shown a remarkable treatment efficacy on motor dysfunction in children with cerebral palsy, especially when performed on the motor area of Jiao's scalp acupuncture, which is the most widely used treatment." In particular, the section "especially when performed on the motor area of Jiao's scalp
acupuncture". Perhaps you mean: "SCALP ACUPUNCTURE HAS SHOWN A REMARKABLE TREATMENT EFFICACY ON MOTOR DYSFUNCTION IN CHILDREN WITH CEREBRAL PALSY. IN PARTICULAR, JIAO'S SCALP ACUPUNCTURE WHICH IS THE MOST WIDELY USED TREATMENT WHEN IT IS PERFORMED ON THE MOTOR AREA."

6. The second sentence of the abstract you should replace summarised with INDICATED or FOUND

However, previous studies have INDICATED that the clinical curative effect of acupuncture treatment for children with cerebral palsy remains uncertain.

7. Deleted meanwhile simply state NO RCTS have been performed or undertaken.

8. Line 22 sentence needs editing, suggest "includes" instead of "including" and consider deleting "is added in some chidden" - does not make sense or edit sentence so clear.

9. Follow up page 6, line 49/50 it is the parents who are signing consent - the patients are aged 12 to 72 months so they are not signing forms to indicate their attendance!

* 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: suggest you say "Please refer to Item 2a and registration in: ClinicalTrials.gov, NCT03921281

Item 3: Date and version identifier cannot be N/A eg Version 2.0. Date.

Item 5b: this item cannot be N/A. Please give the contact details for the sponsor.

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 11b: Cannot state N/A. Could state "There will be no special criteria for discontinuing or modifying allocated interventions".

Item 11c: Cannot state N/A. What were the strategies to improve adherence - this field needs to be completed with relevant page number. And monitoring can also be linked to page numbers in the protocol.

Item 17a: It appears this is an open label study - aside from the information in the abstract the only information in the protocol you state in the SPIRIT checklist on page 10 about blinding is
"the research assistant is kept unaware of the group assignments until after the participants are allocated to groups." Please edit to make clear in the protocol that the outcome assessors and data analysts are blinded.

Item 17b: N/A is not acceptable please answer the question. In the abstract you state that the assessor and data analyst are blinded. So suggest editing the SPIRIT checklist (see 17a) "the design is open label with only outcome assessors and data analysts being blinded so unblinding will not occur".

Item 20c: please complete: Analysis needs completion - how will missing data be handled? How will you analyse those that are randomised to the intervention but do not adhere to the intervention? Edit the protocol and put in page number in SPIRIT checklist.

Item 21b: please state why N/A re interim analyses and why there is not anticipated to be no formal stopping rules for the trial.

Item 23: Frequency and plans for auditing trial conduct - needs information, this cannot be N/A. For instance, how often Project Management Group meet to review trial conduct. The Trial Steering Group and the independent Data Monitoring and Ethics Committee meet to review conduct throughout the trial period.

Item 25: protocol amendments - please detail plans for notifying 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. There is some information on page 13.

Consent (item 26) and Confidentiality (item 27) cannot be N/A so please complete. Plus, all other N/A.

Item 26a: page 5 Informed Consent - It was unclear who was actually recruiting the patient? The trial coordinator, therapist? When is this done? Please elaborate on the information on page 5.

Item 26b: Can suggest something like this "On the consent form, participants will be asked if they agree to use of their data should they choose to withdraw from the trial. Participants will also be asked for permission for the research team to share relevant data with people from the Universities taking part in the research or from regulatory authorities, where relevant. This trial does not involve collecting biological specimens for storage."

Item 29: This is on page 13 - you could also state if pertinent "Any data required to support the protocol can be supplied on request."

Item 30: Provisions for post-trial care - you could state "There is no anticipated harm and compensation for trial participation" and it would be helpful to know if there will be any provision for post-trial care.
Item 31a: You cannot say N/A 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 13 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 p13, no professional writers have been involved.

Item 31c: You cannot say N/A - the information on Access to data is page 13 - it is really important so complete information. Consider stating instead "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 N/A. Where can the reader obtain the Informed consent form? This is not currently in an appendix so please state where it can be obtained or perhaps state "These are available from the corresponding author on request."

Item 33: See above 26b there will be no biological specimens collected.

* References: There were 4 article that could not be checked, please check format for websites, include date checked and ensure sufficient information as in guidelines below. THIRTEEN articles are 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:

Needs some language corrections before being published

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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No