Reviewer’s report

Title: The effect of physiotherapy including frequent changes of body position and stimulation to physical activity for infants hospitalised with acute airway infections. Study protocol for a randomised controlled trial.

Version: 0 Date: 19 Mar 2020

Reviewer: Kirsty Loudon

Reviewer's report:

This a review by the SPIRIT protocol editor for Trials.

This is a well written comprehensive protocol for a randomised controlled trial assessing the effect of individualized physiotherapy treatment and a non-individualized intervention programme involving frequent changes of body position and stimulation to physical activity for infants hospitalized with acute airway infections. You taught me a new word "praxis" - thank you!

Few general comments
1. Consider adding Randomised controlled trial to the keywords.
2. Table 2 consider adding (28) after Wang score for people reading quickly who missed earlier reference.

SPIRIT checklist - It is not acceptable for Trials journal for the authors to leave any items blank, with N/A or miss out in the SPIRIT checklist. Further information giving rationale and why an item is not applicable is required. Please either edit the protocol and insert page numbers in the checklist or insert relevant information in the SPIRIT checklist.

I will use the SPIRIT checklist to structure further comments on the manuscript.

*Item 2b. All items from the World Health Organization Trial Registration Data Set. Please state: Please refer to Item 2a and registration in the ClinicalTrials.gov NCT03575091.
*Item 5b: I was not clear on the information on page 17 who was the sponsor. Please also give the contact details for the sponsor. It is the role of sponsor(s) to ensure that proper arrangements are in place to initiate, manage and report on a study. Sponsors must also ensure that appropriate indemnity is in place before research begins. A sponsor does not usually conduct the investigation.
*Item 5c: I could not find information on page 17 on the role of sponsors etc so 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 14: Sample size - could you insert a reference for the pilot study please "A previous pilot study has shown that the standard deviation is approximately 2.8"
*Item 21b: Leaving this blank is not acceptable. Please insert information into the protocol on interim analyses and formal stopping rules for the trial. For instance, perhaps there are no anticipated problems that are detrimental to the participant but please include in the protocol.
*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 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 31 c: I note information on page 13 for access to data. Also, page 17 "Availability of data and materials - Not applicable." Consider stating "The datasets analysed during the current study are available from the corresponding author on reasonable request."

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

*References: There were nine articles that could not be checked, please ensure information as in guidelines below. One article was not validated. https://trialsjournal.biomedcentral.com/submission-guidelines/preparing-your-manuscript/study-protocol/#references

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