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:** 1  **Date:** 27 May 2020

**Reviewer:** Elizabeth George

**Reviewer's report:**

Thank you for the thorough responses. They have addressed my points appropriately. I just have two minor additional points.

They have added a sentence regarding the 'full analysis set' in the statistical and sample size calculations section which is not very clear. Could this be clarified by adding which children are included in the full analysis set i.e all children randomised?

An interim analysis has been added but these are usually then reviewed by an independent data monitoring committee who would make recommendations to the trial steering committee and/or trial management group. The authors indicate there are no independent committees for this trial but it may be worth considering having one if a formal interim analysis is being carried out as they would be best placed for independent review. I would suggest calculating the clinical index and standard deviation on the controls only and use that to inform any sample size revision if that is the sole reason for an interim analysis but I also see that safety data is going to be reviewed, also something an independent committee can be useful for.

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