Author’s response to reviews

Title: Development and feasibility of a wearable infant wrist band for the objective measurement of physical activity using accelerometry

Authors:

Alessandra Prioreschi (alessandra.prioreschi@wits.ac.za)

Tom Nappey (Thomas.Nappey@newcastle.ac.uk)

Kate Westgate (Kate.Westgate@mrc-epid.cam.ac.uk)

Patrick Olivier (Patrick.Olivier@newcastle.ac.uk)

Soren Brage (Soren.Brage@mrc-epid.cam.ac.uk)

Lisa Miclesfield (lisa.micklesfield@wits.ac.za)

Version: 1 Date: 27 Oct 2017

Author’s response to reviews:

Editors' comments (if any):

Thank you for your submission. Your work is unique and innovative. It is not clear how it addresses the scope and aims of the journal: "The journal publishes research articles that are intended to directly influence future clinical trials or large scale observational studies, as well as protocols, commentaries and methodology articles." Usually it is the feasibility of the future trial itself that is being evaluated, or pilot-tested. There needs to be a clearer understanding for the reader what the future trial is and how the results of the study can be used for that future trial. If you choose to revise your paper, fit with the journal will determine whether it can be sent for review.

Thank you for your comments. This manuscript reports on the development of an infant wearable wrist band designed to fit an accelerometer, as well as the feasibility and acceptability of using such a device for the observational measurement of physical activity in infants. This feasibility study was not testing the feasibility of a future trial or observational study per se, but rather testing the feasibility of the device for any future observational measurement of physical activity in an infant sample. This feasibility study could therefore influence future large scale observational studies in general.
When choosing BMC Pilot and Feasibility Studies for submission of this manuscript, we read through some of the published studies with a similar type of outcome to ours (although in totally different fields of research), and thus believed that this manuscript would be of interest to readers of the journal. For example, the articles https://doi.org/10.1186/s40814-016-0053-3 and https://doi.org/10.1186/s40814-017-0150-y which were recently published and both test the feasibility/validity of a certain measure within a specific population, not for a specific trial but rather to advise future research studies within these populations. Therefore, we believe this study falls into the scope of “…testing the feasibility of some other aspects of a study design where uncertainties remain”. We have modified the structure of the manuscript, as well as some of the information reported in order to better fit this scope, and according to the editor’s comments.

Please refer to the CONSORT reporting guidelines for pilot and feasibility trials and consider some of the guidance there in revising your manuscript. For example, if the primary research question is feasibility, what is the primary feasibility outcome, and the criterion for success?

We have now referred to the CONSORT reporting guidelines, and although some of the criteria are not relevant since this manuscript does not refer to a trial, we have modified accordingly where relevant. Specifically, we have adjusted the primary aims and outcomes for clarity, and have defined the criteria that are required for the device to be considered successful.

Consider presenting the feasibility data prior to preferences data if this is truly the primary question. Many of the things assessed in the "feasibility measurement tool" are actually preference outcomes (or things that might explain their adherence), not direct feasibility outcomes. Differentiate between feasibility outcomes and other outcomes.

The feasibility data has now been presented first, followed by the acceptability data. The nomenclature of these tools have also been adjusted to better fit their purpose and according to the objectives of the study.

The feasibility data ignores the fact that 10% of mothers did not complete the data - so outcomes should be reported as such e.g., it says 98% were compliant but the # is less than that when you consider those lost to follow-up etc.

Thank you for pointing out this error in reporting. We have now adjusted the results accordingly to better reflect compliance and feasibility in the whole sample. We have also conducted statistical test to determine any differences that exist between included and excluded participants, and have discussed the influence of these on the feasibility findings.
You are reporting feasibility or acceptability in those who agreed to participate. It is not clear how many declined participation and for what reasons - these might be very relevant.

Unfortunately, we did not quantify how many mothers refused to participate, and so we cannot comment on this. We have now included this as limitation of the study. We did not have many refusals to participate, and those who did refuse largely did so due to time constraints. However, since this data was not empirically collected we cannot report on this potential confounder.