Author's response to reviews

Title: Effectiveness of a behavioural intervention to prevent excessive weight gain during infancy (The Baby Milk Trial): study protocol for a randomised controlled trial

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Author's response to reviews: see over
To
Professors Doug Altman, Curt Furberg and Jeremy Grimshaw
Editors in Chief
Trials
Dear Professors,

Re: MS: 7476813131731525

Effectiveness of a behavioural intervention to prevent excessive weight gain during infancy (The Baby Milk Trial): study protocol for a randomised controlled trial.

Thank you for informing us that our manuscript has been accepted in principle for publication in Trials, subject to revision in light of Reviewer’s & Editorial comments.

The responses to the comments have been included here and we have uploaded the revised manuscript.

We would like to thank the reviewer Dr Bijan Bohra for the helpful feedback, which we believe have helped improve the paper. We would be happy to revise the document further should the need arise, or provide further clarification as appropriate.

Once again, thank you for your kind email and for your consideration of our manuscript.

Sincerely,

Rajalakshmi Lakshman (on behalf of all authors)
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Editorial requests:
1. Please ensure the title conforms to journal style for study protocol articles. The title should follow the format '___________: study protocol for a randomized controlled trial.' Please note that the title in the submission system should match that of your manuscript.

Response: Title has been changed to 'Effectiveness of a behavioural intervention to prevent excessive weight gain during infancy (The Baby Milk Trial): study protocol for a randomised controlled trial'

2. Please remove the Trial Sponsor, funding information and ethics reference number from the title page.

Response: This information has been removed

3. Please include a Discussion section after the Methods section. This can include discussion of any practical or operational issues involved in performing the study, and any other issues linked to the study that do not fall within the previous two headings.

4. Please remove the Conclusions section and incorporate this information into the Discussion.

Response: The discussion has been expanded and conclusions have been moved to the discussion section.

5. Please mention each author individually in your Authors?

Response: The following has been added to the Author contributions 'RL (Chief Investigator) wrote the first draft and obtained funding for the study. RL, SG (PI) and KO (PI) developed the study idea and concept. RL and WH (PI) developed the intervention and promote fidelity. EW (PI) and MS (PI) lead the health economics analysis. FW is study-coordinator. All authors contributed to the critical revision of the paper, and approved the final version'.

6. Please move the figure legend section below the reference list.

Response: This has been moved.

7. For additional files, please ensure that you list the following information after your reference section in your manuscript:

Response: ‘Additional File1: SPIRIT fillable checklist.doc’ has been added after the references.
Reviewer: Bijan Borah

Reviewer's report:

1. Intervention commences between 2-14 weeks when the baby is enrolled in the study. This is a long range of time, and the exact week when the baby is initiated to formula milk needs to be accounted for as a potential confounder in evaluating the primary outcome.

Response: In the data analysis section we have added 'Comparisons will adjust for age, sex, birth weight, age when formula-milk was started and other potential confounding variables'.

2. The "Recruitment and Retention" section states that "General Practices (GP, nurse, other practice staff) will invite participants at the baby's 6 week health check and immunization clinics." This is in contrast to what has been stated in the previous section that the baby might be enrolled in the study as early as 2nd week? Please clarify this inconsistency, write clearly what exactly is being done in terms of recruitment timing.

Response: Babies identified by research staff on a postnatal hospital ward or midwives could be enrolled as early as 2 weeks. We have added to this section ‘Research staff and midwives will identify babies within 2 weeks of birth’. Also second last sentence of paragraph ‘…. check eligibility criteria, and where appropriate, invite them for their baseline visit (at 2-14 weeks age)’. 

3. There are few grammatical mistakes/typos which needs fixing. (e.g., page 12: "...the training is support by...")

Response: This has been corrected and the paper checked for any other errors.