Author's response to reviews

Title: Assessment of LifeLab Southampton: engaging teenagers in improving their health behaviours and increasing their interest in science. Study protocol for a cluster randomized controlled trial.

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Author's response to reviews: see over
Dear Professor Cohen,
Thank you for reviewing our paper.
We have addressed each comment and attach a document showing the tracked changes, and we detail them below:

1. **Intervention** - add further information about who is conducting the process evaluation.

On pages 15 and 16, under the subtitle ‘Process Evaluation’ we have added further information about who will be conducting the process evaluation, including confirmation of their independence from the team undertaking the intervention.

2. **Population** - clarify inclusion/exclusion and justify reasons. The process of approaching schools for inclusion and consent are well described. It is not clear if there are any exclusion criteria at the school or pupil level. For instance, are there any requirements on the ability of students to participate in LifeLab day, or their ability to complete outcome measures? Are there any provisions to enable inclusion for students for whom English is not their first language? It may be impractical but you could discuss why.

On pages 10 and 11, under the sub title ‘Recruitment’ we have added in clarification around exclusion criteria (at school and pupil level).

3. **Randomisation** – who generates the allocation sequence, clarify stratification. At present it is unclear who will generate the allocation sequence, and how the computer generated system will be accessed/ by who – this information would help to show there is no possibility of subversion. Is there any stratification/matching of schools from similar geographical areas/demographics/socio-economic profile? If not required, could you justify why simple block randomisation is sufficient?

On pages 11 and 12, under the sub title ‘Randomisation’ we have added in clarification and further detail around the randomisation procedure.

4. **Blinding** – blinding possible at any level, if not justify. It would clearly not be possible to blind schools/students to the intervention allocation. It may be possible to blind outcome assessors? Again, it may be impractical but a discussion would be useful.

On pages 14 and 15, under the sub title ‘Outcome Measurements’ we have added in a discussion around the possibility of blinding the outcome assessors. We have always recognised the importance of this, but the practicalities and logistics of working with schools throw up some complications. In order to ensure that assessors are not influencing completion of the web-based questionnaire, we have produced a set script (which we have attached) to ensure consistency. We have also produced a short video (https://www.youtube.com/watch?v=7A7Tnvbgl-A), so that it is possible for schools to deliver the follow-up questionnaires, unless they specifically require our support.

5. **Data Management** – add detail of data management arrangements. There is no information about data management such as the study database and data security, or about
data quality. The CONSORT diagram implies that if the student is absent at the 12-month follow-up they will be lost to follow-up. It would be useful to discuss any contingency plans and processes to try and acquire data on a different day/by post if that is possible.

On page 10, under the sub title ‘Trial design’ we add further detail about our discussions with schools to ensure that we minimise the numbers of participants who are lost to follow up. On page 15, we have added a new section with the sub title ‘Data Management’, we have given details of how the data collected will be managed.

6. Research Governance – add detail on research governance arrangements. The funding is stated in the abstract but not the main body of the protocol. A brief paragraph to outline who is funding the research, the Research Governance Sponsor, and who is responsible for trial oversight (e.g. is there a Trial Steering Committee?) could be added.

On page 12, under the sub title ‘Ethics approval and Research Governance’ we have added detail about the research governance arrangements and stated the source of the funding.

On page 24, we have added a figure title and legend, after the references

Thank you again for your helpful and insightful comments,

Yours sincerely

[Signature]

Kathryn Woods-Townsend