Reviewer's report

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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Reviewer: Judith Cohen

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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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1. Will the study design adequately test the hypothesis?

The study is a cluster RCT assessing the impact of a unique educational programme, LifeLab, on the health behaviours of school children aged 13-14. Clusters are defined at the whole school level, which is appropriate to minimise bias, with less chance of contamination than with clusters at the class level. Schools are randomised to either control or intervention arms, with a 'waiting list' control allowing the control schools to access LifeLab in the following year. The study seems adequately powered with the ICC calculated from previous research by the group, and with an effect size comparable to other health behaviour studies. The study team have addressed issues of bias and include a process evaluation. For the reasons described, this study is well-designed and should adequately test the hypothesis.

2. Are sufficient details provided to allow replication of the work or comparison with related analyses: if not, what is missing?

The protocol is written in line with SPIRIT guidance with much of the required detail included. I have listed some items that would benefit from further information in the protocol:

Intervention: The intervention has been appropriately designed and tested in previous studies and is described in detail in other published papers which are referenced in the protocol. The process evaluation work is important to assess fidelity of the LifeLab intervention and other contextual information about delivery. It would be useful to know who will be conducting the process evaluation, is it someone sufficiently independent of the teachers delivering the intervention and those responsible for training?
Population: 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.

Randomisation: 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?

Blinding: 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.

Data Management: 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.

Research Governance: 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.

3. Is the planned statistical analysis appropriate?

The planned main and subgroup statistical analysis are described in sufficient detail and are appropriate for the analysis of a cluster RCT. The main analysis will be ITT.

4. Is the writing acceptable?

This is a well written protocol which is clear and concise, with a good use of English and no grammatical errors. References are correctly cited and listed in the style requested for Trials. The abstract contains all pertinent information and adheres to CONSORT guidance.

Suitability for Publication

I would recommend this article for publication in Trials subject to satisfactory completion of the following revisions:

Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)
The following additions would ensure that the protocol adheres to SPIRIT and CONSORT guidelines:

1. Intervention - add further information about who is conducting the process evaluation.
3. Randomisation – who generates the allocation sequence, clarify stratification
4. Blinding – blinding possible at any level, if not justify
5. Data Management – add detail of data management arrangements
6. Research Governance – add detail on research governance arrangements

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct) None.

Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore) None.

Competing Interests of Reviewer
None to declare

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests