Author's response to reviews

Title: Cluster randomised controlled trial of the Healthy Lifestyles Programme (HeLP), a novel school-based intervention to prevent obesity in school children: Study protocol

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Author's response to reviews: see over
Response to reviewer’s comments:

Title: Cluster randomised controlled trial of the Healthy Lifestyles Programme (HeLP), a novel school-based intervention to prevent obesity in school children: Study protocol

Version: 2 Date: 9 January 2013

Please find below a detailed response and corresponding changes in the manuscript to all the issues raised by the reviewer and from the editor.

Reviewer: Steven Kelder

Reviewer’s report:
My specific comments to authors are below.

1. Please number the pages.

We have numbered the pages.

2. Abstract. Shorten to 300 words. Add detail on the invention components. Provide expected number of children.

The abstract has been shortened to 307 words (although the instructions to authors state that the abstract should not exceed 350 words) and a brief description of the intervention components added as well as the anticipated number of children.

3. Background. Literature review on child obesity is out of date with respect to risk factors, and intervention programs. I suggest you organize the risk factor paragraph to provide justification for the program elements that will be used in the HeLP program.

We have completely rewritten the background section on risk factors and updated the current evidence on childhood obesity prevention interventions. We have emphasized the modifiable risk factors that HeLP targets (pages 5-7).

4. The authors make the statement: “However, situating an intervention within a school is not sufficient in itself to generate group-level behaviour change or maintenance of new behavioural patterns. It is critical to engage and motivate children and to generate a supportive social context involving the whole school and parents [4]. This needs more substantiation than simply reference [4].

In re-writing the background section we have amended this statement. The background now, hopefully, fully justifies all our statements and sets the scene for the use of interactive delivery methods to engage the children. We have added in further
justification and additional references to support the way we have approached the development of HeLP (pages 5-7).

5. **Authors make the case that school alone is insufficient and that motivation is necessary. Please provide more justification for this approach, e.g., what evidence is available to support that this approach will work with childhood obesity?**

Please see response to (4) above: as we have rewritten the background we no longer make this statement.

6. **If motivation is the key ingredient for program success, it should be measured.**

We are measuring motivation as part of the My Lifestyles Questionnaire but appreciate that this was not overtly clear in the previous version of the paper. We have added in additional detail regarding the questionnaire, its testing and the constructs which the questionnaire is measuring, in the mediators and moderators section (page 16).

7. **The abstract provides primary and secondary aims, yet the methods section does not distinguish between the two levels.**

We think there might be some confusion between primary and secondary aims and outcomes. The abstract refers to the primary and secondary outcome measures; we make reference to the primary outcome measure in the aims and objectives (pages 7 and 8) and in the section on outcome measures (pages 13-15).

8. **Provide more detail in the design sentence about the number of units, main outcome variable, and timing of measures.**

We have added in these requested additional details into the sentence on the study design (page 8). As per point 7 above, we have labelled our ‘main outcome variable’ as the ‘primary outcome variable’ throughout this paper.

9. **Although Table 1 describes the intervention in some detail, I am unclear on the timing of events. It would be helpful to have corresponding text that describes in more detail the categories of intervention; e.g., classroom lessons; school presentations, parent intervention.**

We have clarified the timings of the phases in Table 1 and added in more information about the intervention into the methods section (pages 10 and 11).

10. **Some parts of the method section are in outline format versus journal format.**

We have gone through the paper to ensure the format is consistent with journal requirements throughout.
11. Table 2 & Figure 1. Table 1 indicated 35 students per cluster, but table 1 indicated 980 total children (980/32 is 30.6 children). Please reconcile the difference.

We apologise for any confusion regarding these figures. The numbers within Figure 1 are from the detailed sample size calculation (page 21). In this calculation, it was shown that, for the specified assumptions, 952 children are required to be recruited. Local Education Authority data for Devon shows that there are on average 35 children per school, and rounding up to ensure that there are equal numbers of schools allocated to intervention and control groups, leads to a requirement of 28 schools, and thus approximately 980 children, to be recruited. As there is a year’s delay before schools allocated to cohort 2 commence in the trial, a total of 32 schools will be recruited to allow for the possibility that some schools in the second cohort might drop out of the trial before Cohort 2 start. (Should all schools remain in the study, the trial will be conducted in 32 schools). We have annotated the text regarding the sample size calculation (page 21) in an attempt to make this clearer.

12. The timing of cohort 1 and 2 as presented is confusing.

We have further clarified the timings for the two cohorts and explained why it is necessary to deliver the trial in this way (pages 9 and 12).

13. The moderating and mediating variables section is insufficient. Provide more detail on psychometric properties. Also, child motivation appears not to be measured which is curious because it is an important intervention technique.

We believe we have addressed the reviewer’s concerns regarding the mediating variables in our response above to point 6. We are not very clear as to what further information on moderating variables we could add into the paper.

14. Please provide estimation of intervention effects from the pilot study.

We have added in some further detail regarding the intervention effects from the pilot study with a reference to the full results into the background section (page 7).

15. The Food Intake Questionnaire is insufficiently described.

We have added in further detail about the Food Intake Questionnaire into the section on outcome measures (page 15).

16. “Throughout the analysis, emphasis will be placed on estimation rather than hypothesis testing.” I don’t understand this sentence.

We apologise if our phrasing was unclear – what we were trying to briefly explain is that we will not simply rely on hypothesis testing, but that wherever possible we will include
appropriate best estimates of, for example, between-group differences, with corresponding confidence intervals. We have annotated the text to further clarify this (page 18).

Editorial requests:

1. Please include a trial status section. This should state the status of the trial at the time of manuscript submission. The journal considers study protocol articles for proposed or ongoing trials provided they have not completed patient recruitment at the time of submission.

We have updated the trial status section (pages 24 and 25).

2. Please also highlight (with 'tracked changes'/coloured/underlines/highlighted text) all changes made when revising the manuscript to make it easier for the Editors to give you a prompt decision on your manuscript.

We have used tracked changes to illustrate the changes we have made as a result of the reviewer’s comments. Because we have completely rewritten the background section we have highlighted this in yellow rather than use tracked changes.

3. Please also ensure that your revised manuscript conforms to the journal style (http://www.trialsjournal.com/info/instructions/). It is important that your files are correctly formatted.

We have checked the manuscript preparation guidelines to ensure our protocol meets these requirements.