Author’s response to reviews

Title: A pilot investigation to optimise methods for a future satiety preload study

Authors:

Mark Hobden (m.r.hobden@reading.ac.uk)
Laetitia Guérin-Deremaux (LAETITIA.GUERIN-DEREMAUX@roquette.com)
Daniel Commane (d.m.commane@reading.ac.uk)
Ian Rowland (i.rowland@reading.ac.uk)
Glenn Gibson (g.r.gibson@reading.ac.uk)
Orla Kennedy (o.b.kennedy@reading.ac.uk)

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Author’s response to reviews:

Dear Reviewers/Editor,

Many thanks for your additional feedback on the manuscript. I have carefully read through your comments and responded to these below. I have made requested changes to the manuscript and these have been ‘tracked’.

Very best wishes,

Mark Hobden

1. It would be helpful to include pilot or feasibility in the title as recommended by the CONSORT extension guidelines (Eldridge et al 2016 PFS) to enable easier classification of the study as such.

Acknowledged – Title has now been updated.

2. Please add page numbers.

Page numbers added.
3. Under the study design section, please add detail on how the sample was recruited (eg healthy volunteers responding to adverts in a hospital?), from where the sample were recruited and over what time period. Were people consecutively recruited or volunteers?

Additional information has been added.

4. Under the measurement section please identify and state which questionnaires were validated (with reference) or whether they were unvalidated specially created ones for this study.

This section has been updated.

5. Under statistical analysis section please give some rationale and justification for the chosen sample size numbers. This does not need to be a formal calculation just some justification.

Sentence added to first line of statistical analysis section.

6. Please specify somewhere (statistics section?) in the text what the four groups that are being referred to actually are and put (group 1) etc in brackets after each description. It is in the table but needs to be defined in the text also.

This information is clearly shown in Figure 2. I have added more information to the legend for Figure 2.

7. Should ‘Trapezoid’ not be ‘trapezoidal’ line 204?

Either Trapezoid or Trapezoidal can be used. I have kept the original wording.

8. All data are assumed to be normally distributed and described as mean (sd), using pearson correlation and ANOVA. Was this actually the case for all variables? If not please use the appropriate methods for skewed data (median (IQR or range), Spearman correlation, Kruskal – Wallis) when appropriate.

All data was normally distributed.

9. The text states that a Bonferroni correction was used but there is nothing to show this in the results, ie. the p-value has not been changed from 0.05 for testing significance. Please delete this sentence or change the p-value cut off in the tables.

P values have now been removed from the table. Please see comment 10 below.
10. Table 1 – it would be helpful to write out what the four groups are in the heading above the ‘Group 1’ etc headings.

Given that hypothesis testing and the use of p-values is not encouraged in an underpowered pilot study, I do not see the necessity to test for significance between men and women. Wouldn’t you expect them to be different? Is this necessary, if so then please say why, if not then please remove from table and text. What are the ‘/16’, ‘/21’, ‘/14’ values at the bottom of the table. Please make clear what they are.

Agreed – hypothesis testing and p values now removed from the table and text (where applicable). Values (16, 21, 14) given more content.

11. When p-values are presented I the text please include the values of the scores that are being compared. This has been done in the study meal section but not elsewhere. There is no need to include the non-significant p-values in the paragraph under the correlation plot, but values showing a trend might be interesting to show (if any).

Agreed – P values removed.

12. In Figure 4 nothing is explained about the bar charts in relation to the line graph. How would we expect the AUCs to behave compared to appetite scores? Specifically can we see lower post preload AUC in G3 which is reflected in lower appetite score in the graph? G3 does not always have lowest average AUC eg post lunch. Please explain a little more what we are seeing here in the results.

In Figure 5 again is it necessary to test significance between men and women?

I have added more information to this section to cover both AUC and line graph data. I have kept the test significance between men and women in Figure 5, as this is a group comparison after treatment (different breakfasts/protocols) and not just a comparison at baseline (for example anthropometrics).

13. In the discussion section first paragraph (2nd sentence) how did you know that researchers and participants accepted the fundamental aspects of the study? How was this measured? There is no mention of this in the results eg via qualitative feedback.

Updated.

14. There is no need to calculate a post-hoc sample size, it is not recommended, please delete the sentence (line 310-11). It would however be useful to include a cautionary caveat about the use of hypothesis testing in such a small sample and that the results are preliminary and should be treated with caution.
Acknowledged. This has now been removed.