Author's response to reviews

Title: Exercise in obese pregnant women: The role of social factors, lifestyle and pregnancy symptoms.

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Author's response to reviews: see over
Dear Prof Begley,

We would like to thank you for the opportunity to revise our submission, “Exercise in obese pregnant women: The role of social factors, lifestyle and pregnancy symptoms”. We found the reviewers comments extremely insightful and helpful and we are very grateful for the time and effort they put into assisting us to improve this paper. We have substantially revised the paper, including the writing style and the formatting. We believe that this major revision provides clarity to this manuscript. We hope that our efforts have incorporated all the reviewer’s suggestions, and that our paper will now be suitable for publication in your journal. We have provided a detailed response to the reviewer’s comments below:

**Reviewer 1.**

**Major Compulsory Revisions**

1. Methods-Participants (1st paragraph). More information should be provided about the RCT of which this is a sub-study. If published studies are available about that RCT, they should be referenced. In particular, the intervention in that RCT should be identified. Table 2 provides data for control and intervention groups but the paper does not describe the intervention and the reader cannot readily determine what that intervention was.

   The reviewer has raised a very important point with this comment. To address these important concerns, we have added a paragraph in the Methods section that includes more information about the intervention. We have also added a sentence in the first paragraph of the Methods section and a reference to tell that reader that the details of this RCT have been described in another paper.

2. Methods-PPAQ (3rd paragraph). The definitions of the Non-Exercisers and Exercisers are inconsistent with those presented in other sections and appear to be reversed. This would be very confusing for a causal reader.

   We agree with this comment, and have amended this error. We have carefully checked through the paper to try to achieve absolute clarity, to avoid any confusion.
3. Results-Energy Expenditure (1st paragraph). The manuscript asserts that the proportion of Non-exercisers remained relatively stable at time points after twenty weeks. However, Table 1 shows that the proportion of Non-exercisers increases at 36 weeks: it increases by nearly 50%, from 40% at 20 weeks to 57% at 36 weeks. An increase of that magnitude is not consistent with the statement that the proportion was relatively stable.

Thank you for identifying this confusing information. We have extensively revised the first paragraph of the Results- Energy Expenditure to achieve clarity. We have added comments discussing the increase in the numbers of non-exercisers at 36 weeks compared to 20 & 28 weeks in the discussion section of the paper.

Minor essential revisions
1. Background (1st paragraph. I am unaware of any exercise "requirements" for pregnant women. Perhaps a better word would be "recommendations." (Or perhaps the requirements relate to the Intervention which is not described)

We would like to thank the reviewer for raising this issue. We have substantially revised the background section of the paper and in doing so, we have incorporated these useful comments.

2. Methods-Participants (1st paragraph). Probably "outpatient" should be singular as in other parts of the paper ("recruited from the hospital's outpatient clinic").

Thank you for alerting us to the potential confusion around our terminology. This has been changed in the manuscript to “outpatient”. This has also prompted us to check for consistent terminology throughout the paper.

3. Discussion (5th paragraph). Last sentence: it is not possible to determine causality in this study

We have made some changes to this sentence so that it does not infer causality i.e. “this study suggests that…” rather than “this study highlights the importance”.

(typo: "this" not "is").

This has been amended.

4. Study limitations are not clearly addressed.

Thank you for this suggestion. We have added a comprehensive paragraph discussing the limitations of this study in the discussion section.

Discretionary Revisions
1. The writing style would be greatly improved if all sentences beginning with "there is" started with the subject of the sentence. Sentences would be stronger
and easier to read, and the meaning would be clearer.

Thank you for this excellent suggestion. We have substantially revised the paper with these comments in mind and believe that we have achieved a stronger and clearer paper. We would especially like to thank the reviewer for this comment.

Review 2.
Minor Compulsory Revisions
1. Abstract: Under conclusions, the authors state “Women who were in better health prior to pregnancy ...”. “Better health” is a subjective term and should be avoided as it is unclear as to what constitutes better health in this context.

This is a very useful comment. We have avoided using the term “better health” in the revised manuscript and have replaced this with more specific statements, which we believe has strengthened our paper.

Major Compulsory Revisions
2. Page 3, Background, first paragraph, second sentence: As previously indicated, “better” is somewhat subjective. Also, who is the comparison group? (i.e. Women who are physically active and meet physical activity guidelines during pregnancy have improved outcomes as compared to women who are sedentary? Do not meet the guidelines?)

We agree with the reviewer that this was confusing, and this comment had significant overlap with Reviewer 1’s comments. We have substantially revised the introduction of the manuscript and in doing have addressed this comment. We have also added more information about the comparison groups in the studies mentioned in the introduction.

3. Page 3, Background, first paragraph, third sentence: The authors refer to “exercise requirements”, but do not define these “requirements” (or recommendations). Please define and provide a reference for the requirements/recommendations.

Please see response to minor essential revision #1 suggested by Reviewer 1.

4. Page 5, Methods, first paragraph: It is unclear from the methods whether the women included in the sample for this analysis are the entire sample from the RCT, or just a subsample. Please clarify.

Thank you for alerting us to this lack of clarity. Women included in this study were those who completed the Pregnancy Physical Activity Questionnaire (PPAQ). We have added a comment about this in the methods section under the heading statistical analysis and in the discussion section.

5. Page 5, Methods: Given that the intervention/control group status of
participants is likely an important factor, more information about the intervention and control protocols needs to be provided.

Please see response to major compulsory revision #1 suggested by Reviewer 1.

6. Page 8, Results, first paragraph: Data presented here should also be shown in a table presenting data on the study population.

Data presented here reflects the data presented in Table 2 at 12 weeks. We now refer to this table in this paragraph.

7. Results, general comment: The authors use data from a randomized controlled trial, without controlling for trial group in the analysis. It appears there was more loss to follow-up in the control group as compared to the intervention group (at 36 weeks, control n=16; intervention n=19 vs. 25 in each group at 12 weeks), and this uneven distribution may have affected the results.

Because of the small sample size, it was not possible to control for RCT study group allocation in the univariate analyses. However, the majority of the women in our trial withdrew from the trial because of medical or obstetric complications, or had early deliveries. We have added a comment on this in the discussion and acknowledge that this may have affected our results.

8. Results, general comment: While this paper has the potential to present important information, the lack of any multivariable methods make the results questionable. It would be preferable to evaluate these associations, while controlling for other potentially confounding factors (i.e. age, BMI). Given the dichotomous outcome, this could be done with multivariable logistic regression.

We agree with Reviewer 2 that multivariable logistic regression would have been preferable to evaluate the results, but the small sample size did not permit this type of analysis. Univariate analyses were considered to be the most appropriate way to analyse our data. The nature of our data would have violated the statistical assumptions of multivariate logistic regression, producing an unstable statistical model (see Hosmer & Lemeshow, 2000; Peduzzi et al., 1996). Thus, it was not possible to control for other potential confounding factors (i.e. trial group, age, BMI). We have amended our paper to include a comment on this in the discussion.

If despite our concerns, a multivariable approach, is the only way forward we are very happy to provide this. We would welcome further discussion, and would be happy to take further suggestions on board, after consideration of the issues we have outlined above.

9. Results, general comment: The study is under-powered to see an association between these factors and physical activity, particularly at 26 weeks with only 36 of the initial sample of 50 women contributing data. Please address power.

We conducted Fisher’s exact test to examine the association between predictors at 28 weeks and exercise status. A note stating that this analysis was conducted appears to be missing from the
bottom of Table 3 (now Table 2). Thus, we have added a note to the bottom of Table 2. Using this type of analysis, we have adequate power to examine univariate associations between each predictor and the outcome variable. While we agree with the Reviewer 2’s concerns around these issues, we feel very strongly that the detailed information we present in this paper will be helpful for the many other researchers who are conducting exercise studies in obese pregnant women.

10. Discussion, general comment: A discussion of the loss to follow-up is warranted here, given that a substantial number of women no longer contributed data at 36 weeks, and, importantly, that this loss to follow-up differed by study group. Are the characteristics of the women lost to follow-up the same as those retained in the study?

We would like to thank the reviewer for raising this important issue. We have substantially revised the discussion section of the paper and in doing so, have addressed this comment.

11. Page 16, Table 1 can be eliminated as this information is essentially duplicated in Table 2. I would suggest that this Table 1 be replaced with a table as indicated in item #5.

We have removed Table 1. A table containing descriptive characteristics of the intervention and control group has been published while this paper has been under review see reference (Callaway et al., 2010). We now clearly refer to this reference in the new manuscript.

Thank you very much for your time and effort in considering this revision. We believe that this revision has resulted in a manuscript that is clear and has important messages for other researchers in this area. We welcome any further feedback or discussion and are very willing to address any remaining concerns. We hope that our manuscript will be suitable for publication in BMC: Pregnancy and Childbirth.

Kind regards,

Mrs Katie Foxcroft  Dr Ingrid Rowlands