Author’s response to reviews

Title: A randomized home-based childhood obesity prevention pilot intervention has favourable effects on parental body composition: Preliminary evidence from the Guelph Family Health Study

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Version: 1 Date: 22 Jan 2019

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Please see the attached file Krystia_response to reviewers_final.docx.

RESPONSE TO REVIEWER COMMENTS

A randomized home-based childhood obesity prevention pilot intervention has favourable effects on parental body composition: Preliminary evidence from the Guelph Family Health Study

Manuscript ID: OBSY-D-18-00078

Thank you to the reviewers for their detailed and helpful comments which have helped to improve the quality of this submission. Below please find our responses.

Editor Comments: Interesting paper, although both reviewers have pointed out some major concerns. Specifically, the paper would benefit from better positioning of the study, in view of relevant theories in this field. Why this study is an important question that needs to be answered. in addition, the reviewers have some suggestions which would improve clarity of the methods and reporting.

Response: We thank the Editor for their interest in our manuscript and for the opportunity to provide revisions in response to the reviewers’ careful comments. Specifically, we have taken this opportunity to more clearly delineate the importance of our research question by expanding
the background of our manuscript. We have taken into consideration relevant theories in the field, such as the Family Systems Theory. We have also expanded the methods and discussion sections and have reworded the results section to improve the clarity of the reporting in this manuscript.

Reviewer 1 (Christina Niermann): The authors report on a sound study with an appropriate design. They present data of a pilot study with a small sample size and this is a major problem. Nevertheless, I really liked the research question. In my opinion, the research question is quite interesting and important but unfortunately the authors omitted to explain WHY it is interesting and they missed to explain why it could be relevant to focus on the effects on parents, especially regarding the prevention of overweight in (early) childhood. As the study and the result that are presented suffer from a small sample size, it would be even more important to address the relevance of the research question and to include theoretical approaches. In my opinion the manuscript could really benefit from changing the focus away from reporting results of a very small sample size towards a careful derivation of the relevance (for programs that aim to prevent childhood obesity) that parents change their behavior and that family dynamics change (which result in changes in parents body composition). The results could then be used to support this issue and provide first evidence.

Response: We thank Reviewer 1 for their comments regarding our study and their interest in our research question. Throughout the manuscript we have addressed Reviewer 1’s comments by shifting the focus of the study from a focus on the results, considering our small sample size, and to a focus on the importance of the research question, highlighting the Family Systems Theory. This is reflected in an edit to the title of our manuscript and in the expansion of the background section, the discussion, and conclusion.

Abstract:

The use of BMI (Body Mass Index) and BM is confusing (Body Mass). BMI was not introduced

Response: Thank you for pointing this out. We have now introduced BMI in our abstract. To facilitate reading we have changed BM to body mass throughout the abstract and paper.

Why do the authors report BM and BMI and not only BMI? I would suggest using only BMI

Response: BMI is commonly used as a proxy indicator of body fatness or of high body weight, but it was actually developed as a proxy indicator of obesity-related chronic disease risk. It can be falsely elevated if someone is quite muscular; however, the same argument can be made for body weight. Therefore, we agree that there is not a strong biological rationale to include both measures. However, there are some previous studies which have reported body mass rather than BMI. To facilitate comparison to these studies, we have chosen to present both measures.
Background:

Overall the Background is too short and does not provide necessary information for the reader.

Response: We have expanded the scope of the background section to provide more of the necessary contextual information to the reader.

The position of the reference numbers (throughout the manuscript) is confusing, e.g. lines 47, 48.

Response: Referencing throughout the manuscript has been addressed and corrected. Thank you for bringing this to our attention.

The authors should describe what is meant or what they mean by home-based obesity interventions.

Response: This has been clarified to refer to family-based behavioural interventions which are conducted in the home setting. Edits are highlighted in the passage below.

Revision (line 61-68): Interventions which incorporate parents into childhood obesity prevention are termed family-based interventions [11, 12]. Family-based childhood obesity interventions may be effective at preventing and treating childhood obesity [13]. Based on the results of obesity prevention trials conducted in Australia and America, a 2016 Institute of Medicine report identified home-based obesity interventions, a type of family-based intervention conducted in the home setting, as one of the most promising strategies in the prevention of childhood obesity [14–17]. Behavioural interventions which are conducted within the home setting can be particularly tailored to a family’s unique dynamics and living situation.

Please explain why the authors address this research question: why could it be important to focus on parents’ health behaviors or parents' anthropometrics and body composition? The reader needs more information regarding home-based interventions to understand, why there should be an impact on parents’ outcomes and why it is important to focus on parents.

Response: It is important to focus on parents’ anthropometrics and body composition as there are clear negative outcomes associated with adult obesity. If a childhood obesity prevention also positively affects parents, then healthcare resources are being synergistically and more efficiently used. We have edited the background to more clearly explain these benefits, along with more clearly outlining why home-based intervention may impact on parents.

The authors should be careful with the use of the terms "home-based" and "family-based" interventions. Is it the same for the authors or are there different definitions? It could be useful to have a look on Skelton et al., 2012, Where are family theories in family-based obesity treatment?, International Journal of Obesity.
Response: We have edited the wording in the background to more clearly state that behavioural home-based interventions are a subset of family-based interventions conducted in the home setting.

It is not clear to me why investigating the influence of the interventions on the amount and distribution of body fat helps us to understand "HOW interventions affect parents" (line 63). For me HOW is related to mechanisms but mechanisms are not examined. Appropriate would be for example: "the addition of XX would provide a more differentiated view on the effects of a XX intervention on parents XX"

Response: Reviewer 1 makes an excellent point here. The wording of this section has been adjusted to reflect that we are not referring to mechanisms of weight loss. Edits are highlighted in the passage below.

Revision (line 90-92): Additionally, investigating the influence of interventions on the amount and distribution of body fat, rather than proxy measures of overall body composition, such as BMI, would provide a more differentiated view on the effects of these interventions on parents’ adiposity.

The authors should describe the aim of the study more concise. Please delete "several measures" (line 65) and "in a sample of parents". (e.g. … in parents that took part in a XX intervention aiming to prevent childhood obesity). Why do the authors hypothesized that parental improvements are a beneficial? (This issue is related to the comments above!)

Response: The benefits related to parental improvements are now more clearly explained throughout the background. Edits are highlighted in the passage below.

Revision (line 104-110): Our objective was to examine the effect of a 6-month home-based, childhood obesity prevention pilot intervention on parents’ anthropometrics and body composition. The primary outcome of the GFHS pilot study was prevention of childhood obesity by intervening on weight-related behaviours using a family based approach [20]. The current study is formative and investigates if improvements in parental adiposity is a beneficial secondary outcome of a childhood obesity prevention intervention. In turn, results of this study may illustrate the relevance of Family Systems Theory for obesity prevention interventions [11, 18].

Methods:

The authors should use subheadings to structure this section

Response: Subheadings have been added.
Information on gender and age of the parents are missing, children's age in the groups

Response: This has been added (see line 119 for child age and line 172-173 for parent information).

The authors should write out "months" (not M) to simplify reading

Response: “M” has been changed to “months” to simplify reading throughout the manuscript

More information on the families are needed, e.g. one parent or two parents, more than one child (44 children an 79 parents?, final sample 58 parents -> some families took part with two parents and others with one?)

Response: Families could be enrolled with one parent, or two parents. If the family had one parent this could be because it was a single parent household or because the other parent elected to not participate in the intervention. We have added this information to the manuscript. Additional detail regarding the study demographics are available in Haines J, et al. Guelph Family Health Study: Pilot Study of a Home-based Obesity Prevention Intervention. Can J Public Heal. 2018;109:549–60.

line 94: WC for waist circumference is not explained before

Response: WC has now been introduced (see line 155)

Results:

What do the authors mean by "There was no evidence of effect modification by parent sex"? This sentence does not fit in this section. Do the authors mean moderation? Effect on what?

Response: Thank you for pointing out that this comment does not fit in the results section. We have moved it to the methods section where it more appropriately fits (see line 180). With this point we were suggesting that parent sex did not have a moderating effect on the results (i.e., results did not differ by parent sex). Therefore, it was entered as a covariate in the model, rather than reporting results separated by sex.

How many parents have a BMI ≥ 25 and how many have a BMI < 25? By the way the authors should describe in the methods section that they analyzed both groups separately and why they did this

Response: The number of parents within each intervention group, stratified by BMI, per analysis is provided in Table 2.
Revision (line 180-182 in the methods): Differences by baseline BMI status (≥ 25 vs. < 25 kg/m2) were observed when the groups were analyzed separately, so we present stratified results only.

line 113 "experienced an intervention effect" is not a suitable term -> for example "there was an effect of the intervention on parents..." would be more suitable (the authors used "experienced" several times in the discussion, this should be changed)

Response: We thank Reviewer 1 for this clarification and have adjusted both the results and discussion accordingly.

I think it makes no sense to report on BM and BMI, the authors should only use BMI

Response: BMI is commonly used as a proxy for indicator of body fatness or of high body weight, but it was actually developed as a proxy indicator of obesity-related chronic disease risk. It can be falsely elevated if someone is quite muscular; however, the same argument can be made for body weight. Therefore, we agree that there is not a strong biological rationale to include both measures. However, there are some previous studies which have reported body mass rather than BMI. To facilitate comparison to these studies, we have chosen to present both measures.

Due to all the abbreviations the authors used, this section is difficult to read. This should be changed.

Response: We have adjusted this section accordingly by reducing the amount of abbreviations to make the reading of the results easier. We thank Reviewer 1 for the comments to improve the readability of the manuscript.

Table2: The authors should use consistent terms in the first column, e.g. "Body mass, kg" and "%FM" -> "Body mass (kg) and Fat mass (%) or BM (kg) and FM (%) etc.

Response: Thank you for pointing out this discrepancy. It has been changed.

The authors should try to describe the results more comprehensible and not leave out interesting findings such as that the BMI does not changed from t1 to t2 but from t1 to t3. What about the change from t2 to t3? Instead of describing in the text the values that are presented in Table 2, the authors should provide means and SDs for the groups and the measurement points in the text (or in the table). It makes no sense to describe the same values in the text and the table.

Response: We have made a number of edits to this section so that it now includes results not previously reported (e.g., BMI changed from baseline to 18-months but not baseline to 6-months in the 2HV group). Note that t2-t3 was not modelled. Only t1-t2 and t1-t3 were modelled.
With respect to presenting the means and SDs for the groups at each time point. It should be clarified that change scores were not the outcomes modelled (we modeled outcome at follow-up, adjusted for baseline measure of the outcome). Thus, reporting summaries of change scores would be misleading since they would not correspond with the analytic approach we used. Therefore, we have chosen not to present the means and SDs at each time point.

Discussion:

Please rewrite "In a 2014 Australian family-based community obesity prevention-intervention, …" to facilitate reading

Response: The sentence has been reworded to facilitate reading.

Revision (line 220-223): In a 2014 Australian family-based obesity prevention-intervention conducted in a community setting, fathers who were overweight/obese were observed to have significant reductions in BMI (1.0 kg/m²) and WC (~4.0 cm) compared to control at 14-weeks post-intervention [19]

The abbreviation GFHS is not mentioned before (line 139)

Response: It has now been introduced previously in the manuscript.

The authors should highlight and discuss the unexpected and interesting results such as BMI reduction from t1 to t3 but not from t1 to t2 or that the effects are lower for 4HV (more details and ideas why there were no sig. changes in the 4HV group would be nice)

Response: Please see line 230-233 for an explanation of reductions from t1-t3 but not t1-t2.

We have included text in our discussion outlining some thoughts as to why the intervention effect was stronger in families who received 2HV. However, there is no clear answer as to why we saw changes in the 2HV and not the 4HV group. Our process data have been presented in our outcomes paper describing the child results (Haines et al. 2018). The intervention received by the 4 and 2 home visit groups did not differ in any way except for the number of home visits. Of the 17 families randomized to the 4 home visit group, 1 family refused all home visits. All 14 families randomized to the 2 home visit group received their home visits. No differences were found with regards to number of emails opened and weekly mailings received across the two intervention groups. In general, level of satisfaction with the study intervention was similar in the 4 and 2 home visit group (e.g., 100% of families in both the 2 and 4 home visit group identified that they would recommend the intervention to a friend/family member). However, one family in the 2 home visit group identified that “It would have been nice to have more than 2 home visits to discuss what was/wasn’t working.” Given these similar results across the 4 and 2 home visit
groups, it is unlikely that a difference in receipt of the intervention is able to explain the different results we found across the two groups.

Please rewrite the sentence in lines 143-145, this is important information, but the sentence is difficult to understand

Response: In addition to rewording this sentence to clarify the meaning, we have moved this sentence to line 248, as it more clearly describes in this section that clinically significant reductions in multiple measures were observed, which are beneficial to parent health.

149-152 could be written more clear, for example: In the present study, we found BMI reductions… which is consistent with…

Response: This edit has been made, see line 238

The content of lines 154-164 is quite interesting and important, but not concisely and clear enough. The authors should try to highlight that the intervention that aims to prevent children's overweight has an equal effect on parents' weight reduction / improvement of body composition as interventions that focus on adults and discus more clear and detailed what this means

Response: See lines 242-252 for an edited paragraph which more clearly explains this concept.

180: the authors should think about the relevance of the reduction of parents' adiposity (see above) and consider that it is perhaps not an "unintended" benefit but a necessary condition for preventing weight gain in children (see above). This issue is related to several articles that highlight the importance of addressing the family as a whole in treatment and prevention of childhood obesity (e.g. Skelton et al; Kitzman-Ulrich et al.)

Response: We have now addressed this (please see lines 253-265).

References

The authors should check the references, e.g. reference 8. is incomplete

Response: We thank the Reviewer for noticing referencing mistakes that we missed. These mistakes have been corrected.

Reviewer 2 (Ilona Van de Kolk): This was a very interesting and relevant paper. I enjoyed reading it. I do have some remarks on the manuscript that I believe will make it more understandable and complete.
Response: We thank Reviewer 2 for their comments which have helped to make the manuscript more understandable and complete.

General:

Align your in-text citations, as you've now used different ways to cite papers.

Response: Referencing throughout the manuscript has been addressed. We thank Reviewer 2 for pointing this out.

A more elaborate description of some of your sections will increase the understandability of your manuscript, for example the introduction, method and strengths & limitations.

Response: We agree with Reviewer 2 that the manuscript would benefit from more elaborate descriptions in certain sections. Each of the introduction, methods, and strengths/limitations has been extended to increase the understandability of the manuscript.

I would recommend to add the flowchart of the recruitment/inclusion as a figure to your manuscript.

Response: The flowchart of the recruitment/inclusion has been added to the manuscript as figure 1 in place of being part of the supplementary material.

Introduction:

Line 50: use 'that' instead of which?

Response: This has been corrected

Further, home environment interventions may also target more physical environmental factors, maybe you should not be so explicit in this statement?

Response: We have clarified this statement by referring to behavioural interventions.

Line 56: Do you have a reference for this statement?

Response: This statement is based on our search of the literature. We want to emphasize that we are looking for obesity prevention interventions rather than just treatment interventions. We have added “to our knowledge” to note that we are unaware of any other studies that have completed this analysis in the context of a childhood obesity prevention intervention.
line 59: What do you mean with 'while encouraging'?

Response: We have removed this statement as we agree it was confusing.

I would suggest to add already some description of your intervention in the introduction, why was it developed and implemented? And why did you hypothesize the possible effects on parent outcomes? It remains to me a bit unclear whether you've designed your study to include parental measures. This could be added maybe in the introduction or in the method sections.

Response: We have added a description of our intervention to the introduction and have provided a more thorough background explaining how we arrived at our hypothesis/formative research question. In the GFHS pilot, parent outcomes were not a primary outcome. It is a pilot study, so we did not power this study to definitely test the child or parent outcomes. However, we did include the parent measures to investigate the potential impact of our intervention on parent' outcomes as a secondary outcome.

Methods:

line 71: were there any a priori inclusion or exclusion criteria?

Response: In the Guelph Family Health Study pilot, families were eligible to participate in the study if they had at least one child aged 1.5–5 years old and lived in Wellington County, Ontario, Canada. Families were excluded if they (1) planned to move within 1 year, (2) had children outside of the target age range, or (3) were non-English speaking.

Revision (line 117-119): During recruitment, families were excluded from enrolment if they planned to move within one year of the start of the study, had children outside of the target age range (1.5-5 years), or were non-English speaking.

line 76: please specify which supplementary material you are referring to.

Response: This was in reference to the participant flow diagram. This parenthesis has been changed to refer to figure 1.

line 78: Was the study coordinator involved in recruitment or data collection? Could randomization be influence? And if so, also account that in your strengths&limitations. Please elaborate some more on your randomization method.

Response: The study coordinator was involved in the recruitment and data collection for some families in our study. The study coordinator was not involved in the delivery of the intervention. A pseudo-random number generator was used to assign families to their treatment condition.
Lack of blinding to treatment status of the study coordinator and participants is a limitation of this study and has been added to our discussion of limitations.

line 81: What were behavioural supports? Could you elaborate somewhat more on that?

Response: Parents were sent mailed supports for their behaviour change goals. For example, if a family chose to prioritize a sleep time goal at the beginning of the intervention, they may have received a children’s bedtime book to support this goal in the first month. There were 6 mailed supports, one for each month. Each family in the 2HV and 4HV group received the same 6 items. The order of receiving these items was customized to the family’s unique health behaviour goals. If families did not set a health behaviour goal, the weekly emails and mailed supports were sent per a standardized schedule. We have changed the wording to communicate this more clearly.

Revision (line 131-134): Families randomized to the two intervention arms received either 4 or 2 home visits with a health educator (HE) trained in motivational interviewing [23], in addition to weekly e-mails and monthly mailed items to support behavioural changes (e.g., a children’s book to support improved sleep-time goals).

line 90: add were measurements took place, the abbreviations 6M and 8M occur already earlier in the paper, so place the full description of the abbreviations at the right place.

Response: This has been added to line 150.

line 106: body composition measures?

Response: Clarified to add body composition and anthropometrics (e.g., BMI, percentage fat mass, etc.).

Results:

Table 1: Did you test the differences between the groups? In particular, in the >25 kg/m2 stratum, the differences between groups seem quite substantial. So, can you provide some information to support your statement in line 111 (no substantive differences)?

Response: Yes we tested for differences between the stratified groups. There were no significant differences between intervention groups at baseline when comparing the outcome measures (p>0.05).

It may be valuable to also report change scores within the groups for your different outcomes, for future use of your study in systematic reviews/meta-analysis. Did you consider reporting effect
sizes to give an indication of the magnitude of the effect? Do you have some information on the power of your analyses?

Response: Regression coefficients presented in table 2 provide effect size information. We respectfully ask reviewer 2 to clarify what they are referring to here.

In regards to reporting change score summaries. It should be clarified that change scores were not the outcomes modelled (we modeled outcome at follow-up, adjusted for baseline measure of the outcome). Thus, reporting summaries of change scores would be misleading since they would not correspond with the analytic approach we used. Therefore, we have chosen not to present the change scores at each time point.

Please note that we present the results of a pilot study. Power is an important consideration at the study design stage. A post hoc power calculation was not performed as recommended in the literature (e.g. Walters, SJ (2009) Consultants' forum: should post hoc sample size calculations be done? Pharmaceut. Statist. 2009; 8: 163–169.

Discussion:

line 160-162: How do you conclude this from your study? This was only focused on body composition outcomes in parents? Maybe this sentence needs some revising.

Response: The citations after this sentence reference published peer-reviewed studies regarding increased fibre and fruit intake in children and improved body composition in children as a result of the GFHS pilot. We thank Reviewer 2 for pointing out that this is not clear. We have reworded this sentence to more clearly delineate this to the reader.

Revision (253-256): Our results suggest that a home-based childhood obesity prevention intervention may improve parent weight-related outcomes while also offering beneficial effects among the entire family. Previously, we have reported the GFHS pilot intervention increased fibre and fruit intake in children, and improved body composition in children [8], [21].

line 164: should this be 'solely targeting children', as your program was a child-focused program?

Response: In this paragraph we are illustrating that a childhood obesity intervention prevention has similar effects on parent weight loss as adult only interventions. As such, it makes sense to include both statements for “children” and “adults”.

Revision (261-265): Thus, future programs may consider targeting the whole family in the home setting as a more efficient use of resources rather than solely targeting adults or children in a primary care or community setting. Future research should also examine the particular
mechanisms by which a family-based interventions leads to changes in parents’ weight outcomes.

line 165-174: Do you have some process data to explain the differences between the 2HV and 4HV groups? For example, were all visits carried out in all families? Were there any other interventions in the groups? Were there differences in how the home visits were appreciated?

Response: Our process data have been presented in our outcomes paper describing the child results (add citation for our previous paper). The intervention received by the 4 and 2 home visit group did not differ in any way except the number of home visits received. Of the 17 families randomized to the 4 home visit group, 1 family refused all home visit. All 14 families randomized to the 2 home visit group received their home visits. No differences were found with regards to number of emails opened and weekly mailings received across the two intervention groups. In general, level of satisfaction with the study intervention was similar in the 4 and 2 home visit group (e.g., 100% of families in both the 2 and 4 home visit group identified that they would recommend the intervention to a friend/family member). However, one family in the 2 home visit group identified that “It would have been nice to have more than 2 home visits to discuss what was/wasn’t working.” Given these similar results across the 4 and 2 home visit groups, it is unlikely that a difference in receipt of the intervention is able to explain the different results we found across the two groups.

line 173-174: Do you mean further research or additional intervention activities? line 182: You talk about formative research; can you explain more what you will be doing with these results? To what project/research was this formative?

Response: We thank Reviewer 2 for these comments. The results of this analysis are derived from the Guelph Family Health Study pilot. This pilot study was used to inform the implementation of a full-scale home-based childhood obesity intervention prevention study. Therefore, due to the design of the current study, we acknowledge that results from this analysis are formative and exploratory. By providing preliminary evidence that family dynamics may change in response to childhood obesity preventions in a way beneficial to parent body composition, we are hoping to create a call for further childhood preventative interventions to investigate what effects their interventions have had on parents. This is now more clearly explained through expanding both the background and discussion sections.

Conclusion:

line 191: This conclusion is not in line with your results, is one year the 18-month follow-up? And you write in your results that not all effects were sustained.

Response: The one-year follow-up from the completion of the intervention is equivalent to 18-months from baseline (as the intervention is 6-months long). In the overweight group, results were sustained at this time point. We have made edits to clarify that results were not sustained in
the normal weight group. In addition, throughout the manuscript, we have made edits to clarify the timeline of study timepoints.

Revision (line 301-302): These results were sustained one-year post intervention in the overweight/obese group but not in the normal weight group.

line 195: Does this belong here or is it more fitted somewhere in your methods section?

Response: We thank Reviewer 2 for highlighting this sentence. As this sentence was already present in the Declaration section, we have chosen to eliminate this sentence from the manuscript.