Author’s response to reviews

Title: Gestational Obesity Weight management: Implementation of National Guidelines (GLOWING): A pilot cluster randomised controlled trial of a guideline implementation intervention for the management of maternal obesity by midwives

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Author’s response to reviews:

Dear Editor,

Re: PAFS-D-17-00047, “Gestational Obesity Weight management: Implementation of National Guidelines (GLOWING): A pilot cluster randomised controlled trial of a guideline implementation intervention for the management of maternal obesity by midwives”, Nicola Heslehurst; Judith Rankin; Catherine McParlin; Falko Sniehotta; Denise Howel; Stephen Rice; Elaine McColl

Please find the required minor revisions to this manuscript following peer review.

On behalf of the authors, I would like to thank the peer reviewers for their positive comments about this manuscript. We have responded to each comment from both peer reviewers below (our responses are bullet pointed) and have made changes to the manuscript where necessary. Tracked changes to the content of the manuscript have been highlighted in the revised version.

I look forward to hearing from you,

Yours sincerely
Response to peer reviewers’ comments:

Reviewer #1: Thank you for revising your article about "GestationaL Obesity Weight management: Implementation of National Guidelines (GLOWING): A pilot cluster randomised controlled trial of a guideline implementation intervention for the management of maternal obesity by midwives". Maternal obesity is increasing worldwide, and represents a considerable health burden for the mother and her child. This pilot study is a valuable and timely study considering the lack of implemented guidelines in daily practice in most regions today.

Globally, this pilot study is described in deep detail and very conscientiously.

I miss some structure and overview in a quick to read table, especially regarding the clustering and included respondents from different groups. I suggest to present this more clear in a table, for the ease of readers.

- A figure has been developed to provide an overview of the cluster trial design and the flow of participants

Remarks/questions:

Line 74: can you add refs about association obesity development in offspring and maternal obesity as the refs 4-9 not really support this association.

- Ref 5 (Poston et al) discussed this association but we have replaced this reference with a research paper rather than discussion paper (Gademan et al 2014)

Line 76: I don't think 'metabolic plasticity' is the appropriate term here: the way you describe it here, it is the nutrition behaviour that is changing, rather than the metabolic system. The latter could potentially be a consequence of the behaviour change. Please re-write.

- The point relating to metabolic plasticity was separate to the point relating to behaviour change (this is more of a list of reasons why pregnancy is a good time to intervene). The Foresight report which has been referenced specifically states that pregnancy is a period of metabolic plasticity hence a good opportunity for obesity intervention. The wording has been changed to clarify that metabolic plasticity is one of a number of reasons and separate to the behavioural reasons for intervention in pregnancy.
Line 81: "pregnancy is a vulnerable life stage for increased risk of weight gain" - weight gain is normal and very important during pregnancy. You should elaborate a bit on healthy and unhealthy (excessive) weight gain here.

- This has been amended to reflect excessive weight gain, weight retention and long-term obesity development

Line 178-182: I don't understand the meaning of this, can you please re-write? What is the focus of what you try to say here.

- Additional information has been added for clarity – this section of the manuscript relates to the sources of evidence that we drew upon for developing the intervention.

Line 210: not clear to me what you mean with 'standardised delivery'?

- Clarified in the manuscript – this relates to the methods used to aim to standardise the intervention content and delivery for each intervention session with midwives

Line 218-221: how did you select these midwives?

- We defined the population of midwives to target and the research midwives in the NHS trusts identify which midwives in their employment were eligible (explained in recruitment section). The discussion section of the manuscript provided further information on why these particular groups of midwives were targeted. We have now briefly provided justification in the participants section as well.

Line 223: -227 I don't understand these sentences. Please include a bit on the consequence of weight loss during pregnancy - e.g. nutritional deficiencies for both mother and child. Also, please elaborate a bit on what the study group will do in case of adverse events as a consequence of the intervention.

- This section relates to the inclusion of pregnant and postnatal women for the purposes of data collection only. Pregnant women are not research participants receiving an intervention directly. The intervention targets midwives and not pregnant women, but if effective (which we will not know in the pilot study) then this would result in evidence-based provision of care for pregnant women as per guideline recommendations. Weight loss is not advised as part of the UK guideline recommendations (other than stating weight loss is NOT recommended). UK guidelines also do not include gestational weight gain recommendations. The intervention does not focus on weight gain or loss but rather on having a nutritionally healthy diet and being physically active during pregnancy. Additional clarity on this has been provided. How we will handle adverse events (unrelated to the intervention which only targets midwives) are detailed in the participant withdrawal section. These relate to ensuring the necessary checks are in place.
before each round of data collection so we do not cause unnecessary distress to participants by contacting them for data collection in the case of an adverse event (e.g. miscarriage).

Line 275 and 278: can you be more specific how midwives were selected (method), including a 'random subset of midwives'?

- The section on midwife recruitment and consent has been amended for clarity

Line 286: idem remark, be specific about selection of pregnant women please.

- Detail added to this section on selection and recruitment of pregnant women

Line 401-402: What do you mean by 'no follow up for pregnant women' and further .. op to one year (line 403)?

- This is the difference in follow up between pre-intervention pregnant women recruited to provide one-off baseline questionnaire data, and women recruited post-intervention who will be followed up for up to 1 year postnatally. This section has been changed to only reflect the follow up of women recruited post-intervention to avoid confusion.

Line 462: Is double data entry necessary in this type of RCT?

- As this data is being used to inform the sample size calculation for a definitive trial we want to minimise the risk of data entry errors that might influence this calculation.

Line 480-483: can you be more clear here about … in the evidence base of HCP barriers & facilitators, as we don't understand what you try to mention here?

- Amended for clarity

Reviewer #2: This study reports the protocol for a pilot study to assess whether training midwives to give weight loss advice to obese pregnant women is feasible and acceptable to both midwives and pregnant women. This is an interesting study, and, having read the protocol, I only have minor comments as detailed below:

1) There are several points in the manuscript where the word "participants" is used, but it is not clear whether it is the midwives or the pregnant women that are being referred to (e.g Page 2 line 45, Page 11, line 323). This could be clearer in the manuscript

- Amended throughout for clarity
2) Although it is clear when the protocol is read in full, on just reading the abstract alone, it's unclear why, or how the selection was done to recruit the subset of midwives and pregnant women to the study from all those that had received the intervention. I appreciate that the abstract word count is limited, but it may be helpful to re-word, perhaps by removing the word "plus" as this suggests that it's extra patients over and above those in the study. Out of interest, are the midwives selected to complete the questionnaires different people to those selected for the interview study?

• The “plus” has been removed from the abstract. The women participating in interviews are a subset of those who have complete questionnaires. The midwives participating in focus groups are a subset of those who received the intervention and may or may not have completed questionnaires.

3) On page 10, line 279, should it also say that it's a random subset of midwives that are chosen to provide quantitative as well as qualitative data?

• The section on midwife recruitment and consent has been amended for clarity

4) Page 10, line 288. Do the pregnant women who completed the baseline questionnaire also complete the follow-up questionnaire. If this isn't the case, what is the justification for using different samples at baseline and follow-up?

• The women recruited pre- and post-intervention have to be different women due to nature of pregnancy and the way care is provided. The duration between pre- and post-intervention data collection means that the women at baseline will have delivered by the time we are ready for post-intervention data collection. Women also only have one booking appointment and the majority of discussions with midwives on this topic would be during that appointment. The purpose of pre-intervention data collection is to compare clusters at baseline and not to look at change in women’s behaviours/data before and after the intervention. Detail has been added to this section.

5) Page 8 line 226. I'm understanding from this that women can be recruited at any point during their midwifery care e.g. at their first visit to see the midwife early on in pregnancy or after the baby has been born, but to assess their eligibility it's their BMI measure on their first visit to midwifery that is used to define eligibility for the trial and to see if it's >= 30kg/m2? Is this true? Overall, the description of the method used to recruit the pregnant women could be clearer as it's hard to follow at which point in time the eligibility criteria are applied….

• More details has been added to this section. Women are to be approached at their 20 week scan appointment which had been omitted from the description and is now included. The other details are factors for pre-screening for eligibility including the BMI measured at their first visit (early pregnancy BMI measurement as a proxy for pre-pregnancy BMI).
6) Page 12 line 329. Should the first trial outcome be....."calculated as a percentage of all eligible midwives who were invited to attend the intervention session"?

• Yes, amended

7) Page 15, line 419. What is meant by a 5-number summary? Could this be explained further?

• the minimum, lower quartile, median, upper quartile, and maximum – detail added.