Author's response to reviews

**Title:** Developing a complex intervention for diet and activity behaviour change in obese pregnant women (the UPBEAT trial); assessment of behavioural change and process evaluation in a pilot randomised controlled trial.

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Author's response to reviews: see over
Dear BMC Pregnancy and Childbirth Editorial Team,

Re: MS: 2005889438938252

Title: Developing a complex intervention for diet and activity behaviour change in obese pregnant women (the UPBEAT trial); assessment of behavioural change and process evaluation in a pilot randomised controlled trial.

Authors: Lucilla Poston, Annette L Briley, Suzanne Barr, Ruth Bell, Helen Croker, Kirstie Coxon, Holly N Essex, Claire L Hunt, Louise Hayes, Louise M, Howard, Nina Khazaezadeh, Tarja I Kinnunen, Scott M Nelson, Eugene Oteg-Ntim, Stephen C Robson, Naveed Sattar, Paul T Seed, Jane Wardle, Thomas AB Sanders and Jane Sandall

Please find below a detailed response to the referees comments which we found most helpful.

Best wishes,

Professor Lucilla Poston

__________________________________________________________________________

Poston et al, reply to reviewer's comments.

Relevant extracts requiring responses have been extracted from the reviewer reports and responses made, including changes to text.

Reviewer 1 : Jodie Dodd

We thank this reviewer for her very positive comments.

Reviewer's comments and authors response:

The authors highlight refinements that have been made to the current trial protocol in view of the process evaluation. Of note approximately 16% of women recruited were lost to follow-up, and it would be valuable for the authors to indicate whether processes have been established in the on-going trial to minimise this.

Authors response: In response to the above comment regarding loss to follow-up, the authors have implemented several strategies in the on-going trial to minimise this loss. These are highlighted on page 25, line 579-582.

Reviewer 2: Helen Cheyne

Author’s general comment: The authors thank the reviewer for her valuable comments and suggestions. We have endeavoured to address the issues raised within the manuscript and have provided further details below for clarity. We hope these revisions have improved the manuscript.

Comment 1. Use of the phrase – complex intervention in obese pregnant women in the title and start of the abstract reads oddly – as if a complex intervention is a thing in its own right. Later on in the
paper the intervention is described as – a complex intervention for diet and activity behaviour change – this seems a better description.

Authors response: We agree with this comment and have changed the title as suggested, clarifying that this is a complex intervention for ‘diet and activity behaviour change’. Additionally we have taken the advice from this reviewer, and have called the study a ‘pilot’ rather than an exploratory study. We have also added the name of the study (the UPBEAT trial).

Comment 2. What is triple –pass 24 hour dietary recall? The phrase is (I think) only used in the abstract.

Authors response: The triple pass recall was mentioned in page 8, lines 163-165 of the original manuscript. The following new text has been added to the manuscript to elucidate this method (page 9, lines 200-208).

‘The 24 hour dietary recall is a standard retrospective, interviewer led dietary assessment methodology used to capture information on all food and drinks consumed in the preceding 24 hours. This is carried out in three stages (the triple pass), which includes 1) recording a ‘quick’ list of foods eaten or drunk, 2) collecting more detailed information of these foods and 3) reviewing all items once more in order to clarify any ambiguities or omissions. A short food frequency questionnaire (FFQ), for later validation, was also completed’

For information only: The triple pass 24 hour dietary recall is a standard retrospective, interviewer led dietary assessment methodology, where an individual is interviewed about their food and beverage consumption during a defined period of time (in this case the preceding 24 hours). The method is commonly used in several national dietary surveys because of a high response rate received and ability to obtain detailed information. The interview can also be carried out in person or by telephone which increases flexibility for both the researcher and participant (no significant differences have been found in previous studies when comparing face-to-face recalls with telephone recalls). A single 24-hour recall is not considered to be representative of habitual diet at an individual level, which is why a repeated recall is undertaken.

The’ triple pass stages refer to:

1st pass: A quick list of foods eaten or drunk - respondents are asked to report everything that they had to eat or drink in an uninterrupted free flowing list.

2nd pass: Collection of detailed information - for each item of food or drink in the quick list, respondents are asked to provide additional detail, such as time eaten, description of the food ,recipes and other combinations of foods e.g. sandwiches, quantity consumed (based on standard measures and any leftovers or second helpings.

3rd pass: The review - the interviewer reviews all of the food eaten and drunk in chronological order, prompting for any additional eating or drinking occasions and foods or drinks consumed, and clarifying any ambiguities regarding the type of food or drink consumed and portion size.

The methodology is often described as ‘dietary recall’ however ‘triple pass 24-hour dietary recall’ is more accurate.
Background

Reviewer comment 3. Efficacy, effectiveness and feasibility – this is a really interesting point which is threaded through the paper and I feel needs more explanation. The paper reports- limitations of existing evidence include poor study design, small sample size, absence of theoretical basis but most importantly no a priori demonstration of efficacy of the intervention in regard to the behaviours targeted. Are the authors really suggesting that the most important limitation of most previous trials is that they have not been preceded by a demonstration of efficacy? Would a demonstration of efficacy not, itself, require a trial? As I understand it an efficacy trial would demonstrate that an intervention ‘worked’ in ideal conditions while effectiveness would be demonstrated in a trial of more ‘real life’ conditions. Given that most healthcare interventions such as the one tested here are complex ‘real life’ interventions which do not lend themselves to laboratory type testing the difference between efficacy and effectiveness is rather obscure. Is this study an efficacy trial? I am not sure that it is, I think it would be underpowered for that, and as the authors describe – there were no prior statistics to inform calculation of sample size for a full scale RCT. I do not think it is necessary to demonstrate a significant difference between groups for an intervention in a feasibility study - otherwise this would be a definitive trial. Surely prior evidence of a direction of effect is what is required? The point of a feasibility study is to test study processes and procedures, and gather data that would give an idea of mean and standard deviation for a small study population, with a view to making an inference as to likely definitive RCT numbers to confirm effect size in a larger population. I think that is what is provided by this study. However, it seems as if the authors start by describing this study as a feasibility study and rather move towards describing it as an efficacy trial later on. I suggest that if this is how they feel it should be described then more clear definitions of efficacy/effectiveness and feasibility studies are required.

Authors response: We have discussed the meaning of efficacy and agree that in contemporary terminology that an ‘efficacy’ study should address primary outcomes- which in this study would be gestational diabetes and delivery of a large for gestational age infant ie the outcomes of the main trial. Here we address behavioural outcomes in a pilot study to determine if the direction of effect is anticipated. We have therefore described this as a pilot paper trial assessing feasibility, and have amended the text throughout the manuscript to reflect this.

Subjects / setting

Reviewer comment 4. The paper reports that potentially eligible participants were approached in four centres. It would be helpful to know more about the centres- for example were they maternity hospitals? Who were the potentially eligible participants and how were they identified? Were they drawn from the general population of women receiving antenatal care, from specific clinics for obese women? Given the importance of context in the implementation of trials of complex interventions it would be helpful to have a little more detail.

Authors response: We apologise for the lack of detail. The text has been amended to provide details of the study centres and the population recruited from (page 5, lines 95-98).

Inclusion/ exclusion criteria

Reviewer comment 5. The very narrow gestation criteria for inclusion / exclusion i.e. <15 weeks does not make sense until later on in the discussion (why not just wait another week?) when the study time frame is discussed. This maybe should be described earlier for clarity.

Authors response: We have expanded the relevant section in the methods for clarity (page 5, lines 101-109).
The intervention

Reviewer comment 6.

….. I suggest separating descriptions of the intervention from description of assessments and questionnaires etc. received by both groups as much as possible.

Authors response: Thank you for the helpful suggestion. We have altered the order and separated out the text to improve clarity (pages 8-10, lines 162 - 212).

The process evaluation

Reviewer comment 7. The approach described provides an excellent framework for describing the aims of the process evaluation – context, reach, dose, fidelity and acceptability, and these issues are subsequently followed through and discussed. However, I do feel that some aspects could be more critically appraised. For example while the differences between women who consented to participate and those who did not are discussed in terms of parity and ethnicity etc. surely the issue that only around one third of potentially eligible women agreed to take part is an important aspect of feasibility – how large would the pool of potential participants require to be in order for a full scale trial to be feasible? This comment is not intended to be over critical; recruitment to any trial is a challenge possibly in particular for this group of women.

Authors response: We have reviewed the appraisal of the process evaluation sections and made additions to the relevant discussion (page 22-24; lines 502- 556). In regard to the numbers of participants needed to be approached to achieve adequate recruitment, we have calculated that since 38% of women agreed to take part, at least 4100 women will be require for the main trial. The manuscript text has been amended to highlight this in the results section (page 18, lines 412-414). A comment has also be added in the ‘reach’ section of the discussion (Page 23; lines 521-524)

Reviewer comment 8. Context – there is scanty description of context in the process evaluation. What aspects would be considered context here? Model of maternity care, availability of specialist bariatric clinics, family support? Socio demographic characteristics of the study group are important; this data was collected but not reported. The paper reports that comparable estimates were not available between Scotland and England, surely SIMD data would have provided high and low estimates of deprivation. This is an important aspect of the feasibility of conducting a trial across UK sites and it is an important aspect of context. I feel that some description of differences would have been possible.

Authors response:

We have increased the information regarding context. In the description of the subjects it has been clarified that the hospitals were all in urban settings (Page 4; line 93). In the section on the intervention delivery, the site of delivery has been identified (Page 8; line 180-181). The definition of ‘context’ has been enhanced in the methods section (page 10, lines 215-216). In the discussion (Page 22, lines 501-506) details on setting, socio-economic context and ethnicity have been added to the existing comment about media coverage of obesity and public health

The socio demographic data was originally included in Table 1. To facilitate comparison of the most meaningful quintile i.e. the ‘most deprived’, the data are now shown for both English and Scottish women (Table 1 and results section; Page 14; lines 328-330). Comment regarding the method of analysis have been added to the text (Page 6 line 126-128; Page 12, lines 272-276).
Reviewer comment 9. Fidelity – an interesting aspect of this study was the rigorous assessment of outcomes for both groups – these both yielded very interesting findings (in relation to accuracy of self report and depression) and highlighted some difficulties which would require addressing in a future trial or implementation in routine care. Both groups received a fairly intensive intervention, although the control group received ‘usual care’ this was supplemented by around five sessions with a researcher at which weight and diet, activity etc. was assessed. What are the implications of this for fidelity in a future trial? The study found some positive results which are likely to be clinically relevant for this population of women who are at significant risk as are their babies. However, the intervention was highly intensive – eight sessions plus several sessions with a researcher. I feel the implications of this – costs versus benefits and the implications for a future ‘effectiveness trial’ are worthy of discussion.

Author response: We agree that the research visits in both arms could confound interpretation and could in themselves be considered an intervention. However, to counter this the trial intervention showed significant differences in dietary behaviour in the anticipated direction. In order to minimise confounding effects and to improve fidelity in a clinical setting, the protocol has been amended since the pilot study and the number of visits reduced. The text on Page 25, lines 573-576 reflects this. In addition we have added comments in the discussion on Page 23, lines 542-547, reflecting pre-clinical work undertaken to keep costs of intervention low.

Reviewer comment 10. Finally the discussion and conclusions are rather vague. The authors are correct in reporting that the paper highlights the importance of feasibility trial and process evaluation but the findings could be brought together more clearly in relation to future directions for this intervention.

Author response: We have revised the discussion, notably a summary has been added and the conclusion re-written to improve clarity and highlight future directions for the intervention (page 24, lines 556-582). We believe this is now much clearer.