Reviewer’s report

Title: Developing a complex intervention in obese pregnant women; assessment of behavioural change and process evaluation through a randomised controlled exploratory trial.

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Reviewer: Helen Cheyne

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Developing a complex intervention in obese women: assessment of behavioural change and process evaluation through randomised controlled exploratory trial.

Thank you for inviting me to comment on this very interesting paper. The topic is of course highly relevant to current maternal and child health and the research team are to be complimented on their work in undertaking a complex research project.

Conducting and subsequently writing up a feasibility study for a RCT of a complex intervention is not an easy task, overall the authors of this paper have achieved this well. My comments are intended to highlight areas where I think some more clarity could be achieved rather than identifying major flaws, so I hope they will be found helpful. All may be considered minor essential revisions.

Title/abstract

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.

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

Background

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.

Subjects / setting

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.

Inclusion/ exclusion criteria

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.

The intervention

6. The research team are to be congratulated in developing a theoretically informed intervention – this is well described in the paper, although at times I feel the description of the intervention and the description of the assessment measures such as EPDS, attitude to change etc. becomes interwoven and this is a little confusing. For example the intervention is described – SMART goals etc., this is followed by a description of two questionnaires which I think all participants received. Then dietary advice and assessment is described, I think all participants received dietary assessment but I presume only intervention group received advice? I suggest separating descriptions of the intervention from description of assessments and questionnaires etc. received by both groups as much as possible.

The process evaluation

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.

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.

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.

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.

**Level of interest:** An article of outstanding merit and interest in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**
I declare that I have no competing interests