Author’s response to reviews

Title: Protocol for a two arm feasibility RCT of lifestyle information and commercial weight management groups to support postnatal maternal weight management and positive lifestyle behaviour: The SWAN feasibility trial

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Response to reviewer’s comments

Thank you for the opportunity to respond to the reviewer’s comments, which present quite contrasting views on our protocol paper. We have some concerns that reviewer#1 misunderstood some sections of our paper, so hope our responses to their comments in particular will be carefully considered by the Editors.
Reviewer #1:

Comment: This is a protocol paper and as such describes the background and methodology for an RCT to determine whether a larger RCT is feasible, but also to test the effectiveness of an intervention to reduce excessive weight gain in mothers after birth.

Response: As a feasibility trial, we are testing to see if a future definitive trial of effectiveness ‘can be done’. To avoid any confusion and ensure readers are clear that this is a feasibility trial, we have revised sections of the text where relevant which refer to the objectives of our feasibility trial (page 5), including highlighting that we will provide an estimation of the weight difference between our groups at 12 months which may be the primary endpoint in a future definitive trial.

Comment: The postnatal period provides an ideal time for a weight management intervention for many reasons, but these are not mentioned in the introduction, which is an important oversight, and the reason for choosing this population is not highlighted. Justification for the study is weak - the results of irrelevant studies are reported in great detail but the overall rationale for the study is patchy. Current evidence should back up your argument, not be described in detail with no critical input.

Response: We were a little unsure as to why the reviewer refers to no mention of the postnatal period in the Introduction, with ‘irrelevant’ studies reported in ‘great detail’, as we do not consider this to be the case. Nevertheless, we have revised the Introduction to emphasise why postnatal interventions may be more important, given the lack of evidence of effectiveness of pregnancy interventions, and why a feasibility study was an important first step due to the lack of evidence specific to the postnatal period.

Comment: The primary objectives, outcomes and endpoints do not align. In particular, the study is powered to detect a difference in weight change - which turns this study into an RCT to detect the effectiveness of the intervention, not a feasibility study. For a definition of a feasibility study please see: ref to NIHR guidance.

Response: To confirm, this study was not powered to detect a difference in weight change, but to meet a range of objectives relevant to informing progression to a definitive trial (including an estimation of weight difference as referred to above). We have revised our paper to make this clearer (p5) and included a table, as recommended by the Editor, which shows the links between our trial aims, objectives and outcomes in line with a feasibility trial.
Comment: The term 'weight management' is misused in places, and consideration should be given to the use of the term 'healthy BMI' rather than 'normal BMI', given the population of interest.

Response: We disagree. ‘Healthy BMI’ denotes that we know all about an individual’s current physical and psychological health (what does a healthy BMI actually mean?), when we do not have this information. ‘Normal BMI’ means that women’s weight met this definition according to international criteria – not that we knew all about her health status.

Comment: I advise revisiting the design of this study, first making sure that the objectives are clear and well-justified. Then design and the sample size justification for the study to achieve these objectives should be addressed.

Response: We hope that this concern will be negated by the further clarity we have included about our feasibility trial objectives. We cannot revisit the design of this study, as the design, objectives and outcomes were reviewed, approved and funded by the UK NIHR. In addition, it has been through all relevant ethics approval boards, and is registered on the UK Clinical Research Network and ISRCTN. The design and sample size are clearly justified in our protocol in terms of informing sufficient numbers of women to meet all of our objectives as a feasibility trial.

Reviewer#2

Comment: Page 5, line 54, please include the name of the Hospital and some further details including birth rate of the hospital, demographics etc.

Response: We would prefer that the site remains anonymous but have added in ‘inner city London’ and provided some information on birth rate and demographics.

Comment: Page 8. Are there further details online about 'Slimming world' if so could you please include the URL.

Response: We have included the URL for Slimming World on p8.

Comment: Page 14, line 14, please include the ethics approval details as per page 2.

Response: Thank you, we have added this.
Comment: Page 15, line 36, figure 1 not included in the document

Response: Apologies for this, we will ensure that the CONSORT diagram is uploaded with our revised paper.

Editor

Comment: Please see our editorial on how to use both the SPIRIT guideline and CONSORT Extension to pilot trials for protocol manuscripts of trials:

Response: These have been noted, section headings revised as appropriate and checklists submitted as appropriate with the resubmitted paper. We have added paragraphs on data management and confidentiality (in line with SPIRIT) and the Discussion has been expanded slightly.

Comment: Consider providing a summary table with the following columns: Objectives (primary/secondary), Outcomes, Criteria for Success of Feasibility/Hypothesis, Method of analysis. This will provide the readers with a clear summary of the protocol for the trial.

Response: Thank you, a table is provided. We have indicated in the text where this should be included.