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

Authors:

Debra Bick (debra.bick@warwick.ac.uk; debra.bick@kcl.ac.uk)
Cath Taylor (cath.taylor@surrey.ac.uk)
Vanita Bhavnani (Vanita.Bhavnani@nct.org.uk)
Victoria Craig (victoria.craig@gstt.nhs.uk)
Andy Healey (andy.healey@kcl.ac.uk)
sarah McMullen (Sarah.Mcmullen@nct.org.uk)
Bimpi Oki (BOki@lambeth.gov.uk)
Eugene Oteng-Ntim (eugene.oteng-ntim@gstt.nhs.uk)
sheila Oconnor (soconnor1@nhs.net)
Lucilla Poston (lucilla.poston@kcl.ac.uk)
Paul Seed (paul.seed@kcl.ac.uk)
Sarah Roberts (sarah.roberts@kcl.ac.uk)
Michael Ussher (mussher@sgul.ac.uk)

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Author’s response to reviews:

Protocol for a two arm feasibility RCT to support postnatal maternal weight management and positive lifestyle behaviour in women from an ethnically diverse inner city population: the SWAN feasibility trial
We would like to thank the Editor and reviewer for their comments on our revised paper. Please see our responses below, and where appropriate, our tracked changes in the text of the main paper.

1) There is no need to perform sensitivity analyses to assess robustness of the results of comparisons between groups -- because the study is not designed to provide definitive inferences on comparisons between groups.

Authors’ response: As an institution, King’s College London (which hosts this trial) is committed to the Alltrials Initiative (https://www.kcl.ac.uk/ioppn/news/records/2014/May/Kings-joins-AllTrials-campaign), which calls for all clinical trials to be registered and their results reported. This applies particularly to randomised controlled trials of an intervention that may prove to be of benefit to patients, and where the results may be included in a meta-analysis. For this purpose, the same reporting standards apply to small feasibility/pilot studies as to larger, definitive studies. The Consort Guidelines (Consort Group, 2010) take a similar approach.

2) The analysis plan includes comparisons between groups based on the analysis of outcomes at 6 and 12 months "adjusting for baseline prognostic factors". This is an uncommon approach for analysing trials unless the choice of prognostic factors is based on the evidence that these are strong predictors of the outcomes. However, in this case, the trial is not powered for comparison between groups let alone adjusting for baseline factors. Therefore consider deleting this part in the analysis section.

Author’s response: We are sorry to hear that this approach is uncommon. It has been well publicised, and has many advantages. Adjustment for baseline prognostic factors, as the reviewer notes, will in general tend to increase the power of a study, and can increase the power of a study substantially. Not presenting the best analysis would weaken the value of the study for meta-analysis purposes. An important aim of the feasibility study is to decide the main endpoint for the main study. To do this, it is essential to carry out the analysis as it would take place in the main study, and consider the standard error of the estimates. As such, we have not deleted this part from our analysis section.

3) State the software and version that will be used for analyses.

Author’s response: Stata version 15.1 or later (StataCorp, College Station, Texas).