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: Jodie Dodd

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As indicated in the title, the manuscript represents a detailed analysis of a complex antenatal dietary and lifestyle intervention for women who are obese, involving a pilot trial of 183 women. The evaluation was conducted to inform the intervention to be provided in a larger trial of approximately 1500 obese pregnant women that is currently recruiting. The authors describe in detail the intervention provided, in addition to the observed effect on measures of dietary intake, physical activity and psychological health, as well as undertaking a detailed process analysis, including barriers and enablers to change.

The methodology is well described, including the inclusion & exclusion criteria, the process of randomisation, minimisation variables, and statistical analysis utilising intention to treat principles.

The results of the analysis indicate that the intervention was successful in modifying women’s dietary behaviour, with less impact on changes in physical activity. The process evaluation is extremely detailed, and addresses a key deficiency in the available literature to date, with very few pregnancy interventions reporting a similar breadth of information.

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 ongoing trial to minimise this.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I have no competing interests to declare.