Reviewer’s report

Title: Effects of a lifestyle intervention during pregnancy to prevent excessive gestational weight gain in routine care - the cluster-randomised Gels trial

Version: 0 Date: 08 Jun 2018

Reviewer: Jodie Dodd

Reviewer's report:

Thank you for the opportunity to review this manuscript describing a cluster randomised trial evaluating a prenatal dietary intervention for pregnant women on gestational weight gain, involving over 2000 women.

Much of the background focuses on the specific problems associated with overweight and obesity during pregnancy. As the trial includes women of normal BMI, it would be helpful to have the background expanded to indicate the rationale for including women of normal BMI in this intervention.

The description of the study design requires more detail and needs to more clearly describe the clusters, and how they were chosen. The text as it currently reads is a little confusing.

The methods should indicate if screening for gestational diabetes is part of routine clinical care, or if this was required only for study participation. In addition, it would be helpful to have a brief description of the treatment offered as part of standard care / to trial participants.

The sample size statement contains insufficient information to assess its accuracy - specifically the expected frequency of the primary outcome and rationale for any anticipated change.

It is unclear why women with preterm birth were excluded from the analyses.

With regards to the statistical analyses, there are some points that need to be addressed. With the imputation, why 10 complete datasets generated (more standard would be 100). Were analyses conducted to determine if the missing data were missing at random? Was the per protocol analysis pre-specified?

There were a number of counsellors providing the intervention - what measures were taken to ensure ongoing consistency in the delivery of the intervention?

At baseline, there appears to be an imbalance across the groups with regards to maternal parity - was this considered?

There are many differences in clinical outcomes reported, including hypertension, preterm labour, caesarean section and induction of labour, as well as birth weight and birth length - all of these findings are glossed over or not mentioned at all in either the results or the discussion - this needs to be addressed, and possible reasons for these observed differences discussed.
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I recommend additional statistical review

Quality of written English
Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

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