Reviewer’s report

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

Version: 0 Date: 07 Aug 2018

Reviewer: Terry Haines

Reviewer's report:

Overall comments: This is a large trial reporting a no-effect finding. The primary limitation of this manuscript is not that it is reporting a trial with a null result, rather, that the potential reasons for the null result were not measured (or possibly were measured but not presented here) and examined. Specifically, it is not clear how well participants engaged with the intervention (did they turn up?), did counsellors provide the intervention as they were supposed to, what were the types of health behaviours were focused upon for change, what behaviour change strategies were employed, and whether these behaviours (eg. physical activity, food intake) actually changed. Readers (and reviewers) want to know whether it is the intervention that failed to change health behaviours, or whether the changed health behaviours failed to change the health outcomes in particular. The authors may intend for these issues to be the subject of a separate process evaluation paper, but their absence renders the present paper somewhat impotent in terms of what can be gleaned from its findings.

Introduction: Be specific about the effect size in the previous studies (refs 15-18). Is there a pooled effect size available that can be reported here?

Normally, interventions tested in academic settings lose effectiveness when tested in more "real life" conditions. Why was this intervention anticipated to result in changes to GWG when tested in a real life setting, when previous attempts in academic settings have not resulted in improvements? The discussion section mentions a pilot study with a significant reduction in GWG but it is not discussed in detail in the introduction. Discussing this pilot study in the introduction would help the logic behind why this study was conducted to be revealed.

Procedure: "Pregnant women were motivated to consume a healthy balanced diet, engage in physical activity and to self-monitor gestational weight gain" - Change to pregnant women were encouraged to…

The intervention does not have a particularly detailed description. I would recommend presentation using the TiDieR guidelines. Also, some discussion of any theoretical model underpinning the approach is warranted.

The study was designed to have 90% power to detect a between group difference of 10% in the primary outcome, with a 5% significance level. However, the 95% CIs were substantially wider than what was indicated to be likely given this power analysis. Was the difficulty of recruiting the full sample size solely responsible for this or was there a higher ICC than anticipated? The
ICC used for the power analysis was not clearly presented. ICCs need to be reported for all analyses arising from the cRCT design to be consistent with CONSORT guideline recommendations for reporting of cRCTs.

Discussion of why the intervention failed to show an effect is the critical issue arising from this trial but is not really discussed in a comprehensive way here. Mention is made about the adequacy of the training and ability of staff to deliver, but without data to support these points, this is highly speculative.

**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.

Yes

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