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: 28 Jun 2018

Reviewer: Christine Marie Olson

Reviewer's report:

The authors are to be congratulated for taking on this very important project that addresses the problem of excessive gestational weight gain at the population level using the existing health care system. It is disappointing that the intervention did not have a significant influence on weight outcomes but that does not necessarily mean that there is nothing to be learned from the trial. What are the lessons to be learned from this null findings trial? How does the null finding from this trial advance the field? It would be very helpful to see these questions addressed directly in this paper. I will come back to some specifics related to these questions in my comments below.

1) Pg. 5, line 55 - In the Abstract for the paper and later on Pg. 6, lines 89-91, the authors state that there were 4, not 3, counseling sessions. Here it says 3. Early postpartum weight retention is included as an outcome in this paper so why not be consistent throughout the paper in stating that there were 4 counseling sessions for the intervention group? It will be less confusing.

2) Pg. 5, lines 66-67 - The wording here is very unclear. Reword or add punctuation to make the sentence clearer. The description in the design paper is much clearer. Possibly borrow some of that wording.

3) Pgs.7-8, lines 131-135 - There is no universally agreed on the definition of a per-protocol analysis. Some experts use this analysis as one that includes only those individuals in both treatment groups who are adherence to study procedures. If this is done, the same measure of adherence is used in both treatment groups. In the current study, the authors did not use the same measure. Research participants in the intervention group were excluded from the per-protocol analysis if they missed a lifestyle counseling session or had a counseling session more than two weeks later than planned, in addition to some research procedures that applied to both treatment groups. Control group participants could not be excluded from the per-protocol analysis for lifestyle visit reasons. But nonetheless, the per protocol analysis included 46.5% of control group participants and 45.4% of intervention group participants, essentially similar proportions. From my experience with conducting lifestyle interventions, it seems highly unlikely that these proportions would be so similar when session attendance is included in the measure. In the manuscript, I'd suggest using the same measure for both treatment groups and including that in Supplemental Table 1 as the per-protocol analysis.

A second concept this especially of interest in a lifestyle intervention study such as this one is engagement with the intervention. Very often data from a process evaluation is included in a
manuscript such as this. For example, the following statistics are often included in the manuscript: the % of participants who participated in each of the four sessions, the proportion who did not attend any sessions, and mean number of sessions attended, etc. In addition, there is often a description of how quality control over implementation of the intervention was monitored and maintained across time in the manuscript. This manuscript would benefit greatly from the inclusion of more information on the methods and results of the process evaluation that was conducted as part of this study.

4) Pg. 9, line 163 (minor comment) - "Amount" does not seem to be the correct word here, possibly "proportion" would be better.

5) Pg. 11, line 214 (minor comment) - "Demanded" does not seem like the right word here. "Suggested, recommended"?

6) Pg. 12, lines 246-247 - What specifically is meant by "differences in the implementation"? Do you mean that the counselors said they did the counseling session with a participant, but they didn't do it? Do you mean that the health care provides did a counseling session, but is was low quality? Do you meant that women did not attend the number of sessions they were supposed to attend? If the authors are going to give "differences in implementation" as the primary reason for the results of this null findings trial, they need to provide much more detail on the evidence that they have in hand to support this explanation. This is critical in light of the highly improbable proportion of women in the intervention group who are included in the per protocol analysis. The results in Supplemental Table 1 imply that all the women in the intervention group attended every lifestyle counseling session (because the proportion is equivalent to that of the control group.) (See comment number 3 above.)

An expansion of this Discussion adds to the potential for this manuscript on a null findings trial to make a greater contribution to the literature.

6) Pg. 24, Table 4 - In the manuscript, no mention is made of the significance of the finding that the infants in the intervention group are about a half cm shorter than those in the control group. This seems to be a stronger result than the birth weight result and may be at least a partial explanation of the birth weight result. The birth length results may be important, because I think at least some people will think that the birth weight difference is related to fat mass of the infant at birth and shorter length appears to be a more likely explanation.

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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