Author’s response to reviews

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

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Author’s response to reviews:

Dear editor,

Dear reviewers,

We’d like to thank you very much for your helpful comments and suggestions which we have carefully considered. Please find our point-by-point reply below.

Editorial comments:

Regarding the following statement in the Methods (lines 176-179):

"Data from the Bavarian prenatal register suggest at least 40 % of women (BMI > 18.5 kg/m2) in the control group to gain weight in excess (Beyerlein A, November 2009, personal communication on the basis of Bavarian perinatal data from 2007)."
Rather than "personal communication", this should be supported by a published reference.

Thank you for this comment. We have replaced this statement with a reference showing the high rate of excessive GWG in Germany and changed the text accordingly: “It was suggested that at least 40% of women (BMI > 18.5 kg/m²) in the control group would gain weight in excess [14].”

Furthermore, we have detected a mistake in the presentation of the expected drop-out rate, which was given as 25% and now corrected to 20% (Methods section, line 184, page 10).

Reviewer reports:

Reviewer #2: Rubén Barakat
I appreciate the effort made by the authors in order to attend to my comments and suggestions.
Good job and excellent article!
Congratulations!

Thank you very much for this positive feedback.

Reviewer #3: Christine Marie Olson
Overall, the authors have done a very good job in responding to the reviewers’ recommendations and comments, especially related to the process evaluation. This version of the manuscript demonstrates a high-level of responsiveness to reviewers.

Thank you for this kind acknowledgement.

One consequence of this responsiveness is that the DISCUSSION section has gotten quite long and frankly, seems a bit rambling. I would recommend a very thorough editing and tightening up of this section.
Thank you very much for this helpful advice. You’re right that the discussion section needed some focussing. Therefore, we significantly revised and shortened the discussion section (lines 296-514, pages 14-22).

One of the points that may get lost in the long DISCUSSION is that the authors' major explanation for the null finding is the quality of the intervention as delivered. The authors expand on this to say the intervention was not based on behavioral science principles and it was not delivered by a dietary expert. They make a reasonable case for both of these. But from my experience and understanding of the literature on public health interventions, it is quite common for "scaled-up" projects to be unsuccessful in achieving the same results as the pilot project. I wonder if there are some key findings in this area that could be included here. The challenge of "going to scale" is a common theme in nutrition interventions.

We fully agree that this is an important additional point. We addressed this in the discussion (lines 490-492, page 21) and added three references that also discuss this issue (reference 24, 48 and 49).

My other comments are more specific and minor:

1) In the ABSTRACT, the authors indicate 10 regions in Bavaria were included and in the body of the manuscript they say 5 were included. Please be consistent.

Thank you for raising this. Our presentation was misleading. We have changed the information in the abstract to “5 Bavarian regions” (line 10, page 2).

2) Line 85 on page 6 - I don't think "pairwise" is needed in this sentence since it is already stated that "paired cluster randomization" was done.

We agree and have deleted the word “pairwise” (line 85, page 6).
3) Line 141 on page 8 - "Protocoling" is not the right word to use here.

You’re right, the wording was changed to “to assess” (line 143, page 8).

4) Lines 187-191 on page 10 and line 210 on this same page - The primary results that are presented exclude the 132 preterm births which means the sample size for women is 1885, as stated clearly in the cited lines. On line 210, it says that data are included for 2017 women. To me, this seems misleading. There are 2,261 women included in Table 1 and 1,885 in Table 2. Nowhere in this paper are data presented for 2017 women.

Thank you very much for highlighting this. Our wording is misleading, as primary outcome data was available for 2017 women, but only 1885 women were included in the analysis. We have changed the sentence in the results part: “Primary outcome data of 1885 women was included in the complete-case analysis.” (lines 215-215, page 11)

5) Line 230 on page 11—A result is presented on the intra-class correlation coefficient in the text. If it is going to be presented, something more needs to be said so the meaning is clearer to the reader.

We agree that this statement may need some explanation. We changed the sentence accordingly: “The intra-class correlation coefficient, reflecting potential systematic differences between the clustered study regions, was low (0.8%).” (lines 236-237, page 12).

6) Lines 382-386 on page 17 - I don't see how recruiting more nulliparous women into the trial explains an imbalance between the treatment groups. I'd suggest deleting this statement. You had an imbalance and you adjusted for it in the analysis. That seems to me to be a sufficient explanation.

Following your advice, we have deleted the statement in the discussion (lines 414-418, pages 18-19).
7) Lines 406-409 on page 18 - Reference 26 seems to me to be about an intervention that is integrated into routine prenatal care. It is in the reference list, but not cited or discussed here. That seems to be an omission.

Reference 26 is a study protocol of an intervention integrated in routine care. We cited this reference in our introduction due to the public health approach of the study (lines 59-60, page 5). Unfortunately, results of this trial are not published yet and can therefore not be included in our discussion.

Authors’ responses to comments from Reviewers 1 and 4: Overall, I think the authors have responded appropriately and effectively addressed each comment. Reviewer 4 has some philosophical differences with the approach to the study that the authors have taken so the authors say more in their response to reviewers than they do in the manuscript. But nonetheless, I think the authors have responded appropriately.

Thank you for your feedback and please apologize, we agree that some of our explanations were more detailed in the response letter than in the manuscript.

Reviewer #5: Terry P Haines

The authors have responded appropriately to my comments.

Thank you very much for your positive feedback.

With best regards

Hans Hauner, MD, for the authors