Author's response to reviews

Title: Feasibility of a controlled trial aiming to prevent excessive pregnancy-related weight gain in primary health care

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Author's response to reviews: see over
FEASIBILITY OF A CONTROLLED TRIAL AIMING TO PREVENT EXCESSIVE PREGNANCY-RELATED WEIGHT GAIN IN PRIMARY HEALTH CARE

Tarja I Kinnunen, Minna Aittasalo, Päivikki Koponen, Katriina Ojala, Kirsi Mansikkamäki, Elisabete Weiderpass, Mikael Fogelholm and Riitta Luoto

We are grateful for the editor and for the reviewers for their relevant and helpful comments. The comments have been taken into account when revising the manuscript. The manuscript has been checked by a language consultant who is a native speaker of English.

To avoid overlaps between this manuscript and the manuscript by Aittasalo et al., the following changes were made to this manuscript. The safety component of the feasibility evaluation was removed from this manuscript. In addition, when reporting the realization of the intervention (Table 2), the results for physical activity and dietary counselling were combined in this manuscript. After these changes, this manuscript more clearly focuses on the feasibility of the whole study protocol, not on the feasibility of counseling.

Response to Mireille van Poppel

Major compulsory revisions

Results, Recruitment and participation:

According to the ethical principles of RCTs, individuals may refuse to participate and participants may withdraw without telling the reason to the research team. Therefore, the public health nurses did not inquire and record the reasons systematically. Because the reason was only recorded for 17 (30%) of the women who refused to participate and the overall participation rate was high (77%), we prefer not to report the reasons in the text. Anyway, these reasons were mostly related to time constraints (n=6), life situation (n=4) or the study was regarded burdensome (n=3).

Information on the drop-out reasons was recorded for most drop-outs, however. Of the reasons related to this study, some drop-outs in the intervention clinics were unwilling to fill in more questionnaires, food records or the follow-up notebook. Other reasons, reported mostly in the control clinics, were reluctance to give the blood samples or difficulties to find time to give the sample. This information has been added to the text.

Realization of the intervention:

We have reported the realization rate of the counselling sessions, which actually means that the sessions were also realized as intended. The content of the counselling sessions was assessed from the counselling cards of each participant. If all essential parts of the card were filled in for a session, the session was regarded to be realized in the intended way. We have now clarified this issue in the methods and results sections.
Discussion:

We have taken the reviewer’s comments into account when revising the discussion. The structure of the discussion is now as follows: We first point out what went well in the pilot study. We then describe the difficulties, discuss reasons for them and give suggestions for further studies. Finally, the other strengths and limitations of the pilot study are brought out.

Minor essential revisions

Background:
Information on the amount of average weight retention (0.5 to 3 kg) and the size of the subgroup (up to 20 percent of women) has been added to the text.

Methods:
We have specified the following terms in the text:
“Otherwise problematic pregnancy”: The women were not included if a doctor had defined their pregnancy as problematic based on other reasons than those listed in the exclusion criteria.
“Tiredness and fatigue” refers to excessive tiredness and fatigue experienced by the participants. This has been specified in the text.

Discussion:
The reviewer is right in saying that in addition to the feasibility aspects, we also need to think the effect of the intervention on gestational weight gain when deciding whether to offer group exercise for pregnant women in the larger study or not. The main purpose of the group exercise was to support physical activity counselling by offering the participants peer-group support, rather than having a large effect on their total energy expenditure and body weight. We have revised our conclusions related to group exercise in the Discussion.

Table 2 has been removed and the information on the evaluation of the feasibility is included in the text.

Discretionary revisions:

The reviewer is right in stating that the objective of the study was both to prevent excessive weight gain during pregnancy and to reduce weight retention after pregnancy. In our opinion, however, “pregnancy-related” is a concise term to cover both time periods.

The term “study proper” has been replaced by terms “the larger study” or “further studies” where appropriate.

Response to Wanda K Nicholson

Major compulsory revisions

Introduction:
We now describe the specific objectives and a hypothesis in the introduction.
Methods:
1. The reviewer’s comments are addressed in a separate chapter “Baseline comparability of the clinics” in the Methods.

2. The sample size of this pilot study was not based on power calculations, which is now explained in the Study protocol chapter after describing the recruitment process. We made preliminary power calculations for the larger study before initiating the pilot, but these calculations will be revised. The intention to treat principle was not applied in this pilot study. After describing the data collection in the Methods, Study protocol chapter, we state that no attempt was made to collect data from the drop-outs.

Figure legends:
The legends for figures are provided after the references in the manuscript.

Discussion
We have taken the reviewer’s comments into account when revising the discussion. The structure of the discussion is now as follows: We first point out what went well in the pilot study. We then describe the difficulties, discuss reasons for them and give suggestions for further studies. Finally, the other strengths and limitations of the pilot study are brought out.

Yours sincerely,

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