Author's response to reviews

Title: Safety and efficacy of a lifestyle intervention for pregnant women to prevent excessive maternal weight gain: A cluster-randomized controlled trial

Authors:

Kathrin Rauh (kathrin.rauh@tum.de)
Elisabeth Gabriel (elisabeth.gabriel@mytum.de)
Eva Kerschbaum (eva.kerschbaum@mytum.de)
Tibor Schuster (tibor.schuster@tum.de)
Ruediger von Kries (ruediger.kries@med.uni-muenchen.de)
Ulrike Amann-Gassner (ulrike.amann-gassner@tum.de)
Hans Hauner (hans.hauner@tum.de)

Version: 2 Date: 1 March 2013

Author's response to reviews: see over
Reply to the Reviewers

Firstly, we thank the Reviewers for their helpful comments. The following letter provides a point-by-point reply to these comments. We considered each point raised by the reviewers carefully.

Reviewer’s report 1:

“This is an interesting paper on a very important topic. The results presented are encouraging and likely to be of great interest to those working in the field. The finding that GWG reduction can be produced without adverse effects on inadequate weight gain is often particular importance. I feel, however that the paper could benefit from a number of revisions.”

Minor compulsory revisions:

1. “The paper would benefit from some rewriting in order to ensure that the English used is accurate. In places the tense changes and there is the odd incorrect word/phrase.”

Thank you for critically reviewing the manuscript in terms of language. We carefully checked our manuscript for the correct use of tenses and phrases, and sent it for proofreading to a native speaker. We hope that we could address all your concerns. If there are further language problems, please do not hesitate to tell us, and please point out the passages for rewriting.

2. “I think that the authors need to consider and make explicit that the experience of the participants in the control condition was not exactly the same as standard care. These women experienced additional measurements of weight etc. and this may have inadvertently affected their behaviour. Thus the aims listed on page 4 should be amended to make clear that the comparison was with women in a control condition. This should also be listed as a potential limitation in the discussion.”

We agree that the control condition in our study was not exactly the same as standard care, as women in the control group were aware of participating in a trial aiming at promoting a healthy lifestyle and optimizing gestational weight gain. Participants in our control group filled in questionnaires concerning lifestyle and received additional information material, which may have influenced their behavior and consequently resulting in an underestimation of the intervention effect. We specified the aims on page 4 according to your suggestion, and added this aspect to our discussion section.
3. “The paper would benefit from a more clear description of the activities which occurred in the counselling sessions. It is not clear at the moment whether the focus of these sessions was information giving and advice and feedback, or whether efforts were made to assist the women to make behavioural goals. A detailed description here is vital since it is important to be able to identify the 'active ingredients' of the intervention. The authors may find the behavior change taxonomy helpful in describing the contents of the intervention in full (Michie et al., 2011, A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: theCALO-RE taxonomy. Psychology & Health, 26, 1479-98. doi:10.1080/08870446.2010.540664).”

Thank you very much for this important comment and the helpful reference. We specified the activities that occurred in our counseling session in the methods section of the manuscript.

4. “Related to point 3 above, it would be helpful if the authors could report variables related to the success of the counselling. For example, how many participants completed the dietary records and PA questionnaires? Also, were measures put in place to ensure the quality and parity of counselling between difference practices? I wonder if the authors took any measures of behavior change following the sessions. Did the participants actually exercise more, or eat more healthily? It would be very helpful for subsequent intervention to know how and why the intervention produced the effects. If this was not measured it should be included as a limitation of the study.”

We added data on behavioral change to our manuscript to answer your questions. Energy intake and physical activity measures in the control and intervention group are given in Table 4 of the revised manuscript. Women in the control group statistically significantly increased their daily energy intake from baseline to the end of pregnancy, while women from the intervention group maintained a stable energy intake throughout their pregnancy. All women significantly decreased their total physical activity during the course of pregnancy. Nevertheless, women in our intervention group showed a smaller decrease in physical activity, which may have contributed to the effects of the intervention. These data give some hints as to how the intervention produced the observed effects. Further analyses of the dietary records and physical activity questionnaires are being done, and may provide additional insights about causes for the observed effects.

The quality and parity of counseling was ensured by the fact that only three carefully trained researchers were responsible for the counseling sessions and followed a standardized counseling curriculum. All women were independently and equally distributed between the counselors.
5. “(p.8) Why was 5kg higher defined as substantial weight retention?”

This cut off point was chosen as 5 kg weight retention represents a substantial shift in weight, and data analyses suggest this cut off point predicts later obesity and its consequences [1,2].

A number of other studies in this field of research used the same cut off point to define substantial weight retention [3–5].

6. “I think the authors try to play down the considerable baseline differences in weight categories between the conditions. I think this should be considered more carefully and an explanation for the strategy by which these were controlled for in subsequent analysis provided.”

We did not intend playing down the baseline differences in weight categories between our study groups. As indicated in the methods section and stated in the results, prepregnancy BMI was included as an adjustment variable in all our analyses. Based on your comment, we added this point as a further limitation of our study thereby highlighting this problem.

Reviewer’s report 2:

“The authors have studied the effect of lifestyle and dietary interventions through a cluster randomised trial adding to the growing literature published in this area.”

Methodology

1. “The sample size calculation was changed half way through the trial rather than recruiting more practices to the control group. The power calculation did not take into account the clustering effect and this should be highlighted as the weakness of the trial.”

We completed the recruitment of practices before randomization as this is a requirement of the cluster randomization process. As mentioned in our methods section, the power calculation did not take into account the clustering effect. According to your suggestion, we included this issue as a limitation of the trial.

2. “The authors mention that intense counselling was provided, but from the manuscript, it appears that participants were contacted only twice. It is possible that knowledge of participation in the trial could have motivated the health care providers to provide additional input regarding weight management outside the trial protocol, accounting for the group doing well.”
Both health care providers in control and intervention practices were aware of participating in a trial aiming to optimize gestational weight gain, and may therefore be motivated in the same extend to provide additional information. However, all gynecologists participating in the study were instructed to maintain their usual prenatal care.

3. One major concern is the absence of data on compliance, especially for physical activity. It is difficult to ascertain the effect physical activity may have on the outcome. It is well documented that compliance for physical activity is poor in pregnancy and the observed benefit could solely be attributed to the dietary component. The work by Thangaratinam et al (BMJ 2012) has shown that diet based interventions consistently perform better than both diet and lifestyle.

We addressed your concern by adding data on behavior change to our manuscript (see answer to reviewer 1, comment 4). Data regarding energy intake and physical activity showed that the dietary component of the intervention might be more effective than the physical activity component, which is in line with the findings of Thangaratinam et al [6]. Nevertheless, women in our intervention group showed a smaller decrease in physical activity, which may have contributed to the effects of the intervention. We think that the inclusion of a physical activity component is justified as it may exert other beneficial effects like improving cardiovascular conditions, physical fitness, and muscle mass [7,8], and might be beneficial in preventing inadequate gestational weight gain and weight retention after birth, which was not assessed in previous reviews and meta-analyses.

4. “May be preferable to use RR instead of OR.”

We used generalized linear mixed models for the analyses of binary outcomes. The results returned from such logistic regression models are odds ratios. There is a common agreement, according to our statisticians that odds ratios can be used regardless of study type and design.

Applicability:
“I am uncertain if the intervention could be recommended in pregnancy to improve outcomes for the following reasons. Firstly, it is not clear if all components contributed to the minimal GWG or it was mainly due to diet. Secondly, in the absence of evidence that mixed interventions actually improve pregnancy outcomes, it may be better to limit the conclusion as follows: they may minimize GWG, but effect on pregnancy outcomes is unclear.”

We changed our conclusion according to your suggestion.

Thank you very much for your notable comments and questions.

The authors
References