Author's response to reviews

Title: Effect of an individually tailored one-year energy balance programme on abdominal fat and body weight in recent retirees: a cluster randomised controlled trial

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Author's response to reviews: see over
The Hague, October 6th 2009

Dear editors,

Herewith we present our response to the concerns that were raised by two referees on the manuscript entitled ‘Effect of an individually tailored one-year energy balance programme on abdominal fat and body weight in recent retirees: a cluster randomised controlled trial’ offered for publication in BMC *Public Health*.

We are pleased that both reviewers find this article of interest for publication, though they provided some considerations and comments which will be addressed point-by-point in this letter.

A major change of the manuscript is the inclusion of new data on physical activity and dietary intake, as requested by reviewer #2. These data are analysed in the same way and provide a full picture of the changes in behaviour and body composition after retirement. Therefore, the paper is reshuffled and inevitable a notable number of words and pages are added, though we tried to be as concise as possible. Furthermore, the manuscript has been edited by a person with a degree in English.

We believe to have fulfilled all points of concern that were raised by the two reviewers and therefore sincerely hope that the editorial board will decide to accept this relevant paper for publication in the BMC Public Health.

Yours sincerely, on behalf of all authors,

Andrea Werkman, MSc
Jantine Schuit, PhD

*For your information: the study was performed while AW was affiliated with the Wageningen University. Currently she is working at the Netherland Nutrition Centre.*
Comments of reviewer #1 and our responses:

Major issues

1. The study included both men and women, although 353 were men and 61 were women. Since the authors performed a gender stratified analysis, I am unconvinced that the analysis was adequately powered for women. My suggestion is that you demonstrate adequate power for women, or remove them. With the current set up I suspect you have a problem with type 2 error.

   *We agree that group of women may be too small to have sufficient power to draw (firm) conclusions. Therefore, we removed the women from the analyses and results. This is described at the end of the statistical analyses (page 13). However, in the description of the study and flowchart (Figure 1) women are still included in the manuscript.*

2. The analysis was intention to treat, but I could not find any information about how you handled missing data from drop-outs. Furthermore, in Tables 2a and 2b, you show the number of subjects in each analysis, which suggests that you only analysed completers. Please clarify how such an analysis is consistent with intention to treat principles.

   *We used the term ‘intention-to-treat principle’ in our initial manuscript, though we did not perform a 100% ITT analyses. We only included those participant who had at least provided data at one follow-up measurement. We realise now that this was confusing. Therefore we reformulated this part to avoid confusion (see page 12).*

3. What was the primary endpoint? Please be more specific about your results in general, for example what was the primary endpoint, and what were the secondary endpoints?

   *The primary endpoint of the trial were waist circumference and body weight. This has been clarified at the end of the background section, at page 4. Secondary endpoints were other body composition measures, blood pressure, and different aspects of physical activity and dietary intake. This is added to the background, methods and result section.*
4. You also perform hypothesis tests of baseline values, comparing the intervention group with the control group, which is not appropriate.

   Although we cluster randomised our participants to either the intervention or control group, we checked the ‘success’ of the randomisation by analysing baseline difference. However, this is not presented in the manuscript. Baseline measures are only included as covariate in the analyses, as stated at page 13.

5. It would be helpful if you appended a CONSORT-checklist with the manuscript.

   We have completed a CONSORT-checklist which is included in the uploaded files.

Minor issues

Background

6. Too long, this can probably be trimmed down by 30%.

   We reduced the Background section as can be seen on page 3 and 4, though the inclusion of physical activity and dietary data also needed some space.

Methods

7. Please make your inclusion and exclusion criteria more clear.

   The inclusion and exclusion criteria are extended and clarified in the Study design, Participants and recruitment section on page 5.

8. Please explain the clusters of participants in more detail.

   The clusters of participants are explained in more detail in the Study design, Participants and recruitment section on page 5.

9. The intervention needs clarification, maybe a figure or table would be more helpful here.

   The intervention is clarified by adding a figure (Figure 2) and some editing in the text on page 6-8.
10. Programme utilization: do you know how often participants used the different modules?

The self-reported utilisation of the modules only provides data on whether participants used the module ‘once’ or ‘twice or more’. We have shown these data now within the description of the intervention (page 7-8).

Results

11. Please be more specific about your reporting, for example what constitutes a “logistical” reason for drop-out, or “no important baseline differences”, “slightly more anti hypertensive…”, and so on.

In the Results section we have revised the text in order to be more specific about the reporting of for instance “logistical” reason for drop-out (from page 14 onwards).

12. Again, you are not supposed to test baseline differences in an RCT, although it’s fine to adjust for baseline values in the main analysis of outcomes at follow-up.

We have deleted all ‘baseline testing’ from the manuscript, see #4.

13. While confidence intervals are usually more informative than P-values, it would be nice to have P-values as well in this section, since they are not in Tables 2a or 2b.

We have added P-values to the Result section, see page 14-16.

Discussion

14. This section may benefit from commenting on some of my general points above.

The discussion was updated taking into account the comments that were stated above (from page 16 onwards).
Comments of reviewer #2 and our responses:

15. However, the authors should revise the manuscript and report on additional data (dietary and physical activity habits and psychosocial determinants of these behaviors) collected as per their original method's study published in this journal in 2006. I strongly believe that the manuscript could be enriched considerably if that data was presented. Once that data is incorporated the manuscript will need to be reviewed by a statistician.

   We have added that data on physical activity and diet as requested by the second reviewer based on the paper published in the BMC Public Health, December 2006. As stated before, this has led to substantial prolongation of the manuscript.

Specific Comments:

Methods Section:
16. Need to specify that the intervention is of 12 months duration and that the 24 month is simply a follow-up for sustainability in the methods section

   With the inclusion of Figure 2 (page 32) we have tried to be more clear about the study design and the distinction between the intervention period and the follow-up period to test whether effect would be sustainable. Within the Results section we have added headings to distinguish between the different follow-up measurements (from page 14 onwards).

17. The assessment of program utilization is not clear. It seems to be based on returning a CD-ROM indicating what behavioral aspect they are most interested in modifying. However unless the CD contains continuous login information from the subjects it does not indicate program utilization, only compliance with the study request. This needs to be further clarified.

   The assessment of program utilisation was performed by self-report and is, indeed, a rather crude measure (see also # 10). No continuous information was gathered unfortunately. Nevertheless we do present some more data on the compliance/ adherence within the Discussion section (page 18-19).
Discussion section:

18. The results at 24 months –that is the lack of sustainability- should be discussed.

The results at 24 months –that is the lack of sustainability- are mentioned throughout the Discussion section, from page 16 onwards.

19. The discussion needs to finish with what the authors plan to do with their intervention program in the future. The earlier methods paper (2006) stated that if the intervention was effective and sustainable it may be implemented in about 100,000 retirees per year. Are the authors planning to stop the program or maybe test the program in a larger cohort trying to use a different recruitment system?

We have included a final sentence on the possibilities for use in the future of the study (page 19).

20. Limitations: The authors need to acknowledge that the fact that few women were included limit the generalization of the results of the study.

Data on the women are excluded from the analyses, as stated at page 13, see also comment number 1.

21. Additionally, visits to the community health centers may have also confounded the results by acting as an intervention in the control group. Personal contact with a known individual could be a very strong motivator for behavior change. This may be important considering that exposure to the real intervention was perceived to be low.

Participants visited the community health centers only for the follow-up physical examinations. At these centres the person at the reception desk did not mention topics related to the study and while being examined, related topics were not discussed. Therefore, this possible external motivator is assumed to be low (page 17).