**Reviewer's report**

**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

**Version:** 1  **Date:** 18 June 2009

**Reviewer:** Erik Hemmingsson

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

This large randomized controlled trial evaluates a weight balance programme in Dutch adults who have recently retired. The main finding was that intervention group did not differ in adiposity compared to the control group at 24 months. Trials that evaluate weight gain prevention programmes for recent retirees, such as this, is a public health priority. Strong points include the public health relevance, long follow-up, random allocation of treatment and control, and an adequate sample size. While I feel that the study was generally well designed and executed, there are some issues that need clarification.

**Major issues**

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.

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.

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?

You also perform hypothesis tests of baseline values, comparing the intervention group with the control group, which is not appropriate.

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

**Minor issues**
Background
Too long, this can probably be trimmed down by 30%.

Methods
Please make your inclusion and exclusion criteria more clear.
Please explain the clusters of participants in more detail.
The intervention needs clarification, maybe a figure or table would be more helpful here.
Programme utilization: do you know how often participants used the different modules?

Results
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. 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. 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.

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

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests