Reviewer's report

Title: The 40-something randomized controlled trial to prevent weight gain in mid-age women

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Reviewer: Caroline Horwath

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1. This manuscript describes the protocol for a RCT evaluating a weight gain prevention intervention in non-obese women about to enter menopause. This is an important life stage for weight gain prevention, yet this RCT is one of very few internationally to address this important issue.

Particular strengths of the design are its focus on a relatively low-intensity intervention that could be delivered within the current Australian healthcare system.

2. The manuscript is well-written, clear and detailed. The study is thorough in terms of the outcomes measured, randomization and nature of the interventions. It also includes evaluation, using MITI, of whether consultations are consistent with MI practices.

Several comments are included below for further strengthening the manuscript.

Major Compulsory Revisions

3. The study sample size calculation was based on detecting a difference in weight between the 2 groups of 3.5kg. This is a large effect size. Smaller differences between the two groups are likely to be practically and clinically relevant, especially given the low-intensity nature of the intervention (eg 2kg difference between the groups would also be very meaningful). However, detection of somewhat smaller but still meaningful differences would require a much larger sample size.

It would be more usual for power calculations to be undertaken to detect the smallest interesting difference.

Thus, I would suggest that this study be described in the title and abstract as a pilot study. Currently, the term “pilot study” appears 5 lines from the end of the manuscript:

“the small number of study participants resulted in this study being underpowered, however, as a pilot study it can test feasibility, study materials and provide data to inform a larger scale study which would be sufficiently powered”.

4. The ‘sample size’ section (p10-11) states that a total sample size of 55 women is required. Figure 1 shows that 54 women were randomised. This does not fit with the description (p22) of the study being ‘underpowered’. The study has been powered to detect a 3.5kg difference at 24mo. The study is underpowered to be
able to detect differences less than the 3.5kg stated on p11.

In my view, it would be more appropriate to:

1. Reword the hypotheses along the lines of ‘women in the intervention group will experience statistically significantly more weight loss at 12 mo and 24 mo than women in the control group’, rather than stating the hypotheses in terms of the actual weight change in each group (p6).

Prevention of weight gain rather than loss could be viewed as a positive outcome. It would also, for example, be of interest whether the intervention group gained less weight during the maintenance phase that the control group.

2. Describe the study in the title, abstract and from the start of the manuscript as a pilot study, rather than mentioning it as a pilot at the very end of the manuscript.

5. Currently, women in the control group are hypothesized to gain 1kg over 24 months, the same amount of weight as gained in the general Australian population of mid-age women managing their weight by self-directed means. However, the control group will be receiving individualised advice from health professionals tailored according to their assessments, so it is plausible that they will do somewhat better than the general population re weight outcomes. This also supports a rephrasing of the hypotheses along the lines of 1 above.

6. The intervention has been framed according to Social Cognitive Theory (SCT). However, no details have been provided which describe how SCT has determined the intervention design. A brief description of the SCT constructs and learning strategies applied in the intervention would be useful.

7. The intervention includes seven ‘weight gain prevention’ dietary intake messages. It would be useful to provide the rationale for selection of these seven messages as being key messages for achieving the prevention of weight gain.

Minor Essential Revisions

8. P10 wording – The brochure also outlined… (not outline)

9. P12 wording – ambivalence regarding behaviour change

10. P12 wording – discrepancies between current behaviour and important goals, and supporting self-efficacy….

11. P18 reword more clearly “Limited validation is available for the TFEQ with 51 items”.

12. P19 wording “The survey when participants…..”

‘was conducted’ is missing from this sentence.

“..and any suggestions for study improvement”….. should this read “…for intervention program improvement”?

13. P19 Validity of the compliance score? Social desirability bias?

14. P21

2nd sentence of discussion needs rewording, ie…
“...this paper describes a pilot RCT to test whether a structured, but relatively low intensity intervention based on an existing health system model..., leads to more successful weight control....”

The reference to weight control in this sentence appears to acknowledge that outcomes other than the 3.5kg weight difference described on p11 would be of interest.

15. Table 3. The wording in some areas could be strengthened.
   Eg Collaboration section
   Could read “…when requested by the patient or after consent..... This included permission......”
   “by facilitating monitoring discussion” could be reworded for greater clarity.
   Evocation.
   Would be useful to clarify whether/how participants were assisted in identifying values as people tend to find this difficult to do when simply asked what they value.
   Was the importance rating done for each of the 6 SMART goals?

16. Figure 1.
   To the left of allocation, why does it state “give reasons”?
   Discretionary Revisions
   17. Why as the TFEQ been included? A rationale for including this measure would be useful.

18. Was the inclusion of any SCT measures considered? (eg self-efficacy, outcome expectations?)

19. Table 3.
   Support Self-efficacy
   “the patient shoulders the responsibility for making a change” – could consider rewording to reflect belief in the possibility of change as an important motivator.

**Level of interest:** An article of importance in its field

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

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare that I have no competing interests