Author's response to reviews

Title: A pilot study comparing two weight loss maintenance interventions among low-income, mid-life women

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Author's response to reviews: see over
Manuscript #: 1161030280890815  [Revision 1]

Cover Letter (Response to reviewers’ comments)

Thank you for the opportunity to improve this manuscript. Please see our responses below to reviewers’ comments. We hope these responses (along with the manuscript revisions) address the comments and concerns noted.

Reviewer's report: #1

Title: A pilot study comparing two weight loss maintenance interventions among low-income, mid-life women
Version: 1  Date: 13 March 2013
Reviewer: Perry Foley

Reviewer's report:
Major Compulsory Revisions:
None

Minor Essential Revisions:
1. Is the second definition of weight loss maintenance inclusive of a 3% change? Sometimes the manuscript says < 3% (not including 3%), sometimes it says ± 3% (which does include 3%). The criterion should be consistent throughout the manuscript.

RESPONSE: The definition proposed by Stevens et al, defines maintenance as a change of < 3% (non-inclusive). The text is now revised to make this clear.

2. Did all participants who were eligible to participate in the maintenance phase based on weight loss agree to participate (or was the maintenance intervention built into the original study design and informed consent)? If not, how many refused and what were their reasons for refusal (can also put this under Results)?

RESPONSE: Yes, the maintenance intervention was part of the original study design/informed consent. All eligible participants participated in the maintenance program (no refusals).

3. Figure 1: the right arm of the flow chart (Face-to-Face only) should read “2 individual + 10 group”, as there was no phone contact in this group.

RESPONSE: Thanks for catching this error. The figure has been revised.

4. Figure 1: the figure should include 6-month assessment numbers since 6-month outcomes are reported.

RESPONSE: Figure 1 now includes 6-month assessment numbers.
5. Methods: This section mentions that the primary focus of this pilot work was feasibility and acceptability, which seems discordant with the primary outcome of weight maintenance. Feasibility and acceptability seem to be strong secondary outcomes of interest.

RESPONSE: You raise a good point. The primary focus of this research was on the weight loss phase. That said, we knew that including a maintenance phase would be important. All of the outcomes of the maintenance phase were thus viewed as secondary outcomes, in the context of the larger trial. Naturally, our primary outcome for this report on the maintenance program is weight loss maintenance, but when the study was designed, our initial focus was on assessing feasibility and acceptability. To fix this discrepancy and focus on the intended purpose of this report as stated on page 3 of the introduction, we have removed the text in the methods section (page 6) that referred to the primary focus being feasibility and acceptability.

6. Methods: Who is the health counselor in the maintenance phase? Is this the same counselor as in the weight loss phase?

RESPONSE: Yes, the same counselor from the weight loss phase led group sessions and completed phone contacts during the maintenance interventions. We've added this information with a minor edit to the methods section (page 7).

7. Methods: The authors describe several topics included in the weight maintenance skills training (problem solving, stress management, etc.). Were these same topics covered at all in the weight loss intervention? If so, how was the overlap handled?

RESPONSE: Typically with weight loss maintenance interventions, there is overlap with some of the behavioral content emphasized in weight loss. This behavioral focus makes sense in that it is the day-to-day decision-making about diet and physical activity behaviors that results in weight loss and maintenance success. Additionally, some participants in the maintenance phase actually decide to continue with weight loss (especially in the first 6 months). Even though new topics such as relapse prevention are included in maintenance but not in weight loss interventions, the skills in problem-solving, stress management, etc. are critical for participants to retain, so they are revisited in maintenance.

8. Methods: The authors mention food records – what other tools were used for self-monitoring, if any?

RESPONSE: No other tools were used. It should be noted that the ‘Food and Fitness diaries’ used in this study included both diet and physical activity self-monitoring data.

9. Results: Table 1: The Table and the Results text indicate an n of 51 for the 12-month outcomes, but Figure 1 indicates an n of 50 (34+16).

RESPONSE: Figure 1 has been corrected (n=34 changed to n=35).

10. Results: Why did 7 women not complete their 6- or 12-month assessments?
Did they become ineligible or were they lost to follow-up?

RESPONSE: They were all lost to follow-up.

11. Results: This section would be strengthened by a report of the number of participants that met both criteria for weight maintenance – are the 24 women who maintained the 5% weight loss and the 25 women whose weight changed less than 3% a very similar group of women?

RESPONSE: Good point...We looked at our data and find that there is considerable overlap, with n=19/24 (79%) in both groups. A statement about this overlap appears in the revised text (page 11, Results)

12. Results: When was program satisfaction assessed - at 12 months?

RESPONSE: Yes it was. We have made a minor edit in the text to indicate that acceptability was assessed at the end of the maintenance (e.g., at 12 months). Please see edited text on page 13 of the ‘results’ section.

13. The authors may want to include a more thorough discussion of the various modalities included in this pilot weight maintenance intervention – particularly given the characteristics of the WW participant population. What are the advantages/disadvantages of phone vs. in-person and what are the implications for dissemination? What would be next steps in terms of thinking about the number and types of contacts necessary to produce the desired weight maintenance in a RCT?

RESPONSE: We have added the suggested topics to our revised discussion (page 16).

Discretionary Revisions:

1. The abstract Methods section may want to mention that the primary weight-loss intervention was conducted among low-income midlife women (to tie back to the abstract Background).

RESPONSE: Done

2. The Background could benefit from a brief discussion of how SES relates to risk with respect to obesity.

RESPONSE: We have added additional information about SES and obesity risk.

3. Methods: This section would be strengthened from a breakdown of intervention contact time in hours (as is done in the Discussion). While the number of contacts is the same, the authors point out in the Discussion that the total contact time in hours is nearly doubled in the Face-to-Face only group.
RESPONSE: Good point! We have included this information about planned intervention dose for each program (page 6).

4. The Discussion (and/or Results) might benefit from more specific data regarding attendance at the group sessions and adherence to the counseling calls.

RESPONSE: We have added the suggested information about ‘intervention receipt’ (page 13 of ‘results’).

Reviewer's report: #2
Title: A pilot study comparing two weight loss maintenance interventions among low-income, mid-life women
Version: 1 Date: 18 March 2013
Reviewer: Wagner Luiz Prado
Reviewer's report:

Major Compulsory Revisions
What is the rationale to focus on SES women? Is weight loss/maintenance influenced by the SES? It is essential that the authors present this in the introduction.

RESPONSE: In the original ‘Background’ section (second sentence; page 3), we cite 2 references that identify middle-age and low socioeconomic status (SES) as independent risk factors for overweight and obesity in women. Our main point with this paper is that most interventions do NOT specifically target this high risk group, and the contribution of this pilot is to fill an existing gap. Some studies use proxy measures of SES such as income and education to examine the predictors of weight loss success, but actually designing and testing interventions that fit the needs of low-income women remain understudied areas. In our revised text we have expanded on the data linking SES to obesity.

Why 8lbs was used as cutoff? Please provide reference.

RESPONSE: Commonly weight loss studies select a weight loss goal that represents what is likely attainable by study participants. The rate of weight loss generally prescribed for such interventions is in the range of 0.5 to 2.0 lbs. per week. Our cutoff of 8 lbs. was based on the intervention duration of 16 weeks and the lowest rate of weight loss (0.5 lbs/week). Please see page 5 (Methods section) for the revised text and citation.

The methods section is too long and confused; the authors should rewrite it in a more clear way. The results section is confused, with several data regarding the secondary variables which hide the main outcome of the study. In my opinion the authors should focus on the main question of the paper: there are differences between the interventions in weight loss maintenance?
RESPONSE: We are sorry that you find these sections confusing. Hopefully this response and our revisions will help. Because our maintenance program immediately followed a weight loss intervention trial and was not a stand-alone program, we wanted the reader to know more about what happened prior to maintenance. Additionally, we wanted this paper to stand on its own, and to do that, we needed to include information about the weight loss study and not simply refer the reader to the publication. For this reason, we begin the Methods section with a brief summary of the 'Weight Wise Program'. Likewise, in the results section, we begin with a summary of how participants made it into the maintenance study and let the reader know that both maintenance groups started with participants similar in basic characteristics. We believe this information provides important context for the findings. Concerning the statement that the 'secondary outcomes hide the main outcome of the study', we have reviewed our results section and find that most of the content (pages 9-12) focuses on the outcomes as presented in Table 1. Only 2 paragraphs (the last two) addressed secondary outcomes. We have revised the text in both of these sections to partially address your concern with edits that help with clarity, but believe our basic approach in providing contextual data related to the weight loss phase is warranted.

In the discussion the authors did not comment anything regarding the SES. All comparisons are made with studies with other population. The discussion needs a spin over to be in accordance with the introduction, and the rationally to develop the study.

RESPONSE: We certainly wish that there were more published maintenance studies in this population that would allow for direct comparisons. The reason we compare our outcomes to other studies (that do not target low SES populations) is because at the time, there was no studies with which to compare our maintenance outcomes. We found only one study (a low-dose intervention among low-income minority patients in a primary care setting) that was not well suited for comparisons. Even when low-SES participants are included in larger samples, the outcomes are not necessarily reported by SES. Additionally, the intervention we tested was adapted from evidence-based programs used in study samples that were not low-income. These pilot findings, in some ways, should be related back to outcomes of the original interventions. Moreover, our ultimate goal with treatment should be to have equitable outcomes across income groups. We’ve added text to our discussion that we believe addresses this comment.

Minor Essential Revisions
The units of BMI are missing in the whole manuscript.

RESPONSE: Units are now included.

What is the statistical power of the analyses? There was a sample size calculation for the second phase of the study?

RESPONSE: The statistical power for the study was determined for the weight loss phase (and reported in the main outcome publication). The maintenance phase was designed as
pilot research, therefore, no sample size calculations were done. This lack of power is noted as a limitation.

Tables should be reformulated using a more appropriate format

RESPONSE: We are not sure what represents ‘a more appropriate format’, but have revised Table 1 (in response to comments by Reviewer #3). We trust that these revisions are consistent with a more appropriate format.

Reviewer's report: #3
Title: A pilot study comparing two weight loss maintenance interventions among low-income, mid-life women
Version: 1 Date: 21 March 2013
Reviewer: Gustavo Silva
Reviewer's report:
General Comments
Overall, the manuscript entitled “A pilot study comparing two weight loss maintenance interventions among low-income, mid-life women” is well written. The topic is very interest and up to date. It seems to be a follow-up study from a randomized controlled trial, which successfully reduced weight in low-income women. The study’s rationale, purposes and methods are clear and well described. However, the statistical procedures and the presentation of results seem confused. Thus, some suggestions are made in order turn the presentation of results in a comprehensive way.

Major Compulsory Revisions

Data presentation and analysis are unclear. Authors should consider a different approach. The presentation of continuous variables, such as weight (and weight gain or loss), should be presented as mean ± standard deviation. For the above-mentioned continuous variables, please consider using Student T-tests, ANOVAs or the respective alternative for non-parametric test. I honestly suspect that there are differences between groups and across time in the mean for weight, weight change and weight regain. If the mentioned differences exist, the maintenance weight program might not be that effective. Also, the addition of some effect size measure, such as partial eta square, would be informative. If these changes in the analyses lead to different conclusions, please make changes in the manuscript accordingly. Please, if the authors disagree with the suggested approach, give us some thought about it.

RESPONSE: Thank you for providing suggestions to improve our presentation of study results. Your comments regarding the comparison of maintenance programs (Table 1) made it evident that we should present the p-values in Table 1 along with the data. In the original manuscript, we include in the results section text (page 11) a statement that ‘no statistically significant differences were found between program outcomes”. Table 1 has now been revised to include these statistical values and instead of reporting SE, we have included SD. We find that some journals prefer one over the other and we have
accommodated your request for SD. Please note that in the ‘Statistical Methods’ section, we stated in our original manuscript that “t-tests or their equivalents were used to assess differences between means”.

With regard to your suggestion for including an ‘effect size measure, such as partial eta square’, I’ve consulted with the statistician who is a co-author on this paper. While we can certainly include outcomes expressed as ‘effect size’, the statistician believes that partial eta square may not be well suited for this study. In these types of pilot studies, researchers report effect size defined as the ratio of the mean change (or regain) between treatment and control groups, relative to the standard deviation of changes (or regain). Many other weight loss and weight loss maintenance studies have included effect size data, but without a control group, we are limited to comparing the two pilot maintenance programs, or simply comparing the magnitude of weight maintenance with outcomes in other studies. We used t-tests in comparing differences in mean weight changes/weight regain between two study arms. However, we also calculated the amount of variation explained by the interventions using simple linear regressions (equivalent to t-tests) and proportions of variation explained were very small, ranging from 0.04% to 3%.

Based on your comment, we have added text to our discussion that refers to the effect size calculated from comparing outcome differences between our two programs.

**Minor Essential Revisions**

Table 1 – Please, consider change “Weight Change” and Weight Regain” to “Weight Change (kg)” and “Weight Change (kg)”

RESPONSE: Edits were made as you’ve suggested.