Author's response to reviews

Title: Weight-Loss Intervention Using Implementation Intentions and Mental Imagery: A Randomised Control Trial Study Protocol

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Author's response to reviews: see over
RE: Letter in response to reviews reports

Thank you for the email addressed on the 17 February 2015 and 06 January 2015 and the review comments in relation to the manuscript entitled “Weight-Loss Intervention Using Implementation Intentions and Mental Imagery: A Randomised Control Trial Study Protocol” for consideration for publication in BMC Public Health. The protocol paper manuscript is co-authored with Sebely Pal and Martin Hagger. This cover letter addresses the reviews comments as required to further the application. Please refer to page 6 which outlines and addresses the most recent reviewer comments as per the email dated on the 17 February 2015.

The trial is registered on the Australia and New Zealand Clinical Trials Registry (Trial registration number ACTRN12613001274763; Trail registration date 19/11/2013). The trail submission date was the 21 October 2013, and registration date 19 November 2013. The study protocol has been submitted to, reviewed, and approved by Curtin University Human Research Ethics Committee (Approval no.: HR 137/2013). This has been acknowledged in the manuscript. Copies of the ethical approval document were emailed to BMCSeriesEditorial@biomedcentral.com on the 30 July 2014. The ethics review documents relevant to when the study was reviewed by an internal panel of researchers at Curtin University was also emailed on 04 August 2014.

No external funding has been received for the conduct of the study and no other publications have been submitted or are currently under review resulting from the study. We declare we have no competing interests and I would like to clarify that there are no published or submitted publications containing any study results to any journals. The manuscript has not been submitted for publication or published in its current form elsewhere. I would like to confirm that the submitted protocol is for an ‘ongoing’ study. We are currently in the process of recruiting participants and collecting the data.

The research reports the study protocol for the HEALTHI (Healthy Eating and Active LifesTyle Health Intervention) Program, a 12-week randomised-controlled weight-loss intervention that adopts two theory-based intervention techniques, mental imagery and implementation intentions, shown to be effective in promoting health-behaviour change. The effectiveness of goal reminder
text messages to augment intervention effects will also be tested. The trial will determine the effects of a brief, low cost, theory-based weight-loss intervention to improve dietary intake and physical activity behaviour and facilitate weight-loss in overweight and obese individuals. The research is original and makes contribution to the area of obesity as it adopts a theory based intervention to test the unique and interactive effects of multiple intervention components on biomedical, behavioural, and psychological outcomes. Furthermore, the study has been designed to maximise applicability to real world settings and could be integrated into existing weight management practices.

06 January 2015 Reviewer comments

The necessary changes have been made within the manuscript. Please note that the manuscript has page numbers starting with page “0” for the title page.

Reviewer 1: Philip Brantley J

REVIEWER’S COMMENT 1 and 2 state that the topic would interest readers and does targets a major public health concern. Also stated was that the primary and secondary outcomes are clearly identified and appear appropriate for this study.

REVIEWER’S COMMENT 3: I would ease off the soap box on theoretical models a bit. Paper seems to be setting up a straw man concerning health psychology’s lack of theory driven treatment. I realize it is good grantsmanship to emphasize one’s theory driven approach, however, weight loss interventions have always been based on theory, just not on a single theory. We do not take time in intervention studies to remind the reader of the theoretical foundations of our procedures; most treatment journals only allow a line or two at most. It is hard to get the editors of JAMA to allow a large theory section. Interventions use a variety of components (typically the same ones proposed for the current study) and often do post-hoc analyses of the most important components of treatment. Frequency of self-monitoring and goal setting are typically most associated with successful weight loss so it is good your theoretical model dictates their use. My point is this is old wine in a new bottle and the study will use most all the same weight loss components all good lifestyle studies use. More emphasize on your novel components (e.g., use of imagery) and their theoretical model is interesting.

AUTHORS’ RESPONSE: We agree with the recommendation of Reviewer 1 and have toned down the detailed emphasis on the theoretical model leaving emphasis on the study’s novel components such as the use of imagery and their theoretical model. The reduction in the theoretical description has been made on pages 1 (lines 4-6), 3 (lines 12-14), 5 (lines 11-22), 7 (lines 18-23), and 28 (lines 3-10) of the revised manuscript.

REVIEWER’S COMMENT 4: I have concerns about the power of the data analyses. I would like to see more justification provided for expecting a “large treatment effect size” between the interventions. After all, the use of a 12 week intervention is not likely to produce large weight loss
totals; most intervention studies these days allow 20 to 26 weeks to allow for maximum weight loss. Why only 12 weeks?

AUTHORS’ RESPONSE: We based our power analysis and projected sample size on a number of studies that have found a large effect size using the same techniques as those adopted in the present study for even shorter interventions. For example, a study by Andersson and Moss’ (2011) explored a two-week intervention using mental imagery and implementation intentions to increase exercise behaviour and a large effect size was found. Another study by Prestwich and colleagues (2010) conducted a four-week intervention to promote brisk walking among sedentary individuals and found a large effect size; the study had three conditions including a control, implementation intentions and goal-reminder text messages, and implementation intentions and plan-reminder text messages condition. The current study decided a 12 week intervention should be sufficient to detect changes among conditions, and the chosen timeframe was decided on as the study aims to test how effective this brief intervention is which could later be easily administered in the health care setting. Please refer to page 26 (lines 10-15) of the revised manuscript.

REVIEWER’S COMMENT 5: The purpose/aim of this study seems to change throughout the paper. It is confusing to read in the abstract that the primary outcome is weight loss and the trial will test the effectiveness of interventions to produce weight loss…. and later e.g., in the Discussion Section, to read that the purpose of the study is to promote adherence with diet and physical activity guidelines.

AUTHORS’ RESPONSE: Thank you for the comment, in response we have gone through the article systematically to ensure that all of the aims and reference to the primary outcomes are consistent. Specifically, we have reworded a sentence within the “Discussion” section on page 26 (lines 19-21) to clarify the study aims and to provide consistency throughout the document.

REVIEWER’S COMMENT 6: The procedure for the interventions could benefit from some clarity. What happens after all participants watch the initial video? I get the weekly text message component but what about the implementation Intentions and mental imagery components? What are these (table2?), how are they carried out and by whom? Do participants in the intervention watch a second movie on the same day as the first movie to learn all this material? What procedures are in place to help guarantee treatment integrity? My manuscript pages are not numbered so maybe a page is missing.

AUTHORS’ RESPONSE: This necessary information has been added within the revised manuscript which now has page numbers for easy reference. Please refer to pages 11 (lines 11-15), 13 (lines 16-20), and 14 (lines 6-7).

Reviewer 2: Kate Jolly
REVIEWER’S COMMENT 1, 4, and 5: The protocol paper is rather long and has quite a bit of repetition and could benefit from some trimming. I can see from the trial registration that recruitment should be virtually complete, so will not make comments on the methods (comment 1). Page 10: The start of the section ‘The present study’ repeats points that were made earlier on page 6. They do not need to be repeated (comment 4). Page 9/10 ‘summary of intervention’ really summarises the design and the intervention. I think everything in it is covered elsewhere and it could be omitted (comment 5).

AUTHORS’ RESPONSE: Many thanks for the comment, we agree and have made changes to remove unnecessary content from the manuscript such as the overemphasis on the theoretical rationale (see also Reviewer 1’s similar comment). In addition, repetitive information within the sections “The present study” on page 7 (lines 18-23) and “Summary of intervention” on pages 9, (lines 8-23), 10 (lines 1-8), and 28 (lines 3-10) was omitted. Some information under “The present study” subheading on page 8 (lines 1-23) remained as we considered this to be an important summary, as prior to this paragraph, the literature review discussed aspects of the weight-loss intervention only. Some of the information from the sections which were deleted that was deemed necessary was rewritten in other sections; this includes the information added on pages 8 (lines 10-13), 9 (lines 3-5), 11 (lines 8-9 and 11-15), 14 (lines 16-21), and 28 (lines 16-18) in an attempt to reduce the repetition and shorten the article.

REVIEWER’S COMMENT 2: Early in the article you need to explain what intervention intentions are; this is a public health journal, not a psychology journal, so understanding should not be assumed.

AUTHORS’ RESPONSE: We agree and have altered the manuscript so that an explanation of implementation intentions appears earlier on in the article. The changes have been made within the abstract section on page 1 (lines 9-11) which explains that implementation intentions are a behaviour-change technique based on planning.

REVIEWER’S COMMENT 3: Justify why you selected the two primary outcomes and why two, rather than one.

AUTHORS’ RESPONSE: The reviewer has raised an important point and only one primary outcome has been selected which is changes in weight (kilograms). These changes have been made on page 2 (line 1) and 10 (lines 12-13).

REVIEWER’S COMMENT 6: The section on basal metabolic rate and the Katch-McArdle formula is not quite clear. Whilst you explain that the age, gender and weight of a person is used for the calculation, the formula given uses none of these parameters. This needs clarifying.

AUTHORS’ RESPONSE. Reviewer 2 commented that the section on basal metabolic rate and the Katch-McArdle formula was not clear thus the unnecessary information which was causing confusion has been omitted to address this issue; please see page 16 (lines 4-5).
REVIEWER’S COMMENT 7: In the section describing the intervention, it would be useful to know the duration of the video for each intervention and control group. How long does the session take, with the If-then planning etc?

AUTHORS’ RESPONSE: More information regarding the video duration for the three conditions has been included within the “Procedure” section on page 13 (lines 16-20) describing the intervention. Please note that Reviewer 1, comment 6, highlighted that the procedure for the interventions could benefit from some clarity and thus changes were also made on pages 11 (lines 11-15), and 14 (lines 6-7).

REVIEWER’S COMMENT 8: In the statistical analysis section (page 25), it would be helpful to describe how you intend to deal with missing data?

AUTHORS’ RESPONSE: Information regarding the method to be used to deal with missing data has now been incorporated within the “Statistical analysis” section on page 26 (lines 3-6).

REVIEWER’S COMMENT 9: In the discussion there should be some acknowledgement that given the large number of questionnaires, only motivated and potentially compliant people are likely to take part and complete the study. This will lead to issues of generalizability.

AUTHORS’ RESPONSE: The “Discussion” section on pages 27 (lines 14-23) and 28 (lines 1-2) now mentions these generalizability issues. That is, “a large number of questionnaires and assessments completed by participants may have the potential to introduce considerable response burden on participants and lead to increased measurement error and affirmation bias. Furthermore, it is possible that only motivated and potentially compliant people will be likely to persist with the study introducing bias to the eventual findings. As with all research the number of measurements selected is a trade-off between collecting adequate data to evaluate the effectiveness of the intervention relative to participant burden and demand. However, it must be stressed that we have put a number of strategies in place to manage the issue of participant burden and allay associated confounding effects. Specifically, during the video intervention manipulation participants will be encouraged to take as many breaks as needed and have the opportunity to pause the video at their own volition. In addition, following the first appointment most of the measures and assessments will only be completed relatively infrequently i.e. at six-week intervals.”

REVIEWER’S COMMENT 10 and 11: Table 2: the definition of outcome expectancies could be more clearly defined (comment 10). Appendix A: please define ‘major illnesses/diseases’ more clearly. Perhaps give an example of what would and would not constitute an exclusion (comment 11).

AUTHORS’ RESPONSE: The definitions of “outcome expectancies” within Table 2 on page 2, and the term “major illnesses/diseases” within Appendix A on page 1 (lines 16-21) have been modified to provide more clarity.
REVIEWER’S COMMENT 12: Page 5 penultimate line of ‘diet and physical…’ activity para: should be calories per serving.

AUTHORS’ RESPONSE: This change has been made within the “Diet, and Physical Activity, and Weight Loss” section on page 4 (line 8).

REVIEWER’S COMMENT 13: Page 5: the paper by Mitsui has a small sample size. It might be better to use a trial of larger sample size and higher quality as an example.

AUTHORS’ RESPONSE: Thank you for this comment. When re-reading the section it was found that the example was not very relevant and thus this reference has been deleted from the paragraph as shown on page 4 (lines 13-16).

17 February 2015 Reviewer comments

Reviewer 2: Kate Jolly

REVIEWER’S COMMENT 1: The authors have made satisfactory changes to the manuscript. I note that the registered primary outcomes on the Australian and New Zealand Clinical Trial Register are body weight and body fat percentage. I think that a change to a single primary outcome is acceptable provided that you have not started to analyse the data.

AUTHORS’ RESPONSE: Thank you for this comment. Please note that the data analysis has not yet commenced.

REVIEWER’S COMMENT 2: Page 11, line 9: I think you did mean 12 week study (not intervention).

AUTHORS’ RESPONSE: On Page 11, line 9, the word “intervention” was deleted and instead replaced with the word “study.”

REVIEWER’S COMMENT 3: In figure 2 the arrows have slipped and need to be corrected. There are 2 arrows going nowhere and I wonder whether a box is missing?

AUTHORS’ RESPONSE: In Figure 2, I have found that the arrows all appear to be correct in my word document, however when the document is uploaded on the website the preview button does show the error described in the above comment. I have changed the document format to a PDF as this was the only method that could correct for this formatting error. Thank you for this comment.

Thank you for the reviewer comments and I hope that the revised manuscript addresses the concerns. If you require any further information please do not hesitate to contact me.
Yours sincerely,

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