Author's response to reviews

Title:"Not just another walking program": Everyday Activity Supports You (EASY) Model - A pilot study for a parallel randomized controlled trial

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Author's response to reviews: see over
Thank you for reviewing our manuscript and for the comments and suggestions that make it stronger. Below we respond to the Editor’s and Reviewers’ comments, and highlight the changes in the manuscript in bold font.

Editor's Comments

"Minor amendments identified by Lucas Carr (Referee 1) in his review, and the following additional minor amendments from me:

RESPONSE AND ACTION: We outline the responses to Referee 1 in the section below.

1. Figures 1 and 2 should be the other way around, as the current Figure 2 is referred to the text (line 235) prior to the current Figure 1 (line 375).

RESPONSE AND ACTION: Thank you for pointing this out; we made the change to the manuscript and Figure legends.

2. Line 377 - M is not a standard abbreviation for mean, and it is better to write mean in full. This follows through to the tables too.

RESPONSE AND ACTION: We made these changes throughout the manuscript and in the tables.

3. The clarification of the p values given in Table 3 is helpful, but a little further clarity is needed in the manuscript. Is it only the p-value that's derived from analysing the log-transformed data or is the reported model R squared and beta coefficient also from this analysis? If so, it would be best to change this section to log MVPA with a footnote to explain the 95% confidence interval. If not, a footnote is needed to clarify that the p-value comes from analysis of the log-transformed data.

RESPONSE AND ACTION: Thank you for the opportunity to clarify. We included more information in the statistical analysis section and added the footnote to Table 3 as suggested.

Lines 358-362, Page 17

The P-values and model R^2 values for MVPA and step counts were obtained from analyses of log-transformed data. The beta coefficients, however, were obtained from analyses of original data to allow for interpretation of treatment effects as the arithmetic mean of the differences in MVPA and step counts between the two study groups.

Table 3 footnote

MVPA=moderate to vigorous physical activity; *P values and Model R^2 for MVPA and step counts were obtained from log-transformed data; **95% CIs were estimated from original data using nonparametric bootstrapping with 1000 resamples and random seed set to 1234; all other values were obtained from original data.

4. There is a reported p-value of 0.000 in Table 4 (weight adjusted for baseline). An actual value of zero is not possible, although rounding in software may suggest otherwise, and small p-values should be reported as <0.001.
RESPONSE AND ACTION: Thank you, we made this change to the table.

5. The CONSORT flow diagram is very useful, although a little confusing. For example, it looks rather odd to have N=0 lost to follow-up, but then n=3 discontinued control and n=1 discontinued intervention. The result is that it's difficult to marry up the numbers in the flow chart with the text. This should be revisited.

RESPONSE AND ACTION: We recognised that the previous formatting was confusing. We reviewed the flow diagram, and compared it with the CONSORT Statement and made the following two changes: (1) made the Lost to Follow-up and Discontinued intervention as the same level and font size; and (2) capitalized the N to show that these are two separate items reported.

6. Whilst both reviewers have expressed some concern over the primary objective of assessing recruitment and retention, it would not be appropriate to make any changes to this objective in the manuscript. The manuscript could be strengthened a little further by extending the discussion of the limitations in this regard, highlighting how the assessment of recruitment and retention in this particular pilot study helps to inform the design of the proposed effectiveness trial.

RESPONSE AND ACTION: We appreciate these comments and suggestion and added the following sentence to the Discussion.

Lines 479-484, Pages 22-23

as participant recruitment and retention to guide the development and planning of the next phase of this research (e.g., interest in the study, feasibility of delivering the intervention, estimating a sample size for the larger study). Although our current strategies were successful in enrolling participants in a short time period, a recruitment strategy that included a known sampling frame (such as with a workplace intervention) would provide additional information to guide future studies. Second, the difference in outcomes between
Reviewer 1

Title: "Not just another walking program": Everyday Activity Supports You (EASY) Model - A pilot study for a parallel randomized controlled trial

Version: 2 Date: 22 September 2014

Reviewer: Lucas LC Carr

This is a good pilot study that tests the feasibility of a physical activity promotion program targeted to older females. Overall, the paper is well written and the methods and statistics are sound. The reviewers partially responded to the reviewer’s previous comments. Some concerns remain:

Major compulsory revisions:
1. The authors failed to explain and or justify why they chose to focus on the retention and recruitment data as the primary outcome as opposed to a secondary outcome. This is unclear, especially considering they collected health and physical activity data. Reporting that the research team was able to utilize all outcome measurement instruments does not seem to be a primary outcome that advances the literature. Given this is a physical activity intervention, it would seem prudent to list the physical activity and health data as primary outcomes and the feasibility data as secondary outcomes.

RESPONSE AND ACTION: Thank you very much for your very helpful comments that strengthen our paper. We added the following sentence to the Discussion.

Lines 479-484, Pages 22-23

as participant recruitment and retention to guide the development and planning of the next phase of this research (e.g., interest in the study, feasibility of delivering the intervention, estimating a sample size for the larger study). Although our current strategies were successful in enrolling participants in a short time period, a recruitment strategy that included a known sampling frame (such as with a workplace intervention) would provide additional information to guide future studies. Second, the difference in outcomes between

Minor Essential Revisions
2. Line 296 – Please clarify the details of the satisfaction scale (0 = ???; 10 = ???).

RESPONSE AND ACTION: We added the following information to the manuscript.

Lines 298-299, Page 15

program (scored out of a possible 10 points, where 1 was not satisfied and 10 was highly satisfied).

3. Line 413 – Clarify that this may be the first intervention to target reduced sitting in middle-aged women, not just middle-aged adults.

RESPONSE AND ACTION: We change the manuscript to specify the population.

Line 417, Page 20

To our knowledge, the EASY model is the first intervention in middle-aged women to specifically target reduced sitting time as a catalyst for engaging in more physical activity.
4. Line 415 – It is arguable that interest and enthusiasm were clearly demonstrated in the program given both groups had the exact same score on the satisfaction scale. This would suggest these participants were equally interested in the treatment program as they were not receiving the treatment. The language needs to be tempered on this topic and discuss reasons why both groups provided such high an equal ratings.

RESPONSE AND ACTION: Thank you, we expanded on the high level of satisfaction within both groups.

Line 421, Page 20
Specifically, participants in both groups had a high level of satisfaction with the program and we retained 92% of intervention group participants at six months.

Lines 449-451, Page 21
The control participants who remained in the study had a highly level of satisfaction, which may reflect group interactions with other study participants, and/or program organization and delivery.

5. Line 452 – The authors state “our objectives were to assess the effect of the intervention on physical activity and health outcomes.” Please revise to indicate these were additional or secondary objectives.

RESPONSE AND ACTION: We changed the manuscript to clarify the secondary outcomes.

Line 458, Page 22
Our secondary objectives were to assess the effect of the intervention on study participants’ physical activity and health outcomes.

6. It is still unclear what ‘Activity 4-1-1-1’ means. Given the authors came up with this program, it is necessary to clearly define each component.

RESPONSE AND ACTION: Thank you for the opportunity to provide the clarification to our individual sessions. We included the following sentences in the revised manuscript.

Lines 240-244, Page 12
The Activity 4-1-1 was the individual time that study participants had with an exercise professional to discuss their progress to date, goals and individual walking (step count) prescription. We called the individual time spent with the exercise professions as Activity 4-1-1 because, it was the opportunity that study participants could seek activity “information” from the exercise professionals.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

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
Reviewer 2

Title: "Not just another walking program": Everyday Activity Supports You (EASY) Model - A pilot study for a parallel randomized controlled trial

Version: 2 Date: 18 September 2014
Reviewer: Graham Baker

GENERAL COMMENTS

I feel that the authors have made a commendable effort in addressing the comments suggestions made by the editor, the other reviewer and myself. On the whole the revised manuscript addresses these in a comprehensive fashion and specifically I am satisfied with the changes the authors have made in response to all but one of my comments (see below under major compulsory revisions). I have also reviewed the additional useful comments made by the editor and other reviewer and conclude that the authors have addressed these in a satisfactory manner in my opinion. In any instances where the authors have not revised the manuscript according to a reviewer/editor suggestion then I believe the authors have provided a sufficient justification for not doing so.

The revised manuscript provides greater justification for the study to target older women using the intervention approach adopted. There is greater clarity as to the ultimate aim of the intervention and how this is being evaluated from a theoretical perspective.

I do feel that the manuscript has merit in publication given the specialist nature of this journal in publishing pilot and feasibility studies. I would also consider that this revised manuscript achieves the 7 guidelines that the journal suggests a reviewer adopts, with the exception of guideline 5 in relation to the suggested major compulsory revision below.

MAJOR COMPULSORY REVISIONS

1. In my opinion there is one outstanding issue that I feel still needs to be fully addressed by the authors; that is the potential of the data collected during the study to address the primary research objective (related to feasibility) of assessing recruitment and retention rates.

I appreciate that in this revised manuscript the authors have provided the retention statistic of individuals who completed the study, and that data displayed in text and in the CONSORT diagram has been collected to demonstrate participant flow through the study. I also appreciate that the authors now make the distinction between what is judged as successful in terms of recruitment to allow this pilot study to be conducted and successful recruitment for a larger trial (p14 of manuscript).

However, I still believe that the authors have not collected, or at least displayed here, any data that would allow them to calculate actual recruitment rates which they state is their
main research objective (see pages 9, 14 of revised manuscript). Therefore, whilst a final number of individuals participating in the intervention from initial responses to the recruitment campaign, and underlying reasons for drop-out, is useful information I am unable to determine whether achieving any subsequently calculated sample size would be achievable. Additionally I do not believe the authors have really assessed the feasibility of recruiting individuals and would be able to confidently predict how to recruit participants in a larger trial. For example, there is no information on the “neighbourhood” that recruitment was focused on – how many residents live there (according to local statistics) would have been useful to know. One question that arises is, if it was collected from individuals, how they heard about the study? Was it from the posters or the newspaper adverts and how many of the recruited participants were from that neighborhood if the newspapers adverts went wider. These data are necessary in calculating recruitment rates, assessing feasibility of conducting a large-scale trial and also providing the necessary insight for the authors to design this larger trial.

However, I do not feel that this issue around recruitment rates is sufficient for the manuscript not to be published, as there are several important components to pilot and feasibility studies that this study also addresses. Nevertheless, if the authors’ primary objective is to assess feasibility for the purpose of conducting a future larger trial I do not think they cover this issue satisfactorily in this revised manuscript. If the above information has not been collected then I feel this should be acknowledged as a limitation and potentially a revision of the main aims of this particular manuscript. I do not think that the main finding that the authors “demonstrated interest in our study” is a satisfactory conclusion. Can the authors conclude that it is feasible to conduct this intervention on a larger-scale?

Level of interest: An article whose findings are important to those with closely related research interests
Quality of written English: Acceptable
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

RESPONSE AND ACTION: Thank you very much for your thoughtful review of our paper. We added the following information to the limitations section in the Discussion.

Lines 479-484, Pages 22-23

as participant recruitment and retention to guide the development and planning of the next phase of this research (e.g., interest in the study, feasibility of delivering the intervention, estimating a sample size for the larger study). Although our current strategies were successful in enrolling participants in a short time period, a recruitment strategy that included a known sampling frame (such as with a workplace intervention) would provide additional information to guide future studies. Second, the difference in outcomes between