Author’s response to reviews

Title: Relating process evaluation measures to complex intervention outcomes: findings from the PACE-UP primary care pedometer-based walking trial

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We have also attached a letter with these details in.

Reviewer 1:

My main comments are in relation to the conclusions in the discussion. At line 18 on page 10 the authors comment that one of the novel aspects of their study in the inclusion of 2 perspectives;
nurse intervention delivery and the participant responsiveness. However, I feel this is an over-representation of the process measures. Although the nurses recorded the sessions attended, the number of session attended seems to be another factor relating to participant responsiveness. In addition all three of these process measures would seem to relate to participant motivation - although the authors make it clear that they are reporting on an association and not causality. There would be value in directly commenting on this particular issue in the paper. Do they have any information from their qualitative study which may support or refute this?

Response:

We thank the reviewer for this helpful comment. We have changed the wording in line 18 page 10 to make a more objective description of who the data were collected from. We have also added a comment to the limitations paragraph of the discussion to directly address the issue raised by the reviewer, that although data on nurse attendance were collected by nurses, the number of sessions attended relates most strongly to participant responsiveness. We have also taken on board the reviewer’s suggestion to provide more information on how the qualitative evaluations form both the nurses and participants’ perspectives supports our findings that the pedometer, the PA diaries and the nurse appointments were all important intervention components.

Location of changes in manuscript: Page 10 & 11 Strengths and limitations paragraph.

Reviewer 2:

1) Abstract:

Please be aware that there seems to be several inconsistencies between the numbers in the abstract and table 3:

- 605 is the total weekly minutes of MVPA after 3 months, daily step count after 12 months is 74?

- The 95% CI is 20161 in the abstract and 2061 in table 3 (Postal group: YES vs. NO).

- nurse 47 (95% CI, 17, 75) is nurse 47 (95% CI, 18, 75) in table 3.

- MVPA 47 (95% CI, 17, 75). is MVPA 47 (95% CI, 18, 75) in table 3.

- and 606 (95% CI, 22, 1990), is and 606 (95% CI, 22, 1190) in table 3.

Response:
We have rewritten the abstract and table 3 correcting the discrepancies with the text.

Location of changes in manuscript: Abstract page 2, Table 3 page 18

2) Background:

Good background section: concise and to the point.

On p. 3, l. you write: "Without evaluating the processes of the intervention, it is impossible to assess the validity of the contribution of an intervention to the research outcomes." This is a quite strong statement (cf. the word impossible) and it may apply in some areas of RCTs in public health, but not necessarily everywhere.

Response:

We agree with the reviewer that the wording was too strong and we have changed the word ‘impossible’ to ‘challenging’ to better reflect the statement.

Location of changes in manuscript: Page 3

3) On p. 3 l. 10-11 you write: "The MRC framework, developed in 2014, built on the 2008 guidance and on previous incomplete frameworks used to assess implementation fidelity (e.g., the modified conceptual framework and RE-AIM), offers the first useful tool to evaluate the entire process of a complex intervention." It is unclear to me, what you mean with: "…previous incomplete frameworks…”?

Response:

This has been changed to read ‘less comprehensive frameworks used to assess implementation fidelity alone’ to reflect that previous frameworks are not incomplete, however do not address process evaluation as a whole, but specifically fidelity.

Location of changes in manuscript: Page 3

4) On p. 3, section 2 (l. 18) begins quite abruptly, a little more context and framing could be useful.

Response:

Wording has been amended to address this, hopefully this now frames the section more appropriately.
5) p. 3. L. 59. What is "…usual care"? (Important, cf. PMID: 24609605 p. 4, l. 40-41.

Response:
Changed the term ‘usual care’ to ‘control’ as this is how we refer to this group throughout text.

Location of changes in manuscript: Page 4

6) What is HTA?

Response:
The Health Technology Assessment (HTA) full name is now included in the text.

Location of changes in manuscript: Page 4

7) Discussion:

It is a good and adequate discussion. In the background, you mention the RE-AM framework (PMID: 23597377), which is a very useful conceptual tool when it comes to important aspects of public health interventions. Looking at your table 3, a question here is if the difference between 3 and 12 months could be seen as a case of ‘declining effects’? This could direct attention towards the 'Maintenance' part of the RE-AIM and the whole question of the sustainability of interventions (PMID: 22417162).

Response:
We thank the reviewer for their very helpful suggestion that we comment on the reduction in effect between 3m and 12m, particularly for the nurse intervention group and the opportunity that this affords us to comment on the importance of considering maintenance of intervention effects and linking this back the RE-AIM framework. We have added a comment to the section on comparison with other literature and we have included the new reference suggested by the reviewer.

Location of changes in manuscript: Page 11 Comparison with other studies and new reference 21.