Reviewer’s report

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

Version: 0 Date: 20 Nov 2017

Reviewer: Anders Hansen

Reviewer's report:

I would like to thank the authors for this well written paper requiring further detailed attention to reporting. The authors may wish to consider the following points:

Specific comments

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.

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…

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…"?

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

Methods:

Good and clear section.

p. 3. L. 59. What is "…usual care"? (Important, cf. PMID: 24609605).

p. 4, l. 40-41. What is HTA?

Results:

No comments, very clear.

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).

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