Reviewer’s report

Title: Operationalizing a model to quantify implementation of a multi-component intervention in a stepped wedge trial

Version: 0 Date: 11 Aug 2017

Reviewer: Nancy Salbach

Reviewer’s report:

IMPS-D-17-00301

An operationalized model for quantitative evaluation of implementation in multicomponent Interventions

Manuscript Review

Overall comments

In this paper, authors address the challenge of describing the implementation of a multi-component intervention and in doing so highlight the complexity of a quantitative process evaluation. The proposed model, its operationalization in the context of a stepped wedge trial, and the findings make a valuable contribution to the implementation science literature. The model and its operationalization make explicit the steps that can be taken in the design phase to comprehensively document implementation for later reporting. Authors should consider the following suggestions for improving the manuscript and uptake of the proposed model.

Title

1. Consider rephrasing to something like "Operationalizing a model to quantify the implementation of a multi-component intervention in a stepped wedge trial"

Abstract

2. Consider framing the relevance of the study as part of a process evaluation and mentioning the aim of the stepped wedge trial.

Background
3. Supportive references are needed for several statements, for example p 5, line 7, 16, 19, 33, 36. There were no page numbers in the manuscript, page numbers in this review refer to page numbers in the pdf file generated with submission.

4. Consider highlighting the challenge of how to quantify variable participation of individuals within sites across learning sessions in cluster randomized trials in which the intervention is implemented at the site level as one problem the proposed model attempts to address.

Methods

5. Authors describe the responsiveness of participants to the intervention. Responsiveness may relate to how the intervention was designed to act (proposed biological mechanisms), and effectiveness of the intervention in comprehensively addressing barriers to behaviour change. To evaluate this, some investigators measure proposed intermediate outcomes or mediators, such as knowledge and self-efficacy, using validated tests or questionnaires. Authors may wish to explain in the Background why a different method than measuring intermediate outcomes is needed to justify the study.

6. Understanding the terminology used throughout the manuscript is a major challenge. This problem could be mitigated in a number of ways:

   a. Authors should determine whether they have proposed a "model", a "step by step model" or a "step by step guide" and use the term consistently.

   b. Terms used in Table 1 should align with terms used in the methods and in Figure 1.

   c. Table 1 should be revised to indicate what questions were used to evaluate content vs quality, just as was done for participation vs responsiveness. Also, it would be helpful to add to the table the Responsiveness sub-constructs of "satisfaction, social support, and motivation" that authors use in the text (p13, line 36) so the table terminology aligns with the text. Further, specify in the table who completed the questionnaires (ie Participant questionnaires) just as was done for the log books.

   d. p10, line 1, "adoption of workplaces' is unclear.

   e. the order in which the variables evaluated are described should be consistent in the methods, in the tables, and in the results section.

   f. p11, lines 25-32, unclear.

   g. consider including a glossary of terms eg dose, fidelity, responsiveness, delivery, etc.

7. Authors state they designed "a multi-faceted stepped wedge randomized controlled trial" however, the term multi-faceted is better used to describe the nature of the intervention, not of the trial. Eg stepped wedge randomized controlled trial of a multi-faceted intervention
8. Steps 1-3 on pages 7-8 are more of a discussion of considerations than a step by step guide. Consider whether your guidance could be more specific (see the CONSORT checklist) about what researchers could do in different scenarios.

9. When describing the multifaceted intervention on p9, it would be helpful to indicate the group size for the PT, PT, and CBT sessions. The description on p9 implies that only 12 sessions were conducted at each of the four sites as part of the trial. By contrast, the Table 2 title indicates that a total of 753 sessions were intended to be held and authors indicate there was a sample size of 596 participants. How the authors went from 12 to 753 sessions should be more clearly outlined in the manuscript.

10. On p10, authors should indicate what the reader will find in Table 1.

11. The units of measurement for each aspect of intervention implementation evaluated are unclear. Consider adding a column to Table 1 that indicates the scoring assigned to the response categories and clarify whether the values of 0, 50, and 100 mentioned in the text (eg p11, lines 29-32) are percentages as this is unclear. Also, considering providing ranges to scores in the text. Presenting the constructs, questions, response categories, scoring, equations used to derive implementation scores for analysis in the same table may be the solution to this problem.

12. In the methods section, authors use terms "organization level" and "individual level". Provide a brief clarification in the methods section on how these levels were conceptualized so the reader can better understand the methods and results.

13. Avoid use of the term participation "rate" as "rate" often implies the incorporation of time. Instead consider using the term participation consistently throughout.

14. p13, line 46, "Likert" scale refers to a scale of agreement, would simply describe this as an ordinal scale.

15. The analysis is difficult to follow and this can limit uptake. I don't find Figure 1 particularly helpful mainly as it doesn't align with Table 1. I've suggested above to centralize the information in a table and perhaps constructs and calculations at the organization and individual level could be categorized there. In addition, consider revising certain equations to yield percentages instead of proportions as most of the results are percentages. Number of decimal places used for calculated percentages should be consistent (see p15 line 20 vs line 32).

16. P 14, line 43, should Dd be the "number of sessions delivered" not the "proportion" of sessions delivered?

17. Analyses, p17. The use of PCA was surprising because it was not linked to a study objective, are authors suggesting that all researchers do this as part of operationalizing the proposed model?

Results
18. Table 4. Are these results at the organizational level? If yes specify in title as was done for Table 3 title.

19. p19, lines 39-41: specify general overestimation of what?

Discussion

20. The statistical results indicate differences existed across delivery timing for fidelity and intervention components but why and how this occurred is unclear. Consider adding some discussion about the important role of qualitative methodology in process evaluations of complex interventions to complement the described quantitative approach. Also consider discussing how the results should be used to revise the program theory initially outlined, as per a realist approach.

Level of interest
Please indicate how interesting you found the manuscript:

An article of importance in its field

Quality of written English
Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?
If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

I declare that I have no competing interests

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal.