Reviewer’s report

Title: Fidelity and moderating factors in complex interventions: A case study of a continuum of care program for frail elderly people in health and social care

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Reviewer: Wendy Hardeman

Reviewer’s report:

This study aims to evaluate implementation fidelity, factors moderating the relationship between interventions and fidelity and their relationship to one another, in the context of a care continuum intervention for frail elderly people. I enjoyed reading the manuscript which is a useful contribution to the literature about intervention fidelity. A key strength is the use of multiple methods to capture the delivery of a complex multi-component intervention. The authors provide a range of helpful insights into the delivery of complex interventions in practice and the relationships between the moderating factors, and they are well aware of the limitations of their study. A key weakness in the current manuscript that needs to be addressed is the lack of detail about the methods used for observation, interview and document analysis, which limits the extent to which others can replicate the study.

- Major Compulsory Revisions

1. Background, 2nd paragraph. The authors state that ‘fidelity acts as a potential moderator of the relationship between interventions and their intended outcomes’. The framework depicted in Figure 1 depicts fidelity as a mediator rather than a moderator of the relationship between intervention and outcomes. This needs to be clarified.

2. Background, 3rd paragraph. It would be helpful to provide a few more details about the care continuum intervention at this point, including study design and any findings. For instance, did fidelity predict patient outcomes?

3. Methods, data collection and analyses, 1st paragraph. I wondered why data collection stopped during the middle phase of the intervention. Please explain why the conceptual framework for implementation fidelity was modified, and why these six moderating factors were selected.

4. Methods, data collection and analyses, 2nd paragraph. Please provide more details about how practices were selected for observation. Did the researcher shadow the case manager? More details about the sampling, recruitment and consent procedure for the interviews would also be helpful. I wondered why the elderly participants themselves were not interviewed. Finally, more details of how data were extracted from relevant documentation are needed.

5. Methods, data collection and analyses, 3rd paragraph. The authors mention that they used the modified framework as a coding scheme. It would be helpful to have more details about how data was extracted for each of the six moderating...
factors, giving examples of items if appropriate and scales used (e.g., frequency or quality). Could the authors quantify the ‘high level of agreement’?

6. Methods, data collection and analyses, 3rd paragraph: It is unclear how the authors assessed adherence (content, coverage, frequency, duration).

7. Results, complexity and facilitation strategies: Hospital sites and municipality sites reacted differently to the amount of information available, with indications that the municipality sites adapted the intervention more than the hospital sites. This made me wonder to what extent this was desirable; was the study pragmatic or explanatory? Which intervention components were core and which were optional? Perhaps the authors could add a few more details to the introduction so that the reader can put these findings into context.

8. Results, evaluation of adherence: There seems to be overlap with the moderating factors, which made me wonder about the conceptual distinction between adherence and its underlying factors. Did the authors quantify adherence at all?

9. Discussion, 1st paragraph: The authors recommend that others use the conceptual framework of implementation fidelity. It would be helpful to read their reflections about which aspects were particularly useful or perhaps less useful.

10. Discussion, responsiveness. The discussion is restricted to staff delivering the intervention; earlier on (results, recruitment) the authors mention that the intervention did not seem to reach those most in need. I feel that this is an important issue to discuss.

11. Discussion of moderating factors. The authors offer helpful insights into relationships between the moderating factors. Having conducted the study, are any factors particularly important in the authors’ opinion? The authors mention that weaknesses in some factors may be compensated by strengths in other factors, but I wondered whether this is the case for all factors. If there were limited time and resources, which factors should be prioritised for assessment? I also wondered to what extent the findings of this study generalise to other complex interventions.

12. The authors discuss the moderating factors in detail but do not seem to discuss the assessment of adherence (content, coverage, frequency and duration) in much detail. For instance, how useful are the four dimensions of adherence, and could the authors make any recommendations about how to measure adherence in future complex intervention studies?

- Minor Essential Revisions

13. Methods, study design: What did the control group receive?

14. Methods, description of the intervention, 2nd paragraph: the authors refer to a Table 3 which does not exist.

15. Results: I would prefer reading the findings about levels of adherence first, followed by the findings about moderating factors. This would help to put the latter in context.

16. Results, context. The authors use the abbreviation PC for primary care, but
the sentence suggests that this is a person rather than a setting.

17. All abbreviations used in the tables need to be either written in full or explained in a footnote.

- Discretionary Revisions

18. Background, 2nd paragraph. The authors state that program adaptations involve modifications of content or form. They provide a helpful overview of a range of factors that may impact on fidelity, and I wondered whether these could be grouped under either content or form.

19. Methods, data collection and analyses, 1st paragraph: I found the recommendation to assess all intervention activities if no active ingredients have been identified interesting. It is challenging to identify active ingredients of complex interventions like the one reported in this manuscript. I have a similar comment in relation to the statement that quality of delivery can only be measured of an external benchmarking has been established. As far as I’m aware there is no agreement in the literature about the optimal degree of adherence or competence of delivery. I would be interested to hear the authors’ views.

20. Discussion, 2nd paragraph: Enthusiastic staff may add components that either enhance or dilute the effectiveness of the intervention, so I would recommend that future studies assess both positive and negative impact of adaptations on program outcomes.

"Minor issues not for publication"

21. Results, recruitment: change ‘inclusions’ to ‘inclusion’.

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.