Reviewer's report

Title: Did the trial kill the intervention? Experiences from a randomised controlled trial of a complex intervention.

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Reviewer: Suzanne Moffatt

Reviewer's report:

This is a well-written paper on an important topic of increasing importance within health research – the experiences of participants and professionals involved in trials of complex interventions. However, the paper as currently presented is not yet ready for publication. The authors aim to explore the challenges of using an RCT to evaluate complex interventions drawing on experiences of participants and staff. Greater clarification of the methods is required, as well as a more robust results section and the discussion would benefit from reference to some of the wider literature about the problems with trials of complex interventions, eg Riley et al 2005; Rapley et al 2006; Murtagh et al 2007. As it stands, the discussion and conclusions are not adequately supported by the data as they are presented.

Major compulsory revisions

1. The authors present some information about the nature of the trial, but additional information such as the basis of the intervention, who was responsible for designing and piloting the intervention, the numbers who left the trial is required as essential background.

2. Methods

Patient Interviews – more information required. Mean length of interview, by what means were the data collected?

Professional interviews – why these five professionals? Was this because these were the only professionals involved, or were they selected? Why this range of professions? Which, if any, had greatest investment in the intervention? Which professionals had developed and piloted the intervention?

Was data saturation reached for patients and professionals?

Analysis – how were comparisons undertaken? Were the patient and prof interviews analysed separately or together? How were the main (explanatory) themes derived from the data?

3. Results

The data presented did not adequately support the results. Data from four out of five professionals was presented. Presumably for reasons of anonymity it was not possible to state which professional group the data were from. It is therefore necessary to know whether this is the number of professionals involved in the trial, or whether this is a sample of the trial professionals. The perspective of the
researchers is mentioned (p10), were there any data concerning the researchers’ perspective, and did any of the researchers had a clinical/professional role? The amount of data presented from the patients is sparse – four quotes from patients in the HPL arm and one from a patient in the SM arm. As well as presenting more data to back up the findings, more explanatory text is required to accompany these findings, and this needs to be linked in the discussion to the literature.

The authors might want to consider re-organising their data around themes that relate to patients only, professionals only and those that relate to both. In the case of the themes that relate to both, they may wish to draw out similarities and differences.

The section on organisational context contains a paragraph with several assertions, not backed up by data, followed by four quotes to illustrate these. This needs to be re-written in such a way as to incorporate the data to illustrate the assertions made, and to illustrate using patient data as well as professional (if there is patient data to support this).

4. Discussion

Includes a discussion of strengths and limitations of the study. However, there is no discussion about the degree to which these data may or may not be transferred to other settings, and no general reference to the literature on the generalisability of qualitative data.

Overall, the data presented did not adequately support the conclusions. More data and more robustly presented data are required.