Reviewer’s report

Title: Optimising trial design: pre-trial qualitative work with healthcare professionals to refine the design and delivery of a kidney care randomised controlled trial

Version: 0 Date: 04 Dec 2018

Reviewer: Marita Hennessy

Reviewer’s report:

Overall

Thank you for the opportunity to review this manuscript in which pre-trial work with healthcare professionals to refine the design and delivery of a kidney care RCT is reported. Such focus on the dissemination of qualitative research in trials is most welcome, and key to understanding and enhancing trial delivery and recruitment and retention issues.

Overall, the paper would benefit from more information on the study design, specifically the methodological orientation (e.g. ground theory analysis terminology but with descriptive themes) and use of triangulation. The inadequate reporting of such issues in qualitative research in trials has been noted (Lewin et al. 2009) and it is essential that it is addressed to ensure rigor and maintain the credibility of qualitative research in trials. Please find below, comments specific to the methodology, issues requiring clarification, and general comments.

Specific comments - methodology

1. Page 7 - Sampling and recruitment: More context on the setting, and processes, would be useful to contextualise participant recruitment. For example, where were the six sites located, how were they selected, what was the 'internal pilot phase'? The phased nature is only mentioned later in the discussion of limitations; it should appear here also.

2. Page 8, lines 5-6: The purpose of the site visits is unclear; further contextual information would be helpful.

3. Page 8, lines 13-14: There is a lot of debate about 'data saturation' in the literature. Please add a sentence or two about how saturation was defined, and decision around when saturation reached (more than just 'new insights').

4. Page 8 - data collection: In line with COREQ guidelines, the personal characteristics of the interviewer and their relationship with participants should be described.

5. Page 8 - data collection: How was the topic guide developed? Was it pilot tested?
6. Page 9, lines 3-5: 10% double-coding undertaken. Further information should be provided to support the author's actions - justification, and also procedures for undertaking and making sense of findings from the two coders. This is an area of great debate in the field.

7. Page 10 - Participants: 5 out of the 16 people interviewed were PIs/Co-applicants on the trial. Did their views differ in any way to the other 11 participants (e.g. eligibility criteria, no. of home visits, etc)?

8. Page 16/17, lines 20-2: It should be mentioned within the study design, that findings from the interviews informed/fed into other method, i.e. PPI meeting.

Issues requiring clarification

1. Abstract: The authors refer to 'introductory site visits' and 'visits to internal pilot sites', respectively in the methods and results sections of the abstract. Were the introductory site visits conducted in internal and external pilot sites? Would be useful to have context to 'internal' here. Also, it would be useful to use a standard description of the site visits, i.e. 'introductory site visits' or 'visits to internal pilot sites'. This should be applied consistently across the manuscript.

2. Page 5, lines 1-2: States that the aim of the qualitative pre-trial work was to explore the various issues from the perspective of the clinical professionals who would be delivering it. How do the observations of the patient advisory group fit with this? This also applies to the discussion on page 22 and should also be addressed in the abstract. The focus of the patient advisory group workshop should be made explicit, so it is clear to the reader what was being observed.

3. Page 6, lines 9-10: Suggest changing this sentence to focus on nurses first and foremost, e.g. "The recruitment process was designed to be led by research nurses, but multiple healthcare professionals could be involved". Were renal consultants the only other professionals involved in recruitment, or were other professionals taking the place of research nurses? This is unclear; no other professionals mentioned in Figure 3.

4. How were the ethics of observation managed by the research team?

5. Page 9, lines 6-10: Can you clarify if only findings from interviews were presented at this meeting? Were some interviews conducted after this date, seems like they might have been according to Figure 4.

General comments

1. Abstract - It would be helpful if one line on the exact focus of the 'Prepare for Kidney Care' trial was provided, for context.

2. Abstract - Methods: The term "anticipated to be involved" is used twice in relation to health professionals. Is there a better way of saying this? They were either target recruiters or not.
3. Abstract - Results; Page 8, lines 2 & 23: There is debate about the use of the term 'emerging' in relation to themes. The authors should consider re-phrasing "key themes emerging".

4. Abstract - Conclusions: The true value of the pre-trial work will be evidenced during recruitment. Perhaps the authors could add a line to this effect and any plans in this area.

5. Page 4, line 3: Insert 'in the UK' after 'publicly-funded RCTs'

6. Figures 2-5: Need better resolution images for each of these as they are difficult to read

7. Figure 3: The flow chart is a little unclear on first view. Perhaps lines instead of right arrows should be used for links to boxes that provide further information, to make it clear that this is explanatory information as opposed to a pathway?

8. Page 5, line 6: Insert 'inclusion in' before PrepareME

9. Page 6, line 3 & Page 17, lines 16-17: prepare for conservative care -> 'Prepare for conservative care'.

10. Page 7, line 20: Spell out 'CI' (first mention)

11. Page 8, lines 3-4: 'Those who agreed to take part were asked to suggest…' not just 'those who were interested'?

12. Page 10, lines 7-9: It would be useful to separate out the analysis of both observational methods (either under each method, or have another 'analysis' sub-heading, for clarity. More information on how the data was triangulated would be helpful.

13. Page 10, lines 14-15: Was there any particular reason why health professionals from 2 of the 6 sites were not invited to participate?

14. Page 16, lines 5-6: More information on this exception could be provided; what were their thoughts?

15. Page 20, line 9. It could be useful, and impactful, to include a figure with 'before' and 'after' to enable the reader to see what changes arose because of this qualitative work.

16. Page 22, section 4.3: This section could be removed completely as these issues are reported and discussed (including within the context of the literature) on page 23.

17. Page 22-23, lines 14-13: Findings should be discussed in relation to literature - commonalities with issues identified by previous research in this area?

18. Page 24, lines 6-9: The essential nature of PPI to the trial should be flagged within the introduction; this would also provide context for the chosen methodology.
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:

Acceptable

Quality of figures
All images and figures within the manuscript should be genuine i.e. without evidence of manipulation. No specific feature within an image may be enhanced, obscured, moved, removed, or introduced. If you have concerns about the veracity of the figures you should choose the first option below.

Statistical review
Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.

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

Were you mentored through this peer review?

No