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

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Reviewer: Julia Lawton

Reviewer’s report:

This is a nicely written paper which provides a useful example of how pre-trial qualitative work can be used to help optimise trial design. I do have some questions and comments which the authors may wish to consider in another iteration of their manuscript.

Whilst the paper is clear and accessible it is a little on the long side and might be read by more people if it is cut down. The authors might consider removing some quotes where health professionals say similar things; I also felt the discussion could be tightened up through a bit of editing and pruning.

The authors acknowledge (and I strongly agree) that a major limitation of this study is that they did not interview patients as part of their pre-trial qualitative work. It would be helpful to know what their thinking was at the time they designed the study and decided not to include these individuals’ perspectives.

Please consider offering a more detailed rationale for including observations from site visits and the patient advisory group in order to triangulate findings. It would be helpful for the authors to clarify what their understanding of triangulation is and why they considered it important to do this rather than just to report findings from the interviews. On a related note, I noted that in subsection 1.2 of their findings "age and health status" the authors described how health professionals, in their interviews, questioned whether certain groups of patients might be more suited to one treatment pathway over another and also how these kinds of concerns did not tend to be raised in the site visits. How do the authors reconcile these potentially contradictory findings with their claims about triangulation?

It was unclear to me what, if any, opt-in/informed consent procedures were used for the observational work undertaken as part of site visits and during the patient advisory group. Technically, for these kinds of observations to be reported as findings in a research paper, the necessary opt-in and consent procedures should have been put in place. Please clarify.

It would be extremely helpful to know how the expert consensus meeting worked. This paper, like others, is very thin on detail regarding the mechanisms and procedures used to translate the qualitative findings into tangible recommendations and I think the paper's impact and reach could be improved considerably by fleshing out the section "4. Changes to the trial design."
I was really struck by the very tight timelines for the study as outlined in figure 4. It was noteworthy, for instance, that interview findings were sent in a report to the CI whilst data collection and analysis appeared to be on-going. It would also appear that some of the initial site visits happened after the expert census meeting. I also felt that the patient advisory group workshop could have been made to work even better for the trial had this workshop been convened after all of the interviews had been undertaken and analysed and key findings shared. Given the authors’ claim about the importance and usefulness of doing pre-trial qualitative research it would be good to get their reflections on how this kind of work could be done better in the future e.g. in terms of the time needed to do the work properly, realistic costings and how to order events (e.g. timing of the patient advisory group). My impression is that this study was under-costed and it should not be used to set a precedent for future qualitative studies of this kind.

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