Reviewer's report

Title: Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers

Version: 1 Date: 5 May 2015

Reviewer: Alison Porter

Reviewer's report:

I have structured my report in line with the guidelines to reviewers on your website, rather than the spec above. Any suggestions for changes should be considered as 'Discretionary Revisions'.

1. Is the question posed original, important and well defined?
The paper addresses an important topic – how to maximise the impact of qualitative research in feasibility studies for trials. The authors define it clearly and show how the topic sits within a wider picture of research and guidance on conducting trials and on the role of qualitative research. The paper is useful addition to the methodological literature.

2. Are the data sound and well controlled?
This question is not directly relevant as this is not a paper reporting a research study.

3. Is the interpretation (discussion and conclusion) well-balanced and supported by the data?
The conclusions drawn by the authors seem reasonable and well balanced. There is no discussion section as such, but there is discussion woven through the paper. The authors findings are presented as thoughtful guidance rather than more formal recommendations or a tick box checklist, which I think is appropriate.

4. Are the methods appropriate and well described, and are sufficient details provided to allow others to evaluate and/or replicate the work?
The authors describe the collaborative process of agreeing the guidance, drawing on their experience of reviewing relevant literature (referenced).

5. What are the strengths and weaknesses of the methods?
The approach taken by the authors seems appropriate, and draws on a range of relevant expertise. The authors correctly identify that the lack of formal consensus methods is a weakness. They acknowledge that other researchers may have something useful to add to this guidance.

6. Can the writing, organisation and tables and figures be improved?
The paper is well written. I am assuming that the figure and table will be embedded in the text.
7. What revisions are requested?
On p17, the section on relationships between quali researchers and the wider study team is expressed in very cautious terms, and seems to concentrate on identifying potential problems rather than identifying solutions or ways of avoiding problems. It would be strengthened if it were a bit more directive in terms of suggesting ways to avoid problems.

Pp11-12: there is a discussion of equipoise which uses the word in a way which I have never seen before – as an attribute of the researchers involved, rather than of the study question. So, the authors discuss whether researchers are in equipoise, rather than whether equipoise exists in relation to the study question. It may be that this is grammatically correct – it just threw me slightly.

At various points (eg on p14, reference 41) the authors make reference to examples of studies. It is not clear how these have been selected. In each case the references is so concise as to be almost a passing comment. The authors may like to consider expanding on a few of these to give fuller examples of the use of qualitative methods in feasibility studies, in order to give a fuller illustration of the issues involved.

Ref 15 to Moore et al is shown as ‘in press’ – is this correct? This looks like a publication from 2013. Also worth referencing the full MRC guidelines.

8. Are there any ethical or competing interests you would like to raise?
None.

Level of interest: An article of importance in its field

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.