Reviewer's report

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

Version: 1 Date: 4 April 2015

Reviewer: Brittany Dennis

Reviewer's report:

Manuscript Review

“Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers” O’Cathain et al. (2015)

Reviewers Report

General remarks

The authors provide a useful guide detailing important ways qualitative research compliments the design and conduct of randomised trials. Due to the lack of guidance available on the conduct of mixed methods research, there is no question about the importance of any efforts to compile a users guide for performing qualitative research in the context of evaluating feasibility in trials. The manuscript is concise and well written with a logical flow of ideas. Tables 1 and 2 neatly summarize guidance for qualitative research, providing readers with a concise frame of reference. The increasing number of randomised trials for complex interventions renders the clinical relevance and implications of this research to be of high importance. I foresee this work being a piece of methodological importance and arguably conducive to the design of future trials. There are however some methodological issues requiring further clarification.

Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)

1. While the authors provide strong guidance for researchers wishing to conduct qualitative studies to assess feasibility for RCTs, they provide little detail as to how these recommendations were reached. A great deal of work was put into a review leading to these recommendations, as noted by the What can qualitative research do for randomised controlled trials? A systematic mapping review paper in BMJ Open. However, the authors only provide reference to this article. It is important to understand the evidence generation methods behind this paper and the final manuscript will benefit from a brief description of this previous work. The authors may wish to attach this in a supplementary appendix.

2. There is no discussion of the risk of bias or quality of the studies informing the guidance in this review. The authors should employ the Grading of Recommendations Assessment, Development and Evaluation (GRADE)
evidence profiles to summarize the strength of the evidence used to inform these recommendations. I acknowledge this may be unconventional since GRADE is commonly used to rate the strength of recommendations used in clinical guidelines. However, the real advantage to using GRADE is that it provides researchers a tool to disseminate evidence from systematic reviews while simultaneously providing readers an idea of the quality of this evidence.


3. The authors should consider discussing the common risk of bias tools used to evaluate qualitative studies. This will help readers gain an understanding of how their work will be evaluated, possibly highlighting some problems they may be unaware of.

4. Recommendations for conducting research may in theory seem easy to apply, however we often run into problems when attempting to fit our research within the mold set out by the guideline. The authors should consider using a case study to guide readers through the recommendations since nothing will help illuminate your message better than a strong example. I would suggest the authors think of a research question and walk readers through a step-by-step application of their recommendations.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

None

Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)

This study will be highly valuable since there is a serious lack of guidance for the conduction of qualitative research to assess trial feasibility. As such, the authors should consider and discuss the cutting edge methods used in pilot studies today. One such method includes persona-scenario exercises, which is a structured approach to evaluating and designing an intervention from different end users point of view. This is a type of role playing activity may be useful to the feasibility assessment of interventions. Please see reference below to the study describing this methodology.


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