Author's response to reviews

Title: An Audit of Sample Sizes for Pilot and Feasibility Studies being undertaken in the United Kingdom registered on the United Kingdom Clinical Research Network database

Authors:

Sophie A.M Billingham (sbillingham1@sheffield.ac.uk)
Amy L Whitehead (a.whitehead@sheffield.ac.uk)
Steven A Julious (S.A.Julious@sheffield.ac.uk)

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Author's response to reviews: see over
Associate Editor’s Comments:

Please pay particular attention to all of the comments by the reviewer. In addition, please respond to my comments below:

1. State in the abstract that you are focusing on pilot or feasibility RCTs in particular.  
Completed

2. Explain what you mean by: “The results in this paper could assist researchers in sample size justifications when designing pilot and feasibility studies. In this context we recommend the results to be applied”. Are you saying that researchers could justify their choice of sample size based on the ranges of sample sizes used in other pilot RCTs? But how do you know that these sample sizes are appropriate? To me this is a descriptive study of the observed sample sizes in current pilot RCTs, which is interesting in itself, but no recommendations can be made based on these data as to what is an appropriate sample size range.  
Changed conclusion

3. In the sentence: “we looked at if the sample sizes chosen varied between the two study types as defined by the principal investigator”: replace IF with WHETHER.  
Completed

4. “if the study was labelled a pilot of a feasibility study" OF should be OR  
Completed

5. Make clear early on in the manuscript (e.g., background section) that you are focusing in particular on RCTs.  
Inserted the term randomised controlled trial into the definitions in the first paragraph and changed the terms to trial instead of study throughout

5. Reword the research questions as descriptive, e.g., “TO DESCRIBE sample sizes for studies labelled pilot versus feasibility studies”. In addition, delete research question 2 as this is not actually addressed in the paper.  
Completed

6. Delete the paragraph following research question 4  
Completed

7. Delete the first sentence under “analysis plan”  
Completed

8. “Medians and ranges were CALCULATED” (not estimated) “overall for the different types of trial and then broken down by [factors such type of] endpoint....” - delete “factors such type of”  
Completed

9. “After discounting duplicates”: replace “discounting” by “eliminating”  
Completed

10. ”Considering the median sample sizes for pilot and feasibility studies our data shows that on average feasibility studies are larger than pilot studies.” The difference is only 6 - do you consider this to be a relevant difference? This seems to be an important conclusion of your paper as you also include it in the abstract, but the significance of this finding is not clear to me. Does it suggest that feasibility studies are actually a different type of study than pilot? Given the large variability in sample size ranges, this difference is not inconsistent with chance. Consider revising the conclusion to something like “feasibility studies have similar sample sizes than pilot studies”. Otherwise the implications of your conclusion (having “smaller” sample sizes) ought to be discussed.  
We have added a caveat that there is wider variability in the sample sizes but we do think the result is genuine. Does it suggest feasibility studies different? Personally we think not but there are some that do. Interesting to note these are only done for publicly funded trials (industry trials are in the main pilot) and if you looked just at publicly funded trials the sample
size difference between pilot and feasibility is even bigger. We think though we are drilling down to too low numbers of studies.
Any reason why would be speculation. It could be feasibility studies are less tightly controlled but we would have no way to investigate and so we would rather state the results.
Note though we have changed out conclusions a little now to say also publicly funded trials tend to be bigger (which is consistent with the results and our discussion)

11. "The total median sample size overall the types of study was 30." "Total median" is confusing. "Over all" should be two words.
Completed

12. Caption for Table 3 indicates mean but no means are presented. Delete.
Completed

Responses to Reviewer 2

The reviewer commented in the text of the pdf and we have taken on board comments – many of which were proofing. We reviewer queried why we have excluded health volunteer studies

In our first paragraph we quote NETSCC in a definition of a pilot trial as being 'a version of the main study...run in miniature to test whether the components of the study can all work together' and a feasibility study for an RCT as ‘research done before a main study to answer the question “Can this study be done?”’. So for both types of trial there is a clear objective to do an investigation in a patient population with a view to inform later efficacy studies. For this purpose we have removed healthy volunteer studies. Healthy volunteer studies are enabling studies with for example rate of recruitment controlled by the trialists.

We have not changed the text at all