Reviewer's report

Title: An Audit of Sample Sizes for Pilot Studies being Undertaken in the United Kingdom

Version: 1 Date: 3 December 2012

Reviewer: Chenglin Ye

Reviewer's report:

Most pilot and feasibility studies did not justify their target sample size. However, it is important to provide rationales for the minimum number of patients needed to meet the objectives of those studies even though they are not the main studies. In this paper, the authors reviewed the target sample sizes of on-going and eligible pilot/feasibility studies in UK. They aimed to assess the sample sizes by the type of endpoints, funders, interventions, etc. The findings are valuable to researchers in understanding this issue.

- Major Compulsory Revisions

1. The design is appropriate but the methodology can be improved. The methods were insufficiently described.
   a. The authors relied on a single trial registry in UK to search for eligible studies. I wonder what other efforts the authors had made to identify the studies that were not registered but potentially eligible for inclusion? Could that potentially change the conclusion?
   b. The authors only used two key words in the search: ‘pilot’ or ‘feasibility’. Would that miss some pilot/feasibility studies that were framed as, e.g. ‘experimental’, ‘exploratory’, ‘test’, ‘try-out’, or ‘preliminary’ studies?
   c. It was unclear if more than one reviewer conducted the search independently. If so, what was the agreement on retrieving the studies among reviewers? How was any disagreement resolved?
   d. The authors did not provide a statistical plan for their analysis. For example, what statistical test would they use for testing if there was any difference between the type of funders/endpoint?

2. Although this is not a systematic review, the authors need to describe their search in a more systematic way. For example, how many searches did they conduct? What issues did they come across? How did they screen the studies initially?

3. The authors tended to separate pilot from feasibility studies. Most current studies would use those two words interchangeably, and even for some other meaning. The authors need to provide some details as how they made sure the selected studies were consistent with their definitions of pilot/feasibility used in this paper.
4. I am not clear why the authors chose to exclude the trials that were using healthy volunteers in the search. That needs some clarification.

5. The authors solely relied on descriptive statistics to draw the conclusions, e.g. a difference between publically funded pilot studies with a binary endpoint and those with a continuous endpoint. It would be more credible if the authors conducted some statistical testing to make the inference and report in p value.

6. The authors would need to provide deeper discussion as how the findings could help and guide future researchers to plan the sample size to meet the objectives of their pilot/feasibility studies. What is the impact of the finding in designing pilot/feasibility studies?

7. The authors did not address the limitations of the study, for example, the population, the methods, the generalizability of the results.

- Minor Essential Revisions

1. Although the authors acknowledged previous work upon which they were building, they did not explain why they were interested in the impact of the factors: the type of funders, study endpoints, etc. on the sample size of pilot/feasibility studies. It would be good if the authors can provide some rationales as why they chose those factors not the others.

2. The title “An Audit of Sample Sizes for Pilot Studies being Undertaken in the United Kingdom” is a bit too broad, given the scope of the review and the factors being assessed. The authors may consider reframing the title to convey what has been actually targeted and found.

3. The authors need to report the n for each mean calculated in all tables. For example, in tables#2, 3 and 4, that information was missing.

4. The paper needs revision on some spelling and grammatical errors, and citation for the software.

Level of interest: An article whose findings are important to those with closely related research interests

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