Reviewer’s report

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

Version: 1 Date: 26 November 2012

Reviewer: Lawrence Mbuagbaw

Reviewer’s report:

- Major Compulsory Revisions

1. The title is misleading hence my second point. Audit may not be the most appropriate term and according to the authors this paper is about pilot and feasibility studies. The title/abstract should have some component of study design.

2. The research question is also unclear. The objectives in the abstract differ from those in the main manuscript.

3. It is unclear why there is a distinction between pilot and feasibility studies, as the use of the term may be interchangeable or the authors may not adhere to the definitions reported in the article.

4. The format of the paper doesn’t follow BMC recommendations. There are tables in the text. The subtitles and title page should be modified.

5. The search in not described in sufficient detail to be replicated and data extraction is not done in duplicate. The search terms should have been more specific. This would have prevented them from getting all the irrelevant hits.

6. Statistical tests should be used to show if the sample sizes are different in groups.

7. The conclusions seem to be a repetition of the results. How can these results help other researchers designing pilot studies?

8. No limitations are stated for this research.

9. Are these results relevant outside the UK?

10. There are no recommendations.

- Minor Essential Revisions

1. There are many spelling and grammatical errors throughout the manuscript. For example in the abstract:

   a. Pilot studies were found to have a smaller sample size per arm (median = 30) then (THAN) feasibility studies (median = 38.)

   b. Public and Industry funded pilot trials (TRIALS) appear to be of an equal size (both medians = 30.)
2. UKCRN and ISRCTN should be written in full in the abstract.

3. The URL for the websites searched should be provided [UK Clinical Research Network (UKCRN)].

4. Normal and binary should be replaced with continuous and dichotomous; likewise survival should be replaced with time-to-event.

5. Differentiate between sample size (what was achieved) and target sample size (what they hoped to achieve)

6. The tables are titled mean sample size, yet means and medians are reported. The authors should specify why they chose to report both means and medians (table 3). Average is also used in some tables (table 4).

7. “Observational trials” are a misnomer. Trials are typically not observational.

8. Data are not presented consistently in the article. It should be n (%) or median (range) or mean (Standard deviation).

- Discretionary Revisions

1. The data in the appendix can be presented better, such that the tables are smaller and there are less zeros.

2. Please see the additional file.

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

**Quality of written English:** Needs some language corrections before being published

**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