Author's response to reviews

Title: What is a pilot or feasibility study? A review of current practice and editorial policy

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Author's response to reviews: see over
Dear Editor

Title What is a pilot study? A review of current practice and editorial policy

Thank you for the reviewers’ comments to the above paper. We have modified the text accordingly and give a detailed reply below.

Yours sincerely

MJ Campbell

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Reviewer’s comments

1) I’d like to a few more sentences on the methods used in the various searches. What were the inclusion criteria? In Results it becomes clear that review papers were excluded, for example. How many of the authors checked abstracts, full text etc and agreed that a particular study should be included. And who (and how) were data extracted from included studies?

Text inserted in Page 6 and P14

“GL reviewed 20 papers and classified them into groups as described in her original paper [1]. Subsequently MA, in discussion with MC, designed a data extraction form to classify the papers. We changed one category from GL’s original paper. We separated the category ‘Phase I/II trials’ from the ‘Piloting new treatment, technique, combination of treatments’ category. We then classified the remaining paper into the categories described in Table 1. “

2) The authors say that pilot studies rarely act as a precursor for a bigger study and give some reasons for why this might be so. Do the authors think that authors of pilot studies should say up front what results would mean further work was or was not required? In other words, should they be explicit in defining what would kill a future trial, or necessitate a bigger study?

Text modified on page 11

“We think that authors of pilots studies should be explicit as to their purpose, e.g. to test a new procedure I preparation for a clinical trial. We also think that authors of proposals for pilot studies should be more explicit as to the criteria which lead to further studies being abandoned, and that this should be an important part of the proposal.”
3) The authors mention the encouraging attitude of funders but, on my reading, it seems that the views of journal editors are less encouraging, especially that given on page 9 about editors mostly not encouraging the publication of pilot studies. It would be interesting to read what the authors think of this given, for example, the encouragement given by funders and the MRC complex intervention guidance for running more exploratory work prior to full-scale trials.

Text modified on P13 and reference added P15

“There is an increasing awareness that publishing only ‘significant’ results can lead to considerably error [9]. The journals we considered were all established, paper journals and perhaps the newer electronic journals will be more willing to consider the publication of the results from these types of studies.”

4) Page 2, first paragraph. ‘case law’ - I don’t think this is a good term here; I suggest dropping it.

Sentence on P2 modified to

We sought evidence for what comprises a study described as a ‘pilot’ or ‘feasibility’ study.

5) Page 3, first paragraph. I found the sentence ‘Twelve studies with sufficient..’ a bit lacking; I guess you need to give an indication of what ‘sufficient’ means for the sentence to make sense.

Sentence modified to

Twelve studies which were interventional pilot/feasibility studies and which included testing of some component of the research process were identified through the UKCRN Portfolio database.