Reviewer's report

Title: A Tutorial on Pilot Studies: The What, Why and How

Version: 2 Date: 17 September 2009

Reviewer: Michael Campbell

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This is not really research, but should prove a useful article for others to consult.

Compulsory revisions

1) The authors should refer to the paper by Lancaster (2004) which covers some of the same ground

2) I think they should distinguish between Phase II and feasibility studies. A Phase II study is a precursor to a Phase III trial, a feasibility study could be a qualitative study to evaluate whether patients would be willing to be in a clinical trial.

3) I think they could make more of the British MRC guidance on complex interventions (MRC, 2008), (Craig et al 2008). This explicitly recommends the use of feasibility studies prior to Phase III clinical trials, but stresses the iterative nature of the processes, in contrast to the linear development from Phase I through II to III in pharmacological trials.

4) The sample size calculation in the 3rd paragraph on page 9 is unclear and should be revised. They should use proper notation and not ‘computer language’ (eg *SQRT)

Minor essential revisions

5) On page 10, the percentages for determining success in the PROTECT Trial are unusually precise and unjustified (eg why should 91.7% receive every scheduled dose in a blinded manner. If only 90.5% did would this be a failure?)

6) P14. In the consent form I suggest the authors actually state a definition of a proof-of-concept study

7) I would be interested to know the authors opinion of randomization. Should pilot studies be randomised and if so why?

References


http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC004871

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:

Non-financial
I am working on a similar paper