Reviewer's report

Title: The reporting of progression criteria in protocols of pilot trials designed to assess the feasibility of main trials is insufficient: a meta-epidemiological study

Version: 0 Date: 23 Apr 2019

Reviewer: Michael Campbell

Reviewer's report:

This paper seems rather ill-focused. It is an observational study with no prior hypotheses but a large number of hypothesis tests.

1) The main outcome variable is whether progression criteria were reported in the protocol. It would appear this was decided by one reviewer and verified by an independent reviewer. Given the importance of this variable, and the possible vagueness of reporting, it would be helpful to know how often the reviewers agreed on this variable. Similarly the justification of the sample size could have a variety of opinions.

2) The reporting of the statistical methods could be improved. It is not clear for example, whether the unadjusted OR adjusts for clustering or not, and it has to be assumed that the adjusted OR adjusts for all other prognostic factors. Writing down a model would help. Whilst I appreciate GEE adjusts for clustering, and so does not explicitly use the ICC, it would be helpful to know what the ICC was to see whether there is a journal bias. Also did the GEE use robust SEs and what package was used? Actually I am not convinced about the random effect model, since the three journals are not a random, non-repeatable sample and there are only three of them so GEE is not efficient. Also they appear as fixed effects in Table 3 so something is wrong. I think a fixed effect model would be informative and better.

3) I don't believe that ORs could change so much when adjusted, and my rule of thumb is that is a crude and adjusted OR differ a lot, then something is wrong. For example to go from 0.78 unadjusted to 3.64 adjusted is not credible. The QIC criterion is mentioned (line 159) but not reported. Do the models fit? I think there must be a huge interaction somewhere. Reporting the marginal estimates is misleading.

4) In Table 2 there are a number of issues. I think the denominators should the total number of papers in each category, as in Table 1 so the %s should be 9/42=21% , 16/71=22% , 20/114=0.14% from which one can derive the figure 0.78 given earlier. This make PAFA better than Trials for reporting progression criteria and I can't see how adjustment can make it worse, especially since the numbers are so small! In my opinion the confidence intervals in Table 2 are unnecessary and also probably wrong since they are probably binomial CIs but the variable is in most cases categorical. The CI for journal PAFA reporting progression criteria does not even include the point estimate.
Minor

line 87 add to end 'if they are not pilot studies'
line 83 drop comma
line 188 Table 3 not 2
Table 1 State that Sample size small is ≤60

Why do we need to know so much about REDCap but so little about the statistical methods?

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