Reviewer's report

Title: Quality of reporting of non-inferiority and equivalence random-ised trials - update and extension

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Reviewer: Emilia Bagiella

Reviewer's report:

This is an interesting manuscript exploring the quality of reporting of equivalency or non-inferiority trials in medical journals. The authors performed a reviews of articles published in 2009 and investigated to what extend the CONSORT guidelines were followed. In addition the authors attempt a comparison of their results with results of a similar review conducted in 2003-2003.

The manuscript is interesting, although not very well organized. A couple of important issues should be addressed.

1. The rationale for conducting the review is not completely clear in the manuscript. While the attempt to determine whether the CONSORT guidelines had any impact on the quality of equivalence and non-inferiority trials published, the focus seems more on comparing the current review with the review previously conducted in 2003-4. Some of the CONSORT criteria were reported in that first review, however, it seems that the comparison in predicated only on 4 criteria.

2. Unfortunately, only major medical journals require compliance to the CONSORT guideline for publication (e.g. JAMA or the NEJM). Many other journals, while recommend the guidelines, do not enforce them and completely rely on the reviewers to request a more rigorous approach. Given this, the analysis should be stratified by whether or not the journal in which the article were published did or did not require adherence to the guidelines. The change between before and after the guidelines were published may merely be due to an increased number of papers published in specific journals rather than a change in adherence to the guidelines.

3. The manuscript should be reorganized. The comparison between the current and the previous review is presented in the discussion. It should be presented in the result section instead (again it should be more clear what the main scope of the paper is...).

4. The discussion should address many different issues around the results reported. To begin with, are the results the author report consistent with results on other trials? Again, if the aim here is to determine whether the CONSORT guidelines were effective, a comparison with other types of trials (e.g. superiority) should be made.

5. The difference between equivalence and non-inferiority trials is not usually
clear and well understood. The authors should give a definition in their introduction.

6. The paper should be reviewed for English language. The punctuation is often inappropriate and there are a couple of awkward sentences.

**Level of interest:** An article of importance in its field

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

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests