Reviewer's report

**Title:** Modified versus standard intention-to-treat reporting: Are there differences in methodological quality, sponsorship, and findings in randomized controlled trials? A cross-sectional study.

**Version:** 1  **Date:** 28 November 2010

**Reviewer:** Rob J Scholten

**Reviewer's report:**

Major Compulsory Revisions

1. The authors present the concept of “modified intention to treat” as an item that has a widely accepted definition and with which the whole scientific community is familiar with. At least I’m not familiar with this concept and I’m afraid that many readers will suffer from the same handicap. In addition, I find it difficult to understand what is meant with and what the purpose is of the statements of the background section beginning with “Furthermore, in the 475 mITT trials included in the review, while all of the 123 equivalence or noninferiority” and ending with “The appearance of mITT reporting in modern RCTs could be a consequence of the widespread financial ties that exists among investigators and industry “ of the background section. So, the authors may wish to rewrite the background section and start (also the abstract) with a short explanation of what is meant with ITT and mITT, and why the latter is not good practice. Also the sentence “Nonetheless, postrandomization exclusion appear to be the primary factor that characterizes mITT trials.” seems to come out of the blue and the authors may wish to clarify in more detail the point they want to make.

2. I found the statistical methods section very difficult to follow, especially lines 5-17 of page 8. I also don’t understand why the type of the journal and the use of placebo are potential confounding variables. I acknowledge the skills of the authors, but is a complex multinomial logistic regression analysis really necessary? Wouldn’t simple contingency tables (like presented in Table 1, but then with the addition of the p-values of the Chi-square test) be sufficient?

3. Elaborating on my previous remark: the authors discriminate between 3 groups (ITT, mITT and no (mentioning of) ITT) of which they wish to describe the characteristics (like methodological quality, reporting quality, conflicts of interest, sponsoring). If this is indeed the case, shouldn’t the type of ITT in all analyses be the independent variable (with indicator terms for 2 of the 3 categories) and the various characteristics the dependent variables (as described in the second half of the statistical methods section)? For investigating funding source and author’s conflicts of interest as determinants of type of ITT, however, one could make a plea for having type of ITT as independent variable (but not for the other associations. Anyway, the authors may wish to motivate and explain more clearly why type of ITT should be the dependent or independent variable.
4. To me the Discussion section includes a lot of “industry bashing”. Especially the section “Interpretation” contains many subjective elements and may be a little bit over the top (and much too long, with an extensive description of the bad behavior of industry). I challenge the authors to be more succinct here and more objective and to the point.

Minor Essential Revisions

5. Page 3. The conclusion of the last sentence of the abstract seems to be a little bit too strong.

6. Page 8. What’s the use of calculating kappa’s? The purpose of two independent authors doing the job is to be as precise and objective as possible. The purpose is not to reach high inter-observer agreement. If you wish to use the level of disagreement as an indicator of how difficult it apparently was to assess a particular, you may wish to report the percentage of (dis)agreement (instead of kappa’s).

Discretionary Revisions

7. Please, leave out the redundant p-values; the confidence intervals do already the job.

8. Page 5. Selection of studies: please, explain why “The results were then cross-checked against a search of the Cochrane Central Register of Controlled Trials.”?

9. Page 5. Please, move the paragraph starting with “Two other reviewers independently and in duplicate, extracted the following information from the journal articles:” to a separate heading “Data collection” (or combine with assessment of meth quality).

10. Page 5. Please, move the paragraph starting with “The relevant RCTs were subsequently classified according to the type of intention-to-treat analyses” to the Statistical Methods section (which may have to be renamed to “Analysis”).

11. Page 12. You may wish to move the description of your hypotheses to the end of the Background section (which would provide the reader with much more guidance).

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

Declaration of competing interests:

I declare that I have no competing interests. However, I have to declare that I
know both the first and last authors personally, but I don’t think that this has influenced my report.