Author’s response to reviews

Title: An Evaluation of the Completeness of Safety Reporting in Reports of Complementary and Alternative Medicine Trials

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Author’s response to reviews: see over
Author's response to reviews

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Version: 2 Submission Date: 15th June 2011

Author’s response to reviews: See over page
Reviewer's report

Title: An Evaluation of the Completeness of Safety Reporting in Reports of Complementary and Alternative Medicine Trials

Version: 1 Date: 12 May 2011

Reviewer: Zhaoxiang Bian

Reviewer's report:

1. Is it possible to have the data to analyze the linkage between the endorsement of CONSORT for Harms and quality of reporting of Harms?

   This is a very interesting question. Endorsement of CONSORT would need to be obtained from the journal instructions to authors; this would not however, ensure that the harms extension had been endorsed by the authors of the trial. It is possible that readers would share this question, so we have included this in the discussion section. Alternatively, we could provide proxy information with regards endorsement of the CONSORT for harms extension and adequacy of reporting. For example, we could obtain current information on the endorsement status of CONSORT for publishing journals for the included trials.

2. Although the author mentioned in their methodology that they compared the percentage of words in the body of the text given to safety reporting and the percentage of words in the body of the text given to author affiliations, it is problematic. Authors should provide some discussion about this in their limitation.

   We have included details on the limitations to this comparison in the discussion section, highlighting that there could be slight confounding due to editorial policy, number of investigators involved in multicentre studies, or when trail reports clearly state that no harms were reported, however, given the extent to which affiliations have more words than safety reporting compared to safety greater than affiliations is so considerable (69% to 29%) we do not believe this negates this finding.

Level of interest: An exceptional article

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests
Reviewer's report

Title: An Evaluation of the Completeness of Safety Reporting in Reports of Complementary and Alternative Medicine Trials

Version: 1 Date: 13 May 2011

Reviewer: Lehana Thabane

Reviewer's report:
This is a systematic review to assess the quality of safety reporting in complementary and alternative medicine (CAM) randomized controlled trials (RCTs) and to explore the influence of different trial characteristics on the quality of safety reporting.
This is a statistical review of the study focusing primarily on the design, methods, analysis plans, reporting an interpretation of the results. Overall, the review was well designed, conducted, analyzed and reported. Below are some minor editorial suggestions

1. Abstract: Background: Replace “Our objective,” with “The objectives of this study are:”

   This has been corrected. The objective is now merged with the ‘background’ heading for the abstract as suggested by the manuscript template.

2. Results:
a. Adequacy of safety reporting: Qualitative measures:
i. Replace “IQR” with “Q1-Q3”, which is how the results are currently presented. Please note that IQR=Q3-Q1, which is the length between the two quartiles. This needs to be corrected throughout the paper.

   This amendment has been made, not only to the Qualitative measures results section, but also to the tables which included this abbreviation (Table 1 and Table 3).

b. Regression analysis:
i. Replace “multivariate” with “multivariable”. Please note that the former refers to analysis of multiple outcomes at the same time, while the latter deals with analysis of a single outcome or dependent variable as a function of several predictors.

   Incidentally, this discussion arose whilst drafting the manuscript with regards to reader comprehension. We have amended to the more statistically correct terminology where is appears in the manuscript.
Overall, this is a very good review!

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

**Quality of written English:** Acceptable

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

**Declaration of competing interests:**
'I declare that I have no competing interests'

*Editorial comments:*
All suggested editorial amendments have been made with track changes in the uploaded updated manuscript, formatting according to the instructions for authors has been verified and the full manuscript has been proof read.

Thank you for your feedback, we look forward to hearing from you in due course.