Reviewer’s report

Title: Randomized trials in China: How many are randomized?

Version: 1 Date: 23 October 2008

Reviewer: Janice Pogue

Reviewer’s report:

The paper presents a truly important issue for the readers of the Chinese medical literature, and the results found are shocking. An admirable amount of work went into this project and it deserves to be published. Unfortunately in its current form, the major messages of this paper are lost. Major revisions are necessary.

Major comments: Unfortunately the paper needs to be entirely restructured to prevent losing the interest of the reader in a large mass of numbers. The structure currently followed is to present all the outcomes (authentic RCT, multiple versions, not able to contact, refusing to answer questions, unintentional false RCT claim, and intentional false RCT claim) for each stratifying factor (location, intervention type, trial purpose, institution, funding source), but it would be much clearer to address each outcome in its own section and present those factors which were more closely associated with outcomes. Table 1 should be restructured to match this. The reader will want to know what type of paper is more likely to be an authentic RCT, what type of paper is more likely to be a multiple version, rather than an original manuscript. Similar analysis could be done for all the other outcomes. For example, what factors were more associated with authors refusing to answer questions, was it location, intervention type, trial purpose, institution type, funding source, or some combination of these factors? Also, these stratifying factors are likely also correlated with one another. Some effort should be taken to identify which are the best predictors of being an authentic RCT. You could use a logistic regression on authentic RCT outcome and see what combination of stratifying factors is more closely associated with this outcome (and other outcomes as well).

Minor comments: The paper should not present all the numbers in table 1 again in the results section, as this makes the paper difficult to read. Lead the reader through the most important results and refer to the table for the less important ones.

The authors have not done an adequate literature review on this topic, as they have missed other similar papers. For example, see Berger V and Bears J Vaccine 2003. How do the current authors’ results compare to the analyses of others?

Lastly, I am not sure that the use of the term “stratification” is appropriate, when referring to the characteristics of the research papers reviewed. It seems to be an unusual use of the word.
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'