Author's response to reviews

Title: Country development and manuscript selection bias: a review of published studies

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Author's response to reviews: see over
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Dear editor of the BMC Medical Research Methodology,

Attached, please find the revised manuscript entitled: “Country development and manuscript selection bias: a review of published studies” which is resubmitted to your prestigious journal for evaluation.

We wish to thank the esteemed editor and reviewer for thoughtful and sensitive reviews of our manuscript. Please find the revised manuscript according to the prestigious reviewer’s comments and a “Response to Reviewers” attached below.

Sincerely yours

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Major revisions:

1) The authors should clearly state how the study sample size was selected. Moreover, it seems that the authors selected the sample size and then excluded animal studies, intervention studies or conference abstracts. Which rule did they use in order to replace the excluded studies with the eligible ones?

We decided to choose 50 articles in each group based on our time schedule limitations for data gathering phase. As you can see below we used more conservative cut-points for statistical significance for reducing chance effect.

It was not possible to select the articles without reading the abstracts. The Cochrane CENTRAL theoretically consists of controlled clinical trials; but practically some of articles are case reports or animal studies. These articles should be excluded from our study. Therefore we selected 50 articles in each income group each year and after reading the abstracts we excluded some of them and performed sampling once more to replace them. Hypothetically we don’t believe the excluded and replaced citations as lost samples. This part is added to the text.

What part of the initial sample size were the excluded studies?

The number of replaced articles was about 2 to 4 articles in each group.

2) Chi-square test for trend was used to assess the differences between levels of country income. Is this test applied on the absolute changes of proportions of randomized studies, use of blinding and statistical significance?

The Chi square for trend test was applied to the cross-tab of randomization (or blinding, significance) and country income, not for changes. This part is added to the text.

What the authors mean when they refer to a non-significant inverse association with the presence of randomization and direct non-significant association with the use of blinding? The direction of the trend (even if it is not significant) should be clearly described.

The changes have been made in the text and the Chi-square for trend is added for each analysis. The p-value=0.008 for blinding is correct. Because the other one (0.05) is the p-value of Chi-square not Chi-square for trend and was placed there wrongly. Therefore the statement “Country income had a non-significant inverse association with the presence of randomization (p=0.02) and a direct non-significant association with the use of Blinding (0.05).” is changed to “Country income had a non-significant inverse association with the presence of randomization (Chi square for trend=5.6, p=0.02) and a direct significant association with the use of Blinding (Chi square for trend=6.9, p=0.008).”

Why the authors choose to be so conservative (p-value less than 0.01) in order to consider a result as significant?

Because of the large number of comparisons in the study, for preventing multiple testing chance effect we decided to be conservative a priori.

The impact factor of which year was used for the linear regression model?

All available citations in 1993 and 2003 were included in regression analysis. For each citation its associated impact factor was used. If the article published in 1993 for example, its impact factor was for 1993 and so on.

3) Results and abstract are not in accordance. Authors state that country income had an inverse linear association with the presence of randomization and a direct
association with the use of blinding. Based on the fact that authors used \( p < 0.001 \) in order to define significance this statement could be misleading.

As stated in the manuscript, the \( p \) value of less than 0.01 was considered significant. See above.

**Different \( p \)-values are presented for blinding (0.008 in abstract vs 0.05 in results).**

See above.

**Frequency of statistically significant results of high income trials is said to be 88\% instead of 82\% which is the correct one, based on table 2.**

How this 53.5\% came up as a probability of blinding in 2003 in low income countries?

As stated in the cover letter the abstract of this work was presented in Cochrane colloquium last year. There the denominators of the percentages were the available data. But as it could be seen in the table 1 the denominator is 50 for all proportions. We used a more conservative solution and considered the missed data as the worst. Therefore the percentages are less in the full text. The abstract is corrected according to the rest of manuscript.

4) **The main hypothesis of the authors is that journals may publish articles based on study characteristics other than quality indicators.** The authors compare the methodological quality and statistical appeal of published trials from countries with different developmental status and try to determine their association with the journal impact factor and language of publication!

However, quality assessment is restricted to documentation of randomization, blinding and intention to treat analysis. The final analysis includes only randomization and blinding.

The findings are restricted to the data available in abstract and keywords. We accept this limitation but we consider the results as a sign to attract attentions to conducting more comprehensive future research on this topic because of its importance.

The statistical comparison of the proportion of studies reporting an intention to treat analysis wasn’t performed because of the small number of them. This statement is added to the results: “There were 2 studies in high-middle income group and 3 in low-middle income group reported an intention to treat analysis.”

**Differences in the frequencies of blinding and randomization could be chance findings (in fact they are based on my calculations).**

Differences in frequency of blinding were statistically significant. But about randomization it is possible to be due to chance effect, although the \( p \)-value is borderline (0.02).

**Poor (or even fraudulent) documentation and adoption of CONSORT statement from journals may have affected this quality assessment and authors should comment on that.**

The related part in the discussion is changed to “Second, all assessments are done based on the data provided in title, abstract and keywords and obviously several useful information might be omitted. Abstracts from higher impact journals might contain more information and therefore yield higher quality scores than those from other types of journal. If so, the real differences between low and high income countries may be more than what is reported in our study. Poor (or even fraudulent) documentation and adoption of CONSORT statement from journals may affect the results.” If it doesn’t suffice we can explain it in more detail.
Minor revisions:

1) The authors state in p.4 that a trial was called significant when the 95% confidence interval excluded 0. But this depends on the statistical estimate that is used in the particular study.
   The sentence “the 95% confidence interval excluded 0” is changed to “the 95% confidence interval excluded no effect”.
2) In table 1 it should be added that numbers in the parentheses represent the 95% CIs of the absolute change
   The correction is made.
3) In abstract “Blinding” should be changed to “blinding”. In p.4 “Blinding” should be changed to “blinding”. In p.6 “Data extractors” should be changed “data extractors”
   The corrections are implemented.

Discretionary Revisions:

1) Please re-do calculations on OR of blinding for year 2003 (table 2)
   We recalculated it using Mantel-Haenszel common odds ratio method. It seems correct.