Author’s response to reviews

Title: Completeness of reporting in abstracts of randomized controlled trials in subscription and open access journals: cross-sectional study

Authors:

Iva Jerčić Martinić-Cezar (ijercic@gmail.com)

Ana Marusic (ana.marusic@mefst.hr)

Version: 1  Date: 04 Oct 2019

Reviewer #1

1. line 8: I don't agree that abstracts are the only record of trial results. This sentence needs to be changed somehow. For instance, in the EU, clinical trials are to be posted in the Eu Clinical Trial Register (which will soon be transformed into the EU Database) and clinical summary results must also be posted. One can argue with the completeness of this register, but there is a regulatory requirement to do so

Answer: We thank the reviewer for this comment – we agree that the sentence is not clear and may be interpreted in a way that is different from our intended message – the sentence is now rephrased to emphasize that abstracts may be the only source of information about a study in some settings, such as developing countries with limited access to full text articles.

2. In table 1, it is shown that harms in both types of journals are not widely reported. I would like to see more discussion regarding this aspect.

Answer: We thank the reviewer for this comment and suggestion. Reporting of harms in clinical trials is far from complete or fully transparent, and we discuss this now in the Discussion section of the revised manuscript.

3. A final general comment: it would be interesting to understand the provenance of the trials, if industry or academic and see if there is any type of relation with the quality of the posted information

Answer: We thank the reviewer for this comment. We extracted this data for the sample of trials in our study and discuss the findings in the revised manuscript.

Reviewer #2

1. Please could you explain why the included trials had to be 'double-blind'? This seems like an unnecessary and stringent criterion.

Answer: One of the items in the CONSORT-A is Blinding, and we decided to consider only the
“standard” double-blind design in order to make the samples for comparison as similar between the two groups as possible. As we explained in the answer to the next comment, we focused on the basic form of RCT – two-group, parallel, double-blind so that we do not introduce possible biases by introducing different variations of trial designs which may have different prevalence in the OA and subscription journals.

2.
- I am also a little confused about some of the exclusion criterion. A number of the excluded study designs relate more to analysis considerations than design aspects, for example, superiority trials. A trial can be both a two-arm double-blind parallel group RCT and a superiority trial; the two are not mutually exclusive in the same way that a crossover trial and a parallel-group trial are. In the same vein, I would also question 'pragmatic studies', 'non-inferiority trials' and 'open-label studies', and I'm not even sure what is meant by a 'fixed-size trial'? Perhaps the inclusion and exclusion criteria need to be revisited

Answer: The original CONSORT checklist was developed for the "standard" two-group parallel design and there are different extensions for different variations of this standard trial methodology or interventions or data. As CONSORT-A was developed for the main CONSORT checklist, we decided to use only the two-group parallel design, so that we do not introduce a possible bias because of differences in the OA and subscription journals in the complexity of published trials. Our hypothesis would be that subscription journals would have more complex study designs, and by restricting the sample to the basic design we were able to measure possible basic differences between the two journal groups. We have revised this section of the Methods and deleted the “fixed-size trial” term, which should not have been among the list, as we did not exclude this type of trial.

3.
- The article would benefit from a thorough proof-read, a (not exhaustive) list of typographical/grammatical errors are below:
  Consider replacing 'abstracts about randomized controlled trial' with 'abstracts of randomized controlled trials' throughout abstract and manuscript.
  Abstract>Results paragraph - add hyphen between 77 and 81% in first 95% CI; consider reporting inter-quartile range instead of 95% CI alongside median number of completely reported items; add 'the' before 'Title' in final sentence.
  Background - remove 's' from end of 'abstracts' in third sentence, consider rewording sentence to avoid repeated use of 'important', add 's' to end of 'abstract' (…abstracts are sometimes…). Insert 'The' before 'CONSORT-A' at start of fifth sentence.
  Methods - add 's' to end of 'trial' in first sentence of Methods section. Add 'a' between 'be' and 'fully' in final sentence of first paragraph of Methods section.
  Results - Add 'A' at the start of first sentence; insert 'the' before 'subscription journals' and 'OA journals' throughout;

Answer: We thank the reviewer for constructive language comments, which we introduced in the revised manuscript.

4.
- consider reporting inter-quartile range rather than 95% CI for median reported items; report p-values to 2 significant figures rather than 3.

Answer: As we used a sample of abstracts, we consider that reporting 95% CI interval would be more appropriate way of presenting data, in order to provide estimate for the whole population. In the presentation of P values, we followed the usual standard in medical journals. We leave the decision on the presentations to the editor and will be happy to make appropriate changes in the next revision of the manuscript.