Author’s response to reviews

Title: Spin in the reporting, interpretation, and extrapolation of adverse effects of orthodontic interventions: protocol for a cross-sectional study of systematic reviews

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Full Title: Spin in the reporting, interpretation, and extrapolation of adverse effects of orthodontic interventions: protocol for a cross-sectional study of systematic reviews

Article Type: Study protocol

Section/Category: Research and publication ethics

Authors: Pauline A.J. Steegmans, Nicola Di Girolamo, Reint A Meursinge Reynders

Dear Dr. Meerpohl and peer reviewer # 1,

I wish to thank the editor and peer reviewer # 1 for their critical appraisal of our manuscript "Spin in the reporting, interpretation, and extrapolation of adverse effects of orthodontic interventions: protocol for a cross-sectional study of systematic reviews". The detailed comments raised by reviewer #1 were very useful and (in our view) have greatly improved the manuscript.

We have included a point-by-point response to all comments of peer reviewer # 1 and have highlighted in red all changes that were made in the manuscript. The figures and tables were not modified. The revised manuscript conforms to the journal style and all authors have read and approved the revised manuscript.

We hope that our revision is to your satisfaction, but we will gladly revise our manuscript again if needed.

Sincerely,

Reint Meursinge Reynders (the corresponding author on behalf of all authors)
Reviewer reports:

Reviewer #1: It is really surprising and refreshing to see such a nice and transparent study, especially in the field of orthodontics. The authors have done a very very nice job on this protocol and are to be commended. I am supportive of this protocol and have only some few very minor comment that might be considered. Thanks for letting me see this.

Authors’ response

We thank the reviewer profoundly for these kind words and we hope that the findings of this paper have an impact on the way adverse effects are assessed and reported in systematic reviews of orthodontic interventions.

Comment 1

I am somewhat confused as to why the first research question is given (and given first), since it is not the study's main outcome according to the title.

Authors’ response to comment 1

Thank you very much for this important comment. For a trial or a systematic review we would have definitely defined our primary and secondary research question in advance and in the appropriate order, but cross-sectional studies usually address numerous questions and it is often difficult to give the order of their importance. We presented our questions in the current order, because we believe that it makes the flow of the paper more logical and easier to read. Our initial questions should be seen as springboards for setting the paper up for the questions on spin. We are willing to reorder these questions and rewrite the entire paper, but we believe that this will jeopardize its flow and clarity.

Comment 2

I'm not sure if I understood correctly your text regarding sample size calculation. Have you set a goal towards how many reviews you want to include or will you include all reviews available according to your criteria?

Authors’ response to comment 2

Thank you very much for this comment. After rereading this section we see why this issue is not clear.

What did we do? We conducted our pilot tests on the same sample of systematic reviews (n=14) as was described in our previous protocol [15]. Additional file 2 reports on the methods of this pilot test. The outcomes of the pilot tests are reported in our methods section on page 6 in lines 122-129.
Indeed, our goal is to include all systematic reviews according to our eligibility criteria published from 01 August 2009 until 31 July 2019. We reported this item in the section ‘Information sources’ on page 7 in lines 138-141.

To improve the clarity of these issues we have modified our methods and information sources sections and have highlighted these changes in red in the revised manuscript.

Comment 3

Is there a reason why you are searching the database of each journal and not 2-3 wide-coverage databases like PubMed, Scopus, Web of Knowledge, etc?

Authors’ response to comment 3

Thank you very much for this comment. We could have consulted the search engines as reported by peer reviewer #1 and it is definitely much faster than our time consuming hand-searches of each journal. However, we wanted to avoid the risk of excluding eligible articles that were mislabeled by these search engines as a result of incomplete or inappropriate keywords. All searches will be conducted by 2 reviewers independently.

Comment 4

I can think of several limitations of using the impact factor as measure of the journal's quality.

Authors’ response to comment 4

Thank you very much for bringing up this important issue. Journal selection was based on 2 criteria: (1) the journal has been published for 10 years or more and (2) the impact factor. Selecting the leading journals in a particular field of research is common practice in meta-epidemiological studies in biomedicine. Findings from leading journals of a specific specialty represent the quality of findings in that field and have a high external validity for its stakeholders. Orthodontic journals with lower impact factors can take notice. Indeed, if our completed research study will identify optimistic answers to our research questions it makes sense to conduct a large scale cross-sectional study that includes all systematic reviews of orthodontic interventions. In this preliminary research phase this would be a waste, particularly in the context of the suboptimal standards for conducting and reporting of many systematic reviews (Ioannidis JP. The Mass Production of Redundant, Misleading, and Conflicted Systematic Reviews and Meta-analyses. Milbank Q. 2016 Sep;94(3):485-514.). We have further expanded on this issue in the discussion (Page 12 lines 257-260) where we have stated that including only orthodontic intervention reviews published in the 5 leading orthodontic journals and in the Cochrane Database of Systematic Reviews was a limitation of this research study. We expect that the findings in this subgroup of journals will underestimate the true severity of spin on adverse effects of interventions in the abstracts of these reviews.
Comment 5

Minor language issues like the "an adverse effects". You can do another quick check to the manuscript.

Authors’ response to comment 5

Thank you very much for point this out. We corrected this language issue and checked the entire manuscript for spelling errors.

Comment 6

You can also consider evaluating (a) involvement of a statistician/methodologist/epidemiologist in the review team and (b) any conflicts of interest or funding that a review has.

Authors’ response to comment 6

We thank the author for this suggestion. To assess the impact of these variables precisely, will require in depth assessments of the specific characteristic of each individual member of the systematic review team and their potential conflicts of interest and funding. This will require contacting of multiple reviewers. Obtaining valid information from these reviewers is often complicated as we recently experienced in a paper that we just published on contacting of authors (Meursinge Reynders RA, Ladu L, Di Girolamo N. Contacting of authors modified crucial outcomes of systematic reviews, but was poorly reported, not systematic, and produced conflicting results. J Clin Epidemiol. 2019. 2019 Jul 8;115:64-76. doi: 10.1016/j.jclinepi.2019.07.001)

However, we definitely agree with peer reviewer # 1 that the suggested issues are very interesting and we could indeed consider to assess them in future research studies, but at this moment they go beyond our financial resources.

Comment 7

Please add the effect size that you will choose for your regression model. Is it OR or RR?

Authors’ response to comment 7

OR

Comment 8

Please consider adding in-text the repository where the study's dataset will be made openly available.
Authors’ response to comment 8

Thank you for this important point. We included Dryad as our planned data repository. We modified the section (Page 11 lines 228-233) ‘Reporting of the research study and data management’ as follows:

‘A data management plan was prepared for the long-term storage of our research data [43] in the case that the publisher of our completed research study will not or will only partly store our raw data. We consulted the Registry of Research Data Repositories [44] to identify an appropriate repository for our type of research data. We selected Dryad [45] for 2 reasons: (1) it is an international repository of data of peer-reviewed scientific and medical research and (2) it also includes data sets for which no specific data repository exist such as meta-epidemiological research data of systematic reviews in orthodontics.’