Author’s response to reviews

Title: Clinical drug trials in general practice: How well are external validity issues reported?

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Clinical drug trials in general practice: How well are external validity issues reported?

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Dear Editor

Thank you for the opportunity to submit a revised version of our paper. We hope you will find the revised paper satisfactory.

Best regards,

Anja Brænd on behalf of all authors

Reviewers’ Comments to Author:

Merrick Zwarenstein (Reviewer 1):

In your introduction you now say:

"However, although there are items in the CONSORT checklist connected to external validity, the main focus is on adequate reporting of trial elements affecting the internal validity of a trial, i.e. the extent to which the design and conduct of a trial eliminates the possibility of bias [5]. Nonetheless, concerns have been raised regarding the lack of focus in the CONSORT statement on external validity [7]."
My point is that the CONSORT extension for pragmatic trials specifically addresses this gap, and should be acknowledged here. In other words, there IS a CONSORT statement that deals with external validity. Your paper does not yet acknowledge this.

* We have moved and elaborated the sentence regarding the CONSORT extension for pragmatic trials to acknowledge this point. It is also mentioned in the conclusion and implications paragraph, as some of the issues we found to be frequently not reported are highlighted both in the CONSORT statement and the CONSORT extension for pragmatic trials.

I believe that reference 7 predates the CONSORT statement referenced in your paper, and so it seems not to be a good reference to use to point out the lack of focus on external validity (in a Consort statement that did not exist when reference 7 was published).

* We agree and have removed the sentence and reference 7.

I think that your mention of the PRECIS @ statement does not add to your argument where it is presently placed, so I would suggest that you either leave out mention of PRECIS or link it more clearly to the argument you are making.

* We have closely thought over how we could include a discussion of the PRECIS tool, and we agree that the former mention did not do the tool justice. However, as this paper is mainly concerned with the reporting of external validity issues, and not primarily the planning and design of trials, and since the paper is quite extensive as it is, we have decided to leave out the PRECIS tool in this paper instead of elaborating this point further.