Reviewer’s report

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

Version: 1 Date: 05 Sep 2017

Reviewer: Merrick Zwarenstein

Reviewer’s report:

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.

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).

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.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes
Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

**Quality of written English**
Please indicate the quality of language in the manuscript:

Acceptable

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