Author's response to reviews

Title: Clinical drug trials in general practice: a ten-year overview of protocols

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Author's response to reviews: see over
Dear Editor,

Thank you for a new opportunity to revise the manuscript Clinical drug trials in general practice: a ten-year overview of protocols. We appreciate helpful suggestions made by the reviewers in the re-review. A revised manuscript is enclosed highlighting all changes with “track changes”.

In the following we give point-by-point response to the concerns raised by the two reviewers who had new suggestions for revision of version 2. We hope you find our responses and revision of the manuscript satisfactory.

Yours sincerely,
Anja Maria Brænd, Kaspar Buus Jensen, Atle Klovning, Jørund Straand
Oslo, 5th of April 2013

Reviewer's report. Reviewer: Louise Berendt
Major Compulsory Revisions
1. The conduct of the hand-search has now been described in more detail. However, it is stated that the total number of applications (n=2,045) was calculated from various sources, but also that all files available at the NoMA archive were included in the hand-searching of the archive. If all files were hand-searched, why was it necessary to calculate the total number of applications? Is the actual number of hand-searched applications equal to 2,054? Otherwise, this should be specified.

As this study aimed to describe general practice trials, we have not systematically recorded information regarding other clinical drug trials. Unfortunately, the exact number of investigated files was not recorded either, and therefore the total number of drug trial applications in the ten-year period was summed up from numbers provided by NoMA. However, because the NoMA archive has to be complete for regulatory purposes, we believe the number of missing files in the NoMA archive is negligible. We have made an amendment in the Discussion section hopefully clarifying this.

Minor Essential Revisions
2. The methods section is now structured into subsections. The two first paragraphs of the data analysis subsection (“Main diagnostic criteria…” and “One of the authors…”) should be moved to the variables subsection. The last paragraph of the data analysis subsection (“Ethical approval…”) should be removed from the data analysis subsection, e.g. to the end of the first subsection in the Methods section.

The sentences are now moved as suggested.

Reviewer's report. Reviewer: Puvan Tharmanathan

The manuscript has been improved based on reviewer's comments. The relevant sections are more structured and easier to follow. However, a few gaps remain with regard to the overall presentation in the article, as listed below.

Minor Essential Revisions:
- Background, paragraph 1: The last three sentences need restructuring, as they
seem either incomplete or abrupt at present.
We have restructured this section according to the remark.

- **Background, paragraph 3&4:** There needs to be a sentence in either of these paragraphs that connects the problem set out in Paragraph 1 with the aim stated in Paragraph 4.
  We have included a sentence connecting the paragraphs.

- **Methods, paragraph 1 and sub-heading “case study”:** The purpose and choice for the single case study is not made explicit in the methods section. This needs to be done, I am assuming it is to give the reader a better sense of a “seeding trial”, this should be made clear. Also, no description is given on how the trial was assessed in a structured manner, for instance, whether this was done in relation to the suggested criteria in Text Box 1, which seems to be what was done.
  We have made adjustments to the manuscript according to the suggestions.

- **Methods, suggest changing sub-heading “Data Material” to “Dataset”**.
  The sub-heading has been changed as suggested.

- **Results, Trial characteristics, paragraph 2:** Please clarify/re-phrase “planned included”. Is this recruitment targets?
  This has been rephrased as suggested.

- **Discussion, Case Study:** The description here should be streamlined with regard to my comment about the case study methods above.
  The discussion of the Case study has been restructured somewhat, to follow the structure outlined in the criteria in Text box 1.