Author's response to reviews

Title: Multi-site randomized controlled trial of fluoxetine in children and adolescents with autism (FAB): Rationale and design

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Version: 2 Date: 28 May 2014

Author's response to reviews: see over
Re: Requested Changes for Submission: Study Protocol: Multi-site randomized controlled trial of fluoxetine in children and adolescents with autism (FAB)

To whom it may concern,

Please find attached an edited version of our study protocol, as per requested. In the table below, please find your request and how we addressed each concern:

<table>
<thead>
<tr>
<th>Requested Edits</th>
<th>Changes Made</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Title conforms to journal style for study protocol articles. The title should follow the format ____: study protocol for a randomized controlled trial.</td>
<td>We have addressed this issue by rewording the title to say: Study Protocol: Multi-site randomized controlled trial of fluoxetine in children and adolescents with autism (FAB)</td>
</tr>
<tr>
<td>2) Include date your study was registered next to the registration number.</td>
<td>We have now included the registered date, which is: 9th April 2008. We have included this in both the abstract and study design section.</td>
</tr>
<tr>
<td>3) Include a trial status section.</td>
<td>We have included a trial status section in the abstract: “Trial Status: Currently recruiting.” We have also added a trial status section after the discussion as per website guidelines. We wrote, “Trial Status: At the time of this manuscript submission, participants were still being recruited.”</td>
</tr>
<tr>
<td>4) Mention each author individually in your Authors Contributions section.</td>
<td>We deleted the previous submission’s authors’ contribution section and changed it to the following: “DR, MK, CM and JW assisted in the conception and design of the study and are involved in recruitment and the ongoing conduct of the study. KL contributed to the statistical design of the study. PH participated in the design and coordination of the study and helped to draft this manuscript. AM drafted this manuscript and is involved in recruitment of the study. All authors read and approved the final manuscript.”</td>
</tr>
<tr>
<td>5) Include a figure title and legend section after the reference list. The figures should not be included in the main body of the manuscript.</td>
<td>We have added the figure titles/ legends to the last page after the reference list (just figure 1). We have also changed one of our figures and</td>
</tr>
</tbody>
</table>

28th May 2014
categorized it as a table instead. Hence, Figure 1 has been changed to Table 1: Inclusion/exclusion criteria. We named formerly figure 2 now figure 1 and added a label: Figure 1: FAB Consort Flow Diagram.

6) Include a statement in your Methods section explaining that you obtained informed consent from each participant.

We added to the enrolment/randomisation section that is in methods the sentence “Following consent that will be obtained from participants and/or their caregivers as per protocol guidelines”.

Other editing changes

As per online submission guidelines, we initially structured the end of the paper with: abbreviations, acknowledgements, author details, authors’ contributions, competing interests, references. As per guidelines we rearranged the paragraphs so that they are structured in the following way: Trial Status, Abbreviations, Competing interests, authors’ contributions, author details, acknowledgements, references.

We also added one more person in our acknowledgements section.

As we are using Australian text, we corrected an error on page 9. Initially we wrote “randomized” but we have changed the “z” to “s”, hence we wrote “randomised” to make the paper consistent with Australian spelling and grammar.

We hope that we have addressed and fulfilled your requirements with the requested changes for our submission. Please do not hesitate to contact me for any further questions and/or clarifications.

Your Sincerely,

Anissa Mouti