Author’s response to reviews

Title: Baclofen as relapse prevention in the treatment of Gamma-Hydroxybutyrate (GHB) dependence: an open label study.

Authors:

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Version: 2
Date: 21 February 2015

Author’s response to reviews: see over
Monday, 20 February 2015

Dear Editor-in-Chief

We are delighted to have the opportunity to submit a revision of our study manuscript entitled: "Baclofen as relapse prevention in the treatment of Gamma- Hydroxybutyrate (GHB) dependence: an open label study." We answered to the acquired changes by the editor. Below, we have pasted the comments and provided our replies in italic following your instructions. We uploaded the revised manuscript in word format without highlighting the changes or using any track changes.

We hope that this revised version of the manuscript meets the criteria for publication in BMC psychiatry. Of course, we are willing to make further modifications in the manuscript if you would consider this desirable.

On behalf of the co-authors, Please address all correspondence concerning this manuscript to Rama Kamal, e-mail (rama.kamal@novadic-kentron.nl).

on behalf of all the authors

Sincerely,

Rama M. Kamal, MD

Study protocol

Baclofen as relapse prevention in the treatment of Gamma- Hydroxybutyrate (GHB) dependence: an open label study.

Rama M Kamal, Boukje AG Dijkstra, Arnt Schellekens and Cornelis AJ De Jong

BMC Psychiatry (Section: Substance-related disorders, addiction and impulse control)
Dear Mrs. Rama Kamal,

Thank you for your recent submission to BMC Psychiatry. Before we can proceed with peer review we will need you to make some changes to your manuscript. We would be very grateful if you could make these changes promptly, as we cannot start the peer review process until we have received a version containing these changes.

As you may be aware, it is the policy of the journal not to peer review study protocols where ethical and external funding approval have been obtained, as these processes usually involve peer review and as there is little possibility to change a protocol after enrolment begins.

Therefore, could you please respond to the following points below and provide the requested responses in your cover letter.

1. Ethical and Funding Approval Documentation

Before we can proceed with your submission, can you please forward copies of all ethical approval and funding approval for our records. These documents should be sent as email attachments to the following email address, BMCSeriesEditorial@biomedcentral.com. Please DO NOT upload these documents as additional files in the submission system. If your documents are not in English, please could you provide translated versions of the relevant parts. These should be endorsed and signed by a contactable person at the institution. Please also include the original documents. Can you please confirm in your cover letter that you have forwarded the requested documentation to BMCSeriesEditorial@biomedcentral.com.

Please clarify if the funding body reviewed the protocol.

A: 1- The original proposal of the research was reviewed by the Dutch Ministry of Health, Welfare and Sports, as funding body the ministry was informed about the decision of the Medical Ethical Commission Twente after reviewing the study protocol.

2- An e-mail attachment was send to BMCSeriesEditorial@biomedcentral.com with the following documents:

- A copy of the ethical approval of Medical Ethical Committee Twente in Dutch, and the translation in English of some of the relevant parts indicating the approval of the study (in page 1 and page 2) in another document.
- Funding agreement with the Dutch Ministry of Health, Welfare and Sports in Dutch.
2. All authors e-mail addresses on the title page. Title page - It should contain, at minimum, the names, institutions, countries and email addresses of all authors, and the full postal address of the submitting author.

**A: Authors e-mail addresses are added to the title page as follows**

*Rama M. Kamal, MD¹ ²*

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¹ Nijmegen Institute for Scientist-Practitioners in Addiction (NISPA), the Netherlands

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3. Date of trial registration needs to be added.

Please submit a revised version of your manuscript with the number included in the abstract. The last section of the abstract should be Trial Registration: listing the trial registry and the unique identifying number and the date of registration, e.g. Trial registration: Current Controlled Trials ISRCTN73824458. Registered 28 September 2004. Please note that there should be no space between the letters and numbers of the trial registration number.

**A: The required information is added to the manuscript abstract as follows;**

*Trial registration: The Netherlands Trial Register with number NTR4528. Registered 19 April 2014.*

4. Ethics statement needs to be removed from the trial registration statement.

**A: The Ethics statement is removed from the trial registration statement.**
5. Name of ethics committee needs to be included. Please update your ethics statement to include the name of the ethics committee that approved your study.

A: Name of the ethics committee was added under Ethical considerations.

“The study was approved by the Medical Ethics Committee, Twente Medical School, Institute for Applied Scientific Research (METC/14015.kam), study number NL40321.044.13. Participants are informed about the trial and about the voluntary nature of their participation with both written and verbal communications. Participants are only included following the provision of informed consent.”

Members of the committee are listed in the attachment addressing the actual approval of the study.

6. Funding information needs to be included in an Acknowledgement section.

A: An Acknowledgement section is added as required

Acknowledgments

This study is funded through the Dutch Ministry of Health, Welfare and Sports

To submit your revised manuscript

When you have revised your manuscript having taken the requested comments into consideration and made any required changes to the format of your paper, please upload the revised version by following these instructions:

1. Go to http://www.biomedcentral.com/manuscript/login/man.asp?txt_nav=man&txt_man_id=1984862842159022 and log on with your email address and password.

2. With the 'Manuscript details' tab, please update the title, abstract and author details if they have changed since the previous version. It is very important that all changes are updated on this page, as well as in the manuscript file as the information on this page will be used in PubMed and on BioMed Central if your manuscript is accepted for publication.

A: Is done

3. With the 'Cover letter' tab, please provide a covering letter with a point-by-point description of the changes made.
4. With the 'Upload files' tab, please upload the revised version of the manuscript and press 'Submit new version'.

Please wait for the confirmation page to appear - this may take a few moments. We would be grateful if you could resubmit your files with the changes requested until February 16, 2015.

Please note that all submissions to BMC Psychiatry must comply with our editorial policies. In particular, please ensure that your manuscript contains any required statements regarding ethical approval and consent from patients/ participants; adheres to any relevant standards of reporting with a completed checklist where appropriate; Further information about our editorial policies can be found at the following links:

Ethical approval and consent: http://www.biomedcentral.com/about/editorialpolicies#Ethics

Standards of reporting:
http://www.biomedcentral.com/about/editorialpolicies#StandardsofReporting