Author’s response to reviews

Title: Transcranial direct current stimulation (tDCS) for treatment of major depression during pregnancy: study protocol for a pilot randomized controlled trial

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Author’s response to reviews: see over
August 27, 2014

RE: Revision Submission for “Transcranial direct current stimulation (tDCS) for treatment of major depression during pregnancy: study protocol for a pilot randomized controlled trial”

Dear Editors,

Thank you for the opportunity to submit a revision for our paper entitled: “Transcranial direct current stimulation (tDCS) for treatment of major depression during pregnancy: study protocol for a pilot randomized controlled trial”.

Our responses to reviewer comments and editorial requests are itemized below.

Reviewer comments (minor essential revisions)

1. Background: Please add information about the effect sizes of tDCS from previous studies, and effect sizes of the current available treatment options for depressed pregnant women (anti-depressant medication and psychotherapy).
   
   We have now added information on the effect sizes of tDCS (0.49), anti-depressant medication (0.61), and psychotherapy (ranging from 0.15 to 0.39).

2. Which diagnostic instrument will be used to assess DSM-5 MDD diagnosis?
   
   A diagnosis of major depressive disorder will be confirmed using the Mini International Neuropsychiatric Interview (MINI). This has been clarified in the methods section of the manuscript.

3. Please add information about the background/training of assessors.
   
   Assessors are, at minimum, Masters-level trained research staff who have received additional training in the procedures of MINI, Good Clinical Practice (GCP), Responsible Conduct of Research (RCR) and the Second Edition of the Tri-Council Policy Statement for Ethical Conduct for Research Involving Humans (TCPS-2). This information has been added to the manuscript.
4. Please add psychometric properties when describing the included measurements (reliability, validity coefficients).
   
   Information on reliability and validity has been added to the manuscript for the efficacy outcome measures (i.e. Montgomery-Aspers Depression Rating Scale; Edinburgh Postnatal Depression Scale).

5. Please ensure the title conforms to journal style for study protocol articles.
   
   We have revised the study title to conform to the journal style. The title of our manuscript is now “Transcranial direct current stimulation (tDCS) for treatment of major depression during pregnancy: study protocol for a pilot randomized controlled trial.”

6. Please include all author affiliations and email addresses on your title page.
   
   All author affiliations were included on the title page. We have updated the title page to include the email address for each author.

7. Please include the date of registration with your trial registration number at the end of your abstract.
   
   We have updated the abstract to include that the study was formally registered with ClinicalTrials.Gov on April 15, 2014.

8. Please move your funding information to the Acknowledgements.
   
   Our sources of financial support are now in the Acknowledgements section of the manuscript.

9. Please only cite published or in press articles or remove the Walton et al. 2014 reference.
   
   The Walton reference has now been published and the referencing within the manuscript has been revised to reflect this. All articles cited in this paper are now published.

Editorial requests

1. Please ensure the title conforms to journal style for study protocol articles. The title should follow the format “________: study protocol for a randomized controlled trial.”
   
   We have revised the study title to conform to the journal style (see reviewer comment #5).

2. Please include all author email addresses on your title page.
   
   We have updated the title page to include the email address for each author.

3. Please include the date your study was registered with your trial registration number at the end of the Abstract.
   
   We have updated the abstract to include that the study was formally registered with ClinicalTrials.Gov on April 15, 2014.

4. Please include the reference numbers provided with ethical approval with your ethics statement in the Methods section.
We have added the reference numbers for ethical approval at each institution involved in the study (Women’s College Hospital Reference Number 2013-0085-B; Mount Sinai Hospital Reference Number 13-0320-A) to the methods section.

5. Please move your funding information to the Acknowledgements section.
   Our sources of financial support are now in the Acknowledgements section of the manuscript.

6. Please include a figure title and legend section after the reference list.
   We have included the figure title and legend section after the reference list.

7. Please include an additional file title and legend section after the figure legend section.
   We have added the Figure File Title after the figure legend section.

In addition, we have ensured that the revised manuscript conforms to the journal style to the best of our ability. All content changes are in red script.

Thank you so much for the opportunity to submit our revised manuscript to your journal.

Sincerely,

Dr. Simone Vigod, Study Principal Investigator
Scientist, Women’s College Research Institute, Women’s College Hospital
Assistant Professor, Department of Psychiatry (Faculty of Medicine) and Institute of Health Policy, Management and Evaluation (Dalla Lana School of Public Health) University of Toronto; Adjunct Scientist, Institute for Clinical Evaluative Sciences