Author’s response to reviews

Title: Evaluation of the efficacy of Transcranial Direct Current Stimulation in the treatment of cognitive symptomatology in the early stages of psychosis: study protocol of a double-blind randomized controlled trial

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Author’s response to reviews:

March 05, 2019

Dear Dr. Shaun Treweek:

Thank you for reviewing the original study protocol entitled “Evaluation of the efficacy of Transcranial Direct Current Stimulation in the treatment of cognitive symptomatology in the early stages of psychosis: study protocol of a double-blind randomized controlled trial” which was submitted to Trials. We appreciated the comments, which once again significantly improved the article. The revisions appear marked in bold in the SPIRIT Checklist.
Reviewer reports:

- “I'm looking over your revised manuscript for your protocol 'Evaluation of the efficacy of Transcranial Direct Current Stimulation in the treatment of cognitive symptomatology in the early stages of psychosis: study protocol of a double-blind randomized controlled trial'. Basically I'm happy with the new version but there's one thing I'm unsure about, which is your SPIRIT response re. sponsor ('Non-sponsored study'). My expectation would be that all trials have a sponsor, ie, as the Europeans define sponsor – 'An individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial.' It may well be there there is no organisation providing funding but I'm guessing that your own institution at the very least has legal responsibilities linked to the trial, for example ensuring that the trial is conducted to Good Clinical Practice standards or equivalent or that records are kept regarding ethical amendments etc. An example of UK sponsor requirements is here:
  http://www.cttoolkit.ac.uk/routemap/sponsorship/downloads/sponsorship_principles_V5Jun16.pdf. Obviously this is a UK document but I'm sure that there must be similar legal responsibilities in Brazil. Could you have a look again at that entry in the SPIRIT checklist and paper re. sponsor and see what you think? If you'd like to make a change, upload a new version. IF there really is no sponsor, can you amend the text to say why this is?”

♫ We are delighted to know that you are happy with the new version. We’ve been working hard to improve the manuscript. Thank you for your guidance. As suggested, we revised the SPIRIT checklist.

Thanks again for revising this manuscript. Look forward to receiving your comments for this revised version of paper.

Sincerely,

Thais Rabanea-Souza and Colleagues

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