Reviewer’s report

Title: Photobiomodulation using Low-Level Laser Therapy (LLLT) for patients with chronic Traumatic Brain Injury: a randomized controlled trial study protocol

Version: 0 Date: 27 Sep 2017

Reviewer: Xinxing Lai

Reviewer’s report:

Thanks for inviting me to review this protocol. Since current treatment options for TBI remain limited, the photobiomodulation has garnered a greater interest as an alternative approaches to treat TBI. Up to date, there is no published randomized controlled trial to investigate the efficacy of transcranial light therapy for TBI. I am pleased to see such a study protocol for TBI. However, there are several methodological deficiencies to be improved in this protocol. Followings are the comments to the authors that should be considered.

1. Title

"stydy protocol for a randomized controlled trial"? study protocol?

2. Background

(1) The authors reported, "It is also a global health problem, exerting great socio economic impact worldwide with annual expenditures involving billions of dollars." However, the cited publication was incidence and lifetime costs of injuries in the United States. Publications of epidemiology and disease burden on TBI worldwide are necessary. (Page 3)

(2) Is there any previous study focus on transcranial light therapy for TBI such as preclinical research, case report, and case series study?

3. Method

What are the primary and secondary outcomes in this study?

4. Patients

The authors reported, "Will be asked 36 patients [28], of both sexes which entered the Neuro Traumatic Clinic of the Hospital das Clínicas (USP). After thorough screening, ambulatory patients will be divided into 2 groups (1: 1) or placebo optical active device in accordance with the randomization list." These sentences are in confusion. And the cited article (28) is a
randomized trial of low-frequency rTMS in chronic stroke. Why did you cited such article in this section? (Page 4)

5. Inclusion criteria

What does it mean that "with time of TBI from 3 months"? Do you mean patients of TBI within 3 months after trauma? (Page 5)

6. Randomization and blinding

(1) What is the method of generating the allocation sequence?

(2) The authors reported this study as a double-blind trial, why the researchers involved with TBI sessions assign participants to the intervention group? Is it a single blinded trial? (Page 5)

(3) The randomization (sequence generation, allocation concealment, and implementation) as well as blinding sections are in confusion. Please improve them according to SPIRIT statement [1].

(4) Is there a SPIRIT Checklist for this protocol?


7. Data collection and management

Any plans for data collection and management?

8. Data analysis

For primary and secondary outcomes, the relevant statistic methods should be declared in detail. (Page 6)

9. Sample size

The cited article (29) is a randomized, double-blind trial of low-frequency rTMS on naming abilities in early aphasic stroke patients. Why did you cited such article about rTMS in this section? (Page 7)

10. Quality of written English
The English of this manuscript is poor. The following but not limited to sentences are necessary to be improved.

(1) An aleatory double-blinded clinical trial will be made in 36 patients with moderate and serious cases TBI. (Page 2, abstract)

(2) The primary hypothesis of this study, therefore, that the present optical active device group will improve between baseline and late > 1 standard deviation about the Trail Making Test B (TMTB) in comparison with control group patients. (Page 3, background)

(3) As secondary measure; assess the early and late performances after sessions TLT with neuropsychological evals, which include: memory, executive functions, attention, processing speed and visual construction; intensity of symptoms of depression and anxiety; also expected to assess the technical difficulties of the proposed protocol as basis for improving further studies. (Page 3, background)

(4) With data collection extension authorized the Salgado Institute, Londrina. To keep patient’s compliance in the trial will be performed regular contacts via phone. (Page 3, method)

(5) For a normal sample will be used SPSS version 10.0 for Windows. (Page 6, data analysis)

**Level of interest**

Please indicate how interesting you found the manuscript:

An article whose findings are important to those with closely related research interests

**Quality of written English**

Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

**Quality of figures**

All images and figures within the manuscript should be genuine i.e. without evidence of manipulation. No specific feature within an image may be enhanced, obscured, moved, removed, or introduced. If you have concerns about the veracity of the figures you should choose the first option below.

**Statistical review**

Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.

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