Reviewer’s report

Title: Photobiomodulation therapy on the palliative care of temporomandibular disorder and orofacial/cervical skull pain: study protocol for a randomized, controlled clinical trial

Version: 1 Date: 12 Feb 2019

Reviewer: Daniela Hesse

Reviewer’s report:

Dear authors, thank you for submitting a revised version of your study protocol. Although some important corrections and clarifications were made during the review process, some points of concern still remain.

The authors state that the manuscript was reviewed concerning the English language, grammatical and typing mistakes. However, I still could find some typing mistakes and sentences that does not make sense. Therefore, I insist in the advice that the manuscript go through a comprehensive text revision is advised, including review of the English language, preferably with a native speaker.

Abstract

Page 2 - line 22: please delete the word photobiomodulation and keep only the abbreviation (as it appear already in the background section of the abstract).

Background

Page 3 - line 41: Please include the full term "Photobiomodulation therapy (PBMT)", as it is the first time this abbreviation appears in the text.

Page 3 - line 56: Please rephrase the sentence "Khaligh et al. [15] conducted a study comparing the use of a nonsteroidal anti-inflammatory drug (NSAID, Naproxen 500 mg) to the PBMT and concluded that the PBMT reduced pain intensity and increased mouth opening amplitude". There are some repeated words and it is not clear here what is the comparison (NSAID versus PBMT?)

Page 4 - line 5: the word "result" is repeated and should be deleted

Page 4 - line 13: In my opinion, the objectives help elucidating the importance of the study and it would help the reader if it was placed right after the introduction. Therefore my suggestion is that the hypothesis are placed after the objectives of the study.

Page 4 - line 36: Please substitute "PBM therapy" by "PBMT"
Methods/ Design

Page 5 - line 37: The phrase you have written in the answers to the reviewer was, in my opinion, better. (Other researcher (P.M.F.), not involved with laser application, will be in charge of setting the equipment for each experimental group: active and placebo (without emission of laser light).)

Page 5 - line 56: please use a "space" between researcher and (PMF)

Page 6 - line 4: first time this abbreviation appears in the text, so it should first be fully written. Or could TMJ be substituted for TMD? If yes, please substitute TMJ by TMD in the entire manuscript

Page 6 - line 8: What is DTM? or did you mean TMD?

Page 6 - line 46: The sentence "Despite the data available in the literature we take them into account to use the magnitude of effect of 50% among groups." is not clear for me... you want to say that although there is data in the literature, you will use them in order to calculate the sample size? To what publication are you referring here? It would be better to include the reference here, so the reader knows the success rate that you based your sample calculation.

Page 6 - line 50: The sentence "We will consider increase the sample size in order to compensate for possible drop-outs in case of compromise the results." appears again in the next paragraph, therefore I think it could be excluded.

Page 7 - line 7: the information "the clinical sessions will take place at the Special Laboratory of Lasers in Dentistry (LELO) of the School of Dentistry of the University of São Paulo." Was already given before, and therefore it could be deleted.

Page 7 - line 18: Regarding the phrase "After randomization, the group in which the participant will be allocated will be defined: Group 1 (active treatment - PBMT) or Group 2 (placebo)." This will be defined during the randomization process and this information was actually already given. Please delete this phrase.

Page 7 - line 31: The clinical examination will be performed by the operators, right? In the intervention group a laser will be applied and in the other group (placebo), the same machine will be used, but no laser will be irradiated. My question here is: how can you make sure that the operators (who are the examiners) will be blinded to the 2 groups?

Page 8 - line 39: Thank you for addressing my question. I still miss some more clarification on how this calibration will be performed. As this is one of the primary outcome of the study, it should be well explained here (i.e.: what kind of training they will undergo, first theoretical discussion, then evaluation of patients, training based on the evaluation of those patients). Are you going to calculate inter and intra-examiners' agreement, to make sure they are calibrated? Or you think a training will be enough?
Discussion

Overall, I believe the discussion

Page 10- line 47: please add a reference to support your statement that TMD impacts the quality of life of patients

Page 10- line 51: please add a reference to support your statement that PBMT can be used to treat PBMT (you can use the same ones you already have in the introduction)

Figure 2

The figures should be well understood without going back to the text. So please make clear here what RDC means. Also, I understand that you will perform a block randomization in which 50 patients will be randomized per time, but when I see this figure, it leads to the interpretation that only 50 patients will be included in the research. Please make it more clear (that a total of 200 patients will be included).

Table 1

Please translate the word "potência"

Level of interest
Please indicate how interesting you found the manuscript:

An article of importance in its field

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.
Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

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3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

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Were you mentored through this peer review?

No