Author’s response to reviews

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

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TRLS-D-18-00596

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

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Response to reviewers’ comments:

Reviewer #1:

1. “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.

Answer: Manuscript was reviewed by a native speaker and the certificate was attached to this document. You can find it below.

2. “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).

Answer: Changes were made according to reviewer’s comment.
3. “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.”

Answer: Changes were made according to reviewer’s comment.

4. “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?)”.

Answer: Authors agree with the reviewers’ comment and have rewritten the sentence, as follows: "Khaligh et al. [15] conducted a study comparing the use of a nonsteroidal anti-inflammatory drug (NSAID) with PBMT and the results showed that the PBMT was more effective than the NSAID in reducing pain intensity and increasing mouth opening amplitude.”.

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

Answer: Changes were made according to reviewer’s comment.

6. “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.”

Answer: Changes were made according to reviewer’s comment.

7. “Page 4 - line 36: Please substitute "PBM therapy" by "PBMT".

Answer: Changes were made according to reviewer’s comment.

8. “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).)”

Answer: Changes were made according to reviewer’s comment.

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

Answer: Changes were made according to reviewer’s comment.
10. “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.”

Answer: Changes were made according to reviewer’s comment.

11. “Page 6 - line 8: What is DTM? or did you mean TMD?”

Answer: Changes were made according to reviewer’s comment.

12. “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.”


13. “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.”

Answer: Changes were made according to reviewer’s comment.

14. “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.”

Answer: Changes were made according to reviewer’s comment.

15. “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.”

Answer: Changes were made according to reviewer’s comment.
16. “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?“.

Answer: Two items of laser equipments will be used, one for the placebo group and one for the experimental group. The units of equipment will be labeled with different letters (A and B) and only the researcher in charge of the randomization (PMF) will have access to this information. The researchers (FRC; RQB) who will conduct the laser (placebo or active) application will not be informed of which laser equipment is the active or the placebo type.

This information was added to the text (intervention section).

17. “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?“.

Answer: Some information was added to the text, as follows: “After the randomization procedure, each participant will be diagnosed using the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD)[19,20]. The RDC/TMD consists of palpation of the TMJ and orofacial/cervical muscles; measurement of the mouth opening and mandibular movements using a ruler and caliper; verifying collecting presence and types of articular sounds; and information on parafunctional habits, bruxism, pain, psychological aspects, chewing. The researchers (FRC; RQB) in charge of applying the questionnaire have experience in the use of this diagnostic instrument, which is considered the gold standard method. However, prior to beginning with the study, the researchers (FRC; RQB) will undergo a calibration step, focused on training for application of the RDC/TMD. Calibration will consist of reading the RDC/TMD manual together [19,20], discussion of possible doubts, and application of the instrument to one patient, performed by each researcher (FRC;RQB). After checking the results and discussion, should there be any disagreement about the results, researchers will reapply the RDC/TMD form in another participant, and if any discordant points still remain, the form will be applied to other patients for the purpose of calculating the intra- and inter-observer Kappa index of agreement [21].

The RDC/TMD assessment will be applied to all participants, before and after each clinical session, by the same researchers (FRC or RQB). “

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

19. “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)”. 

Answer: Reference was added as suggested by the reviewer.

20. “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).

Answer: Changes were made on figure 2, as suggested by the reviewer.

21. "Table 1 - Please translate the word "potência".

Answer: The word “potência” was translated.

NOTE: Some changes were made in the bibliography, because there was a duplicate reference (references 18 and 21) and 2 new references were added (references 18 and 26)

CERTIFICATE

GALBRAITH COMUNICAÇÕES Ltda.

TO WHOM IT MAY CONCERN

I, Margery J. Galbraith, a native English speaker residing in Brazil since 1974, have been involved in the translation of a wide range of technical documents since 1979, and in review and translation of scientific articles related to dentistry and medicine since 1982. Furthermore, I declare that I am a full partner and co-director of Galbraith Comunicações Ltda, and my part in the company activities is doing the work of translation and review of scientific articles.

I hereby certify that I reviewed the English language in the article entitled “TRLS- D-18-00596 - Photobiomodulation therapy in the palliative care of temporomandibular disorder and orofacial/cervical skull pain: study protocol for a randomized, controlled clinical trial”, at the request of the following authors: Professors Fernando R Carvalho; Rafael Q Barros; Alyne S Gonçalves; Patricia M Freitas, of the Special Laboratory of Laser in Dentistry (LELO) of the School of Dentistry of the University of Sao Paulo (USP), SP, Brazil.
Any changes made to the manuscript after this review will be for the authors' responsibility.


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