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## Reviewer A

First, in the title the authors need to indicate that this is a study protocol and the subjects and outcomes such as efficacy and safety of this study, as well as sham-controlled.

*#1 We appreciate the reviewer's correction. The title has been changed to: Simulation of the auricular branch of the vagus nerve by acupuncture in women with fibromyalgia with severe pain and other functional and emotional problems: study protocol for a randomized, controlled, double-blind clinical trial.*

Second, the abstract needs some revisions. The background did not briefly describe the knowledge gap on this research focus and what the potential clinical contribution of this study is. The methods need to describe the randomization method, details of the sham stimulation, how the outcome scales will be administered, and main statistical methods.

*#2 The abstract was completely modified, following the reviewer's recommendations. The modifications can be seen in the new version of the manuscript and are marked in yellow in the text.*

Third, in the introduction of the main text, the authors need to briefly review the available treatments for FM, have comments on their limitations and efficacy, explain why there is a need for non-pharmacological treatments such as acupuncture, review the strengths of acupuncture for treating FM, analyze the knowledge gaps on the ABVN for FM, and explain why the authors also focused on inflammatory biomarkers as outcomes and compared left and right ABVN.

*#3 Aspects addressed by the reviewer in the introduction have been carefully added or modified. Thus, for a better description of the fibromyalgia treatment (Kwiatek R. doi: 10.18773/austprescr.2017.056) and to explain why to analyze the ABVN treatment in the right and left ear (Neves ML, et al. doi: 10.1016/j.lfs.2022.121000), different references were added. All information is marked in yellow in the text of the new version of the manuscript.*

Fourth, in the methodology of the main text, please describe how the parameters for estimating the sample size were obtained and I suggest the authors to add measures to assess the success of the sham ABVN, because ensuring the successful sham acupuncture is importante. The statistical analysis part is not standardized, which needs to indicate the analytic subsets such as ITT or PP, and the handling of missing data.

*#4 Sample size and statistic description were described again. All details are marked in yellow in the manuscript text.*

## Reviewer B

1. ANOVA should be defined upon first use in the Abstract.

*Response: The text has been modified to "The data will undergo a normality test, mixed factorial analysis of variance (ANOVA), followed by Bonferroni post-hoc or non-parametric Mann-Whitney U tests."*

2. The definition of NPRS is Numerical Pain Rating Scale. Please check the Abstract and the Main Text.

*Response: The definition was modified on page 7, lines 209 and 236.*

3. The definition of LANDI/CCB/UFSC/GDI/EIS/PRSS should be checked for accuracy.

PRSS/TNF should be defined upon first use in the Main Text.

*Response: Laboratory of Neurobiology of Pain and Inflammation (LANDI); Biological Sciences Center (CCB); and Federal University of Santa Catarina (UFSC) are proper names - in the case of the laboratory, center and institution - where the research will be carried out. The acronyms indicated are the terms in Portuguese. For ease of reading, they have been removed from the text. The other terms were also removed because they were not used elsewhere in the text.*