Author's response to reviews

Title: Auricular acupuncture for primary care treatment of low back pain and posterior pelvic pain in pregnancy: study protocol for a multicentre randomised placebo-controlled trial

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Author's response to reviews: see over
Dear Sir,

Please find attached the Author’s replies to the Reviewer’s comments:

Yours sincerely,

Jorge Vas

Reviewer’s report

Title: Auricular acupuncture for primary care treatment of low back pain and posterior pelvic pain in pregnancy: study protocol for a multicentre randomised placebo-controlled trial

Reviewer: Yan Zhang

Reviewer’s report:

Major Compulsory Revisions:

1. The treatment section:
   a. Training: How are the midwives trained to conduct the auricular treatment? Who are the trainers? What are the trainers’ qualifications? What are the strategies to ensure/measure training fidelity?

   The following paragraph has been added in the Treatment section:
   The workshop will be given by two physicians who are specialists in acupuncture and have over 10 years’ clinical experience. At one month after initiating the study, a test will be applied to confirm that the skills acquired in the workshop are retained.

   b. Procedure: What is the treatment protocol exactly? Are both ears involved, or just one side a time? Will the ear(s) be disinfected before implant the press needles? What if the placebo tapes fall off before the one-week withdrawal? Are the participants allowed to press on those needles or tapes? If so, how frequently?

   The paragraph has been modified as follows:
   The points will be located in a single ear, preferably the one on the side of the body corresponding to the location of the pain; if the pain is bilateral, the most sensitive ear will be determined by using a probe to exert a pressure of 250 g. Before placing the implants, the ear will be disinfected using chlorhexidine. The patients will be instructed not to exert pressure on the implants at any time.
2. Data sourcing and compilation: Are the follow-up self-administered questionnaires done in person or via phone, internet or mail? It was not very clear how the information being electronically recorded. What is the program used for data entry and/or analysis? In addition, there ought to be some discussion regarding the response burden since multiple questionnaires are used. There is NO discussion regarding data management. How are patient privacy and information confidentiality being protected?

The following paragraph has been added in the Data Sourcing and Compilation section:

Data collection will be conducted in person, at times T0, T1, T2, and T3. Only the evaluation at T4 will be carried out by telephone. Patient confidentiality will be maintained by removing patient identity data from the database.

3. Statistical Analysis:

a. The statistical analysis plan is too general. All the statistical tests should be addressed based on their outcome/hypothesis. According to the primary outcome/hypothesis, I would think Repeated-Measure ANOVA would be more appropriate. Why linear regression is proposed? Please clarify.

The order of presentation of the statistical tests described in the statistical plan aims to respond sequentially to the objectives proposed. The test corresponding to the main objective of reducing pain intensity is suitable for assessing pain reduction among two groups, while the ANOVA test value is valid for comparisons of three or more groups. Multivariate linear regression analysis was carried out in order to ensure that no unbalanced variable would interfere with the VAAC efficacy evaluation group.

b. How those secondary aims being analyzed need to be elaborated. I suggest the authors to create statistical analysis matrix to include Independent Variable (IV) and Dependent Variable (DV) as well as proposed test for each aim.

The Statistical Plan section is drafted with sufficient clarity and precision for the reader to be able to assess each of the objectives. Therefore, we do not consider a statistical matrix to be necessary.

c. The alpha level used for sample estimation is 0.01 while the confidence levels discussed are 95%. Why?

The value of statistical significance has been modified, both for the overall sample analysis (0.01) and for the intermediate analysis (0.005)

Minor Essential Revisions:
1. Variables: I suggest the authors to use a table to summarize the variables corresponding to each outcome and time collection point.

We believe the variables and the measurement points are sufficiently clear, and that there is no need to include them in a summary table.
Level of interest: An article of importance in its field
Quality of written English: Acceptable
Statistical review: Yes, and I have assessed the statistics in my report.
Declaration of competing interests:
I declare that I have no competing interests.