Author's response to reviews

Title: Motion style acupuncture treatment (MSAT) for acute low back pain with severe disability: a multicenter, randomized, controlled trial protocol

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Author's response to reviews: see over
Dear Reviewer

RE: Motion style acupuncture treatment (MSAT) for acute low back pain with severe disability: a multicenter, randomized, controlled trial protocol (MS: 8033303585635748)

On behalf of my co-authors, I would like to thank you for arranging a peer-review of our manuscript and for your invitation to submit a revised version. We appreciate the reviewer for his thoughtful comments on our work, and for the effort and time they put into the review of our manuscript and believe that his constructive suggestions have resulted in a stronger manuscript for the BMC Complementary and Alternative Medicine’s readers. We addressed the issues raised in the revised manuscript (blue color) as follows.

Reviewer Comments and Answers

Major Compulsory Revisions: This study does not follow all the CONSORT guidelines.

Answer and revised> We revised our manuscript according to the CONSORT guidelines the reviewer pointed out. When modifying the manuscript we highlighted all changes in text in yellow, and we also attached the CONSORT checklist.

Comment 1) Background, page 5: “Motion style acupuncture treatment (MSAT) is different from traditional acupuncture treatments, and it has been shown to be clinically effective for acute back pain treatment in South Korea.” Provide citations for this statement or remove. If the MSAT has already been shown to be effective, what is the purpose of your study?

Answer and revised> MSAT is different from existing traditional acupuncture treatments, and we wished to explain that MSAT is currently used clinically in Korean traditional
medical clinics as a treatment method for acute back pain. But thanks to the reviewer comment, we realized it was an inappropriate expression. Therefore, we removed the phrase “and it has been shown to be clinically effective for acute back pain treatment in South Korea” and modified it to “and it is used to reduce musculoskeletal pain and improve functional status in South Korea” (in page 5 line 7~8)

Comment 2) Sample size, page 9: Declare clinically important effects (e.g., > 0.5 effect size). Does that change your sample size calculation?

Answer and revised> As noted by the reviewer, in order to disclose clinically important effects we added the following. : (in page 8 line 4~6)

“As MSAT is more effective than NSAID injection in previous clinical experience, we set the effect size [Cohen's d] > 0.5.”

We would also like to add that determining the effect size as such does not affect the sample size calculation. But in order to give a more specific explanation of the sample size calculation process, we added the following to our manuscript. : (in page 8 line 14~17)

“According to these estimations, although the difference between the mean difference of two groups is 2.3, we conservatively set it as 2. The standard deviation between the two groups was estimated to be 2.5”

Comment 3) Secondary outcome measures, page 13: Provide the psychometric qualities (reliability, validity, and responsiveness) of the this modified 4-item ODI measure. You cannot assume that the validated 10-item measure and a your 4-item measure are the same.

Answer and revised> As our selection criteria included only patients with physical function limitation due to severe back pain as trial subjects, in order to more effectively assess improvement, we initially selected 4 items mainly related with motor function of the original
10 that constitute the ODI questionnaire and were planning to compare the difference before and after treatment. But as the psychometric qualities (reliability, validity, and responsiveness) of the modified 4-item ODI measure have yet to be evaluated through research, as pointed out by the reviewer the 4-item measure cannot be viewed as equal to the validated 10-item measure. Thus, we modified our paper to use the original 10-item ODI measure of which the reliability and validity has been confirmed as our trial’s secondary outcome measures. The phrase ‘modified ODI’ was revised to ‘ODI’ in the Methods/Design section of our abstract, and the contents of Secondary outcome measures was amended thus: 

(in page 13 line 5~10)

“The patients’ functional status will be evaluated using the ODI questionnaire. It is a 10-item questionnaire developed to evaluate the degrees of disability for lower back pain. Each category is divided into six stages with 0–5 points each. A high number of points indicates severe disability. The accredited Korean version of the ODI questionnaire [23] will be conducted at baseline and 30 minutes and at 2, 4, and 24 weeks after treatment.”

Comment 4) Secondary outcome measures, page 14: Describe the psychometric qualities (reliability, validity, and responsiveness) of SLR and ROM. Are their psychometric qualities good enough to use as a measure in your study?

Answer and revised> We added the following on the psychometric qualities of ROM and SLR: (in page 13 line 21~ page 14 line 1)

“The measurement of ROM is reliable (r = 0.94) and valid (r = 0.97) [25], but it is not very responsive (effect size 0.1–0.6) [26]. Also, the measurement of SLR is reliable (intraclass correlation coefficient = 0.95) [27], and the sensitivity is 0.8 (72–97%), the specificity is 0.4(11–66%) [28], but it is not very responsive (effect size = 0.2) [26].”

In addition, as the responsiveness of ROM and SLR measurement is not high, we decided to
use it as a secondary outcome measure instead of a primary outcome and included the following concerning this matter. (in page 14 line 1~2)

“As the responsiveness of ROM and SLR measurement is not high, we decided to use it as a secondary outcome measure instead of a primary outcome measure.”

Comment 5) Statistical Analysis, page 15: Statistical testing via a t-test is inappropriate and irrelevant. Provide effect size and/or number needed to treat to your statistical calculations with a measure of precision (e.g., 95% confidence intervals).

Answer and revised> As commented by the reviewer, our method of statistical analysis seems inappropriate and irrelevant, and after consulting with an expert on statistics the Statistical Analysis section was modified as follows: (in page 14 line 19~ page 15 line 9)

“The results will be considered to be statistically significant when p < 0.05. For descriptive statistics, normally distributed variables are expressed as mean ± standard deviation (SD) and compared using t-test or analysis of variance as required, accounting for unequal variance as required. Variables with a skew distribution or non-parametric variables will be expressed as median and range, and will be compared using the Mann-Whitney U-test. Categorical associations will be compared using Chi-squared test or Fisher’s exact test. General linear model-multivariate will be performed, considering the mean difference as a dependent variable, and covariates including age, gender, height, weight, and blood pressure, and independent variables including the group. Also, we will calculate the power of our study using the mean difference of NRS of the experimental and control groups, the standard deviation of difference of NRS of both groups, a significance level of 0.05, and the actual number of subjects who successfully completed treatment.”
Comment 6) You need to discuss that you will provide a diagram of the flow of participants through each stage of the study.

Answer and revised> We attached an image file of the diagram of the flow of participants when we initially submitted our manuscript, but in reference to the CONSORT Statement we plan to re-attach a revised diagram reflecting changes in follow-up.

Comment 7) You need to discuss that you will provide data on adverse events.

Answer and revised> Before revision, we stated that we would use the Chi-squared test or Fisher's exact test concerning adverse events in the Safety monitoring section of our manuscript. But with reference to the reviewer’s comment, we revised the statistical analyses part to include the following, more detailed explanation on statistical analyses regarding adverse events in the Safety monitoring section. (in page 15 line 10~13)

“All adverse events reported during the study will be included in the CRFs; the incidence of adverse events will be calculated. The percentage of subjects with adverse events in each group will be calculated and compared using the Chi-squared test or Fisher's exact test.”

Also, in accordance to this revision, the Safety monitoring part contents will also be modified: (in page 16 line 4~9)

“The assessment of safety will be based mainly on the frequency of adverse events, which includes all serious adverse events. Information regarding adverse events will be summarized by presenting the number and percentage of participants that experienced adverse events, with the information also categorized according to the body region affected. Any other collected information (e.g., severity or relevance to treatments) will be included in the safety monitoring reports.”

Comment 8) You need to discuss that you will measure and report the success of your
Answer and revised> As the experimental group in our study receives acupuncture treatment, namely MSAT, and the control group is an active control group as opposed to a sham treatment group and receives NSAID injection, both investigator and subject are aware of the treatment method. Therefore it is impossible to blind both investigator and subject, and it is also difficult to assess whether blinding was appropriately achieved. Although our study was unable to measure and report the success of blinding schemes, we plan to blind the assessor and statistician and the details are described in the manuscript as follows.:

This study is designed as a randomized, controlled, assessor-blinded trial. As the experimental group receives acupuncture treatment, namely MSAT, and the control group receives NSAID injection, we are unable to blind both physician and subject to the modality of treatment. Still, assessor-blinding will be achieved by blinding the assessor performing outcome assessment and CRF data entry to the random allocation and treatment of subjects. Statistical analysis will be performed by an independent statistician who is blinded to the identification of each treatment group.”

Comment 9) Most importantly, you must follow-up on patients beyond one-half hour after therapy. Durability of an intervention is important to patients and providers. You should follow participants at least 6 months after the intervention. You cannot establish effectiveness from one short-term measure and cannot adequately test your hypothesis.

Answer and revised> We initially planned to conduct evaluations 30 minutes after treatment to assess short-term effects, as the pain relief and improvement in motion due to MSAT and diclofenac injection appears immediately after treatment. But as the reviewer noted, we perceived the benefits of assessing the durability of our treatment to further elucidate its
effectiveness and decided to perform additional follow-ups at 2, 4, and 24 weeks. But, as we will use telephone interviews to make assessment simpler, ROM and SLR will not be included as outcome measures. We revised the contents as follows. (in page 12 line 11~15) “We will also perform additional follow-ups at 2, 4, and 24 weeks and assess the outcome to verify the durability of our treatment. But, we will use telephone interviews to make assessment simpler, and range of motion (ROM) and degree of straight leg raising (SLR) will not be included as outcome measures at post-treatment follow-up for that reason.”

Thank you for your valuable comments.