Author's response to reviews

Title: Moxibustion for treating knee osteoarthritis: study protocol of a multicentre randomised controlled trial

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Author's response to reviews: see over
Dear Editor-in-Chief,

We are pleased to resubmit the manuscript entitled "Moxibustion for treating knee osteoarthritis: study protocol of a multicentre randomised controlled trial" by Lee S at al.

We revised our manuscript according to reviewer and editorial comments, and our revised manuscript was edited for proper English language and grammar by native English speaking editors at American Journal Experts. The details are as follows:

**Reviewer’s report**

1. This study is designed to test the effectiveness and safety of moxibustion for knee OA.

2. To clarify the primary and secondary hypotheses, please describe the detailed aims more clearly using numbers.

: We agree with this recommendation. We made “objective” section in Methods/Design, and describe the detailed aims using numbers.

3. In addition to this, authors commented that the cost effectiveness and qualitative research will be performed as well. Authors also need to specify the aims related with these research.

: We agree with this recommendation. We also specified the aims related with the economic evaluation and the qualitative research in “objective” section.
4. There are no rationale why the economic evaluation and qualitative research are essential for this study. Please describe these in the background.

: We agree with this recommendation. We described the reasons why the economic evaluation and the qualitative research are necessary in this study in background and discussion as follows.

“More than half of Korean medical doctors (KMDs) use moxibustion for treating KOA [20], and moxibustion is one of the most common complementary and alternative medicines in Korea [21]. Because of the wide prevalence of moxibustion in Korea, it is necessary to evaluate the economic worth of moxibustion treatment for treating KOA, and to understand why KOA patients seek moxibustion treatment and how they regard moxibustion treatment performed by a KMD, a qualitative study is needed in addition to the quantitative approach.”

“Mixed-method research is the most recent systematic approach of using two or more research methods to answer a single research question. This approach has the advantages of expanding the understanding or verifying results from another perspective than one that uses a single method because the supplemental component enhances the validity of the study [36, 38]. This method has been used to determine the effectiveness of interventions in recent studies on complementary and alternative medicine [39-41]. To comprehensively understand the effectiveness of moxibustion for KOA patients, we will conduct not only quantitative but also economic and qualitative data analysis. A nested economic evaluation and qualitative research within a pragmatic clinical trial will provide a mixed-method approach to answer the question from various perspective on the reasons for using moxibustion for KOA.”

5. The methods for economic evaluation and qualitative research are messing.

Please specify how to collect the cost data, and how to perform qualitative research in separate sections with each heading.

: We agree with this recommendation. We described the details for economic evaluation and qualitative research in separated sections.
6. In addition, do you interview all patients? Or how to select the appropriate candidate for qualitative study? Please specify it.

: We agree with this recommendation. We described details including how to select the candidate in “qualitative research” section as follows.

“Sixteen KOA patients who will be selected by convenience sampling will be included in the qualitative study if they consent to give a recorded face-to-face interview.”

7. Please include quality control for this study.

: We agree with this recommendation. We added this in “Data and safety monitoring” section.

“

8. Please specify how to protect human subjects.

: We agree with this recommendation. We specify this more detail in “participant protections and ethics” section.

9. Discussion is missing, and this needs to be added.

: We agree with this recommendation. We added discussion.

**Editorial comments:**

Previously you have provided us with documentation showing that the protocols of your study have been approved by the Korea Institute of Oriental Medicine. Could we please ask you to detail this fact in the ethics statement in your manuscript.

: We added the statement “The Korea Institute of Oriental Medicine certified the ethics
approval of the clinical centres as above.” to “Participant protections and ethics” section.

In addition, we would now ask you to remove your ethics documentation from the Additional File associated with your manuscript.

: We removed our ethics documentation from the Additional material files.

We thank you in advance for your consideration of this manuscript.

Sincerely yours,

Sun-Mi Choi

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