Author's response to reviews

Title: Rehabilitation for the Management of Knee Osteoarthritis Using Comprehensive Traditional Chinese Medicine in Community Health Centers: Study Protocol for a Randomized Controlled Trial

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**Answer to reviewer:**

1) I am concerned about the value of publishing this protocol at this stage. Recruitment for this trial is almost complete, and there seems little to gain from opening the protocol to public review at this stage. I wonder whether there might not be more value in asking the authors to withhold this manuscript and publish a first report when some early data are available.

**Answer:** Rehabilitation using methods from Traditional Chinese Medicine (TCM), such as Chinese medical herbal patches, traditional exercises and acupuncture have been reported to clinically improve the symptoms of knee osteoarthritis (KOA). According to the difference of this methods used in each hospital in China, a standard, more convenient, effective, simple and inexpensive approach to rehabilitation KOA patients is urgently needed. The aim of this trial is to develop a standard protocol for KOA rehabilitation using Traditional Chinese Medicine. To the best of our knowledge, this is the first time that a standard protocol has been developed for KOA rehabilitation using TCM, not only in China, but worldwide. This type of protocol could be viewed as a milestone for the standardization of TCM and may also have a significant impact on standardization research on TCM and on KOA rehabilitation methods. Recruitment for this trial has begun, however recruitment involves 38 communities in 4 cities in China, and will continue until 2016. Due to the potential significance, and the clinically positive effects of this protocol, the research team would like to publish this manuscript.

2) The trial appears to be of pragmatic design, reflective of TCM practice. As such, doses of some interventions are likely to vary between participants, so conclusions regarding the effects of any discrete part of the treatment program may be impossible.

**Answer:** Treatments in this protocol include Chinese medical herb fumigation-washing, traditional exercises (developed from simplified tai chi and “Yi Jinjing”), tuina, acupuncture, cupping, and blood-letting. Chinese medical herb fumigation-washing along with traditional exercises (basic prescription) will be used in all cases. Basic prescription + cupping and blood-letting will be done when there is significant joint swelling, while basic prescription + tuina will be used when joint strength has decreased significantly. In cases with significant joint pain, the basic prescription + acupuncture will be used. There are some intervention doses that are likely
to vary between participants, since there is no single TCM intervention that is used clinically for KOA. This trial is a clinical protocol so outcome assessments are provided for its clinical curative effect. The research team considered the clinical curative effect to be the most important aspect of this protocol regardless of the number of intervention doses used and believes that it will be possible to draw conclusions.

3) Please specify which non-parametric test will be used for statistical analysis.

   Answer: Wilcoxon test and chi square test will be used for statistical analysis.

4) Please specify which measure of effect size will be used.

   Answer: The safety set (SS), full analysis set (FAS), the per-protocol set (PPS) and cost-effectiveness analysis will be used as measures of effect size.

Finally, I sincerely hope that our revised manuscript will be considered for publication in Trials. Again, thank you for your thoughtful opinions and suggestions.