

Multi-Institutional Pragmatic Randomized Controlled Trial to Evaluate the Effectiveness of Manual Maintenance Therapy for Chronic Botherful Neck Pain [Response to Letter]

Jung Min Yun¹, Ju Yeon Kim², Sook-Hyun Lee², Yoon Jae Lee², In Heo³, Woo-Chul Shin⁴, Jae-Heung Cho⁵, Byung-Kwan Seo⁶, In-Hyuk Ha²

¹Jaseng Hospital of Korean Medicine, Seoul, Republic of Korea; ²Jaseng Spine and Joint Research Institute, Jaseng Medical Foundation, Seoul, Republic of Korea; ³Department of Korean Medicine Rehabilitation, Pusan National University Korean Medicine Hospital, Yangsan, Kyungnam, 50612, Republic of Korea; ⁴Department of Korean Medicine Rehabilitation, Kyung Hee University Medical Center, Seoul, Republic of Korea; ⁵Department of Rehabilitation Medicine of Korean Medicine, Kyung Hee University, Seoul, 02447, Republic of Korea; ⁶Department of Acupuncture & Moxibustion, College of Korean Medicine, Kyung Hee University Hospital at Gangdong, Kyung Hee University, Seoul, Republic of Korea

Correspondence: In-Hyuk Ha, Jaseng Spine and Joint Research Institute, Jaseng Medical Foundation, 540, Gangnam-gu, Seoul, 06110, Republic of Korea, Tel +82-2-2222-2740, Fax +82-2-2222-2737, Email hanhata@gmail.com

Dear editor

We sincerely thank the authors of the letter for their careful reading of our article and thoughtful comments regarding our study design, “Multi-Institutional Pragmatic Randomized Controlled Trial to Evaluate the Effectiveness of Manual Maintenance Therapy for Chronic Botherful Neck Pain.” We appreciate the opportunity to clarify several aspects of the study design. Their comments are valuable in improving the transparency and interpretability of our protocol.

We address each point in turn.

Clarification Regarding the Title and Identification of the Study as a Protocol

We appreciate this important point. Although the manuscript states within the text that it is a study protocol, we acknowledge that the original title may not have sufficiently distinguished it from a randomized controlled trial. To improve clarity, we are willing to revise the title to explicitly indicate that this article is a study protocol.

Concern Regarding the Open-Label Design and Risk of Bias

We acknowledge that participant and clinician blinding was not feasible in this trial because of the nature of the intervention, making full blinding impractical. For this reason, the study was designed with blinded outcome assessment to reduce detection bias. We also recognize that subjective outcomes such as pain intensity may be susceptible to expectation and performance bias. Because this study was conceived as a pragmatic trial intended to reflect real-world clinical practice, additional blinding itself was not feasible; however, we agree that this point should be described more clearly in the Discussion section as study limitation.

Difference in Treatment Exposure Between Groups

We appreciate the concern regarding the difference in treatment frequency between the two groups. We agree that the unequal treatment exposure may introduce attention-related or dose-related effects. However, the purpose of this pragmatic trial was to evaluate the effectiveness of a strategy involving intermittent maintenance therapy, compared with a usual-care context with limited ongoing medical intervention, rather than the specific efficacy of manual therapy under tightly controlled explanatory conditions.



Use of Concomitant Treatments During the Study Period

We agree that concomitant treatments may act as potential confounders. However, in this pragmatic study, we planned to prospectively document all the additional treatments and support appropriate interpretation of the findings and also examine differences in overall healthcare utilization between the two groups. Nevertheless, we acknowledge that unrestricted co-interventions may influence the outcomes independently of the assigned intervention, and we are ready to clarify in the manuscript that the allowance of concomitant care was an intentional pragmatic design choice aimed at preserving real-world applicability, while also acknowledging its implications for internal validity.

Operational Definition of Recurrence Using NRS \geq 6

We appreciate this thoughtful comment regarding the definition of recurrence. The choice of NRS threshold was an operational definition based on the assumption that moderate-level pain may lead patients to seek additional medical services, particularly in the absence of a universally accepted standard definition of recurrence. We also acknowledge that any dichotomous cutoff may carry a risk of misclassification, particularly for values near the threshold. Therefore, we additionally specified the duration of pain as “over 2 weeks” so that recurrence would reflect only pain of sufficient severity that persisted for a clinically meaningful period of time.

In conclusion, we are grateful to the authors of the letter for raising these important points. Their comments have helped us identify aspects of the manuscript that would benefit from clearer explanation. We believe that addressing these issues will improve the transparency and readability of the manuscript.

Disclosure

The authors declare that they have no competing interests for this communication.

Dove Medical Press encourages responsible, free and frank academic debate. The content of the Journal of Pain Research 'letters to the editor' section does not necessarily represent the views of Dove Medical Press, its officers, agents, employees, related entities or the Journal of Pain Research editors. While all reasonable steps have been taken to confirm the content of each letter, Dove Medical Press accepts no liability in respect of the content of any letter, nor is it responsible for the content and accuracy of any letter to the editor.

Journal of Pain Research

Publish your work in this journal

The Journal of Pain Research is an international, peer reviewed, open access, online journal that welcomes laboratory and clinical findings in the fields of pain research and the prevention and management of pain. Original research, reviews, symposium reports, hypothesis formation and commentaries are all considered for publication. The manuscript management system is completely online and includes a very quick and fair peer-review system, which is all easy to use. Visit <http://www.dovepress.com/testimonials.php> to read real quotes from published authors.

Submit your manuscript here: <https://www.dovepress.com/journal-of-pain-research-journal>

Dovepress
Taylor & Francis Group

<https://doi.org/10.2147/JPR.S611921>