



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

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## Dear editor

We read with great interest the study by Yun et al, entitled “Multi-Institutional Pragmatic Randomized Controlled Trial to Evaluate the Effectiveness of Manual Maintenance Therapy for Chronic Bothersome Neck Pain.” The authors deserve praise because they tackle a vital clinical issue that exists in chronic neck pain management through their research on maintenance-based treatment methods, which they assess using practical, real-world conditions. However, several methodology requires additional explanation and improvement work to achieve better transparency and research standards and to make the trial design more understandable for others.<sup>1</sup>

Firstly, the concern regarding the title of the manuscript, which does not explicitly identify the study as a protocol. Although the manuscript is described within the text as a study protocol, the current title may inadvertently be interpreted as reporting the findings of a completed randomized controlled trial. This lack of clarity has the potential to mislead readers, contribute to inappropriate citation, and lead to an overestimation of the level of evidence presented. Research integrity depends on transparent reporting, while SPIRIT guidelines require study protocols to have dedicated titles that should differentiate them from completed trials. Failure to do so may compromise accurate indexing and rapid appraisal by clinicians and researchers.<sup>2</sup>

Secondly, the trial shows an open-label design because both participants and treating therapists did not undergo any form of blinding, while only outcome assessors remained blinded. The study results face credibility issues because both performance and expectation biases exist. The primary outcomes of the study include pain intensity, which researchers measure through subjective methods. Could the authors clarify how the risk of bias arising from the lack of participant and therapist blinding has been addressed, and whether any additional measures were implemented to minimize its impact on the study outcomes?

Thirdly, we would like to seek clarification regarding the difference in treatment exposure between the study groups. The CMT group is scheduled to receive 10 treatment sessions, whereas the control (self-exercise and education) group receives only 5 sessions over the same study period. This discrepancy in treatment frequency may introduce attention and dose-related biases, potentially influencing patient outcomes independently of the intervention effect.

Furthermore, we note that participants were allowed to receive concomitant treatments, including medications and other therapeutic interventions, during the study period. While these cointerventions are documented, their unrestricted use may introduce confounding variables that could influence the observed outcomes independently of the assigned intervention.



Additionally, we would like to highlight a concern regarding the operational definition of recurrence used in the study, which is defined as a Numeric Rating Scale (NRS) score  $\geq 6$ . While this threshold may correspond to moderate pain intensity, it does not appear to be universally standardized or specifically validated for defining recurrence in chronic neck pain populations. The use of such an arbitrary cutoff may lead to misclassification of outcomes, whereby patients with clinically relevant pain (eg, NRS  $< 6$ ) may not be identified as having recurrence, while minor changes around the threshold may disproportionately influence classification. This may, in turn, affect the accuracy and interpretability of recurrence rates.

We urge the authors to consider these points, as addressing these concerns will strengthen the validity of the study.

## Disclosure

The authors report no conflicts of interest in this communication.

## References

1. Yun JM, Kim JY, Lee SH, et al. Multi-institutional pragmatic randomized controlled trial to evaluate the effectiveness of manual maintenance therapy for chronic bothersome neck pain. *J Pain Res.* 2026;19:1–12. doi:10.2147/JPR.S577619
2. Chan AW, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Internal Med.* 2013;158(3):200–207. doi:10.7326/0003-4819-158-3-201302050-00583

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