

LETTER TO THE EDITOR

A randomized clinical trial for neck pain among adults

Dear Editor

We have read with great interest the study of Furukawa,¹ which was conducted at the Minami Seikyo hospital and assessed whether the use of Tasuki-style posture supporter improves non-specific chronic neck pain in adults. The study showed that this simple, affordable, and non-invasive intervention leads to moderate improvement in patients with chronic neck pain following 1 week of use. The study has the potential to offer some benefits by providing an alternative approach among individuals facing similar problems. However, the trial had some methodological shortcomings threatening the internal validity of the study and the interpretation of its findings.

Notably, the author acknowledged study limitations and provided additional recommendations to better conduct future studies. Nevertheless, we would like comment mainly on unaddressed selection bias and unaccounted confounding. First, convenient sampling of study subjects in combination with individual randomization and lack of allocation concealment within a study of such a small sample size, raises serious concerns regarding selection bias. Types of randomization to be selected depend on many factors including sample size, a priori baseline confounders or effect modifiers, and availability of resources among others. In this study, the use of simple randomization might have posed a problem due to the small sample size. Simple randomization is more appropriate in trials with larger samples. Covariable adaptive randomization which is achieved by the minimization method is a more advisable method for small to medium sized trials with identified covariables² and would have been a more robust method for the current study ensuring balanced baseline covariables across the two groups. In addition, allocation concealment could have been achieved by third-party concealment of the allocation sequence. A Cochrane review of clinical trials showed that lack of allocation concealment results in larger effect estimates.³ A more rigorous randomization method should be employed in future studies, as poor choice of randomization could adversely affect the validity and interpretation of research findings.⁴

In addition, the author refers to a possible placebo effect as a study limitation, whereas, the results may also be attributed

to a Hawthorne effect and more recent forms of experimental bias such as demand characteristics and socially desirable responding, given that the participants were provided with an explanation why the Tasuki may help improve neck pain at the beginning of the study.

Furthermore, the author compared only age, gender, and modified Neck Disability Index (mNDI) between the two groups at baseline, which were not sufficient to rule out selection bias. We believe that important confounders and effect modifiers expected to influence the results of this study included the use of other parallel interventions by members of either group (eg, medications, physiotherapy etc), the levels of participant's physical activity (frequency, type, and duration), the duration of Tasuki use (3.9 ± 3.1 hour per day), as well as additional co-morbidities, which were neither compared at baseline nor evaluated during the study or accounted for in the statistical analyses. In Randomized Control Trials (RCTs), confounding is minimized by proper randomization and adequate allocation concealment.⁵ However, this was not achieved in the index study likely due of the methodological approach.

We hope that future studies will be comprehensively designed to account for all possible parameters, and in situations where randomization may be compromised, researchers will apply more rigorous statistical methods to adjust for potential confounders and explore effect modifiers. We believe that it is quite important for researchers to identify and address all major methodological issues at all stages of research in order to reduce significant errors to a minimum and yield high-quality internally valid results that would allow for extrapolation and generalizability of findings.

KEYWORDS

confounding, neck pain, randomized clinical trial, selection bias, social desirability bias, UAE

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest with respect to this publication.

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