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ORIGINAL ARTICLE

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Tasuki for neck pain: An individually-randomized, open-label, waiting-list-controlled trial

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Abstract

Objectives: Neck pain ranks 4th highest in terms of disability as measured by years lived with disabilities. This study was conducted to determine whether Tasuki-style posture supporter improves neck pain compared to waiting-list.

Methods: This trial was an individually-randomized, open-label, waiting-list-controlled study. Adults (20 years or older) with non-specific chronic neck pain who reported 10 points or more on modified Neck Disability Index (mNDI: range, 0-50; higher points indicate worse condition) were enrolled. Participants were randomly assigned 1:1 to the intervention group or waiting-list. Prespecified primary outcome was the change in mNDI at 1 week. The principle of intention-to-treat analyses (as randomized) was applied. This trial was prospectively registered with UMIN (UMIN000034825).

Results: In total, 50 participants (mean age, 40.9 [standard deviation (SD) = 9.6]; 32 participants [64%] were female, mean mNDI, 14.3 [SD = 2.9]) were enrolled. Of these participants, 26 (52%) were randomly assigned to the intervention group and 24 (48%) to the waiting-list. Attrition rate was low in both groups (1/50). The mean mNDI change score at 1 week was more favorable for Tasuki than waiting-list (between-group difference, −3.5 points (95% confidence interval (CI), −5.3 to −1.8); $P = .0002$). More participants (58%) had moderate benefit (at least 30% improvement) with Tasuki than waiting-list (13%) (relative risk 4.6 (95% CI 1.5 to 14); risk difference 0.45 (0.22 to 0.68)).

Conclusion: This trial suggests that wearing Tasuki might moderately improve neck pain. With its low-cost, low-risk, and easy-to-use nature, Tasuki could be an option for those who suffer from neck pain.

KEYWORDS

neck pain, Katakori, posture supporter, Tasuki, randomized controlled trial

1 | BACKGROUND

Neck pain is common and disabling. The global point prevalence of neck pain was estimated to be 4.9% in 2010.[1] Neck pain limits function to various degrees in general population.[2,3] With its prevalence and disabling characteristic, neck pain ranked fourth highest in terms of disability as measured by years lived with disabilities according to the Global Burden

of Disease 2010 Study out of all 291 conditions studies.[1] In Japan, where neck pain is culturally perceived as shoulder and neck pain, or *katakori*,[4-6] 11.8% of women and 5.7% of men state having neck pain, which makes neck pain the most common symptom among Japanese women and the second most common symptom among Japanese men.[7]

Recent meta-analyses of randomized controlled trials found low quality evidence of commonly used intervention.[8-10] Manipulation (adjustments to the spine) and mobilization (movement imposed on joints and muscles), for example, have some evidence supporting their clinical benefits.[8] It should also be noted, however, that more than half of the trials included in the meta-analyses did not report on adverse effects, which are rare but include serious side effects such as stroke, disc herniation or serious neurological deficits.[8] Another review showed the use of strengthening and endurance exercises may be beneficial in reducing pain and improving function.[9] Cognitive behavioral therapy, which was found to be beneficial for the management of chronic pain (excluding headache) in adults,[11] turned out to be statistically significantly effective but the effect size is so small that its clinical importance remains unclear.[10] Considering the burden of neck pain, more evidence-based and clinically important interventions are needed.

The research question for this trial stemmed from personal experiences of some people with neck pain reporting improvement of their pain when wearing *tasuki*, which is a sort of sash that is used to hold up the sleeves on a *kimono* (Japanese traditional clothes). It retracts the shoulders and keeps the head straight up (Figure 1). Some studies suggest that certain postures are associated with neck pain. The greater the forward head posture, for example, the greater the neck pain related disability.[12,13] There seemed to be a possibility that Tasuki could improve posture and relieve neck pain. However, there was little clinical evidence to support or refute it.

1.1 | Patient and public involvement

I aimed to ensure that this research focused on issues relevant to those who suffer from non-specific chronic neck pain. I interviewed some people with neck pain informally before writing this study's protocol. I intended to make sure it was acceptable and feasible to do the intervention and to fill in the questionnaire, and to determine the primary efficacy outcome measure and the follow-up period. During the trial, study participants were asked to help the recruitment. We plan to write a plain language summary for dissemination to the participants and the public.

1.2 | Objectives

To determine whether Tasuki-style posture supporter improves neck pain compared to waiting-list.

2 | METHODS

2.1 | Study design

An individually randomized, open-label, waiting-list-controlled clinical trial was conducted with participants

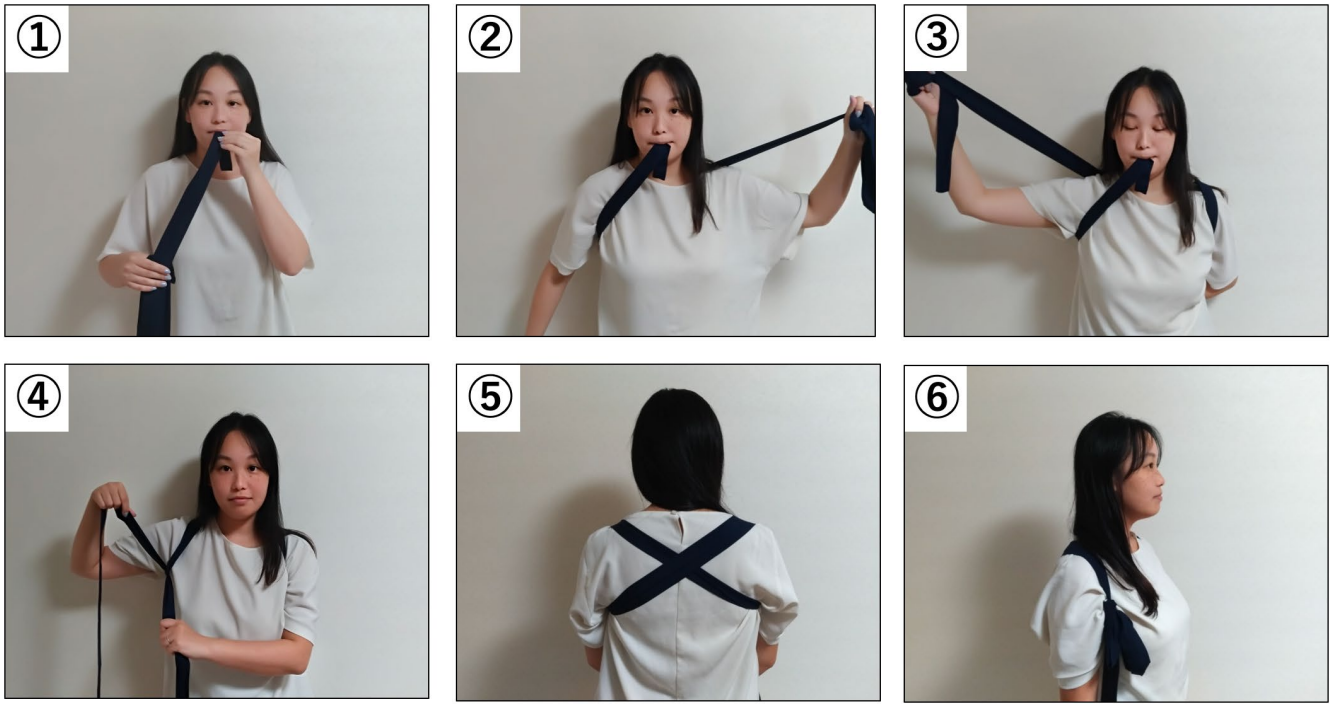

FIGURE 1 How to wear Tasuki

randomly allocated 1:1 to the intervention group or waiting-list group.

2.2 | Population, setting, and recruitment

The target population was adults with non-specific chronic neck pain. Eligible participants were 20 years or older who reported 10 points or more on modified Neck Disability Index (mNDI; range, 0-50; 0 indicates no disability and 50 indicates the most severe disability). Exclusion criterion was: individuals who had organic disorders around the neck or shoulder, such as rotator cuff tear, disc degeneration, traffic accident related pain, fracture, or cancer. Recruitment strategies included promotions at Minami Seikyo Hospital, and word-of-mouth communication of the participants. Recruitment lasted from November 13, 2018 to April 8, 2019, with the final participant follow-up on April 16, 2019.

2.3 | Randomization and masking

Eligible adults who gave written informed consent were randomly assigned 1:1 to the intervention group or waiting-list group. Randomization was performed after the participants made the full baseline assessment and gave written informed consent. All the participants who were randomized were included in the analyses in accordance with the intention-to-treat principle (as randomized). Dynamic allocation by tossing a coin when the numbers of participants in the intervention group and the waiting-list group were equal or shuffling cards with adjusted number of cards when the numbers of participants were not equal (participants were randomly assigned 7:3 to the group with less participants or to the other) was conducted. This process meant that the recruiter knew the allocation probability and therefore, although the randomization procedure was still followed, the allocation concealment was inadequate. Comparison of baseline characteristics was conducted to detect any obvious selection bias. Because this was a behavioral intervention, study participants, who were also the assessors of the primary and secondary outcomes, could not be masked to group allocation.

2.4 | Description of the intervention

Participants in the intervention group received a sash (width c. 4.5 cm, length c. 210 cm), with which they can make Tasuki-style posture supporter by themselves. Brief explanation that lasted about five minutes included how to wear Tasuki and why it might help improve neck pain. Participants were asked to wear Tasuki for at least five minutes a day for 1 week. They were also told that the longer they would wear, the better results could be expected, and encouraged to wear it when they think they were likely to have bad posture, for example, when they work on computers. They were discouraged from wearing it too tightly in the fear of compressing nerves. Waiting-list was used as the control group rather than no-treatment, because the preceding interview suggested it was more understandable and acceptable for the participants. Participants in the waiting-list group also received the same sash but were asked to wait for 1 week.

2.5 | Outcome measures

The prespecified primary efficacy outcome was the change in neck pain at 1 week as measured by modified Neck Disability Index (mNDI). The mNDI is a Japanese translation of the NDI with a minor change from "neck pain" to "neck and shoulder pain." This modification was both necessary and justified because of the Japanese cultural background, in which "neck pain" in the English-language culture is perceived as "*katakori*, or shoulder stiffness."[5] The NDI is a patient-reported, condition-specific functional status questionnaire with 10 items including pain, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation.[14] The NDI has been translated into many languages, tested its validity, and used in numerous studies on neck pain.[15] Participants were asked to provide data at two time points; before-randomization, and 1 week after-randomization. This follow-up period was chosen based on the preceding informal interview with those with non-specific chronic neck pain. They expected some improvement in the first week in order to try new intervention. The shorter the follow-up period would be, the more confident they were to be able to maintain good adherence to the intervention, to answer the follow-up questionnaire and the more acceptable they found the possibility of being allocated to the waiting-list group. A self-completed questionnaire was used to minimize any observer bias. Post hoc responder analyses were performed with the definition by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT), where "moderate benefit" was defined by "at least 30% improvement" and "substantial benefit" by "at least 50% improvement."[16] Post hoc sensitivity analysis was performed by full set analysis, per protocol analysis and worst-case scenario. In the per protocol analysis, only those who adhered to the protocol were included in the analysis. Those in the intervention group who did not wear Tasuki or those in the waiting-list group who wore Tasuki before follow-up were excluded. In the worst-case scenario, data of those who were lost to follow-up in the intervention group was imputed with worst data observed and those who were lost to follow-up in the waiting list group was imputed with the best data observed.

As a secondary efficacy outcome, the Patient Global Impression of Change scale (PGIC) was used. PGIC is a

single-item rating by participants of their treatment response during a clinical trial using a 7-point rating scale with the options "very much improved," "much improved," "minimally improved," "no change," "minimally worse," "much worse," and "very much worse." It is readily interpretable, has been widely used in chronic pain clinical trials, and **is** recommended by IMMPACT for use in chronic pain clinical trials as a core outcome measure of global improvement with treatment.[16]

Acceptability and adherence were evaluated by how many days per week and how many hours per day participants actually wore Tasuki. Any adverse event was reported qualitatively. Qualitative data, including any adverse event and any comment on wearing Tasuki, were obtained 1 week after-randomization, using a self-completed questionnaire. Coding and translation were carried out by FY.

3 | ANALYSES

3.1 | Sample size

Sample sizes were based on detecting a between-group, 0.8 standardized mean difference in the mean change on mNDI at 1 week. To achieve at least 80% power with a type I error rate of 5%, we recruited 50 total participants.

3.2 | Statistical analyses

Baseline characteristics and study outcome measures were summarized by allocation group using descriptive statistics such as mean (standard deviation, SD) or percentage and used to assess between-group equivalence at baseline. Baseline demographic descriptors and the primary outcome measure were compared across groups by using t test for continuous variables and the χ^2 (or Fisher exact) test for categorical variables. Analyses of the primary and secondary efficacy outcomes and the post hoc responder analyses were performed with treatment groups defined by the principle of intention-to-treat analyses (as randomized).

Two-sided $P < .05$ were considered statistically significant. Analyses were conducted using SAS ver. 9.4 on Windows 10 Home or Excel for Mac ver. 16.16.9 on macOS Mojave.

3.3 | Dealing with missing data

Zero improvement was assigned (last observation carried forward (LOCF), which was equal to baseline observation carried forward (BOCF) in this study) to missing participants wherever possible. Full set analysis, per protocol analysis and the worst scenario analysis were performed to check the robustness of the main results.

3.4 | Ethics

This study followed the tenets of the Declaration of Helsinki, and the protocol was prospectively approved by the Institutional Review Board of Minami Seikyo Hospital (Aichi, Japan). Written informed consent was obtained from all participants. This study is prospectively registered with the University Hospital Medical Information Network (UMIN000034825).

4 | RESULTS

4.1 | Participant background

In total, 50 participants (mean age, 40.9 [SD = 9.6]; 32 participants [64%] were female, mean mNDI, 14.3 [SD = 2.9]) were enrolled between November 15, 2018, and April 8, 2019. Of these participants, 26 (52%) were randomly assigned to the intervention group and 24 (48%) to the waiting-list group. Participants background was similar in both groups (Table 1). Attrition rate was low in both groups (1/26 in the intervention group, 0/24 in the waiting list group). The CONSORT flow diagram displays the progress of all participants through the trial[17,18] (Figure 2).

4.2 | Primary efficacy outcome - mNDI

The mean mNDI change score at 1 week was more favorable for Tasuki than waiting-list (−4.6 points vs −1.1 points; between-group difference, −3.5 points (95% confidence interval (CI), −5.3 to −1.8); Student's *t* test, $P = .0002$) (Table 2).

4.3 | Secondary efficacy outcome - PGIC

More participants (24/26, 92%) reported "minimally improved" or more on PGIC with Tasuki than waiting-list (3/24, 13%) (relative risk [RR] 7.4 (95% CI 2.5 to 21.4); risk difference [RD] 0.80 (95% CI 0.63 to 0.97)). More participants (4/26, 15%) reported "much improved" or more with Tasuki than waiting-list, although the 95% confidence interval crossed the null hypothesis (1/24, 4%) (RR 3.7 (95% CI 0.44 to 30.8); RD 0.11 (95% CI −0.05 to 0.27)).

TABLE 1 Participant background

	Intervention group (n = 26)	Waiting-list group (n = 24)	*P* value*
Age (mean ± SD)	42.0 ± 9.7	39.7 ± 9.6	.40
Gender (female, %)	17 (53)	15 (47)	.83
mNDI (mean ± SD)	14.6 ± 2.8	13.9 ± 3.1	.37

Abbreviations: mNDI, modified Neck Disability Index; SD, standardized deviation.
*Student's *t* test was used for the age and the mNDI and the χ^2 test for the gender.

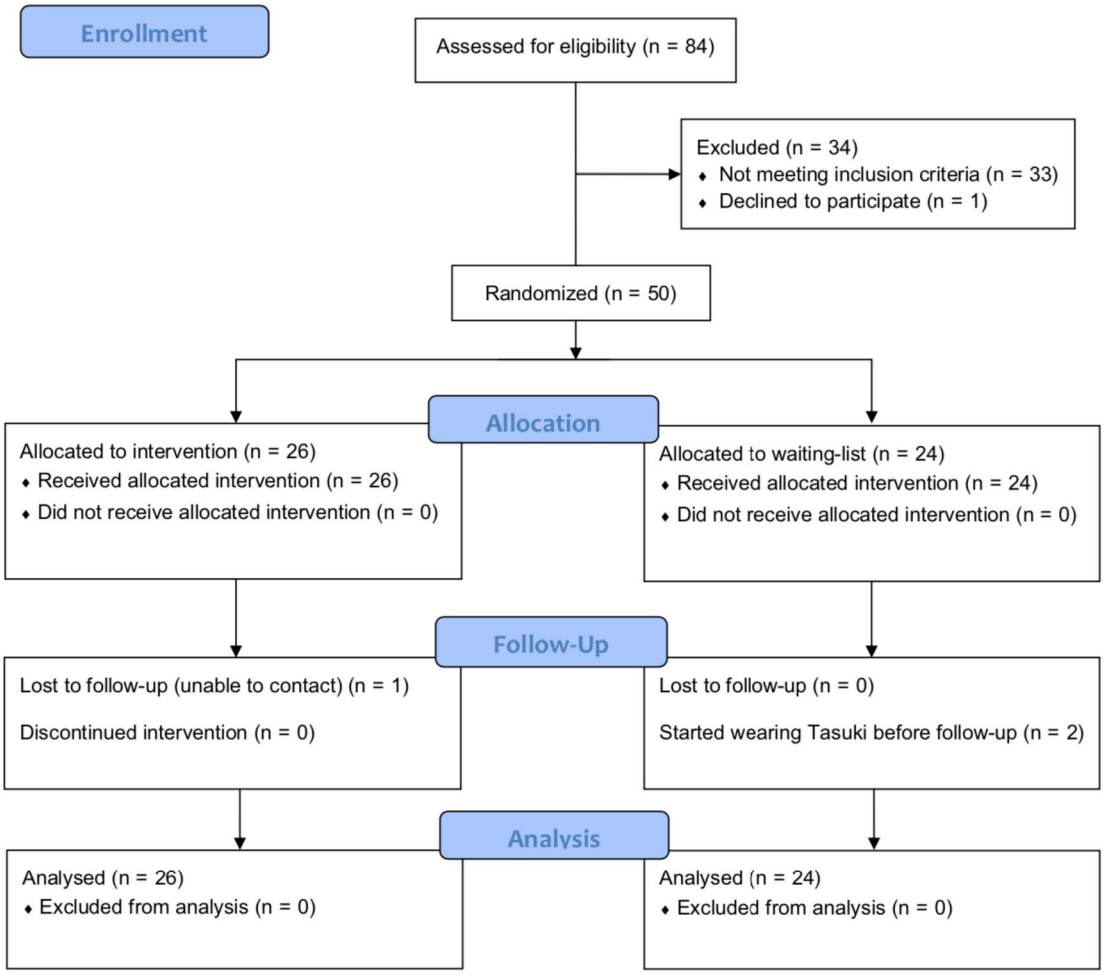

FIGURE 2 CONSORT flow diagram

TABLE 2 Prespecified primary efficacy outcome

Mean difference (95% CI)		Between-group difference (95% CI)	*P*-value*
Intervention group	Waiting-list group		
−4.6 (−5.8 to −3.4)	−1.1 (−2.4 to 0.2)	−3.5 (−5.3 to −1.8)	.0002

Abbreviation: CI, confidence interval.
*Student's *t* test was used.

4.4 | Post hoc responder analyses

Post hoc responder analyses were performed with the responder definition of IMMPACT recommendation.[16] More participants (15/26, 58%) had moderate benefit (at least 30% improvement) with Tasuki than waiting-list (3/24, 13%) (RR 4.6 (95% CI 1.5 to 14); RD 0.45 (0.22 to 0.68)). More participants (5/26, 19%) had substantial benefit (at least 50% improvement) with Tasuki than waiting-list (1/24, 4%), although the 95% confidence interval crossed the null hypothesis (RR 4.6 (95% CI 0.58 to 37); RD 0.15 (−0.02 to 0.32)) (Table 3).

4.5 | Post hoc sensitivity analyses

As there were one lost-to-follow-up and two protocol deviations (3 in total, 6% of all participants), post hoc sensitivity analyses were performed. Full set analysis was performed with all the 49 participants who provided follow-up data. Per protocol analysis was performed with all the 47 participants who adhered to the study protocol and reported follow-up data (one in the intervention group who was lost to follow-up and two in the waiting-list group who did not wait and wore Tasuki before follow-up were excluded). In the worst-case scenario analysis, one missing data in the intervention group was imputed with the worst mNDI change observed. All these three analyses showed statistically significant between-group difference (−3.7 points, $P = .0001$; −4.3 points, $P = .000003$; −3.3 points, $P = .001$; respectively).

4.6 | Acceptability

Acceptability was high (average number of days participants wore Tasuki per week: 6.2 [SD = 1.2] days (number of

TABLE 3 Post hoc responder analyses

Responder definition	No./total no. (%)		Relative risk (95% CI)	Risk difference (95% CI)
	Intervention	Waiting-list		
At least 30% improvement	15/26 (58%)	3/24 (13%)	4.6 (1.5 to 14)	0.45 (0.22 to 0.68)
At least 50% improvement	5/26 (19%)	1/24 (4%)	4.6 (0.58 to 37)	0.15 (−0.02 to 0.32)

Abbreviation: CI, confidence interval.

respondents, 25/26); average hours per day: 3.9 [SD = 3.1] hours (23/26)).

4.7 | Adverse events

No serious adverse events were reported. The most common report was mild pain or discomfort around the neck or shoulders (6/26, 23%). (No. 1-6, Table 4) Another common complaint was the appearance of Tasuki (3/26, 12%). (No. 7-9, Table 4).

4.8 | Qualitative feedback

Other qualitative feedbacks consisted mainly of Tasuki's effectiveness. (No. 1-8, Table 5) Some also mentioned that it was easy to use Tasuki. (No. 9-10, Table 5).

5 | DISCUSSION

In this individually randomized, open-label, waiting-list-controlled trial of adults with non-specific chronic neck pain, Tasuki-style posture supporter was shown to be effective in improving neck pain.

Potential reasons for the treatment effect remain to be answered. It was hypothesized that wearing Tasuki would help improve the posture, which in turn would relieve neck pain. This hypothesis was partly supported by qualitative feedbacks (No. 1-8, Table 5), although no objective indicators were measured. There was a qualitative feedback (No. 1, Table 4) that Tasuki restricted the movement of shoulders when it was worn too tightly. This issue needs to be considered, because a systematic review of longitudinal studies stated constrained posture as a risk factor for work-related musculoskeletal disorders.[19] Wearing Tasuki, however, may have improved neck pain via another mechanism, such as facilitating exercise. Tasuki let you notice immediately when your shoulders go rounded, because it becomes tight under the arms in such cases. This might have worked as a reminder to do stretching. Facilitating exercise, rather than constraining static posture, might be a more plausible mechanism. The underlying mechanism of how Tasuki might work requires further investigation.

TABLE 4 Adverse events

No.	Comments
1	"Because Tasuki is not stretchy, it restricted the movement of shoulders when worn too tightly, which was not good."
2	"On the second day I felt pain at a point where I usually don't feel any lameness. From the third day on the lameness was gone and I felt at ease."
3	"I felt a mild pain on the right low back when I throw out my chest."
4	"I don't know why, but on the third day, I felt mild pain like muscle pain around the neck."
5	"Tasuki was tight under the arms."
6	"On the first day, maybe because I wasn't used to wearing Tasuki, I felt pain and discomfort on the neck. On the fifth day, I felt relieved when I took Tasuki off."
7	"Bad: Everybody in the office looked at me and I felt uncomfortable.
8	"Tasuki was easier to be noticed even under clothes than expected and so I wore it mainly at home. Special, not-easy-to-be-noticed Tasuki-style supporter, if it could be developed, would be better for women who work outside."
9	"I wore Tasuki on my uniform and then wore a cardigan but sometimes the sash could be noticed from outside."

5.1 | Limitations

Several limitations should be addressed. First, dynamic allocation process, which was prespecified in the study protocol, meant that the recruiter knew the allocation probability and therefore, although the randomization procedure was still followed, the allocation concealment was not optimal. A recent review found that inadequate allocation concealment could result in selection biases, though it is not generally possible to predict the magnitude, or even the direction.[20] Although participants background was similar in both groups in this trial, a better allocation concealment would be preferred in further studies. Second, due to the nature of the intervention, participants, who were also assessors, could not be masked to the allocation. This might have resulted in a placebo effect in the intervention group. The brief explanation on why Tasuki might help improve neck pain, or even just being allocated to the intervention group might have had some impact. According to a recent meta-analysis that found placebo interventions in

TABLE 5 Qualitative feedback

No.	Comments
1	"I could feel the rounded shoulders being fixed and that was good."
2	"I think my posture was a little better when I was wearing Tasuki. I feel my neck pain a little relieved."
3	"Tasuki helped me brace up, might improve my blood stream and clear my vision. Tasuki helped me understand the right posture and now I can pay attention to the posture even when I don't wear Tasuki. Just to tell you, I spent yesterday without Tasuki and I felt unease around the shoulders and shoulder blades. Tasuki seems to have become a habit."
4	"I will continue to use it to improve my neck pain, eyestrain and headache."
5	"I think it was quite effective."
6	"It helped me keep my back straight up."
7	"I was surprised by the effectiveness of Tasuki. Even without wearing tightly, somehow I could care about the shoulder blades so I will continue using it."
8	"While wearing the sash, I found my posture fixed and felt better."
9	"It was easy to use, straightened my back, and I felt good."
10	"It was very easy to use! (But) I had trouble figuring out how tightly I should wear Tasuki."

general did not have clinically important effects, there were possible positive effects on patient-reported outcomes in pain, although the effects were very variable, even among trials with low risk of bias.[21] According to another systematic review on trials with patient-reported outcomes, non-masked patients reported a larger effect estimate, but again with considerable variation.[22] Third, the use of waiting-list as the control condition also raises a concern. A network meta-analysis of psychological randomized controlled trials suggested that different types of control conditions lead to substantially different treatment effect estimates and that waiting-list control may generate bigger effect size estimates than active placebo or even no treatment.[23] Therefore, the effect size that was observed in this study should be interpreted with caution. Finally, the follow up period was short and the long-term effect remains unclear. Further studies might be encouraged to use a longer follow-up period in addition to, not instead of, a follow-up after 1 week.

5.2 | Strengths

This study has several strengths. Low attrition rate (1/26 in the intervention group, 0/24 in the waiting-list group) minimized the bias caused by drop-outs. Statistically significant difference was shown not only by the intention-to-treat analysis but also by the worst-case scenario. There are some merits of the nature of the intervention. Tasuki can be made by a sash and does not cost much. It is so easy to use that all of the participants could wear Tasuki on their own within 5 minutes of explanation. It is very low-invasive and if the participants dislike wearing Tasuki, they can just remove it off.

5.3 | Suggestions for further studies

Further studies are expected to use adequate allocation concealment and more active control conditions, such as stretching exercise, strength exercise, endurance exercise, acupuncture, or massage. Tasuki alone or in combination with the control intervention could be used as the intervention. This way, the possibility that between-group difference resulted from a placebo effect could be minimized. Sample size calculation should consider using smaller effect size expectation. Longer follow-up periods in addition to the follow-up after 1 week are also desired.

5.4 | Generalizability

A limited number of inclusion and exclusion criteria (adults with chronic non-specific neck pain without any organic disorder around neck or shoulders diagnosed who reported 10 points or more on mNDI) enabled recruitment of those who represented people with neck pain. However, it should also be noted that this was a single-center study, which is considered to have less generalizability than multi-center studies with larger number of participants.[24,25] The result of this trial, therefore, should be carefully evaluated within the context of clinical situation and the preferences of the participants.

5.5 | Interpretation

When evaluating the results of a study, both the statistical and clinical significance of the findings must be considered. The sensitivity analyses showed the robustness of the statistical significance of the primary efficacy outcome of this study, although the limitations discussed above need to be noted. The results also need to be examined carefully whether the change really matters to the people with neck pain. One way to do this is to compare the between-group difference with minimal clinically important difference (MCID).[26] MCID is the smallest within-individual difference that an individual would find important.[26] MCID in NDI for non-specific neck pain is reported to be 3.5,[27,28] which is almost equal to the between-group difference observed in this trial. It needs to be noted, however, that the between-group difference and the within-individual difference represent different aspects of clinical events. It is shown that even when the between-group difference is smaller than MCID, treatment may have an important impact on many patients.[29] An alternative way to interpret the results is to conduct responder analyses, which compare the proportion of patients who benefit from the treatment.[29] Post hoc responder analyses were performed with the responder definition of IMMPACT

recommendation.[16] More participants had moderate benefit (at least 30% improvement) with Tasuki than waiting-list (RR 4.6 (95% CI 1.5 to 14); RD 0.45 (95% CI 0.22 to 0.68)). More participants had substantial benefit (at least 50% improvement) with Tasuki than waiting-list, although the 95% confidence interval crossed the null hypothesis (RR 4.6 (95% CI 0.58 to 37); RD 0.15 (95% CI −0.02 to 0.32)). All in all, the results suggest that the intervention may have moderately clinically important benefit on about half of the participants.

The benefit needs to be balanced against the harms. Although no serious adverse events were reported, it should be noted that about a quarter of participants (6/26, 23%) reported mild pain or discomfort around the neck or shoulders. High acceptability and favorable PGIC results indicate the adverse events were acceptable and the intervention could be justified, but further development to minimize possible harms is desired.

6 | CONCLUSION

This trial suggests that wearing Tasuki might moderately improve neck pain. With its low-cost, low-risk, and easy-to-use nature, Tasuki could be an option for those who suffer from non-specific chronic neck pain.

ACKNOWLEDGMENTS

I thank all the people involved in this study, especially the participants who convinced me of the importance of this trial. I am especially grateful to Hiromoto Mizuno for supporting me in conducting this study, to Kazuhiro Shimomura for helping statistical analyses, and to Ayako Furukawa for becoming a wonderful model for the figure.

DISCLOSURE

Approval of the research protocol: Ethical approval was prospectively given by the Institutional Review Board of Minami Seikyo Hospital. *Informed Consent:* Written informed consent was obtained from all participants. *Registry and the Registration No. of the study/Trial:* This study is prospectively registered with the University Hospital Medical Information Network (UMIN000034825). *Animal studies:* N/A. *Conflict of Interest:* The author declares no conflicts of interest related to this study.

AUTHOR CONTRIBUTION

FY conceived the ideas, designed the trial, collected the data, conducted unmasked analysis, and led the writing.

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