ORIGINAL ARTICLE

A Randomized Controlled Trial Comparing Manipulation With Mobilization for Recent Onset Neck Pain

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ABSTRACT. Leaver AM, Maher CG, Herbert RD, Latimer J, McAuley JH, Jull G, Refshauge KM. A randomized controlled trial comparing manipulation with mobilization for recent onset neck pain. Arch Phys Med Rehabil 2010;91:1313-8.

Objective: To determine whether neck manipulation is more effective for neck pain than mobilization.

Design: Randomized controlled trial with blind assessment of outcome.

Setting: Primary care physiotherapy, chiropractic, and osteopathy clinics in Sydney, Australia.

Participants: Patients (N=182) with nonspecific neck pain less than 3 months in duration and deemed suitable for treatment with manipulation by the treating practitioner.

Interventions: Participants were randomly assigned to receive treatment with neck manipulation (n=91) or mobilization (n=91). Patients in both groups received 4 treatments over 2 weeks.

Main Outcome Measure: The number of days taken to recover from the episode of neck pain.

Results: The median number of days to recovery of pain was 47 in the manipulation group and 43 in the mobilization group. Participants treated with neck manipulation did not experience more rapid recovery than those treated with neck mobilization (hazard ratio=.98; 95% confidence interval, .66–1.46).

Conclusions: Neck manipulation is not appreciably more effective than mobilization. The use of neck manipulation therefore cannot be justified on the basis of superior effectiveness.

Key Words: Chiropractic; Manipulation, spinal; Neck pain; Rehabilitation.

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M ANUAL THERAPIES ARE commonly used in the treatment of nonspecific neck pain,[1,2] a condition affecting up to two thirds of people in a lifetime.[3] The most common forms of manual therapy are manipulation and mobilization.

Neck manipulation involves the application of a manual, high-velocity, low-amplitude thrust directed at the cervical joints, usually associated with an audible click.[2,4] The use of cervical spine manipulation is controversial.[5] While manipulation is believed to contribute to rapid recovery from an episode of neck pain,[6] several studies have demonstrated an association between cervical spine manipulation and neurovascular injury that can lead to stroke or death.[7-9] Among these studies, Cassidy et al[7] demonstrated that both chiropractic and family physician visits were associated with increased risk of stroke, highlighting the problem of presuming causation from measures of association alone. A recent review that specifically investigated the question of causation reported weak to moderately strong evidence that manipulation can cause stroke in young adults.[10]

Unlike manipulation, mobilization involves the use of slow, oscillating movements directed at the cervical joints. It does not require the rapid thrusting maneuver believed to be associated with vascular injury.[11] Despite widespread use,[2] there are few reports of serious complications from cervical spine mobilization.[12]

Given the current state of knowledge about the safety of manipulation, clinicians have been advised to make decisions about treatment of neck pain based on effectiveness.[7,10]

Both manipulation and mobilization have been shown to be effective treatments for neck pain.[1,12,13] There is, however, currently no evidence to suggest that manipulation is more effective in the circumstances in which it is most commonly used—namely, in the treatment of acute and subacute neck pain.[1] Nevertheless, manipulation remains in widespread use by chiropractors, osteopaths, physiotherapists, and medical practitioners in the belief that, when added to a treatment regimen, it provides more rapid pain relief than other treatments.

In light of ongoing concerns about the safety of cervical spine manipulation and the apparent relative safety of cervical mobilization, we conducted a randomized controlled trial comparing the effectiveness of these treatments. The aim of this study was therefore to establish whether cervical spine manipulation provides more rapid and more complete recovery from an episode of neck pain than cervical spine mobilization.

METHODS

Participants

Participants were recruited from 12 private physiotherapy, chiropractic, and osteopathy clinics in Sydney, Australia. All patients age 18 to 70 years presenting to the participating clinics with an episode of recent onset neck pain were assessed by the treating practitioner for suitability for treatment with neck manipulation. Only patients for whom neck manipulation was the preferred treatment were included in the trial. We defined an episode of recent onset neck pain as pain in the region between the superior nuchal line and first thoracic spinous process[14] less than 3 months in duration and preceded

by 1 month without neck pain. Patients were excluded if they had neck pain related to a motor vehicle collision or other significant trauma; a primary complaint of arm pain; signs of specific or serious pathology such as malignancy, infection, inflammatory disorder, fracture, radiculopathy, or myelopathy; history of neck surgery; or neck pain of less than 2 out of 10 on a numeric rating scale, or were not literate in English.

Participants provided written informed consent prior to participating in the study. The study protocol was approved by the University of Sydney Human Research Ethics Committee.

Interventions

Participants were allocated to 1 of 2 treatment arms: neck manipulation or neck mobilization. Participants in the neck manipulation group were treated with manual high-velocity, low-amplitude thrust techniques applied to the cervical spine. Participants in the neck mobilization group were treated with manual low-velocity, oscillating passive movement applied to the cervical spine.

Both groups received 4 treatments over a 2-week period unless they recovered or experienced a serious adverse event during this period. The treating practitioners chose the particular manipulation or mobilization technique according to their clinical judgment. Participants could receive other evidence-based treatments such as advice, reassurance, and encouragement to resume usual activities and could continue any exercise program that they had previously commenced. This is consistent with practice guidelines[15] and with the generally pragmatic orientation of the trial. The use of manipulation or mobilization for other body regions, such as the thoracic or lumbar regions, was not constrained in either group. Treatment using a combination of neck mobilization and manipulation was not permitted. Participants were asked to refrain from seeking additional treatment during the 2-week treatment period but were not discouraged from seeking further treatment after this time.

To enhance the appropriate selection of patients suitable for manipulation, we used qualified and experienced practitioners. Practitioners were recruited from the directories of the physiotherapy, chiropractic, and osteopathy professions and by recommendation from opinion leaders and academics in these professions. All treating practitioners had postgraduate university qualifications that included specific training in the use of neck manipulation and mobilization. All practitioners had at least 2 years of clinical experience after their postgraduate training, and all routinely used both neck manipulation and neck mobilization in their clinical practice. Practitioners received individual training in implementing the trial protocol.

Outcomes

The primary outcome was time to recovery from the episode of neck pain. The day of recovery was defined as the first of 7 consecutive days in which the patient rated the intensity of neck pain as less than 1 out of 10.

Secondary outcomes included the time taken for recovery of normal activity, as well as pain (Numerical Rating Scale), disability (Neck Disability Index),[16] function (Patient Specific Functional Scale),[17] global perceived effect,[18] and health-related quality of life (12-Item Short-Form Health Survey Physical and Mental Component Summaries).[19] We measured a daily rating of interference with normal activity using a single item scale from the 12-Item Short-Form Health Survey.[19] Participants recorded the degree of activity interference resulting from neck pain on a 5-point scale anchored by "not at all" and "extreme interference." Time to recovery of normal activity was defined as the first of 7 consecutive days in which the

participant rated the degree of interference "not at all." Pain and global perceived effect were recorded at the end of the treatment period (2 weeks) and 12 weeks after randomization. Disability, function, and quality of life measures were recorded 4 and 12 weeks after randomization. Treatment credibility was assessed 24 hours after commencing treatment using a 6-point Treatment Credibility Scale.[20]

Outcomes were recorded by participants in a diary. To ensure an accurate estimate of the recovery day, participants were asked to keep a daily record of pain and activity interference scores. Minor adverse events were recorded in the pain diary using a checklist of symptoms derived from previous studies of adverse effects from manual treatment.[21] Practitioners and participants also answered open-ended questions during the treatment period and at the week 12 follow-up about the participant's general health and any other health care sought, to screen for potentially serious events. Other diary entries enabled calculation of the proportion of participants who, during the treatment period, sought other treatments (n=13; 7.4%), used analgesic medication (n=68; 38.6%), or required absence from work because of neck pain (n=21; 11.9%). To minimize potential for loss of data, data from these diaries were collected by telephone interview at weekly intervals for the first 4 weeks, then monthly or until recovery for the remaining 8 weeks.

Randomization

Patients who met the eligibility criteria were recruited by the treating practitioner. Baseline assessments were conducted prior to randomization. Randomization occurred at the point in the course of treatment at which the treating practitioner chose to introduce manipulation. For some patients, this was after several treatments. Late randomization was used to ensure that only patients deemed suitable for treatment with manipulation entered the trial, and that they did so at the appropriate time in their episode of care.

A statistician not involved in the data collection or analysis generated the randomization sequence and produced sequentially numbered, sealed, opaque envelopes containing the treatment allocation for each participant. The randomization sequence contained equal numbers in each group but was otherwise unrestricted. To ensure concealment, each participant's name was written across the envelope seal prior to opening of the envelope.

Masking and Blinding

Data collection and analysis were conducted by researchers who were blind to treatment allocation. It was not possible to blind the participants or practitioners to treatment allocation because of the nature of the interventions. Participants and practitioners were instructed not to reveal treatment allocation to the researchers who collected outcome measures.

Statistical Analysis

Data were double-entered and analyzed by intention-to-treat. Analysis was conducted by a statistician blind to treatment allocation. For the primary analysis of time to recovery from an episode of neck pain, we used Cox regression to estimate the effect of allocation (mobilization or manipulation). The regression model did not include any covariates.

For the secondary analysis of time to recovery of normal activity, we similarly used Cox regression to estimate the effect of allocation. Other secondary analyses specified in the registered trial protocol[22] were performed to estimate the effect of allocation on global perceived effect of treatment at weeks 2 and 12, and disability, function, and quality of life at week 12,

using independent samples *t* tests. Additional secondary analyses not specified in the registered trial protocol but specified prior to conducting the analysis and breaking the allocation code compared pain scores between groups at weeks 2 and 12 as well as disability, function, and quality of life at week 4. The effect of allocation on the incidence of adverse effects was analyzed using the chi-square test.

The sample size of 182 participants would give an 80% probability of detecting a difference between treatment groups in median survival time from 21 to 12 days, or equivalently from 35 to 20 days (α=.05) allowing for 15% loss to follow-up.

RESULTS

One hundred eighty-two participants were recruited by 7 physiotherapists (n=125), 5 chiropractors (n=56), and 1 osteopath (n=1) from 12 primary care clinics (fig 1) between October 2006 and June 2008. The clinics were located across a broad geographic area that included a diverse urban population. One participant withdrew from the study after the first treatment. The remaining participants were treated according to the trial protocol: receiving 4 treatments (n=179), ceasing treatment after making a full recovery (n=1; 3 treatments), or ceasing treatment after adverse event (n=1; 3 treatments). One participant in the mobilization group who required emergency cardiac surgery in the follow-up period withdrew from the trial. Two participants in the manipulation group and 2 participants

in the mobilization group withdrew from the study before the 3-month follow-up because of the inconvenience of answering follow-up inquiries. All available data from all participants were included in the primary analysis; the 5 participants lost to follow-up were censored at the last date of data collection. Completeness of follow-up[23] was 95.9% of person-time. Some secondary data were missing for 6 participants for secondary analyses (see fig 1).

Participants had moderately high baseline pain scores with a mean score $\pm$ SD of 6.0$\pm$2.0 on a 0 to 10 scale. The pain was frequently accompanied by concomitant symptoms such as upper limb pain (n=144; 79.1%), headache (n=117; 64.3%), and upper back pain (n=115; 63.2%). Participants were moderately disabled by their neck pain (mean disability score $\pm$ SD of 15.5$\pm$7.4 on a 0–50 scale). One hundred fifteen participants (63.2%) had a past history of neck pain (table 1).

Most participants (91.8%) were randomized at their first treatment, indicating that practitioners preferred to introduce manipulation early in the course of treatment. All participants received the allocated treatment. Treatment credibility[20] was equally high in both groups with a mean credibility score $\pm$ SD of 4.9$\pm$0.9 of a maximum of 6 for the manipulation group and 4.9$\pm$0.8 for the mobilization group. A higher proportion of men were randomized to the manipulation group (42.9%) than the mobilization group (27.5%).

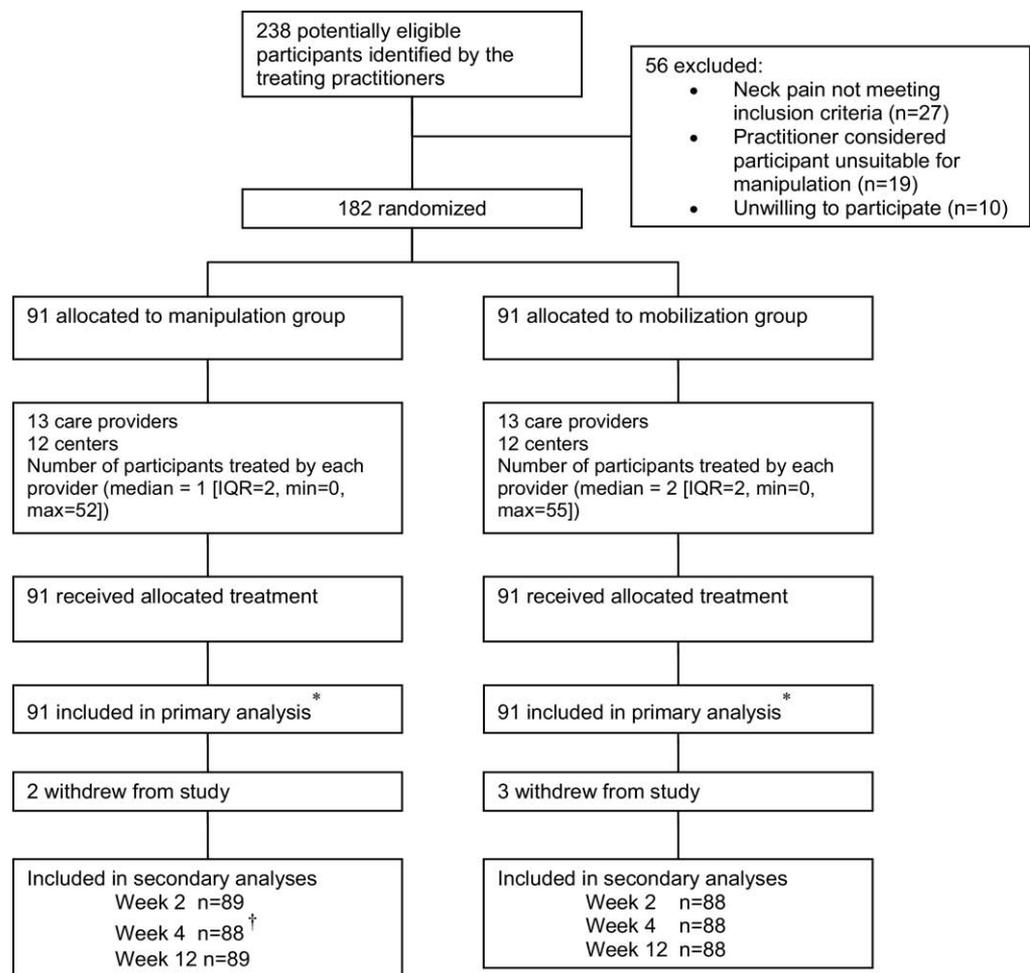Fig 1. Flow chart of progress of participants through the trial. *Participants who withdrew from the study after completion of the allocated treatment were censored at the date of last data collection. These participants' data were included in the primary analysis. †Data missing from 1 participant in the manipulation group at week 4. Abbreviations: IQR, interquartile range; max, maximum; min, minimum.

Table 1: Baseline Characteristics of Participants

Variable	Manipulation (n=91)	Mobilization (n=91)	Total (N=182)
Sex: male	39 (42.9)	25 (27.5)	64 (35.2)
Previous episode of neck pain	56 (61.5)	59 (64.8)	115 (63.2)
Analgesic medication	17 (18.7)	13 (14.3)	30 (16.5)
Compensation claim	3 (3.3)	1 (1.1)	4 (2.2)
Concomitant symptoms			
Upper limb pain	69 (75.8)	75 (82.4)	144 (79.1)
Upper back pain	56 (61.5)	59 (64.8)	115 (63.2)
Lower back pain	36 (39.6)	35 (38.5)	71 (39.0)
Headache	58 (63.7)	59 (64.8)	117 (64.3)
Dizziness/vertigo	29 (31.9)	27 (29.7)	56 (30.8)
Nausea	22 (24.2)	19 (20.9)	41 (22.5)
Age (y)	38.0±10.3	39.7±11.1	38.9±10.7
Duration of neck pain (d)	18.0±19.7	20.8±20.4	19.4±20.0
Neck pain*	6.1±2.1	5.9±2.0	6.0±2.0
Disability†	16.1±8.2	14.8±6.6	15.5±7.4
Function‡	4.0±1.9	4.3±1.9	4.2±1.9
SF-12 Physical§	42.9±8.2	43.6±7.9	43.3±8.1
SF-12 Mental§	46.0±11.62	48.9±9.4	47.5±10.7

NOTE. Values are mean ± SD or numbers and percentages.
*Numerical Rating Scale (0, no pain, to 10, worst possible pain).
†Neck Disability Index (0, no disability, to 50, extreme disability).
‡Patient Specific Functional Scale (0, unable to perform activity, to 10, able to perform activity at preinjury level).
§12-Item Short-Form Health Survey Physical and Mental Component Summaries. (Scores are normalized based on general population; mean ± SD, 50±10).

Recovery From Neck Pain

Kaplan-Meier curves of recovery from neck pain for the manipulation and mobilization groups were nearly identical (fig 2A), so we did not formally test the proportional hazards assumption. Participants treated with neck manipulation did not experience more rapid recovery from neck pain than those treated with neck mobilization (hazard ratio=.98; 95% confidence interval, .66–1.46; P=.909) (see fig 2A). The median time to recovery from pain was 47 days in the manipulation group and 43 days in the mobilization group.

Secondary Analysis

Participants treated with neck manipulation did not experience more rapid recovery of normal activity than those treated with neck mobilization (hazard ratio=1.02; 95% confidence interval, .72–1.47; P=.897) (see fig 2B). The median time for recovery of normal activity was 22 days in the manipulation group and 24 days in the mobilization group.

There were no statistically significant differences between the manipulation and mobilization groups in the secondary outcomes of pain, disability, function, global perceived effect, or health-related quality of life at any time point (table 2). Confidence intervals for estimates of effects did not include clinically important effects.[24]

In the manipulation group, of the 49 participants who recovered by 12 weeks, 14 (28.6%) experienced a relapse or new episode of neck pain during the 3-month follow-up period. In the mobilization group, of the 47 participants who recovered, 7 (14.9%) experienced a relapse or new episode of neck pain. The point estimate of the difference in incidence proportion of relapse in manipulation and control groups favored mobilization (relative risk=1.9). The confidence intervals about the relative risk estimate were very wide (.85–4.33; P=.263) but nonetheless ruled out a clinically important superiority of manipulation.

Adverse Events

There were no serious neurovascular adverse events reported by participants during the treatment period or identified during the 3-month follow-up. In the mobilization group, 2 participants experienced serious adverse events that were deemed by the attending medical specialists to be unrelated to the treatment provided. One participant underwent emergency cardiac surgery for an unrelated condition during the trial period. Another participant developed severe arm pain and weakness 3 days after the third treatment session and was admitted to the hospital.

Participants reported various minor adverse effects that they attributed to treatment. The most frequent of these were increased neck pain, reported by 29.4% of participants, and headache, reported by 22.0% of participants. There were no statistically significant differences in incidence of minor ad-

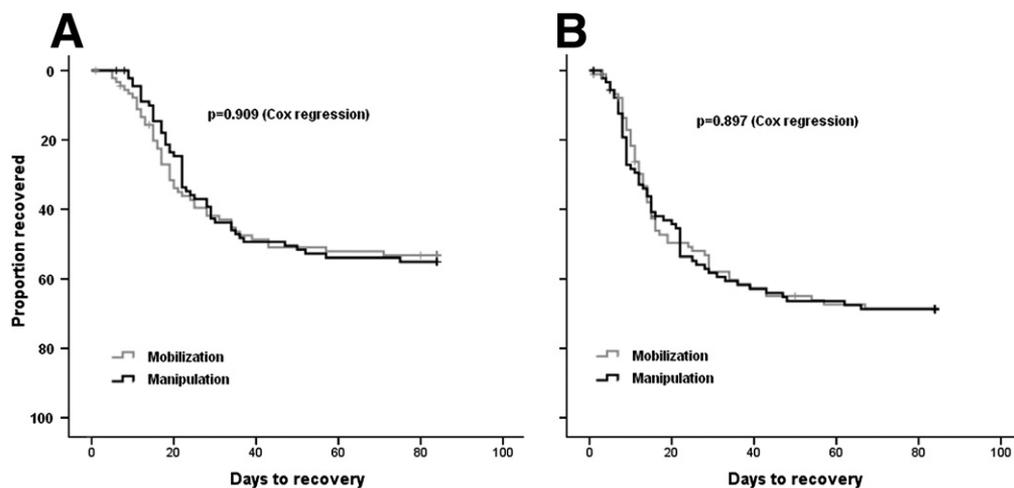Fig 2. Kaplan-Meier survival curves for recovery from an episode of recent onset nonspecific neck pain. (A) Recovery of neck pain. Recovery is defined as the first of 7 consecutive days less than 1 out of 10. (B) Recovery of normal activity. Recovery is defined as the first of 7 consecutive days with an activity interference score of 1 on a 1 to 5 scale ("not at all" to "extreme" activity interference).

Table 2: Secondary Outcomes Measured 2, 4, and 12 Weeks After Randomization

Variable	Manipulation Mean ± SD (n=89)	Mobilization Mean ± SD (n=88)	Mean Difference (95% CI)	P*
Pain†				
Week 2	2.4±2.0	2.5±2.2	−0.1 (−0.7 to 0.6)	.818
Week 12	1.6±2.0	1.4±1.7	0.2 (−0.4 to 0.7)	.504
Disability‡				
Week 4	6.5±6.8	6.9±7.3	−0.4 (−2.5 to 1.7)	.718
Week 12	5.3±6.2	5.5±6.6	−0.2 (−2.1 to 1.7)	.866
Function§				
Week 4	8.2±2.1	7.8±2.2	0.3 (−0.3 to 1.0)	.295
Week 12	8.6±2.0	8.6±1.8	0.0 (−0.6 to 0.5)	.876
Physical health‖				
Week 4	47.9±7.1	47.3±7.7	0.5 (−1.7 to 2.7)	.642
Week 12	50.2±6.2	50.6±7.8	−0.4 (−2.5 to 1.7)	.685
Mental health‖				
Week 4	49.1±8.8	51.5±9.3	−2.4 (−5.1 to 0.3)	.083
Week 12	52.2±8.9	52.7±8.7	−0.5 (−3.1 to 2.2)	.726
Global perceived effect¶				
Week 2	2.9±1.7	3.2±1.7	−0.3 (−0.8 to 0.2)	.259
Week 12	3.3±1.7	3.4±1.9	−0.1 (−0.6 to 0.4)	.698

Abbreviation: CI, confidence interval.
*P values from independent t test (2-tailed) for equality of means.
†Numerical Rating Scale (0, no pain, to 10, worst possible pain).
‡Neck Disability Index (0, no disability, to 50, extreme disability).
§Patient Specific Functional Scale (0, unable to perform activity, to 10, able to perform activity at preinjury level).
‖12-Item Short-Form Health Survey Physical and Mental Component Summaries. (Scores are normalized based on general population; mean ± SD, 50±10).
¶Global perceived effect was measured on a single scale from −5 (much worse) to 5 (completely recovered).

verse effects between participants treated with manipulation and with mobilization (table 3).

DISCUSSION

The main finding of this study was that the inclusion of neck manipulation in a treatment regimen did not result in more rapid recovery from an episode of recent onset neck pain than mobilization techniques. In addition, neck manipulation did not result in better outcome in terms of pain, disability, function, global perceived effect, or health-related quality of life than neck mobilization.

This study tested neck manipulation as provided by experienced and well qualified practitioners in circumstances that closely replicated contemporary clinical practice. A common criticism of manual therapy trials is that many involve the application of standardized techniques to participants from heterogeneous populations for whom the treatment is not well suited or not clearly indicated.[25] These criticisms do not apply to our study because the pragmatic design allowed the practitioners to exclude participants they deemed unsuitable for treatment with manipulation. The practitioners also selected the specific manual technique as well as other adjunctive therapies that they deemed to be appropriate. In addition, by using the late randomization design, we gave the practitioners control over the timing of introduction of neck manipulation according to their judgment.

Study Limitations

A potential limitation of this study, as with other trials of manual therapy, is that we were not able to blind practitioners or participants to treatment allocation as would be possible in some placebo-controlled trials. Empirical studies have revealed that unblind studies report larger treatment effects than blind studies,[26] so we cannot exclude the possibility that the effects of manipulation we report are exaggerated. However, this potential bias is less of a concern in our study given that both groups received plausible interventions that are currently in widespread use, and because the results do not suggest bias in favor of manipulation.

CONCLUSIONS

Nearly half of the participants in this study, irrespective of treatment allocation, did not fully recover from the episode of neck pain with which they presented. This is consistent with prognostic studies that have reported the persistent and often recurrent nature of nonspecific neck pain.[27] Nonetheless, there was rapid and large improvement in pain scores in both groups from a mean score ± SD of 6.0±2.0 at baseline to 2.5±2.1 after 2 weeks of treatment. Because we did not include a placebo or no-treatment arm in this study, it is not possible to determine whether the rapid improvement was a result of manual therapy treatment or natural recovery.

There were no major adverse events related to treatment reported during either the treatment or the follow-up period.

Table 3: Number of Participants Who Reported Minor Adverse Events During the 2-Week Course of Treatment

Adverse Event	Manipulation n (%)	Mobilization n (%)	P
Additional neck pain	28 (31.8)	24 (27.0)	.479
Headache	22 (25.0)	17 (19.1)	.344
Dizziness/vertigo	7 (8.0)	6 (6.7)	.757
Nausea	4 (4.5)	7 (7.9)	.360
Paresthesia	8 (9.1)	5 (5.6)	.376
Other*	7 (8.0)	3 (3.4)	.187

*Other minor adverse events reported in the questionnaire included upper limb pain (n=3), neck stiffness (n=3), fatigue (n=3), mid-lower back pain (n=1), and "unpleasant change in spinal posture" (n=1).

Minor adverse events, however, were commonly reported. This is consistent with reports from previous studies.[28,29] Of some concern was the relatively high frequency of additional post-treatment neck pain and headache in both groups, attributed by participants to treatment. This is of particular importance considering that the main purpose of these treatments is to provide relief from these symptoms. For this study, we were particularly careful to ensure prudent and cautious recruitment of participants because of the risks and concerns surrounding the safety of manipulation. However, evidence-based indications for the use of manipulation are not available. We therefore applied all known important exclusion criteria and then, in addition, allowed clinicians to use their judgment whether individual patients were suitable for manipulation. This meant that even if a patient met the inclusion criteria, the clinician could exclude the patient on the basis of clinical judgment. Despite this very cautious approach, a substantial proportion of participants reported minor adverse effects of treatment.

This study demonstrated that neck manipulation did not provide more rapid recovery from an episode of neck pain or better outcomes in terms of pain, disability, function, or global effect than mobilization. These findings suggest that there is reason for practitioners and their patients to re-evaluate the use of manipulation for recent onset neck pain.

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