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Shi-style cervical manipulations for cervical radiculopathy

A multicenter randomized-controlled clinical trial

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Abstract

Background: There is a lack of high-quality evidence supporting the use of manipulation therapy for patients with cervical radiculopathy (CR). This study aimed to evaluate the effectiveness of Shi-style cervical manipulations (SCMs) versus mechanical cervical traction (MCT) for CR.

Methods: This was a randomized, open-label, controlled trial carried out at 5 hospitals in patients with CR for at least 2 weeks and neck pain. The patients received 6 treatments of SCM (n = 179) or MCT (n = 180) over 2 weeks. The primary outcome was participant-rated disability (neck disability index), measured 2 weeks after randomization. The secondary outcomes were participant-rated pain (visual analog scale) and health-related quality of life (36-Item Short Form Health Survey [SF-36]). Assessments were performed before, during, and after (2, 4, 12, and 24 weeks) intervention.

Results: After 2 weeks of treatment, the SCM group showed a greater improvement in participant-rated disability compared with the control group ($P = .018$). The SCM group reported less disability compared with the control group ($P < .001$) during the 26-week follow-up. The difference was particularly important at 6 months (mean -28.91 ± 16.43, $P < .001$). Significant improvements in SF-36 were noted in both groups after 2 weeks of treatment, but there were no differences between the 2 groups.

Conclusion: SCM could be a better option than MCT for the treatment of CR-related pain and disability.

Abbreviations: AE = adverse event, CR = cervical radiculopathy, FAS = full analysis set, HRQoL = health-related quality of life, MCT = mechanical cervical traction, NDI = neck disability index, PPS = per protocol set, SCM = Shi-style cervical manipulation, VAS = visual analog scale.

Keywords: cervical radiculopathy, manipulations, randomized-controlled clinical trial, traction

1. Introduction

Cervical radiculopathy (CR) is a neurologic condition characterized by dysfunction of a cervical spinal nerve, the roots of the nerve, or both.[1] Its incidence is about 1.79 per 1000 person-years.[2] The most common causes of CR are foraminal encroachment of the spinal nerve due to disc herniation, spondylosis, instability, trauma, or tumors.[1,3,4] Symptoms range from complaints of pain, numbness, and/or tingling in the upper extremity to electrical-type pains or even weakness.[3] In addition, economic, social, and psychological impacts may be severe.[3] An effective treatment is needed in order to facilitate the return of the patients to their normal state of health.

CR may be treated conservatively or surgically,[5] but considering the surgical risks, surgery should only be considered when conservative management has failed.[6] Conservative therapy includes drugs, immobilization, physical therapy, manipulation, traction, and transcutaneous electrical nerve stimulation,[7] but success is variable and most conservative treatments have not been rigorously examined by randomized-controlled trials.[1,6,8]

Traction is the administration of a distracting force to the cervical spine in order to separate the cervical segments and provide relief to the compressed nerve roots.[6] Recently, some studies reported that cervical traction led to a significant effect on neck and arm pain reduction, a significant improvement in nerve function, and a significant increase in neck mobility.[9,10] Moreover, spinal manipulation is commonly used for patients

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with pain and symptoms of spinal origin.[11,12] Cervical manipulation can be used to relieve pain, increase cervical mobility, and improve disability for patients suffering from neck pain.[13–16] Nevertheless, there is no high-quality evidence for the effectiveness of manipulative therapy for the treatment of CR.[8,17,18]

Shi-style cervical manipulation (SCM) is commonly used to treat CR in China. SCM is based on the channels and collaterals theory of the traditional Chinese medicine, in which the symptoms of neck pain are believed to result from channel blockage and joint displacement.[16] Despite its popularity in China, few studies investigated the effectiveness of SCM in the management of chronic mechanical neck pain.[16]

Therefore, this prospective randomized, open-label, controlled trial aimed to compare the effectiveness of SCM versus mechanical cervical traction (MCT) for patients with CR.

2. Methods

2.1. Study design

This was a prospective multicenter, randomized, open-label, controlled trial aiming to examine the effects of SCM on CR. The study was approved by the ethical committee of the Longhua Hospital, Shanghai University of Traditional Chinese Medicine. Written informed consent was obtained from all subjects before participating in the study. No amendments were made after the trial started. The study protocol had been registered with ClinicalTrials.gov (NCT01500967).

Five hospitals participated in the study: Longhua Hospital, Shanghai University of Traditional Chinese Medicine, the First Affiliated Hospital of Tianjin University of Traditional Chinese Medicine, the First Affiliated Hospital of He'nan College of Traditional Chinese Medicine, Xinjiang Uygur Autonomous Region Hospital of Traditional Chinese Medicine, and the Second Affiliated Hospital of Fujian University of Traditional Chinese Medicine.

2.2. Patients

Patients were recruited between February 2012 and May 2013. All participants had a diagnosis of CR confirmed by a senior neurologist. Patients with CR were diagnosed based on clinical manifestations (pain along the cutaneous distribution of 1 or more cervical roots, which may include weakness and hyporeflexia), physical examination, and imaging.[6] The eligibility criteria were 18 and 65 years of age; pain or stiffness in the neck for at least 2 weeks; neck symptoms reproducible during physical examination; neck pain on a visual analog scale (VAS) ≥ 30 mm; radiation of arm pain distal to the elbow, and at least 1 positive test among the following: provocation of neck or arm pain by neck movements, brachial plexus traction test, foraminal compression test, foraminal separation test, sensory changes in 1 or more adjacent dermatomes, or muscle weakness in 1 or more adjacent myotomes; willingness to adhere to treatment and measurement regimens; and signed the informed consent.

The exclusion criteria were history, signs, or symptoms suggested a potential nonbenign cause (including previous neck surgery); any evidence of a specific pathological condition such as malignancy, neurological disease, fracture, herniated disc, or systemic rheumatic disease; clinical signs of spinal cord compression, or previous neck trauma; obvious vertigo; pregnant or lactating women; currently participating in another clinical trials; hepatic, renal, hematopoietic, endocrine, cardiovascular, or nervous system diseases; tuberculosis; vertebral deformities; mental illness; insufficient understanding of the Chinese language; or have been treated with physical therapy or manipulation therapy for neck pain during the previous 2 weeks.

Patients in all treatment groups were allowed to use painkillers when recommended by doctors and when necessary (VAS > 70 mm). Patients with concurrent headaches, nonradicular pain in the upper extremities, and low back pain were not excluded, but neck pain had to be the main symptom for all patients. To ensure the identification of all eligible patients, radiology records were audited.

2.3. Randomization

The randomization table was generated using STATA 12. Patients were randomized using stratified 1:1 randomization (SCM vs. traction) using a web-based randomization system managed by an independent 3rd-party clinical research organization (Institute of Basic Research in Clinical Medicine, China Academy of Chinese Medical Science).

2.4. Physicians

Tractions were performed by physiotherapists or physicians trained in musculo-skeletal problems. The physicians were required to fulfill the following criteria: ≥ 3 years of experience with manual therapy; and participation in the study training sessions about the trial methods, the interventions being tested, and standards for performing clinical trials (ICH-GCP). Forty-one practitioners in 5 outpatient units in China participated in this study. They were taught SCM by a skilled physician (XLY). In order to maximize standardization, all clinicians were given onsite training about SCM and MCT, and were provided with an instruction manual and video. Only the skilled physician (XLY) had the right to determine whether the trained clinicians could participate in the trial.

2.5. Treatments

Because of the nature of the intervention, the patients and therapists could not be blinded. The patients were treated with SCM (intervention group) or cervical traction (control group), for 6 sessions over 2 weeks. We asked the patients to note their drug use, including over-the-counter analgesics during the first 2 weeks after randomization.

2.6. Shi-style cervical manipulations

Figure 1 shows the SCMs.

2.6.1. Soothing tendon step. The therapist kneaded the patient's neck, grasped the back and waist in turn, and rolled the upper limbs; repeated 3 to 6 times.

2.6.2. Osteopathic step. The therapist lifted the patient's head gently, relaxed the neck by turning the head in flexion, extension, right (45°), and left (45°); repeated 3 to 6 times. Then, pulling manipulation was applied to the neck joint if no discomfort was reported by the patient.

2.6.3. Dredging collateral step. The therapist held the hands of the patients with gentle and fast force at full tilt for continuous small amplitude jitter for 6 times, and twisted on sensitive points

Figure 1. Shi-style cervical manipulations. (A) Kneading of the patient's neck with a palm. (B) Grasping of the back and waist in turn. (C) Rolling of the upper limbs. (D) Lifting of the patient's head gently. (E) Relaxation of the neck by turning the head in flexion, extension, right (45°), and left (45°), repeated 3 to 6 times. (F) Pulling the neck joint if no discomfort was reported by patient. (G) Holding the hands of the patients with gentle and fast force at full tilt with continuous small amplitude jitter for 6 times. (H) Twisting of the sensitive points of the ears for 30 s. (I) Rubbing the acupoints Mingmen (GV 4), Dazhui (GV 14), Naohu (GV 17), and Baihui (GV 20), each for 30 s.

of the ears for 30 s. The last step was rubbing manipulation of the acupoints Mingmen (GV 4), Dazhui (GV 14), Naohu (GV 17), and Baihui (GV 20), each for 30 s.

2.7. MCT group

The traction treatment was based on the 2010 "Guidelines for diagnosis and treatment, and rehabilitation of cervical spondylosis." The patients received mechanical persistent cervical traction for 20 min. Each patient was placed in the sitting position, with the head leaning forward at about 10° to 15° of flexion. The traction angle was generally determined according to the lesion site. If the lesion were mainly at the high cervical spinal level, the traction angle was 0° to 10°. If the lesion were at the low cervical spinal level, the traction angle was 15° to 30°. At the same time, all procedures were performed while ensuring patients' comfort. The traction force was started at 6 kg and increased by about 0.5 kg every visit, depending on centralization or reduction of symptoms. The maximum force used was 10 kg.

2.8. Outcomes

The primary outcome was participant-rated disability, measured 2 weeks after randomization. The neck disability index (NDI) was used to measure disability in patients with neck pain, based on a modification of the Oswestry Low Back Pain Index.[19] All

items were measured on a 6-point scale from 0 (no disability) to 5 (full disability). The numeric response for each item was summed, the total score varying from 0 to 50.[20,21] The NDI has been shown to be reliable and valid in many patient populations.[20,21] It exhibits fair to moderate test–retest reliability in patients with mechanical neck pain.[22,23]

Secondary outcome measures included participant-rated pain (measured by a VAS), health-related quality of life (HRQoL; measured by the 36-Item Short Form Health Survey [SF-36]), and medication use (measured by asking if the patients had taken pain-relieving medication for their neck pain during treatment). Adverse events (AEs) were also monitored.

The VAS is a 100-mm line with pain descriptors marked "no pain" on the left end and "the worst pain imaginable" on the right end. The patients were asked to report their perceived pain level, both at rest and on most painful movement, by marking the VAS with a perpendicular line. This has been found to be a reliable and valid measure of pain.[24] SF-36 is one of the most widely used HRQoL instruments. It has been shown to be reliable and valid in many patient populations.[25]

2.9. Safety

Safety was assessed by spontaneous reporting of AEs. We classified serious AEs as events that caused death, were life-threatening, or necessitated admission to hospital. AEs were actively assessed by trial physicians using a specific list at each session. Side effects were recorded in the treatment notes at each visit during treatment.

2.10. Follow-up

Outcome measurements were collected at baseline, and at 2, 4, 12, and 24 weeks after randomization. If patients were not able to visit the outpatient clinic, the research assistant needed to record the reason. All self-reported questionnaires were completed by participants independent of the influence from investigator, study staff, or treatment provider.

2.11. Quality assurance

The study had appointed 5 trained quality inspectors to guarantee the quality of the whole trial. The 5 inspectors visited each center regularly without prior notice. All patients were telephoned and asked some details about the trial such as the informed consent, the use of VAS, the time to follow-up, and the quality of the treatments to judge the normalization of the trial. Any problem occurring in a center was reported in writing by the inspectors.

2.12. Statistical analysis

The null hypothesis (H_0) was that there was no difference between the 2 treatments. The alternative hypothesis (H_1) was that SCM could improve cervical disability and decrease pain and numbness of the affected upper extremity. The sample size was calculated on the basis of the comparison between 2 treatments (SCM vs. traction), with equal allocation in both arms. The sample size was calculated based on the NDI at 2 weeks. Assuming a dropout rate of 20%, $\alpha = 0.05$ and a power of 90%, 180 patients had to be recruited in each group.

All analyses were performed by an independent statistician. The primary and secondary outcomes were analyzed using the per protocol set (PPS) and full analysis set (FAS) according to the intention-to-treat method. The FAS included all randomized subjects who underwent at least 1 treatment and 1 follow-up. The PPS included all patients who received all scheduled treatments and underwent all follow-up visits. Since the results of both sets are similar, only the results of the FAS are presented here and the PPS results are available as Tables S1–S3, http://links.lww.com/MD/B765.

Continuous variables were tested for normality using the McNemar test. Normally distributed continuous data were reported as mean ± standard deviation and analyzed using the Student *t* test. Non-normally distributed continuous data were presented as median (interquartile range) and analyzed using the Wilcoxon rank-sum test. The changes from baseline in each group were tested using the Mann–Whitney test. Categorical variables are reported as frequencies and were analyzed using the Fisher exact test. PASW 18.0 for Windows (SPSS, Inc., Chicago, IL) was used for analysis. Two-sided P values $< .05$ were considered statistically significant.

3. Results

3.1. Recruitment

Between February 2012 and May 2013, 360 patients were assessed for eligibility. The reason for excluding 4 patients was VAS < 30 mm. Figure 2 shows the patient flowchart.

3.2. Characteristics of the patients

Table 1 presents the characteristics of the patients. There were no differences in any of the baseline variables between the 2 groups. About 75% of participants were female. The mean duration of CR was 96 days and 307 (86.5%) were at their first onset. The mean pain VAS was 58 mm, indicating that most of the patients suffered from moderate degree of pain, reflected by an NDI of 22. Neurological deficit consisted mainly of sensory disturbances.

3.3. Adherence to treatment

In the 2 groups, most patients received the scheduled 6 treatments. Because of adverse effects, 1 patient did not receive SCM. One patient in the SCM group and 1 in the traction group only received 1 treatment because of failure to make an appropriate contact, while 3 patients in the traction group declined further treatment because of little effect. Only 1 patient in the traction group took diclofenac sodium sustained release tablets.

3.4. Follow-up

In total, 322 (89.7%) of the 359 participants completed the whole trial, while 344 (95.8%) of the 359 participants completed at least 1 treatment and 1 follow-up. The proportion of patients not completing the trial was similar between the 2 groups. The main reason for loss to follow-up in the SCM group was too great a burden (n = 11) compared with n = 15 in the traction group. Reasons for dropping out were similar between the 2 groups.

3.5. Primary outcomes

Table 2 presents the changes in NDI. NDI was similar at baseline between the 2 groups ($P = .81$). From the FAS data, significant changes from baseline in NDI were seen at 2, 4, 12, and 24 weeks

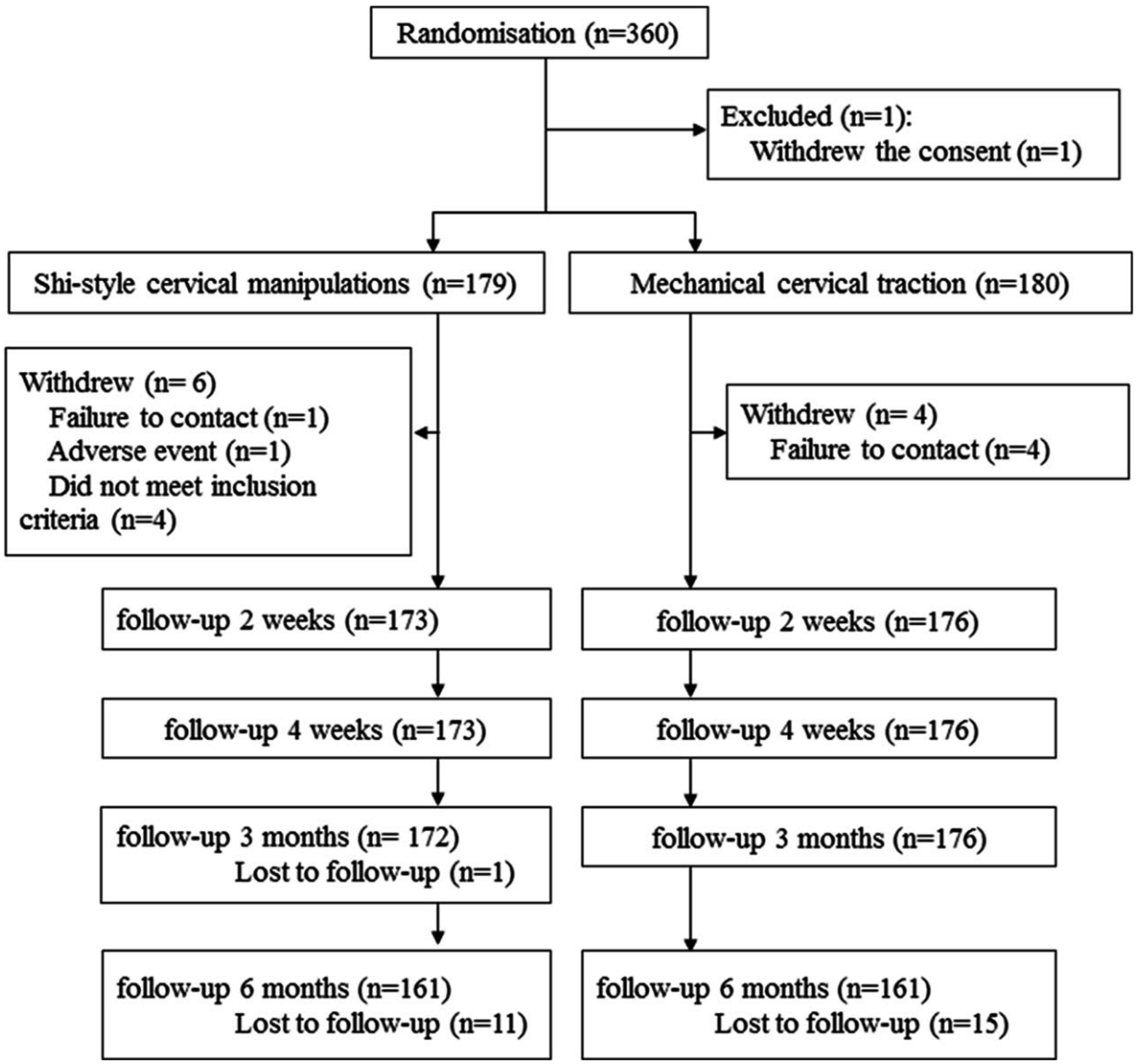

Figure 2. CONSORT flow diagram.

in both groups (all $P < .001$). In addition, at each follow-up time points, compared with the control group, NDI was significantly lower in the SCM group (all $P < .01$) and the change in NDI from baseline was more important in the SCM group (all $P < .01$). Similar results were observed in the PPS (Table S1, http://links.lww.com/MD/B765), except that the difference between the 2 groups disappeared after 24 weeks.

3.6. Secondary outcomes

Table 3 presents the changes from baseline in VAS. VAS was similar at baseline between the 2 groups ($P = .98$). From the FAS data, significant changes from baseline in VAS were seen at 2, 4, 12, and 24 weeks in both groups (all $P < .001$). In addition, at each follow-up time points, compared with the control group, VAS was significantly lower in the SCM group (all $P < .01$) and the change in VAS from baseline was more important in the SCM group (all $P < .05$). Similar results were observed in the PPS (Table S2, http://links.lww.com/MD/B765), except that the difference between the 2 groups disappeared after 12 weeks.

Table 4 presents the changes from baseline in the patient-reported quality of life. In the FAS, there were no differences in SF-36 between the 2 groups at baseline. SF-36 score was improved in both groups after 2 weeks (both $P < .001$), but the difference between the 2 groups was modest ($P = .055$ for absolute scores and $P = .025$ for the change from baseline). In the PPS (Table S3, http://links.lww.com/MD/B765), there was no difference between the 2 groups.

3.7. Safety

No serious AEs were reported. Only 1 patient in the SCM group reported dizziness and nausea. This expected, nonserious AE was self-limited, and no permanent injuries occurred. However, the patient withdrew from the trial.

4. Discussion

To the best of our knowledge, this is the first randomized-controlled trial investigating the effectiveness of SCM compared

Table 1

Characteristics of the patients.

	SCM (n = 173)	Traction (n = 176)	*P*
Gender (male/female), n	45/128	35/141	.173
Mean age, y	44.1 ± 12.2	44.4 ± 11.6	.879
Mean duration of neck pain, d	96 ± 184	97 ± 156	.181
Treatment experience (yes/no), n	24/149	18/158	.295
Visual analog scale, pain (0–100 mm)	58.3 ± 12.8	58.0 ± 12.1	.976
Neck disability index (0–50), %	22.5 ± 6.1	22.6 ± 6.0	.807
SF-36	60.4 ± 15.3	60.0 ± 15.9	.882
Physical functioning	26.1 ± 3.0	25.9 ± 2.9	.359
Role-physical	5.5 ± 1.6	5.6 ± 1.6	.573
Bodily pain	7.8 ± 1.7	7.8 ± 1.6	.717
General health	15.2 ± 3.3	15.1 ± 3.3	.875
Vitality	16.3 ± 3.1	16.5 ± 3.3	.523
Social functioning	8.7 ± 1.6	8.5 ± 1.8	.356
Role-emotional	4.4 ± 1.3	4.3 ± 1.2	.487
Mental health	21.6 ± 3.5	21.5 ± 3.8	.853
Physical examinations (positive/negative), n			
Cervical paraspinal tenderness	166/6	167/9	.455
Intervertebral foramen separation test	58/112	53/122	.446
Intervertebral foramen extrusion test	102/68	107/68	.828
Brachial plexus nerve stretching test	147/24	157/18	.286

SCM = Shi-style cervical manipulations.

with traction for the treatment of pain from CR. The present study suggests that treatment with SCM for 2 weeks resulted in a significant reduction in neck pain and disability compared with mechanical traction. SF-36 scores were improved after weeks in both groups, but without difference between them.

No direct evidence could be found in the literature showing the superiority of SCM in patients with CR compared with traction. Only 2 case reports,[26,27] 2 retrospective case series,[11,12] and an observation series of 8 patients[28] explored the efficacy of SCM therapy, but these previous studies have small sample sizes and there is neither randomization nor control. One of the retrospective case series observed that among patients undergoing spinal manipulation after cervical epidural injection, 50% significant improvement and 30% experienced temporary improvement, while 20% exhibited no change.[11] Another study revealed a statistically significant reduction in pain as quantified by VAS in patients with CR.[28] The mean number of treatments required was 6 to 37 (mean of 12). Only 3 patients required more treatments than the mean plus 1 standard deviation. In this previous study, good outcomes were achieved in 75% of the patients by manipulation of the cervical spine at the level of the radiculopathy.[28] The remaining 25% had an exacerbation of symptoms and deficits.[28]

Cervical traction is frequently used, but its effectiveness has not been adequately examined. A randomized clinical trial in 2014 found that adding mechanical traction to exercise for patients with CR resulted in lower disability and pain, particularly on the long-term.[29] Another study supported that cervical traction combined with electrotherapy and exercise resulted in an immediate improvement in the hand grip function in patients with CR.[30] Atteya[31] showed that electromyographic biofeedback with cervical traction showed a significant effect in avoiding muscle spasm and decreasing root compression during traction,[31] while another randomized clinical trial reported the opposite result.[10] A randomized trial has shown that a traction approach using an improved traction angle resulted in good outcomes.[9] Although there were some case reports or case series of traction for CR,[32–35] the therapeutic effects of traction remain controversial.

Table 2

Changes in the neck disability index from baseline (full analysis set).

	SCM (n = 173)	Traction (n = 176)	*P*
NDI at baseline	22.53 ± 6.09	22.57 ± 6.01	.807
Week 2			
NDI	17.96 ± 4.69	19.51 ± 5.31	.002*
Change from baseline	−4.57 ± 5.02	−3.06 ± 4.47	.005*
P	<.001*	<.001*	
Week 4			
NDI	17.36 ± 4.66	18.99 ± 5.43	.002*
Change from baseline	−5.17 ± 5.51	−3.58 ± 4.57	.004*
P	<.001*	<.001*	
Week 12			
NDI	16.95 ± 4.62	18.66 ± 5.37	.002*
Change from baseline	−5.57 ± 5.82	−3.91 ± 4.77	.005*
P	<.001*	<.001*	
Week 24			
NDI	16.82 ± 4.73	18.23 ± 5.17	.004*
Change from baseline	−5.71 ± 5.91	−4.34 ± 5.10	.012*
P	<.001*	<.001*	

NDI = neck disability index, SCM = Shi-style cervical manipulations.
* $P < .05$.

Table 3

Changes in participant-rated pain from baseline (full analysis set).

	SCM (n = 173)	Traction (n = 176)	*P*
Pain score at baseline	58.34 ± 12.79	58.04 ± 12.10	.976
Week 2			
Pain score	33.55 ± 14.73	38.14 ± 13.79	.001*
Change from baseline	−24.79 ± 15.80	−19.90 ± 13.43	.002*
P	<.001*	<.001*	
Week 4			
Pain score	31.39 ± 14.62	35.97 ± 13.25	.002*
Change from baseline	−26.95 ± 16.89	−22.07 ± 12.76	.003*
P	<.001*	<.001*	
Week 12			
Pain score	29.98 ± 14.57	34.07 ± 14.95	.010*
Change from baseline	−28.36 ± 16.40	−23.97 ± 15.25	.010*
P	<.001*	<.001*	
Week 24			
Pain score	28.46 ± 14.63	31.82 ± 14.35	.009*
Change from baseline	−29.88 ± 16.39	−26.22 ± 15.05	.031*
P	<.001*	<.001*	

SCM = Shi-style cervical manipulations.
* $P < .05$.

Table 4

Changes in participant-rated quality of life from baseline (full analysis set).

	SCM (n = 173)	Traction (n = 176)	*P*
SF-36 at baseline	60.37 ± 15.32	59.96 ± 15.88	.882
Week 2			
SF-36	67.48 ± 15.06	64.15 ± 16.21	.055
Change from baseline	7.11 ± 11.77	4.18 ± 10.99	.025*
P	<.001*	<.001*	

SCM = Shi-style cervical manipulations, SF-36 = 36-Item Short Form Health Survey.
* $P < .05$.

Strengths of this study include a relatively large patient sample, a randomized-controlled design, and high participation and follow-up rates. Different from drug trials, the compliance of manipulation and traction can be ensured. The trial had a relatively perfect quality assurance plan to ensure the authenticity and reliability of data. Each of the branch centers was appointed with a trained quality inspector to ensure the authenticity of each patient and guarantee the quality of data.

Nevertheless, the study has some limitations. Participants were recruited primarily through outpatient departments and may not be representative of all patients with CR. Of course, just like all studies on manipulation, blinding was impossible. Finally, outcome measures such as VAS and NDI rely heavily on self-reporting, and their positive outcomes are likely to be over-estimated.

In conclusion, SCM might a better option than traction for the treatment of CR-related pain and disability. Nevertheless, additional studies are necessary to confirm these findings.

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