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Musculoskeletal Ultrasound Assessment of the Clinical Efficacy of the Combination of Acupressure and "Three Methods of Neck Movement (TCM)" Therapy in the Treatment of Cervical Spondylosis: A Study Protocol for a Randomized Controlled Trial

Jinhong Zuo*, Xiayang Zeng*, Hongyi Ma, Peng Chen, Xinlei Cai, Zhenyu Fan, Jianpeng Qu

Massage Department, Zhejiang Hospital, Hangzhou City, People's Republic of China

*These authors contributed equally to this work and co-first authors

Correspondence: Jianpeng Qu, Massage Department, Zhejiang Hospital, No. 12 Lingyin Road, Xihu District, Hangzhou City, 310000, People's Republic of China, Email qjp0007@126.com

Background: Neck-type cervical spondylopathy (NTCS), a common degenerative disorder affecting the spine, poses challenges for patients and society. Research has demonstrated the effectiveness of traditional tuina techniques in treating NTCS, although some limitations still exist. Our study aimed to evaluate the effectiveness of combining regular massage techniques with three methods of neck movement (TCM) therapy for managing NTCS, utilizing musculoskeletal ultrasound measurements.

Patients and Methods: In this study, 70 eligible patients with non-traumatic cervical spondylosis will be randomly assigned in a 1:1 ratio to either the experimental group, which will receive Tuina combined with a three-method neck movement treatment, or the control group, which will receive standard Tui Na manipulation. All participants will receive treatment for four weeks. Assessments will be conducted using musculoskeletal ultrasound, the McGill Pain Scale, and the Neck Disability Index (NDI) at three-time points: before treatment, at the end of treatment, and after 12 and 16 weeks of treatment.

Conclusion: This paper investigates the utility of musculoskeletal ultrasound as a tool for evaluating the therapeutic efficacy of an integrated Traditional Chinese Medicine (TCM) strategy in alleviating pain and enhancing functional outcomes for patients with NTCS. The objective is to present a clinically viable and long-term treatment option.

Trial Registration: Chinese Clinical Trial Registry, ChiCTR2300072648. Registered on June 20, 2023.

Keywords: neck-type cervical spondylopathy, randomized controlled trial, therapeutic neck movement techniques, musculoskeletal ultrasonography

Introduction

Cervical spondylosis encompasses a spectrum of degenerative alterations that insidiously affect the cervical spine, encompassing the intervertebral discs, facet joints, Luschka's joints, flaval ligaments, and laminae.[1] According to statistics, the annual prevalence of cervical spondylosis has exceeded 30%, of which NTCS is the most common type, accounting for about 60% of cervical spondylosis, and its typical symptomatic manifestation is pain in the head, shoulder, neck, and arm and the corresponding pressure points, without obvious imaging changes.[2,3] According to statistics, the incidence of NTCS is increasing year by year and showing a trend of getting younger, thus becoming the fourth leading cause of disability following back pain, depression, and other musculoskeletal disorders. It has an average prevalence rate of approximately 7.6% and a lifetime prevalence rate of around 48.5%, with more females than males.[4] NTCS is a complex biopsychosocial disorder for patients, which is accompanied by physical and psychological problems, leading

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to a decline in quality of life, reduced work efficiency, limitation of daily activities, and increased economic burden.[4,5] Hence, addressing neck pain effectively represents a pivotal global public health concern.

Massage, a therapeutic modality, eases neck pain by relaxing muscles, easing tension, boosting circulation, clearing metabolic byproducts, and unleashing beta-endorphins that induce overall relaxation, alleviate discomfort, enhance mobility, and ameliorate neck dysfunction.[6–10] Tui Na therapy is widely favored by patients because of its simplicity and effectiveness. However, the short-term efficacy of simple massage therapy for treating NTCS is remarkable, but its long-term efficacy is insufficient, resulting in recurrent and prolonged disease.[11,12] Due to the complexity of the disease, single-treatment modalities are often less effective, and combination treatments may be more effective.[13]

TCM, a traditional Chinese medical massage therapy, was recorded in the traditional Chinese medical work "Zhubing Yuanhou Lun" during the Sui Dynasty, more than 1400 years ago. TCM is now widely used in the nonsurgical treatment of neck disorders. Prolonged retention in an identical posture could result in skeletal muscle damage, categorized as a type of "Bi syndrome" in traditional Chinese medicine. The primary mechanism includes the obstruction and congestion of the body's meridian pathways. Traditional massage aims to harmonize the conflicting energies of yin and yang, clear the meridians, alleviate regional muscle contractions, recover muscle functionality, and mitigate related symptoms.[14] Studies have shown that massage can decrease muscle inflammation in injured skeletal muscle, enhance repair of mitochondria,[15] alleviate delayed-onset muscle soreness (DOMS),[16] minimize the reduction in muscle strength,[17] and aid in the restoration of exercise-induced muscle damage (EIMD).[18]

The cervical spine's biomechanical equilibrium is predominantly sustained by two stabilization systems: an endogenous system, which includes the vertebral bodies, intervertebral discs, and ligaments, providing the core stability; and an exogenous system, comprising the paravertebral muscles, which is essential for supplementary support.[19] The prolonged maintenance of an incorrect posture, which results in the prolonged exertion of muscles in a state of high load, a lack of contractility, increased intramuscular pressure, local ischemia, reduced oxidative metabolism, elevated lactic acid levels, a reduction in muscle fiber conduction velocity, a reduction in muscle contraction force, pathological changes in the neck muscles, and an imbalance of the static force system, all contribute to the induction and acceleration of muscle tension, fatigue, and pain.[20–22] Several studies have shown that decreased muscle strength and neck strain are closely related to NTCS.[23–25] Neck muscles, positioned variably, are segmented into cervical extensors, anterior flexors, and lateral flexors, with the extensors comprising the upper trapezius, cephalic pinchers, cephalic semispinalis, and multifidus. Given the current working and living pattern, the head and neck need to maintain a forward posture for a long period, and therefore rely on the cervical extensors to maintain them, which makes the muscles at the back of the neck susceptible to straining, causing pain and discomfort at the posterior cervical region.[26,27] There has been a growing focus on the cervical spine stabilization system due to reasons such as the trend of NTCS onset at a young age, the discrepancy between imaging and clinical manifestations that cannot be solely attributed to cervical degenerative changes, and the fact that many NTCS patients have seen improvement or even clinical cure of their symptoms with treatments like massage and other therapies.[28,29]

Although it has been established that changes in neck muscle mass are a significant pathogenic factor in NTCS, the clinical focus remains on the static system, such as intervertebral discs. Studies are scarce regarding the assessment of neck muscles, and the current assessment of neck muscles in NTCS is primarily based on the patient's subjective perceptions and the clinician's experience. This leads to a deficiency of effective, accurate, and quantitative assessment methods. At present, electromyography, magnetic resonance imaging (MRI), and ultrasound (US) represent the principal techniques for muscle assessment. Electromyography is a widely utilized clinical tool, offering convenience and sensitivity. However, surface electromyography is rarely used for neck muscle assessment because of the limitations of its signal amplitude, signal-to-noise ratio, susceptibility to interference, and difficulty in measuring deeper muscle layers. With the sequences of T1-weighted, T2-weighted, and diffusion imaging, muscle edema and fat infiltration can be effectively assessed, and MRI has become the best approach to evaluating the quality of muscle tissues; however, its drawbacks, such as long image acquisition time and high price, have restricted its wide application in skeletal muscles.[30] The use of the US in musculoskeletal examination has increased in recent years due to the numerous advantages of this technique. These advantages include convenience, cost-effectiveness, real-time capability, non-invasive nature, and the ability to assess muscle morphology and tissue quality using parameters such as echo intensity and hardness.[31–34] The

existing literature on the US assessment of neck muscles is limited, and the findings of some studies are not widely acknowledged.[35–37] Therefore, this study utilized musculoskeletal ultrasound, the McGill Pain Scale, and the NDI to evaluate the effectiveness of combining traditional Tui Na massage with TCM therapies for the treatment of NTCS.

Material and Methods

Participants

Assessment

All participants will complete a questionnaire at recruitment that covers demographics, such as age, sex, weight, height, education, and occupation, as well as information about previous neck pain, including duration, treatment, and effectiveness.

Recruitment and Ethic

Participants will be recruited from Zhejiang Hospital using recruitment posters and online methods. They will be informed about the inclusion and exclusion criteria, the interventions, how long the interventions will last, and other important aspects of the trial. Eligible participants will receive this information again. After obtaining consent from the participants, they will sign an informed consent document and be randomly assigned to a group. The study protocol will comply with the Declaration of Helsinki and has been approved by the Zhejiang Hospital Ethics Committee (No. 2022 Pro-Audit No. 99 K).

Diagnostic Criteria

Diagnostic criteria for cervical spondylosis have been established as outlined in the 2010 edition of the Guidelines for the Diagnosis, Treatment, and Rehabilitation of Cervical Spondylosis, published by the Chinese Association of Rehabilitation Medicine.

1. The neck is stiff and painful, and there may be stiffness in the entire shoulder and back. It is impossible to nod, raise the head, or turn the head to look over the shoulder. When the neck needs to be turned, the entire trunk must be rotated at the same time, and dizziness may also occur.
2. A small number of patients may experience shoulder, arm, and hand pain, swelling, and numbness, and the symptoms do not worsen when coughing or sneezing.
3. During the acute phase of clinical examination, the cervical spine's movement is severely limited, with minimal range of motion in all directions. Tenderness is present in the muscles surrounding the cervical vertebrae, including the paravertebral muscles of thoracic 1 to thoracic 7, trapezius muscle, sternocleidal papilla muscle, supraspinatus muscle, and infraspinatus muscle. If there is a secondary spasm in the anterior scalene muscle adjacent to the sternocleidomastoid muscle, located at the level of the transverse processes of the third to sixth cervical vertebrae, the spasmodic muscle can be detected upon palpation and gentle compression. This may potentially lead to radiating pain in the shoulder, arm, and hand.
4. Imaging results may fall within the expected range or indicate only minor physiological curvature variations, slight narrowing of intervertebral spaces, or, in rare cases, the development of osteophytes.

Inclusion Criteria

Subjects with the following characteristics will be included:

1. The patient must meet diagnostic criteria for cervical spondylosis, regardless of gender.
2. Age 40–60 years old.
3. Subjects who voluntarily participate in clinical trials must sign informed consent. If any of the above answers is "no", the subject cannot participate in this trial.

Exclusion Criteria

Individuals meeting any of the following criteria will not be included:

1. Other types of cervical spondylosis.
2. Neck sprain, periarthritis of the shoulder, rheumatic myofibrositis, neurasthenia, and other neck and shoulder pain not caused by cervical disc degeneration.
3. Pregnant or planning to become pregnant, lactating women.
4. Those with allergies, sensitive skin, or weak bodies.
5. Severe liver, kidney, hematopoietic system, endocrine system disorders, osteoporosis, cancerous tumors, major injuries, heart attacks, stroke aftermaths, and other critical underlying conditions, individuals with mental health disorders, and severe infections.
6. Those unable to cooperate with scales, treatment, or follow-up due to cognitive dysfunction or communication impairment.
7. Participants in other clinical trials.

If any of the above answers is "yes", this subject cannot participate in this trial.

Randomization and Allocation Concealment

An impartial statistician, not involved in the research, will conduct the randomization process. The numbers will be divided into two groups, A and B, in a 1:1 ratio. Group A (experimental group: massage combined with TCM) and Group B (control group: standard massage treatment) will be determined using SPSS 19.0 software before the formal study. The random number sequence and group information will be securely managed by a designated individual. Brown opaque envelopes will be prepared based on the number of participants, sequentially numbered according to the numbers on the outside. Each envelope will contain the group assignment corresponding to the number on the envelope, such as 1(A) and 2(B). Following the completion of informed consent and basic information forms, envelopes will be opened in numerical order, and participants will be assigned to the appropriate group (experimental or control) as indicated in the envelopes.

Blinding

Before commencing the study, the researchers underwent training and were strictly required to adhere to the principle of separating their duties. Apart from the therapist, raters, analysts, and participants were kept unaware of their assigned group. The participants were not informed about their group assignment during the experiment but were told that they would receive one of two different manual treatments. Each participant received individualized treatment to prevent the sharing of information, and a blinded study was conducted in week 4 to assess the success of the blinding process. This research followed a design in which participants were blinded to their group allocation. Participants had an equal chance of being placed in either the test group receiving massage along with TCM or the control group receiving traditional massage techniques. The group assignment of the patients will also be concealed from the follow-up assessors. Although the massage therapist will not be blinded to the treatments given, they will not participate in the evaluation of results or data analysis.

Trial Design

The primary aim of this research is to evaluate the effectiveness of Tuina treatment in combination with Traditional Chinese Medicine (TCM) for managing Non-specific Neck Pain (NNP). This approach has demonstrated promising long-term results and provides a basis for potential clinical application. The study will involve the use of musculoskeletal ultrasound to measure morphological changes in the cervical muscles, scientifically evaluate traditional treatment methods, and explore the pathogenesis and treatment principles of NNP. The research will focus on optimizing a non-drug TCM treatment for NNP and promoting the use of TCM as described in the "Zhubing Yuanhou Lun", given its wide application range, strong operability, and cost-effective role in the field of TCM rehabilitation and healthcare. This approach is suitable for evaluating the effects of muscle stability training in exercise therapy for patients with NNP.

Additionally, the use of ultrasound for diagnosing, treating, and rehabilitating musculoskeletal conditions such as NNP and other soft tissue diseases will be advanced.

This study is a randomized trial conducted at Zhejiang Hospital to assess the effectiveness of combining Tuina manipulative therapy with three traditional Chinese medicine neck movement techniques, compared to standard Tuina treatment, in patients with NTCS. The evaluators of the outcomes will remain unbiased throughout the duration of the research. A total of 70 patients with NTCS will be randomly assigned to either the experimental group or the control group. The registration protocol can be found on the website: www.chictr.org.cn (No. ChiCTR2300072648). The protocol reporting follows the SPIRIT guidelines in full compliance. The study process is illustrated in Figure 1 with the flowchart depicted. Furthermore, the timeline for recruitment, treatment, and assessment of the trial is displayed in Table 1.

Ultrasound Methods

Ultrasound equipment and instrumentation: GE LOGIQ E9 with XD Clear color Doppler ultrasound diagnostic instrument, XD Clear transducer probe, frequency 3–15MHz, musculoskeletal examination mode.

The patient was positioned as follows: The subject was asked to sit with their back facing the examiner, their neck relaxed, and their gaze directed forward. Their hands were placed naturally on their legs. The upper trapezius muscle was identified at the midpoint between the seventh cervical vertebra's spinous process and the acromion. The cephalic pincer, cephalic semispinalis, cervical semispinalis, and multifidus were identified 2 cm next to the level of the spinous process of the fourth cervical vertebra.

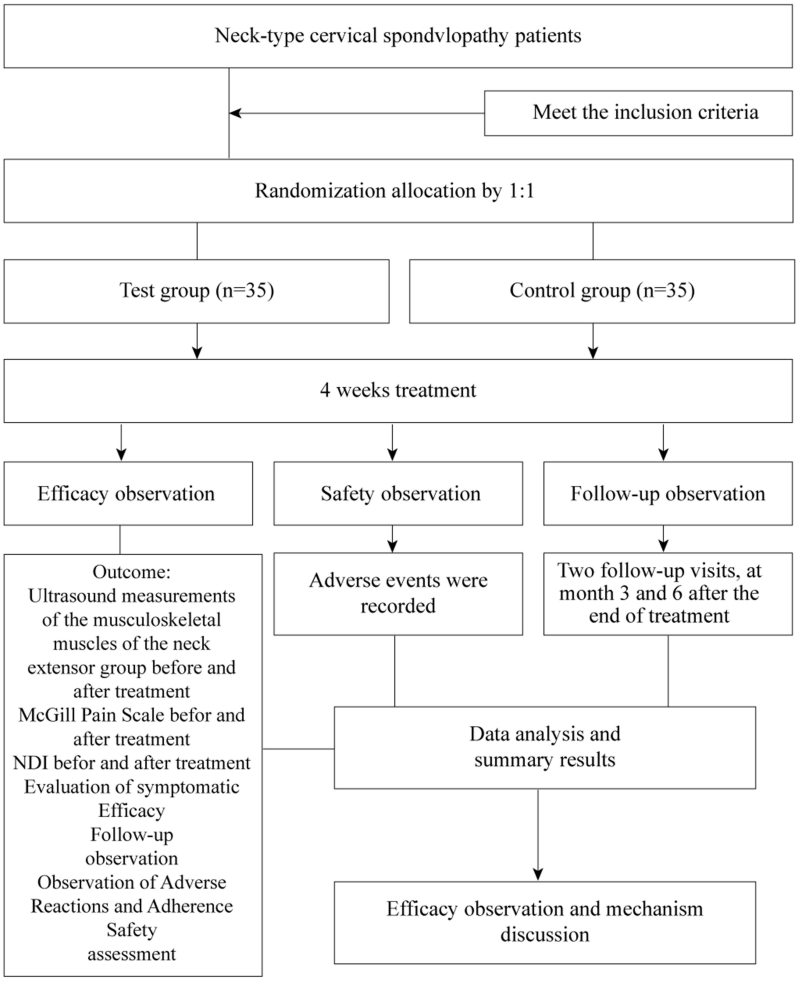


Figure 1 Flow chart of the study process.

Table 1 Schedule of Enrollment, Treatment, and Assessments

Study period	Screening	Before treatment	After treatment	3 months after the end of treatment	6 months after the end of treatment
Eligibility screening	○				
Demographic data	○				
Case data	○				
Inclusion criteria	○				
Exclusion criteria	○				
Informed consent	○				
Outcome assessment					
Ultrasound measurements of the musculoskeletal muscles of the neck extensor group before and after treatment		○	○	○	○
McGill Pain Scale		○	○	○	○
NDI		○	○	○	○
Evaluation of symptomatic efficacy		○	○	○	○
Safety assessment		○	○	○	○

Notes: ○, required.
Abbreviation: NDI, Neck Disability Index.

Qualification of Practitioners

This study involved only registered Chinese doctors with a minimum of 3 years of experience in TCM therapeutic massage. All therapists underwent training in massage therapy programs.

Treatment

Qualified individuals with NTCS will undergo a 4-week treatment in two separate groups. Each participant will be placed in a stable temperature chamber at 23–25 °C while seated.

Control group (conventional massage maneuver treatment group)

Below are the designated acupuncture areas: Feng Fu (DU16), Fengchi (GB20), Jianjing (GB21), Tianzong (SI11), Jingbi (Ex-HN22), Jianwaishu (SI14), Dazhui (GV14), alongside the regions of the neck and shoulders. Please refer to Table 2 for the specific locations of each acupoint.

The detailed operation is as follows. As illustrated in Figure 2, Operations:

The first step is to knead the five threads. The patient will be positioned sitting down with the operator behind them, aligning with the back of the patient's neck (where the governor's vessel runs from the base of the skull to between the

Table 2 Location of Acupoints for Treating NTCS.

Acupoints	Location
Fengchi (GB20))	Positioned on the neck, beneath the occipital bone, within the hollow amidst the sternocleidomastoid muscle and the top portion of the trapezius muscle.
Feng fu (DU16)	At the neck, 1 cun straight up from the middle of the posterior hairline, straight down from the external occipital bulge, and in the depression between the trapezius muscles on both sides.
Jianjing (GB21)	At the midpoint of the line connecting the Dazhui point and the shoulder crest end, there is a spot.
Tianzong (SI11)	Situated in the central depression of the infraspinatus fossa on the scapula, at a level identical to that of the fourth thoracic vertebra.
Jingbi (Ex-HN22)	Located in the neck, at the upper edge of the clavicle, midway between the center of the supraclavicular fossa and the innermost point of the clavicle.
Jianwaishu (SI14)	On the back, when the 1st thoracic vertebra is under the spinous process, 3 cun aside.
Dazhui (GV14)	Located on the midline of the back, in the recess beneath the spinous process of the seventh cervical vertebra.
Jinggen	Located anterior to the oblique muscle and beneath the prevertebral fascia.

Notes: Adapted with permission from the WHO Western Pacific Region.[38]

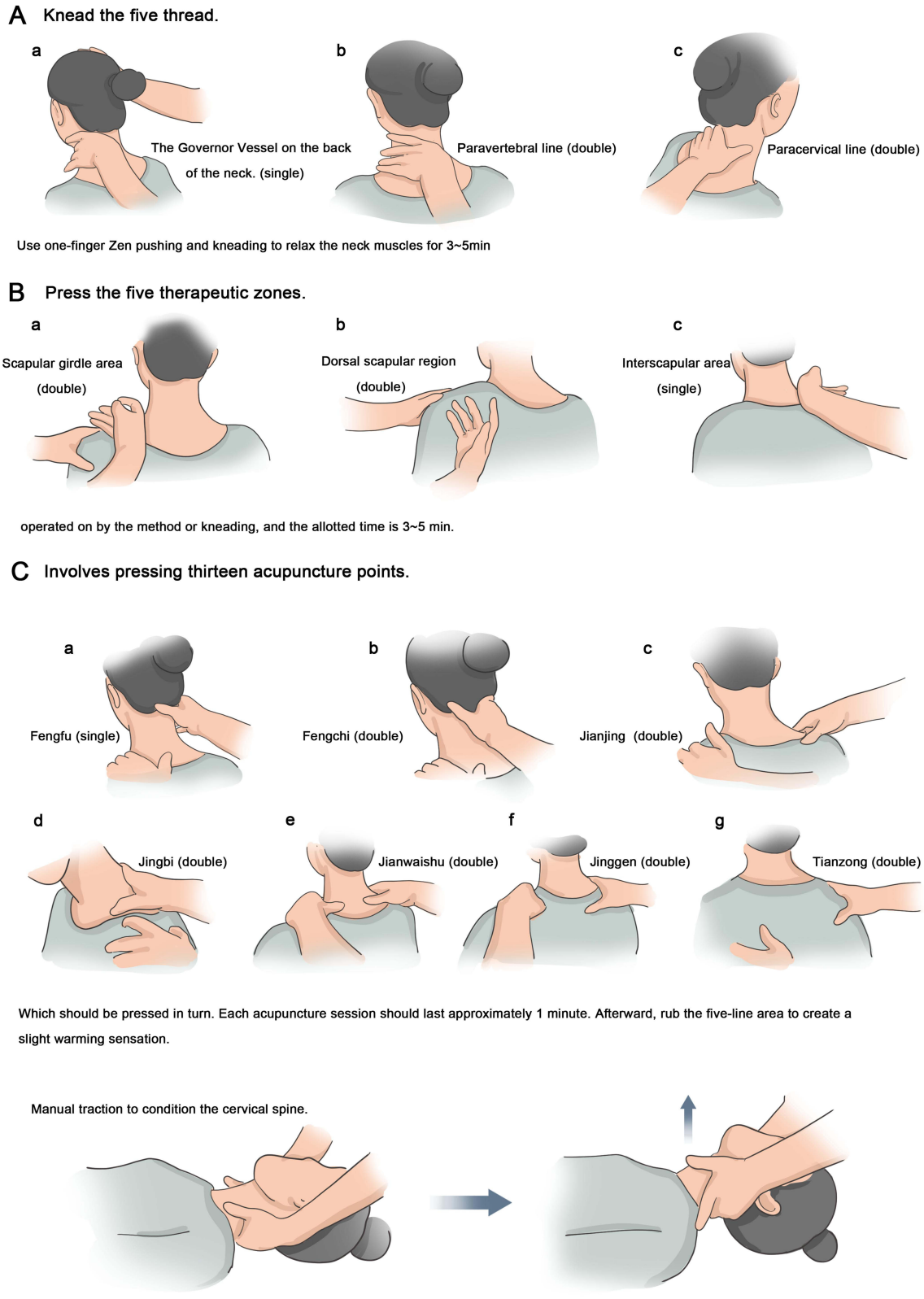


Figure 2 A series of specific maneuvers were performed on the control group. (**A**) Push and knead the five lines: a: vein of the governor line. b: Paravertebral line. c: Paracervical line. Description: Use one-finger Zen pushing and kneading to relax the neck muscles for 3–5 min on the Item back line, Paravertebral line, and Paracervical line. (**B**) Massage five zones: a: Scapular girdle area. b: Dorsal scapular region. c: Interscapular area. Description: Use the kneading method for 3–5 min in the Scapular girdle area, Dorsal scapular region, and Interscapular area. (**C**) Tap the thirteen points: a: Fengfu (single) b: Fengchi (double). c: Jianjing (double). d: Jingbi (double). e: Jianwaishu (double). f: Jinggen (double). g: Tianzong (double). Description: Perform the upward tapping operation on the selected acupuncture points for about 1 min each. Then, rub the area of the five lines using the rubbing method to make the area a little bit warm.

shoulders (GV14)). The line along the sides of the spine (known as Jiaji (EX-B2) points in the neck, connecting GB20 and Jinggen points on both sides) and the line from the ear to the temple (connecting the mastoid process to Ex-HN22 points on both sides) will be used to alleviate muscle tension in the neck. Duration: 3 to 5 minutes.

Step 2 is to press the five therapeutic zones. Remember the following information:

In the patient's scapular girdle area (specifically, the supraspinatus area of the scapula from the base of the neck outward to the acromion area on both the left and right sides), the dorsal area of the scapula (the area along the bottom edge of the scapula on both the left and right sides), and the interscapular area (the area between the shoulder blades on both sides) should be treated using massage or kneading techniques for 3 to 5 minutes.

Step 3 involves pressing thirteen acupuncture points. These include Fengfu (single), Fengchi (double), Jianjing (double), Jingbi (double), Jianwaishu (double), Jinggen (double), and Tianzong (double), which should be pressed in turn. Each acupuncture session should last approximately 1 minute. Afterward, rub the five-line area to create a slight warming sensation. The operator will then perform a cervical extension lever wrenching maneuver on the patient. The surgeon will position themselves behind the patient, using their right hand to support the occipital region at the back of the patient's head. They will utilize the tiger mouth grip and the small fish grip on the ulnar side of their palm against the base of the patient's neck. They will use the left hand to support the patient's jaw upward while pushing backward and adjust the cervical spine under manual traction. This process will be repeated 5–8 times.

The two groups will receive therapy every other day for 20 minutes, three times a week, over a period of four weeks. After completing one round of treatment, we will assess the relevant indicators to determine the effectiveness of the treatment. We will then follow up on their normal daily lives and activities three and six months later.

Intervention test group (massage combined with the TCM treatment group)

The same massage treatment method will be applied to the control group. The TCM treatment operates as follows, also in three parts. As illustrated in Figure 3, Operations:

Here is the revised text:

The first step is as follows: To shrink the neck and raise the shoulders, the patient should stand upright with their back against a wall, hold their hands firmly, and place their feet parallel to each other. This will help the throat to move down to the suprasternal fossa. Additionally, the patient should lift their face upwards and raise their shoulders and neck to stretch the muscles in the head and neck in an upward and downward direction as much as possible. Then, the patient should move their head from side to side, left and right, 21 times, two times a day.

In step 2, for the neck rotation method, the participants will stand upright on both feet. They should lift their left hand and place their palm on the opposite side of the forehead. Then, they should lift their right hand and extend both hands outward from their respective directions, holding the chin outward with force to the extreme position, creating opposite tension. They should stretch as much as possible and then relax both hands, tensing and relaxing 14 times. After that, they should change the position of both hands and repeat the process in the opposite direction 14 times.

Step 3: The swinging arm method involves standing upright, firmly on both feet, bending both arms, arching, and swinging left and right 7 times.

The TCM treatment will be administered twice daily, from Monday to Friday, for a duration of four weeks. Subsequently, patients will undergo post-treatment monitoring, with additional follow-up appointments scheduled at three and six months.

Outcome Measures

Primary Outcome

1. McGill Pain Scale: This scale includes three components – the pain severity index (PRI), the visual analog scale (VAS), and the present pain intensity (PPI). The total score for neck pain intensity is calculated for each time frame.

2. The Neck Disability Index (NDI) assesses ten different aspects of a patient's condition, including pain intensity, self-care abilities, ability to lift heavy objects, reading capacity, occurrence of headaches, level of concentration, and quality of sleep. Each item is scored from 0 to 5, leading to a total score of 50. A higher score indicates a more severe illness.

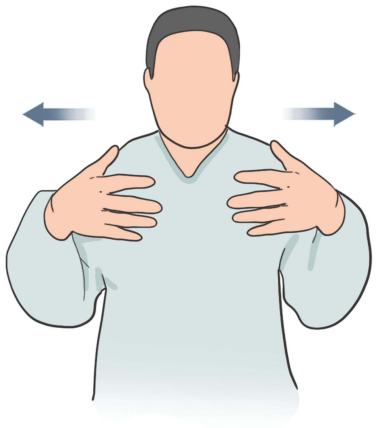
A Shrinking neck and raising shoulder Method

the patient assumes a standing posture, the body is straight, the back is placed against the wall, the hands are firmly held, and the feet are allowed to stand firmly in parallel so that the throat bone shrinks down to the suprasternal fossa. At the same time, the face is lifted upward, and the shoulders and neck are lifted to stretch the head and neck muscle meridians upward and downward as much as possible. Then, the head is moved to the sides, then left and right, 21 times, two times a day.

B Neck Rotation Method

the participants will stand upright on both feet, lift their left hand, and place their palm on the opposite side of the forehead. The right hand is lifted, and the chin is held outward with both hands extended outward from their respective directions and held with force to the extreme position, that is, the opposite tension. Stretching is performed as much as possible; then, after a moment, both hands will relax, with tensing and relaxation 14 times. The position of both hands is changed and operated in the opposite direction 14 times. .

C Swinging arm Method



standing upright, standing firmly on both feet, bending both arms, arching, and swinging to the left and right 7 times.

Figure 3 (**A**) series of targeted maneuvers were conducted on the experimental group. Neck reduction and shoulder lifting method: Stand with your back against the wall, retract the neck bone to the suprasternal fossa, lift the shoulders and neck, and move the head left and right 21 times, two sets a day. (**B**) Neck rotation method: Standing upright, lift the left hand to the side of the head and forehead and the right hand to hold the chin. Pull outward to stretch the head and neck muscles, then relax, 14 times in each direction. Change the position of the hands and work in the opposite direction 14 more times. (**C**) Swinging Arm Method: Stand upright, Bend and raise the arms, make an arched hand position, and swing left and right 7 times.

3. The study will involve measuring the thickness of the cephalic semispinalis muscle and the cephalic clamp muscle using musculoskeletal ultrasound before and after treatment. Additionally, we will observe any morphological changes in the posterior cervical extensor muscle group before and after the intervention. The study will also involve dynamically monitoring morphological and functional changes in soft tissues during the intervention and quantitatively evaluating the treatment effect.

The method for measuring the musculoskeletal ultrasound of the posterior cervical extensor involves the following steps:

1. Ask the patient to expose their neck and rest their chest on a cushion with relaxed shoulders and neck.
2. Use ultrasonic positioning to locate the transverse process of both sides of the neck and record the muscle direction.
3. Scan the ultrasound probe perpendicular to the patient's skin to obtain clear images and store them for analysis.
4. Have the patient support their head and increase neck strength to hold the weight of the head with isometric contraction while acquiring ultrasound images of both muscles.
5. Utilize the built-in software to measure the muscle thickness in the half spine, abdomen, and head, and record the data for further analysis.
6. Symptomatic efficacy assessment will adhere to the "Guidelines for Clinical Research of Novel Chinese Medications (Trial)". The nimodipine method will compute the efficacy index as shown below: efficacy index = [(pre-intervention score - post-intervention score)/pre-intervention score] × 100%, with categorization into 4 levels of clinical outcome, efficaciousness, and inefficaciousness.

1. Clinical improvement: disappearance or near-disappearance of primary symptoms and signs, with efficacy index ≥ 95%;
2. Marked improvement: significant amelioration of primary symptoms and signs, 70% ≤ efficacy index < 95%;
3. Effective outcome: notable enhancement of primary symptoms and signs, 30% ≤ efficacy index < 70%;
4. Ineffectiveness: minimal or worsening changes in primary symptoms and signs, efficacy index < 30%.

Secondary Outcomes

Follow-Up Observation

Patients who have recovered and responded well to treatment need to be monitored consistently. Reevaluation must occur every 90 days, a total of two times. Follow-up appointments may occur over the phone or in the hospital, with the option of a home visit if needed. Symptoms should be reassessed, and if there is an increase of ≥ 1 level, a recurrence is identified, and follow-up must cease.

Observation of Adverse Reactions and Adherence

Study participants were given a logbook for tracking their daily treatment regimen, including medication and any other therapies utilized throughout the research period, along with any adverse reactions encountered. Individuals who failed to adhere to at least 80% of the recommended medications or treatments were classified as poorly following the study guidelines.

Safety Assessment

① Impact on Typical Physiological Condition: This technique does not impact the typical physiological condition. Safety in technical maneuvers is assessed based on the following criteria: timing of occurrence, symptoms, duration, intensity, treatment protocols, and resolution time of any negative reactions are thoroughly evaluated. In instances of adverse effects, medical professionals determine whether to halt the study promptly based on the patient's condition:

Grade 1: No adverse effects, deemed safe.
Grade 2: Relatively safe, mild adverse effects present, and treatment may proceed without intervention.
Grade 3: Moderate adverse effects raise safety concerns, yet treatment can continue.
Grade 4: Cease the trial due to the presence of adverse effects.

Analgesic Consumption

During the experiment, participants who experience neck discomfort will have the option to take celecoxib, which is manufactured by Pfizer Pharmaceutical Co. Ltd. located in New York, United States, if they are unable to endure the pain. Details about the dosage and duration of celecoxib intake will be recorded in their Case Report Forms (CRFs).

Adverse Events

During each visit, researchers will observe any adverse events (AEs) and assess whether they are related to the intervention or not. If an AE occurs, the researcher will promptly address it through monitoring, medical care, or potentially ending participation. Furthermore, details of AEs will be recorded in the case report form (CRF) and promptly reported to the ethics committee. Common AEs in tuina clinical studies include discomfort, dizziness, fainting, and injury. The Ethics Committee at Zhejiang Hospital will be responsible for deciding whether the trial should be terminated after an AE occurs. After investigating the cause of the AE, participants will receive relevant complimentary treatment and appropriate financial compensation.

Blinding Test

Upon completion of the study, participants will be asked to predict the type of treatment after the final session, and the effectiveness of blinding will be assessed at the end of the research.

Withdrawal

During the trial, participants have the full authority to stop treatment or leave the study for any reason. In addition, if a severe adverse event occurs, the trial will be promptly and forcibly stopped.

Data Collection and Management

The data collection process will involve using printed case report forms, which will be entered into an electronic database twice by an independent researcher. The physical copies of the case report forms will be securely stored in a locked cabinet in the researcher's office, while the digital dataset will be anonymized and encrypted. Access to both the physical and electronic files will be limited to authorized data managers and statisticians only. All research documents will be carefully preserved and kept for at least five years after publication.

Data Collection and Management

Data for this study will be collected using paper case report forms, which will then be entered into an electronic case report form (eCRF) by an impartial researcher. The paper case report forms will be securely stored in a locked cabinet in the researcher's office, while the digital dataset will be anonymized and safeguarded. Only authorized personnel, such as data managers and statisticians, will have access to both the physical and electronic documents. All study records will be carefully maintained and archived for at least five years after publication.

The Clinical Evaluation and Analysis Center at Zhejiang Hospital, an entity not involved in the trial and with no conflicts of interest, will oversee data monitoring, bias control, and any potential suspension or termination of the study. They will also manage quality control measures throughout the trial. Before participating in the trial, all researchers must undergo formal training in trial methodology and regular technical assessments to ensure consistency. Any necessary corrections or adjustments to the trial protocol must be submitted to the Ethics Committee and communicated to the Clinical Evaluation and Analysis Center.

Statistical Methods

Patients will be divided randomly into two groups for the study: the test group, which will receive massage combined with the TCM treatment, and the control group, which will receive conventional massage maneuvering treatment. The sample size will be determined based on a two-tailed hypothesis test with a significance level of $\alpha=0.05$ and a test power of $\beta=0.10$. The pre-experimental observation showed an efficiency of 90 for the test group and 56 for the control group.

Based on calculations, approximately 56 patients are needed, with an additional 10% of patients to account for dropout, resulting in an actual sample size of around 70 patients - 35 in each group.

Statistical Analysis

Two researchers working independently will record all experimental findings on the CRF forms and enter them into the computer system. Statisticians will use SPSS 19.0 software to perform the statistical analysis and organize the data. The measurements will be presented using the mean±standard deviation (M±SD) method. Paired sampling tests will be used for pre-and post-group evaluations, and independent sampling tests will be used for inter-group comparisons. Chi-square tests will be used to assess effectiveness. A significance level of $P<0.05$ will indicate a statistically significant difference.

Discussion

The increasing occurrence of degenerative cervical spine conditions, especially among younger individuals, poses a significant challenge to traditional management approaches, including surgical and pharmacological interventions, as well as standard radiological investigations like X-rays, computed tomography (CT), and MRI.[39] This complexity has given rise to a growing interest in complementary and alternative medicine, with massage therapy emerging as a popular choice due to its safety, ease of use, cost-effectiveness, and lack of adverse side effects.

This study aims to build upon previous research on the short-term benefits of massage therapy by assessing its long-term efficacy when combined with traditional Chinese medicine (TCM) therapy for managing cervical degenerative conditions. We will use musculoskeletal ultrasound, the McGill Pain Questionnaire and the Neck Disability Index to assess anatomical changes in the posterior cervical muscles before and after the intervention. This approach will allow us to observe morphological alterations in the posterior cervical extensor muscles and monitor soft tissue modifications throughout the intervention.

The combination of TCM therapy, as outlined in Traditional Chinese Medicine and detailed in an ancient text called the "Zhubing Yuanhou Lun", with Tui Na techniques has not been widely explored in clinical practice. This study is the first randomized controlled trial to combine these approaches, providing a unique insight into the management of cervical degenerative spine issues.

Despite the proven efficacy of massage therapy, its limitations in terms of short-term effectiveness and tendency to relapse are well-documented. Our study aimed to address these limitations by exploring a more effective and durable treatment. Additionally, while radiological imaging is commonly used for diagnosing cervical spine degenerative pathologies, its limitations, such as a restricted scope of examination and potential radiation hazards, led us to seek more accurate and safer examination methods. In our study, we found that musculoskeletal ultrasound provided a more accurate and safer alternative for examination and diagnosis.

The potential clinical implications of our findings are significant and far-reaching. Should this combination therapy prove successful, it could provide a viable long-term treatment option for cervical degenerative spine disease, potentially reducing recurrence rates and improving patients' quality of life. The findings of this study may facilitate the development of novel diagnostic techniques and innovative therapeutic modalities that could, in the long term, alleviate symptoms, reduce the physical and psychological stress associated with the disease, and enhance the overall well-being of patients.

However, it is important to note that this study is not without limitations. Although ultrasonography shows promise as a tool for assessing muscle mass and is more convenient and affordable than other imaging modalities, such as CT, MRI, and electromyography (EMG), there are still limitations to its application. Such limitations include operator dependence and the potential for image quality to affect the results. At present, there is a paucity of research examining the use of ultrasound technology in evaluating neck muscle mass in patients with NTCS. The reliability of this approach remains a topic of debate. Therefore, future research studies must place a greater emphasis on a thorough investigation of the efficacy of ultrasound technology in evaluating neck muscle mass in patients with NTCS. To enhance the reliability of the assessment, a multi-parameter approach should be employed, facilitating the development of more robust scientific evidence and clinical foundations for the prospective application of musculoskeletal ultrasound in muscle assessment.

Conclusion

In this study, we will outline the clinical need, feasibility, and anticipated methodological steps for using musculoskeletal ultrasound, the McGill Pain Scale, and NDI to assess the clinical benefits of combining traditional Tui Na massage with TCM therapies for treating NTCS. The expected results will determine the long-term efficacy of combining traditional Tui Na massage with TCM therapies for the treatment of NTCS and investigate whether musculoskeletal ultrasound can be used as an evidence-based approach for evaluating efficacy in NTCS. These findings could potentially revolutionize NTCS treatment and lead to improved long-term outcomes for patients. Future studies should focus on exploring long-term adherence to NTCS combination therapies and their impact on different populations.

Trial Status

Volunteer recruitment is currently underway. The recruitment period for volunteers will start on June 20, 2023, and end on July 31, 2024.

Abbreviations

AEs, Adverse events; CRFs, Case report forms; CT, Computed tomography; DOMS, Delayed-onset muscle soreness; EIMD, Exercise-induced muscle damage; MM, Manual massage; MRI, Magnetic Resonance Imaging; NTCS, Neck-type cervical spondylosis; NDI, Neck Disability Index; PRI, The pain grading index; PPI, Current pain intensity; SPIRIT, Standard Protocol Items; SRs, High-quality systematic reviews; TCM, Three methods of neck movement; US, Ultrasound; USI, Ultrasound Imaging; VAS, Visual analog scale.

Data Sharing Statement

The China Clinical Trials Registry has completed an audit of this study, and the experimental data will be accessible on the Clinical Trials Public Management Platform at http://www.medresman.org.cn.

Ethics Approval and Consent to Participate

The Zhejiang Hospital Medical Ethics Committee has reviewed and approved human trials with license number 99K for the year 2022. Patients/participants will provide written informed consent to take part in the study. All procedures will adhere to appropriate guidelines and regulations. The design, conducting, reporting, or dissemination of our research did not involve patients or the general public.

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Author Contributions

Jinhong Zuo and Xiayang Zeng contributed equally to this work and co-first authors. All authors contributed significantly to the reported work, including conceptualization, design, execution, data acquisition, analysis, and data interpretation. Additionally, all authors were involved in drafting, revising, and critically reviewing the article. They provided final approval for the version to be published, agreed to the journal for submission, and agreed to be accountable for all aspects of the work.

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Disclosure

The authors state that they do not have any potential conflict of interest arising from commercial or financial interests.

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