Myofascial acupuncture versus routine acupuncture for mechanical neck pain: a protocol for a multicentre randomised controlled trial

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ABSTRACT

Introduction Mechanical neck pain (MNP) is defined as pain in the area of the neck and/or neck-shoulder provoked by body mechanics and which adversely affects physical, psychological and social function. The treatments for MNP are limited. Previous studies and clinical experience have indicated that myofascial acupuncture might be a better treatment option for MNP, but the efficacy is controversial. Therefore, our aim is to compare the efficacy of myofascial acupuncture and routine acupuncture for MNP.

Methods and analysis The study is a multicentre, prospective randomised clinical trial. Patients will be recruited from four tertiary hospitals in China. A total of 438 participants with MNP will be randomly assigned into two groups, namely the ‘Sancai-Tianbu’ myofascial acupuncture group and the routine acupuncture group, at a ratio of 1:1. Each group will receive the acupuncture treatment twice a week for 21 days, totalling six sessions. The primary outcome will be the Visual Analogue Scale score. The secondary outcomes will be the Neck Disability Index, the cervical range of motion and the MOS 36-Item Short Form Health Survey. The assessments will be performed at baseline (immediately after allocation), pretreatment (5 min before every treatment), post-treatment (within 10 min after every treatment), postcourse (within 1 day after the course), and at 1, 3 and 6 months after the course. All patients will be included in the intent-to-treat analysis. Repeated-measure analysis of covariance will be used to determine the effects of the intervention on the outcome measures.

Ethics and dissemination Ethics approval was obtained from China Aerospace Science & Industry Corporation 731 Hospital, with permission number 2022-0204-01. Written informed consent will be obtained from the enrolled patients. Trial results will be disseminated in peer-reviewed publications. Trial registration number ChiCTR2200061453.

INTRODUCTION

Neck pain is a musculoskeletal condition, and the majority of patients with neck pain are classified as having mechanical neck disorders.1 2 Mechanical neck pain (MNP) can be defined as pain located in the cervical spine, including the cervicothoracic junction, which is exacerbated by cervical motion, sustained postures and/or palpation of the cervical musculature.3-7 MNP is classified as either acute or chronic and the treatment is similar for both types. Abnormal imaging findings are not always associated with symptoms,8 while tension of the neck and shoulder muscles is related to MNP.9-12 In recent years, different studies have associated MNP with myofascial trigger points.9-12 A trigger point is a tender point within a tight muscular band that is stimulated by excessive pressure, tension, contraction or loading.13 The most frequently affected muscles are the trapezius, infraspinatus, scalene, levator scapulae, multifidi and splenius cervicis muscles.9 10 12

The prevalence of neck pain is estimated to be 20%, whereas the lifetime prevalence can reach up to 70% in the general population.13 The Global Burden of Disease Study identified neck pain as the fourth most prevalent
condition in terms of the number of years lived with disability. Neck problems can adversely affect physical, psychological and social function and can also lead to high healthcare costs.

According to the clinical practice guideline published in 2017 by the Orthopaedic Section of the American Physical Therapy Association, MNP can be relieved by conservative treatment, including education, modalities, therapeutic exercises, non-thrust manipulation (mobilisation) and thrust manipulation. Acupuncture is widely accepted as an effective treatment option for neck pain and is helpful in relieving pain and improving function in patients with neck pain. However, the efficacy of acupuncture is controversial, which might be due to the selected acupoints or the method of manipulation. Through preliminary research and clinical experience, our team found that myofascial acupuncture, namely ‘Sancai-Tianbu’ myofascial acupuncture, has a good effect on relieving pain and improving function. Different from routine acupuncture, Sancai-Tianbu myofascial acupuncture pricks and gently stimulates the tendon or the surface of the myofascia to induce a muscle twitch, which can relax a tight muscle. In routine acupuncture, the needle is inserted into the muscle belly and then manipulated by twisting and lifting movements, which can relieve inflammation but cannot relieve muscle tension. Considering that MNP is related to muscle tension, Sancai-Tianbu myofascial acupuncture might be better in relieving MNP.

To our knowledge, there is no study comparing the efficacy of Sancai-Tianbu myofascial acupuncture and routine acupuncture for MNP, and this trial is designed to evaluate this.

METHODS AND ANALYSIS

Study design

This is a multicentre, prospective, parallel-group, randomised (1:1) controlled trial comparing the efficacy of Sancai-Tianbu myofascial acupuncture treatment and routine acupuncture treatment for MNP. Patients will be recruited from three class A tertiary hospitals (Sunsimiao Hospital Affiliated to Beijing University of Chinese Medicine, Langfang Hospital of Traditional Chinese Medicine and Pinggu Hospital of Traditional Chinese Medicine) and one tertiary general hospital (China Aerospace Science & Industry Corporation 731 Hospital) in China.

The study protocol has been approved by the ethics committees (2022-0204-01), will follow the Declaration of Helsinki, and will be reported in accordance with the Standards for Reporting Interventions in Controlled Trials of Acupuncture recommendations and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist. This trial has been registered at the Chinese Clinical Trial Register (ChiCTR2200061453). A flow diagram of the trial is shown in figure 1.

Figure 1 Study flow diagram. CROM, cervical range of motion; NDI, Neck Disability Index; SF-36, 36-Item Short Form Health Survey; VAS, Visual Analogue Scale.
Patient recruitment
Patients who meet the MNP criteria (both acute and chronic pain) diagnosed by acupuncturists will be primarily recruited through advertisements posted on hospitals’ social media platform (WeChat) and through posters placed in outpatient clinics and throughout community service centres. MNP is a symptom-based diagnosis that is essentially determined by excluding serious, objective cervical spinal pathology (eg, whiplash trauma, malignancy or radiculopathy). We will include patients with pain in the area of the neck and/or neck-shoulder provoked by body mechanics, including sustained neck postures, cervical movement or manual palpation of the cervical musculature. All patients will be required to provide written informed consent (online supplemental additional file 1) before randomisation.

Inclusion criteria
Patients who meet all the following inclusion criteria will be included in this study:
► Meet the MNP diagnosis.
► Aged 18–60 years (either sex).
► No nonsteroidal antiinflammatory drugs, hormone, acupuncture, moxibustion, massage and sunken cord treatment in the last 1 month and during this treatment.
► No participation in any other research in the last 2 months.
► Agree to sign informed consent file (online supplemental additional file 1).

Exclusion criteria
Patients who meet any one of the following criteria will be excluded:
► History of trauma, previous cervical surgery, cervical radiculopathy or myelopathy.
► Diagnosis of fibromyalgia syndrome.
► Neck pain symptoms combined with any serious or malignant disease, such as malignant tumour, cardiovascular disease, trauma or osteoporosis.
► Any sign of vertebrobasilar insufficiency or upper cervical spine ligamentous instability.
► Fear of needles or any contraindication to needling (eg, anticoagulant medications or presence of psychiatric symptoms).
► Pregnancy or breast feeding.
► Difficulties in attending the trial, such as serious mental and psychological illness, dementia, or illiteracy.

Randomisation and allocation concealment
All eligible patients will be randomly assigned to the Sancai-Tianbu myofascial acupuncture group or routine acupuncture group in a 1:1 ratio. Each of the four sites will be randomised separately using SPSS-generated block sequence created prior to the start of data collection by a researcher not involved in the recruitment or treatment of patients. The randomised group assignments on sequentially numbered index cards will be placed in sealed, opaque envelopes. A second therapist, blinded to the baseline examination findings, will open the envelope and proceed with treatment according to the group assignment.

Blinding
Due to the nature of acupuncture, blinding of acupuncturists is quite difficult to achieve. Patients, outcome assessors and statisticians who perform the statistical analyses will be blinded to the group assignment. The participant’s assigned intervention will not be revealed until the statistical analysis is completed.

Quality assurance of acupuncture treatment
Treatment will be performed by licensed acupuncturists who have at least 3 years of experience in acupuncture. All acupuncturists will be trained on all details of the acupoints, insertion depth and manipulation methods by the principal investigator (KC) and must pass the technical examination before the trials. In addition, we will perform quality testing during the study.

Intervention
Both Sancai-Tianbu myofascial acupuncture and routine acupuncture treatments will consist of six sessions over 21 days (twice a week). The acupoints Jianzhen (SI9), Tianzong (SI11), Zhongfu (LU1), Jianjing (GB21), Tianliao (TE15), Wangu (GB12) and Dazhui (GV14) will be needled in turn. All acupoints were localised according to the WHO Standard Acupuncture Locations and are shown in Table 1. Sterile disposable acupuncture needles with a length of 40 mm and diameter of 0.30 mm (Huatuoz, Suzhou, China) will be used at Jianjing (GB21), Tianliao

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Locations of acupuncture points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acupoints</td>
<td>Location</td>
</tr>
<tr>
<td>Jianzhen (SI9)</td>
<td>1 cun above the posterior axillary fold</td>
</tr>
<tr>
<td>Tianzong (SI11)</td>
<td>At the top one-third and bottom two-thirds point of the line joining the midpoint of the seventh spine of the scapula and the inferior angle of the scapula</td>
</tr>
<tr>
<td>Zhongfu (LU1)</td>
<td>On the level of the first intercostal space and 6 cun lateral to the anterior midline</td>
</tr>
<tr>
<td>Jianjing (GB21)</td>
<td>At the midpoint of the line joining the acromion and the spinous process of the seventh cervical spine</td>
</tr>
<tr>
<td>Tianliao (TE15)</td>
<td>In the depression of the superior angle of the scapula</td>
</tr>
<tr>
<td>Wangu (GB12)</td>
<td>In the depression which is at the lower back of the retroauricular mastoid</td>
</tr>
<tr>
<td>Dazhui (GV14)</td>
<td>On the posterior midline and the depression under the spinous process of the seventh cervical spine</td>
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(TE15), Wangu (GB12) and Dazhui (GV14), while sterile disposable acupuncture needles with a length of 75 mm and diameter of 0.30 mm (Huatuoh) will be used at Jianzhen (SI9), Tianzong (SI11) and Zhongfu (LU1). Acupuncture will be discontinued if the patient suffers from any serious adverse events (AEs).

Sancai-Tianbu myofascial acupuncture group
In Sancai-Tianbu myofascial acupuncture group, the surface of the myofascia will be pricked and slightly trembled to induce a muscle twitch. The needle will then be withdrawn without needle retention. The following acupoints should be needled in turn: Jianzhen (SI9), Tianzong (SI11), Zhongfu (LU1), Jianjing (GB21), Tianliao (TE15), Wangu (GB12) and Dazhui (GV14). First, the tender points will be touched and the acupuncture points fixed. Second, the needle will be inserted in a straight manner until it reaches the myofascia of the muscle. Third, the surface will be pricked and slightly trembled in a narrow range to make the muscles twitch at Jianzhen (SI9), Tianzong (SI11), Zhongfu (LU1), Jianjing (GB21) and Tianliao (TE15), while pricking towards three directions at Wangu (GB12) and Dazhui (GV14). Finally, the needle will be withdrawn.

Routine acupuncture group
The order of the acupoints to be needled in the routine acupuncture group should be the same with the Sancai-Tianbu myofascial acupuncture group. Jianzhen (SI9), Tianzong (SI11), Zhongfu (LU1), Tianliao (TE15), Wangu (GB12) and Dazhui (GV14) will be needled to a depth of 2.5–3.7 mm, 1.5–1.25 mm, 1.25–2 mm, 1.25–2.5 mm, 1.25–2 mm and 1.25–2.5 mm, separately. After needling, all the prespecified acupoints except Jianjing (GB21) will be manipulated by lifting, inserting and twisting until Deqi is reached. After 15 min, the needle will be withdrawn after twisting it without causing an astringent sensation. Jianjing (GB21) will be pricked to a depth of 0.75–1.25 mm without any manipulation for 15 min before the needle is withdrawn.

Concomitant treatment
To avoid other influences on the symptoms, patients will be advised not to receive any other treatments. If other treatments or medications are administered, the treatment or medication should be clearly recorded in the case report form (CRF).

Outcomes
Primary outcome
Visual Analogue Scale
Pain will be assessed by the Visual Analogue Scale (VAS) at baseline (immediately after allocation), pretreatment (5 min before every treatment), post-treatment (within 10 min after every treatment), and at 1, 3 and 6 months after the course. The VAS score ranges from 0 to 10, with a score of 0 indicating ‘no pain’ and a score of 10 indicating ‘the worst pain imaginable’. The minimum clinically important difference (MCID) in the VAS score is 2.

Secondary outcomes
Neck Disability Index
Disability will be assessed at baseline (immediately after allocation), postcourse (within 1 day after the course), and at 1, 3 and 6 months after the course using the Neck Disability Index (NDI) (0%–100%). This is a self-applied questionnaire consisting of 10 items (including pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping and recreation) with six possible answers representing six progressive levels of functional disability, rated from 0 to 5, with 0 being the lowest score and 5 being the highest score in each section. The total score for the NDI is out of 50, with higher scores indicating severe disability. The MCID of the NDI was estimated with two different methods, both of which integrated an anchor-based and distribution-based approach: the minimal detectable change (MDC) and the optimal cut-off point of the receiver operator characteristic (ROC) curve. The results show that the MDC was 10.5 points and the optimal cut-off point of the ROC curve was 3.5 for the NDI. Using the optimal cut-off point of the ROC curve, false positives and false negatives are equally weighted. Therefore, this was deemed to be the more appropriate value for the MCID in clinical practice.

Cervical range of motion
The cervical range of motion (CROM) will be assessed at baseline (immediately after allocation), pretreatment (5 min before every treatment) and post-treatment (within 10 min after every treatment). Participants will be asked to sit comfortably in a chair, with both feet flat on the floor, both hips and knees in 90° of flexion, and buttocks positioned against the back of the chair. Measurements will be made separately for each direction and in a standard sequence: flexion, extension, right lateral flexion, left lateral flexion, right rotation and left rotation. Fletcher and Bandy reported that changes between 5° and 10° are needed to determine a real change in cervical spine mobility in individuals with neck pain.

MOS 36-Item Short Form Health Survey
Quality of life will be assessed at baseline (immediately after allocation) and postcourse (within 1 day after the course) through the Medical Outcomes Study (MOS) 36-Item Short Form Health Survey (SF-36).

Safety assessment
Any AEs will be monitored and recorded throughout the trial by patients, acupuncturists and outcome assessors. Acupuncturists and relevant specialists will categorise AEs as treatment-related (the acupuncture needling procedure) or non-treatment-related within 24 hours of occurrence. Common treatment-related AEs include local bleeding, subcutaneous haematoma, itching at the sites of needle insertion, continuous postneedling pain, dizziness and so on.
Adherence assessment
The treatment sessions will be recorded in the CRF to assess the adherence of the patients.

Blinding assessment
To test patient-blinding effects, all patients will be asked to guess whether they have received Sancai-Tianbu myofascial acupuncture or routine acupuncture within 5 min after receiving the first treatment session and the third treatment session.

The schedule of enrolment, intervention and assessments is shown in online supplemental additional file 2.

Data management
All researchers, including acupuncturists, outcome assessors and statisticians, received training regarding data management. Data will be inputted into the CRF, which was established before recruitment. The clinical research associates are responsible for verifying the accuracy of the data. Online monitoring will be used in this trial. The ‘check’ function in the CRF allows dynamic management by ensuring that data are collected completely, promptly and accurately. Data lockup will be implemented by the data management team on completion of the study. The researchers will then be unable to modify the data.

All research documents, including paper files and electronic documents, will be kept for at least 5 years after publication. If reviewers or readers have any questions regarding our published data, they can contact the corresponding author for access to the original data. The private information of the patients, including name, telephone number and identification number, will be anonymous to ensure participant confidentiality.

Quality control
The trial protocol was reviewed and revised by experts in acupuncture, methodology and statistics. Prespecified standard operating procedures for conducting the intervention, completing the CRF, assessing the outcomes and managing data were used to train relevant staff. An inspection plan will be designed for quality control. For patients, quality control can be carried out according to authenticity and ethical principles. Several patients can be randomly selected and authenticity can be confirmed through phone calls. Patients and researchers will be spot-checked to see if their informed consent process is ethical. For the intervention, the key point is to control the standardisation of intervention manipulation, that is, to investigate whether the implementation process of acupuncture is carried out in accordance with the operator’s manual of this clinical study. Specifically, it includes whether the intervention implementer has received training for this study, the accuracy of the acupoint selection, the standardisation of disinfection, the method and scale of needle insertion, and the standardisation of manipulation. We will conduct face-to-face interviews with the intervention implementers, monitor the actual research process or monitor the implementation process through simulation.

Sample size
The calculation of the sample size was based on the measurement of the primary outcome. Since acupuncture is a complex intervention, it is different from drugs. The efficacy of acupuncture will differ if the acupoints are changed in the study, and there is no study about the efficacy of Sancai-Tianbu myofascial acupuncture for MNP. For these reasons, speculation about the data presented in the literature was not employed in this trial. Based on previous clinical experience and relevant data which are unpublished, the change in VAS score of the Sancai-Tianbu myofascial acupuncture treatment and that of routine acupuncture treatment for MNP is expected to be 4±1.5 and 2.5±1.5, respectively. Considering a 1.2 margin and 5% alpha (two tails), at least 350 (175 patients in each group) patients were needed to have at least 80% power in order to detect significant differences. To compensate for a 20% attrition rate, the sample size was increased to 438 (219 patients in each group).

Statistical analysis
The statistical analysis will be performed by an independent statistician who is not aware of the group allocation. SPSS V.20.0 statistical software will be used for data analysis. The level of significance will be established at α<0.05 with a two-sided test. Continuous data will be represented as mean±SD or median (range), whereas categorical data will be represented by percentages.

All efficacy analyses will be performed using the intent-to-treat approach with all the included, randomly assigned patients. The baseline characteristics will be reported as mean (SD). Normally distributed continuous variables will be evaluated using Student’s t-test, and non-normally distributed variables will be evaluated using the non-parametric Mann-Whitney U test to assess the baseline differences between the two groups. We will use a repeated-measure analysis of covariance that includes mean changes in the VAS score from baseline to each follow-up assessment, with the treatment group as the model factor and the baseline as the covariate. Similar analyses will be performed for secondary outcomes, including NDI, CROM and SF-36. Binary outcomes of the blinding assessment and the proportions of patients having AEs will be compared using the Fisher’s exact test or the Wilcoxon rank-sum test as appropriate.

Missing data will be imputed using the multiple imputation method. A sensitivity analysis will be conducted for the primary outcome using the per-protocol population, including only those patients who complete at least five sessions and have no major protocol violations.

Patient and public involvement
The patients and/or the public were not involved in designing, implementing, reporting or disseminating the research plan.
Trial status
Currently, the trial is in the recruitment stage and the first patient was recruited on 11 July 2022. The trial is expected to be completed by 31 December 2023.

Ethics and dissemination
The trial design has been approved by China Aerospace Science & Industry Corporation 731 Hospital, with permission number 2022-0204-01. Patients will be informed about every detail of the trial, and a written patient consent form will be signed before participation. The results of this study will be published in a peer-reviewed journal and presented at conferences.

DISCUSSION
Neck pain can adversely affect physical, psychological and social function and can also lead to high healthcare costs. Different acupuncture manipulations are suitable for different diseases. For example, the relatively recognised electroacupuncture (EA) that causes muscle twitching is not suitable for all diseases, such as MNP. MNP is a tense state of the muscles in the neck and shoulder. EA stimulates the muscles to twitch continuously during the EA treatment period, which instead strains the muscles. As for Sancai-Tianbu myofascial acupuncture, it pricks and gently stimulates the tendon or the surface of the myofascia to induce a muscle twitch one or two times, which can relax a tight muscle. With the aim of exploring the efficacy of different acupuncture manipulations to inform clinical practice, this trial will provide high-quality evidence on the efficacy of Sancai-Tianbu myofascial acupuncture versus routine acupuncture for MNP. Both subjective and objective outcomes will be assessed, including pain and function. Since pain that is exacerbated with movement of the cervical spine is the major symptom of MNP, the VAS and the CROM are applied to evaluate severity. Considering that neck problems can adversely affect physical, psychological and social function, the NDI and SF-36 are used to assess disability and the influence on quality of life. We did not set sham acupuncture group. Sham acupuncture may select acupoints or non-channel, non-acupoints, with blunt-tipped needles for non-invasive stimulation. However, the effect produced by stimulating acupoints or non-acupoints, regardless of whether they are invasive, deep or shallow, is part of the acupuncture effect. On the other hand, our study was not limited to determining whether clinical acupuncture treatment for MNP is ‘effective or ineffective’, but more focused on the optimisation and selection of acupuncture manipulation for MNP.

A limitation of our trial is that the acupuncturists are not blinded to the nature of the intervention. To minimise possible bias, this research will follow a script to standardise the treatments of the two study groups. Second, the manipulation of Sancai-Tianbu myofascial acupuncture has high technical requirements. To ensure that all acupuncturists can master this technique, they will be trained on all details of the acupoints, insertion depth and manipulation methods and must pass the technique examination before the trial. In addition, we will perform quality testing in the interim. Third, only one outcome (CROM) is objective, while all the other outcomes (VAS, NDI, SF-36) are subjective. However, the VAS, NDI and SF-36 are three of the most common methods because they have good validity and reproducibility as recommended by guidelines. Fourth, because of the limitations imposed by the study setting (four tertiary hospitals in or near Beijing), it may be unsuitable to apply the conclusion of this trial to the whole population. In the future, we hope that different countries and cities, including tertiary hospitals and primary hospitals, will cooperate to complete a study.

In summary, this trial will standardise acupoint selection, acupuncture manipulation and outcome assessment by rigorously following the SPIRIT guidelines. We expect that this trial will provide more reliable evidence and clarify the value of Sancai-Tianbu myofascial acupuncture as treatment for MNP.

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Competing interests None declared.

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