1. Introduction

The participant is invited to take part in this research project because you have mechanical neck pain (MNP) that their doctor has determined would benefit from acupuncture treatment.

This Participant Informed Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not the participant should take part, you might want to talk about it with a relative, friend or your doctors. Participation in this research is voluntary.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read
• Consent to take part in the research project
• Consent to have the tests and treatments that are described
• Consent to the use of the participant’s personal and health information as described.

2. What is the purpose of this research?

MNP can adversely affect 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, the aim of our study is to compare the efficacies of myofascial acupuncture and routine acupuncture for MNP, with a view to finding an effective and safe acupuncture manipulation that can be popularized in
clinical practice.

3. Who can participate in this research?
Patients who meet the mechanical neck pain diagnosis criteria diagnosed by acupuncturists can participate in this research. MNP was defined as pain in the area of the neck and/or neck-shoulder that was provoked by body mechanics, including sustained neck postures, cervical movement, or manual palpation of the cervical musculature.

**Inclusion criteria**
Patients who meet all the following inclusion criteria will be included in this study.
(1) Meet mechanical neck pain diagnosis;
(2) Aged 18-60 years (either sex);
(3) No NSAIDs, hormone, acupuncture, moxibustion, massage, sunken cord treatment in the last one month and during this treatment;
(4) No participation in any other research in the last two months;
(5) Agree to sign informed consent file.

**Exclusion criteria**
Patients who meet any one of the following criteria will be excluded.
(1) History of a whiplash injury, previous cervical surgery, cervical radiculopathy or myelopathy;
(2) Diagnosis of fibromyalgia syndrome;
(3) Neck pain symptoms combined with any serious or malignant disease, such as malignant tumor, cardiovascular disease, trauma or osteoporosis;
(4) Any sign of vertebrobasilar insufficiency or upper cervical spine ligamentous instability;
(5) Fear of needles or any contraindication for needling (e.g., anticoagulant medications or the presence of psychiatric symptoms);
(6) Pregnancy or breastfeeding;
(7) Difficulties in attending the trial, such as serious mental and physiological illness, dementia, or illiteracy.
4. What will you need to do if you participate in the trial?

First, the study doctors will confirm that you are eligible to be enrolled in this research. You will then be asked to sign a consent form before you can participate in the study.

Information regarding your present medical history, past medical history and the result of ancillary tests will be collected in a standardised database. You will receive the acupuncture treatment twice a week for 21 days, totalling 6 sessions. Before starting acupuncture treatment, before every treatment, after every treatment, at the end of the course and again 1, 3 and 6 months after your course, you will be asked to complete questionnaires and functional testing. It will take 5-10 minutes to complete. During this time, in addition to the tests described above, you will be asked about any adverse events that may have occurred so that study doctors can determine the safety of acupuncture.

5. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. But for the sake of your best interests, it is recommended not to drop out of this study and stop treatment. If you withdraw from the study for any reason, you may be asked about acupuncture treatment.

You do not have to take part in this research project to receive treatment at this hospital. If you choose not to participate in this research, your doctor(s) may still decide to offer you acupuncture treatment but it may not be monitored in the way outlined in this research. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your primary doctor.

If you do decide to take part, you will be given this Participant Informed Consent Form to sign and you will be given a copy to keep.
Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the hospital.

6. What are the possible benefits of taking part?
You will receive free diagnosis and treatment from experienced doctors and your treatment will be overseen and monitored by a group of study doctors which are specialists in MNP. Importantly, the information that we collect in this research will help us and other researchers determine a better manipulation to provide acupuncture treatment to patients with MNP in the future. It may also help us be able to make “Sancai-Tianbu” myofascial acupuncture more widely available in China and even in the world.

7. What are the possible risks and disadvantages of taking part?
It may take you 5-10 minutes to record medical information, so please understand the inconvenience. In addition, the acupuncture treatment can cause some adverse events. You may have none or some (including local bleeding, subcutaneous haematoma, itching at the sites of needle insertion, continuous postneedling pain, dizziness), and they may be mild, moderate or severe. In most cases, it is mild. If you have any of these adverse events, talk with your study doctor. Doctors will take corresponding measures according to the duration and degree of common adverse events.

8. Can I have other treatments during this research project?
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).

9. What will happen to information about me?
By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal and health information about you for the research
project. Any information obtained in connection with this research project that can identify you will remain confidential and securely stored. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. It is anticipated that the results of this research project will be published. In any publication, information will be provided in such a way that you cannot be identified, except with your permission.

10. expenses and compensation

There are no additional costs associated with participating in this research project, nor will you be paid. If you suffer any serious adverse events as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If it is identified by the medical expert committee as relevant to this study, we will make appropriate financial compensation.

11. Who is organising and funding the research?

This research has been funded by the Chinese medicine research program of Sun Simiao Research Institute of Beijing University of Chinese Medicine (grant number SSMYJY-1-2021-03). It is being conducted by Beijing University of Chinese Medicine, AMHT Group Aerospace 731 Hospital, Sunsimiao Hospital Affiliated to Beijing University of Chinese Medicine, Langfang Hospital of Traditional Chinese Medicine and Pinggu Hospital of Traditional Chinese Medicine.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

12. How to gain further information?

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any adverse events), you can ask your primary doctor. And if there is important notice during the research, your doctor will notify you in time.
Informed Consent Form

Declaration by Participant

I have read the Participant Informed Consent Form. I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals to release information concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I consent to the storage and use my my de-identified (anonymous) information as described in the relevant section of the Participant Informed Consent Form, for:
(Choose one option below.)

☐ This specific research project only

☐ This research project and other research that is closely related to this research project

I agree to participate in this study and promise to follow doctor's advice whenever possible. I understand that I will be given a signed copy of this document to keep.

TEL ___________________________  Date ___________________________
Signature ______________________ (Name of Study Participant)

Declaration by Study Doctor

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

TEL ___________________________  Date ___________________________
Signature ______________________  (Name of Study Doctor)