Informed Consent Form

The effect of additional neurodynamic intervention

in patients with chronic ankle instability

NCT number: NCT05090423

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Study Title: The Effect of Additional Neurodynamic Techniques on Chronic Ankle Instability

Executing Institution: Department of Physical Therapy and Assistive Technology, National Yang Ming Chiao Tung University

Funding Source: Self-funded

Principal Investigator: Prof. Yi-Fen Shih Title: Professor

Contact Number: 02-2826-7340

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Contact Number: 0982-641-541

Subject's Name:

Contact Number:

Emergency Contact Person:

Contact Number:

I. Study Purpose

This study primarily aims to investigate the effects of additional neurodynamic techniques in individuals with chronic ankle instability, focusing on mechanical sensitization, balance performance, and self-reported functional outcomes.

II. Research Methods and Participant Requirements

This study involves non-invasive physical assessments and rehabilitation procedures. These include evaluations of hamstring flexibility, pain threshold in the lateral calf region, the straight leg raise angle in a neurodynamic test, balance performance, and a self-reported functional scale. The neurodynamic technique, used as an intervention, is a rehabilitative approach that will be performed by a licensed physical therapist. All procedures will be conducted in the Musculoskeletal Laboratory at National Yang Ming Chiao Tung University.

A total of 40 participants with chronic ankle instability (CAI) will be recruited.

Inclusion criteria for CAI participants are as follows:

- Age between 20 and 50 years old
- At least two lateral ankle sprains on the same foot within the past

three years

- The first ankle sprain occurred at least one year prior
- Functional impairment affecting daily life for at least one day after the sprain
- A score of ≤24 on the Cumberland Ankle Instability Tool (CAIT)
- A positive slump test combined with ankle plantarflexion and inversion during the neurodynamic test.

Exclusion criteria include:

- Pregnancy
- History of surgery
- Previous lower limb fracture
- Any pathological condition of the lower limb, such as vascular disease, osteoarthritis, rheumatoid arthritis
- Significant cervical or lumbar pain or injury
- Regular use of medications such as anti-inflammatory drugs, painkillers, steroids, or muscle relaxants
- Acute inflammation (redness, swelling, pain, heat) from an ankle sprain within the past 3 months
- Recent manual therapy or exercise rehabilitation for lower limbs within the past 3 months

Eligible participants will be randomly assigned to one of two groups using sealed opaque envelopes:

The Exercise Group will receive balance training only

The Neurodynamic Group will receive balance training along with neurodynamic techniques targeting the common peroneal nerve

Each participant will undergo 12 rehabilitation sessions, conducted twice per week over 6 to 8 weeks. Data will be collected at two time points: before the first intervention and after the 12th session. The first and final sessions will take approximately 2 hours, while the remaining sessions will last about 1 hour each.

The first phase of the study will involve collecting the participant's basic information, including name, age, sex, height, weight, hamstring flexibility, dominant leg, injured leg, bilateral foot length, and symptom duration.

Measurements will include:

- Hamstring flexibility
- Pain threshold in the lateral calf
- Ankle range of motion
- Straight leg raise angle (neurodynamic test)
- Y-Balance Test
- Foot and Ankle Ability Measure (FAAM)

The second phase will implement the rehabilitation protocols based on group assignment:

The Exercise Group will undergo balance training, starting with stretching, then activating the intrinsic foot muscles, followed by progression from stable to unstable surfaces. Tasks include bilateral and single-leg ball toss exercises, ending with a cool-down routine.

The Neurodynamic Group will receive the same training, plus neurodynamic sliding techniques for the common peroneal nerve. The participant will sit at the edge of the bed while the therapist stabilizes the pelvis. The participant will tuck the chin and flex the cervical and thoracic spine, then hold the ankle in plantarflexion and inversion, and extend the knee into a tensioned position. The therapist will then guide the participant through cervical spine extension. This alternating motion aims to mobilize the peroneal nerve before the balance training resumes.

All participants must sign the informed consent form prior to participating in any testing procedures.

III. Potential Risks, Incidence (Possible Side Effects), and Remedial Measures

This study employs only non-invasive testing procedures. Participant positioning will be assisted by a licensed physical therapist, but the participant will actively perform all test movements. One specific test—the slump test combined with ankle plantarflexion and inversion—requires the participant to maintain a flexed spinal posture.

Individuals with neck or low back pain may feel discomfort in this position, and for that reason, participants with such conditions are excluded during screening.

During the neurodynamic test, the participant will actively extend the knee to provoke symptoms typically felt in the lateral ankle. If discomfort arises, the participant can immediately stop the test by lowering the leg.

The balance training used in this study is self-directed by the participant. Most participants are not expected to experience any physical discomfort. The potential for adverse effects or risk is considered minimal, and no harmful effects are anticipated.

Regarding the neurodynamic technique used in this study, the participant will sit at the edge of a bed while the therapist maintains the pelvis in a neutral position. The participant will tuck the chin and flex the cervical and thoracic spine to create a flexed upper-body posture. While keeping the ankle plantarflexed and inverted, the knee will be extended to a tensioned position. The therapist will then guide the participant into cervical extension (raising the chin). This alternating movement is intended to mobilize the common peroneal nerve.

At the beginning of the stretch, participants may feel a tight or tolerable tingling sensation. These symptoms typically subside through the repetition of tension and release. If any discomfort occurs during the procedure, the session will be stopped immediately. Ice packs, adequate rest, or gentle stretching will be provided to relieve symptoms. If these measures are insufficient, the participant will be referred to Likang Rehabilitation Clinic, which collaborates professionally with the research team's licensed physical therapist.

IV. Alternative Research or Rehabilitation Options and Explanation

If you choose not to participate in this study, you may still receive injury prevention advice and relevant consultation from a physical therapist. Non-participation will not increase your risk of injury.

V. Expected Research Outcomes

Previous studies have indicated that individuals with chronic ankle instability (CAI) often exhibit signs of mechanical sensitization, suggesting that neural-related structures may be affected. Current evidence supports the benefits of exercise training for CAI. However, the potential added effect of incorporating neurodynamic techniques to address sensitization remains to be verified through experimental research.

VI. Restrictions or Prohibited Activities During the Study

There are no specific restrictions or prohibited activities for participants during the course of this study.

VII. Confidentiality

The principal investigator will treat all personally identifiable records and your private information as confidential in accordance with the law and will not disclose them publicly. Your identity will remain confidential in any published research results.

By signing this consent form, you acknowledge and agree that your original records may be directly reviewed by monitors, auditors, the Human Research Ethics Committee, and regulatory authorities. This is to ensure that the research process and data comply with relevant legal and regulatory requirements. These individuals are also obligated to maintain confidentiality and will not disclose any information that could identify you.

VIII. Compensation for Injury

If any adverse events or injuries occur as a result of participation in this study in accordance with the approved research protocol, and are determined by a physician to have caused permanent physical impairment or long-term limitations in daily functioning, National Yang Ming Chiao Tung University will be responsible for providing compensation.

However, foreseeable adverse reactions described in this consent form are not eligible for compensation.

Signing this consent form will not affect any of your legal rights.

IX. Handling and Storage of Research Data

All research data collected in this study will be retained for a period of 10 years. After this period, the data will be destroyed by shredding paper documents and formatting hard drives.

During the study, your identity will be replaced with a code for identification purposes. Personal information (such as name and date of birth) will be recorded only on a paper-based data sheet, which will be stored in a locked file cabinet in the laboratory. The key to the cabinet will be kept by the principal investigator to protect your privacy.

Only authorized research personnel will have access to your identity information and study data. The results of this study will be used solely for academic publication and will not be used for any other purpose. All published data will be presented using research codes. Your privacy will not be disclosed, except as required by authorized agencies under applicable law.

X. Authorized Users of Your Data

According to the Human Research Act, only the principal investigator, co-investigators, and research personnel listed under this project are permitted to access and use your research data during the course of the study in accordance with the approved research protocol.

XI. Post-Study Data Handling

Methods for Handling Research-Related Data:

☐ To be destroyed by National Yang Ming Chiao Tung University

☐ I agree to allow National Yang Ming Chiao Tung University to legally retain the research-related data after the completion of the study for future research related to the effects of neurodynamic techniques on chronic ankle instability. The data will be stored for 10 years following the conclusion of the study and will be destroyed after that period.

All new research projects must first be approved by the Human Research Ethics Committee of National Yang Ming Chiao Tung University. If the data are to be used beyond the original scope, a new informed consent form will be provided, and such extended use must also be approved by the Human Research Ethics Committee.

Signature: _____ Date: _____

XII. Mid-Study Withdrawal Procedure and Data Handling

You are free to decide whether or not to participate in this study. You may withdraw your consent or discontinue participation at any time during the study without needing to provide any reason. Refusing to participate or choosing to withdraw will not cause any negative consequences, affect the principal investigator's evaluation of you in future research, or compromise any of your rights.

Data collected prior to your withdrawal will still be retained and analyzed.

Post-withdrawal data handling options:

☐ To be destroyed by National Yang Ming Chiao Tung University

☐ I agree to allow National Yang Ming Chiao Tung University to legally retain the research-related data after the completion of the study for future research related to the effects of neurodynamic techniques on chronic ankle instability. The data will be stored for 10 years following the conclusion of the study and must be destroyed thereafter.

All new research projects must first be approved by the Human Research Ethics Committee of National Yang Ming Chiao Tung University. If the data are to be used beyond the original scope, a new informed consent form will be provided, and such extended use must also be approved by the Human Research Ethics Committee.

Signature: _____ Date: _____

XIII. Use of Research Outcomes and Intellectual Property

If the research results of this project lead to academic publications, intellectual property, or tangible benefits, National Yang Ming Chiao Tung University may utilize them for medical purposes, including disease diagnosis, prevention, rehabilitation, and research.

XIV. Participant Rights

- There are no fees required to participate in this study.
- You have the right to refuse participation and may withdraw from the study at any time without experiencing any unpleasant consequences or loss of entitled rights.
- If you experience any discomfort or have questions related to this study, you may contact the principal investigator, Prof. Yi-Fen Shih, at 02-2826-7340.
- If you have questions regarding your rights as a research participant, you may contact the Human Research Ethics Committee of National Yang Ming Chiao Tung University at 02-2823-9753 or via email at irb@ym.edu.tw.
- Prof. Yi-Fen Shih has provided you with a copy of this signed consent form for your records. The research personnel have fully explained the nature and purpose of this study and answered all questions you may have. They have also informed you that you may withdraw at any time without experiencing any discomfort or negative consequences.

XV. Signatures

(1) I have explained to the participant the purpose, procedures, and potential risks and benefits of participating in this study. All questions raised by the participant have been fully answered.

Research Explainer: _____ (Signature)

Relationship to the Study:

☐ Principal Investigator ☐ Co-Investigator ☐ Researcher

Explanation Date: _____ / _____ / _____ (Please fill in the date)

(2) I have fully understood the above-mentioned study procedures, including their potential risks and benefits. All my questions regarding this research have been clearly explained by the research team. I

hereby voluntarily agree to participate in this research study.

Participant: _____ (Signature)

Date: _____ / _____ / _____ (Please fill in the date)

This consent form applies to adults aged 20 years or older and must be signed personally by the participant with the date specified for it to take effect.

If the research involves a fetus, the mother must provide the consent.

(3) I hereby confirm that a member of my research team has explained the study to the above individual, including the study's purpose, procedures, and the potential risks and benefits of participation. All questions raised by the participant have been answered, and the participant meets the study's inclusion criteria.

Principal Investigator / Co-Investigator: _____ (Signature)

Date: _____ / _____ / _____ (Please fill in the date)