Participant Information Sheet

University of Medicine and Pharmacy at Ho Chi Minh City

Title	Investigating changes in cervical and shoulder range of motion and adverse effects following different repetitions of cervical and shoulder mobilization exercises in patients with cervical spondylosis
Principal Investigator	Nguyen Huu Duc Minh, MSc. MD.
Associate Investigator(s)	None
Duration	November 2023 – May 2025
Location	Ho Chi Minh City Hospital for Rehabilitation – Occupational Diseases

Part 1 WHAT DOES PARTICIPATION INVOLVE?

1 Introduction

You are being invited to participate in a research study because you have been diagnosed with cervical spondylosis and your participation can contribute valuable clinical information to help evaluate how different repetitions of cervical and shoulder mobilization exercises affect cervical and shoulder mobility and treatment safety.
This Participant Information Sheet explains the purpose, procedures, benefits, and possible risks of the study. Please read it carefully before deciding whether to participate. Participation is voluntary. If you choose not to take part, your usual medical care will not be affected in any way.
If you agree to participate, you will be asked to sign the Consent Form. By signing it, you confirm that you:
• Understand the information provided;
• Agree to participate voluntarily;
• Allow the research team to collect and use your health information for this study.
You will receive a copy of this document to keep.

2 What is the purpose of this research?

Cervical spondylosis is a common degenerative condition of the cervical spine that causes neck pain, stiffness, and functional limitations. Cervical and shoulder mobilization exercises are widely used to restore mobility and reduce symptoms, but suitable repetitions and their effect on cervical and shoulder range of motion remain unclear.
This study aims to:
• Examine how different repetitions of cervical and shoulder mobilization exercises influence cervical and shoulder range of motion, pain level, functional disability, and quality of life;
• Evaluate adverse effects;
• Explore changes after physiotherapist-administered daily interventions.
Findings from this study may help optimize exercise dosage and improve treatment strategies for patients with cervical spondylosis.

3 What does participation involve?

This is an interventional clinical study. If you participate:
• You will receive standard pharmacology (either meloxicam 7.5 mg, celecoxib 200 mg, or diclofenac 50 mg, one tablet twice daily, with or without omeprazole 20 mg one tablet twice daily) along with or without cervical and shoulder mobilization exercises performed by trained physiotherapists for 14 consecutive days;
• You will attend assessment sessions at baseline, after 14 days of treatment, and at follow-up

after 3 months.
Your total participation time is approximately 30 minutes per visit.
There are no additional costs for participating. You will receive daily reimbursement for travel and meal expenses of 100,000 VND.

4 What will you need to do?

If you participate, you will:
• Attend scheduled assessment and exercise sessions;
• Follow physiotherapist instructions during mobilization exercises;
• Inform the study team if you are taking any other medications or if your symptoms change;
• Report any discomfort, pain, or unusual symptoms during or after exercises.

5 Study procedures

Assessment sessions include:
• Measuring cervical and shoulder range of motion using the RomIX photogrammetric instrument;
• Recording pain intensity using Visual Analog Scale, functional disability using Neck Disability Index, and quality of life using Short Form-36 (SF-36);
• Recording any adverse events.
Intervention sessions include:
• Physiotherapist-administered cervical mobilization;
• Physiotherapist-administered shoulder mobilization;
• Different exercise repetitions depending on your assigned protocol;
No blood tests, imaging, or invasive procedures are required.

6 Number of participants

The study is carried out on a total of 120 participants diagnosed with cervical spondylosis.

7 Do you have to take part?

No. Participation is entirely voluntary. You may withdraw at any time without giving a reason, and your medical care will not be affected.
If you withdraw from the study, the data already collected will still be used in the analysis, as required for scientific and ethical integrity. No new data will be collected after withdrawal.

8 Alternatives to participation

Regardless of participation, you will receive standard treatment for cervical spondylosis at the hospital. Not participating will not limit or change your access to routine care.

9 Possible benefits

You may experience:
• Improved cervical and shoulder mobility;
• Reduced neck pain and stiffness;
• Better functional ability;
• Better overall quality of life.
However, these benefits cannot be guaranteed.

10 Possible risks or discomforts

Mobilization exercises may cause temporary cervical discomfort, increased paresthesia, and joint stiffness. Standard pharmacology may induce epigastric discomfort, abdominal bloating, dry mouth, nausea/vomiting, and loose stool/diarrhea.
All exercises are performed by trained physiotherapists to minimize risks.
If any symptom appears, please inform the study team immediately.
If any health issue occurs directly as a result of the research procedures, you will be exempt from

treatment costs according to hospital policy.

11 Will samples be collected?

No. This study does not involve collecting blood, tissue, or biological samples. Only demographics and clinical information will be recorded.

12 New information during the study

If important new information arises during the study, you will be informed. You may decide whether to continue or withdraw. If you continue, you may be asked to sign an updated consent form.

13 Can you continue your usual treatments?

Yes. However, please inform the study doctor about any treatments or medications you are currently using. The study doctor will advise if any treatment should be paused temporarily during participation.

14 Withdrawal by the study team

The study team may withdraw you from the project if:
• Continuing participation may affect your safety;
• You develop symptoms that require separate medical treatment;
• You are unable to comply with study procedures.
Data collected before withdrawal will still be used.

15 Could the study stop unexpectedly?

Yes. Possible reasons include:
• Safety concerns;
• Insufficient participant retention;
• Decisions by regulatory or ethical committees.
If the study stops, you will be informed.

16 What happens at the end of the study?

There is no additional treatment required after the study.
You may request a summary of the study results once the project is completed.

Part 2 HOW IS THE STUDY CONDUCTED?

17 Privacy and confidentiality

Your personal information will be kept confidential and stored securely.
Collected information may include:
• Demographics, including age (in years), sex (male or female), weight (in kilograms), height (in meters), living area (urban or rural), occupation (manual or non-manual), and symptom duration (in months);
• Cervical and shoulder range of motion (in degrees);
• Pain level (in Visual Analog Scale), functional disability (in Neck Disability Index), quality of life (in Short Form-36);
• Adverse events.
Your identity will not appear in any publication or presentation.
By signing the consent form, you agree that relevant health information may be accessed if needed for the study. Information about your participation may also be included in your hospital record, as required by policy.

18 Complaints and compensation

If you are injured or have a complaint related to the study procedures:
• Contact the study team as soon as possible;
• You will receive appropriate medical care;
If the issue is directly caused by the study, treatment costs will be covered by the hospital as per policy.

19 Funding and conflicts of interest

This study is conducted by the research team of the University of Medicine and Pharmacy at Ho Chi Minh City at the Ho Chi Minh City Hospital for Rehabilitation – Occupational Diseases.
There are no financial benefits to the investigators, physiotherapists, or the hospital arising from this study. Participants will not receive financial benefits from the research outcomes.

20 Ethics approval

The study has been approved by the Ethics Committees of the Ho Chi Minh City Hospital for Rehabilitation – Occupational Diseases, under No. 18/HDDD-BVPHCN-DTBNN on November 1, 2023.

21 Contact information

If you have questions or concerns related to the study, please contact:

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