



Participant Information Sheet

University of Medicine and Pharmacy at Ho Chi Minh City

Title

Correlation between point-specific thermal asymmetry and cervico-mandibular function in patients with cervical spondylosis and temporomandibular disorders: a clinimetric and cross-sectional correlation study using the ATHERM infrared thermometer

Principal Investigator

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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 this research study because you are either an adult without neck or jaw symptoms who may help us evaluate the measurement properties of a new infrared thermometer, or a patient with cervical spondylosis who may also have temporomandibular disorders. Your participation can provide useful information on whether temperature differences at selected head and neck points are related to jaw and neck function.

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, and 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?

Temporomandibular disorders are conditions that affect the jaw joint, chewing muscles, and related craniofacial structures. They may cause jaw pain, limited mouth opening, and difficulty with oral activities. These problems may also be associated with neck pain, cervical disability, and reduced cervical movement in patients with cervical spondylosis.

This study aims to:

- Evaluate the test-retest reliability and validity of ATHERM, an infrared thermometer developed for point-specific temperature measurement at Fengchi (GB20) and Fengfu (GV16);
- Measure thermal asymmetry between the left and right GB20 points;
- Examine whether thermal asymmetry is associated with pain intensity, neck disability, jaw functional limitation, jaw range of motion, and cervical range of motion;
- Support the development of objective adjunctive tools for assessing cervico-mandibular dysfunction

The study does not test a treatment and does not replace standard clinical examination or routine medical care.

3 What does participation involve?

This is an observational study. No medication, exercise treatment, randomization, or invasive procedure is administered as part of this study. If you participate, your involvement will depend on the study phase in which you are enrolled.

In the clinimetric phase, asymptomatic adults will undergo non-contact temperature measurement at selected head and neck points using ATHERM and two comparator devices, including a thermal camera and a commercial non-contact infrared thermometer. These measurements will be repeated three times with short rest intervals to evaluate the stability of the instrument.

In the clinical correlation phase, patients with cervical spondylosis will be screened for temporomandibular disorders. Eligible participants will undergo thermal measurement using ATHERM, complete pain and function questionnaires, and perform jaw and neck movement assessments. These assessments are performed at baseline and do not change your routine treatment plan.

A complete assessment session is expected to take approximately 30 to 45 minutes. There are no additional costs for participating. Reimbursement for travel or meal expenses, if applicable, will follow the policy of the study site.

4 What will you need to do?

If you participate, you will be asked to:

- Attend the scheduled assessment session;
- Avoid caffeine, smoking, exercise, and topical products on the measured skin areas for at least 2 hours before thermal assessment;
- Rest quietly for about 10 minutes before temperature recording;
- Sit or stand as instructed during the measurements;
- Inform the study team about current symptoms, medications, or treatments;
- Report any discomfort, pain, dizziness, or unusual symptoms during or after the assessment

5 Study procedures

Thermal assessment will be performed in a controlled room. ATHERM will be placed as an adjustable headband so that its non-contact infrared sensors align with the target points. Temperature will be recorded at GV16 and bilateral GB20. For reliability assessment, each recording will last approximately 15 seconds and will be repeated three times with 5-minute intervals. The device does not emit heat or radiation for treatment; it only records skin temperature.

For comparison in the clinimetric phase, temperature readings may be obtained using a FLIR C5 thermal camera and a Microlife FR1MF1 infrared thermometer. These devices are used only to compare temperature readings and do not involve invasive procedures.

For patients in the clinical correlation phase, the assessment will also include pain rating using the Visual Analog Scale, neck-related disability using the Neck Disability Index, jaw functional limitation using the Jaw Functional Limitation Scale-8, jaw range of motion measured with a calibrated ruler, and active cervical range of motion measured with the ROMIX photogrammetric system. For ROMIX assessment, you will be asked to perform active neck movements, including flexion, extension, right and left bending, and right and left rotation, with a brief hold at the end of each movement.

Clinical information may be reviewed when necessary to confirm eligibility and describe participant characteristics.

6 Number of participants

For the clinical phase, patients with cervical spondylosis are screened for temporomandibular disorders, and eligible patients are included in the correlation analysis. The final analytical sample is expected to include 50 asymptomatic adults and 73 patients with cervical spondylosis and temporomandibular disorders.

7 Do you have to take part?

No. Participation is entirely voluntary. You may decline to participate or withdraw at any time without giving a reason. Your medical care and relationship with the hospital or study team will not be affected. If you withdraw from the study, no new data will be collected after withdrawal. Data already collected may still be used in anonymized form for scientific analysis unless withdrawal of those data is possible under applicable regulations and study procedures.

8 Alternatives to participation

If you do not participate, you will continue to receive routine care according to your clinical condition. Not participating will not limit or change your access to standard medical assessment or treatment.

9 Possible benefits

You may not receive direct personal medical benefit from taking part. However, the findings may help improve objective assessment of jaw and neck function in people with temporomandibular disorders and cervical spondylosis. The information may also help guide future research on thermal assessment as an adjunct to routine clinical evaluation.

10 Possible risks or discomforts

The study procedures are non-invasive and expected to involve minimal risk. ATHERM, the thermal camera, and the infrared thermometer record surface temperature without puncturing the skin. Some participants may feel mild temporary pressure from the headband or may experience temporary discomfort, fatigue, or stiffness when performing maximal jaw or neck movements. 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 receive appropriate care according to hospital policy.

11 Will samples be collected?

No. This study does not involve collecting blood, tissue, saliva, or other biological samples. Only demographic, clinical, functional, and thermal measurement data 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 needed, you may be asked to sign an updated consent form.

13 Can you continue your usual treatments?

Yes. This study does not require you to stop your usual care. Please inform the study doctor about any medications, physical therapy, topical products, or other treatments you are using, especially before the thermal assessment. The study team will advise if any short-term preparation is needed for measurement accuracy.

14 Withdrawal by the study team

The study team may withdraw you from the project if continuing participation may affect your safety, if you develop symptoms that require separate medical attention, or if you are unable to comply with study procedures. Data collected before withdrawal may still be used in anonymized form.

15 Could the study stop unexpectedly?

Yes. Possible reasons include safety concerns, insufficient participant recruitment or retention, technical issues with measurement equipment, or 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 study participation. You may request a summary of the study results once the project is completed and the results are available.

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:

- Demographic information, including age, sex, body mass index, living area, occupation, and symptom duration;
- Clinical information related to cervical spondylosis and temporomandibular disorder screening;
- Thermal measurements at GV16 and bilateral GB20, including thermal asymmetry;
- Pain intensity, neck disability, jaw functional limitation, jaw range of motion, and cervical range of motion;
- Any discomfort or unexpected issue occurring during the assessment

Your identity will not appear in any publication or presentation. Data will be anonymized before analysis whenever possible. 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, please contact the study team as soon as possible. You will receive appropriate medical care. If the issue is directly caused by study procedures, treatment costs will be covered according to hospital 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. The work receives support from the Korea International Cooperation Agency (KOICA) under the project entitled “Education and Research Capacity Building Project at University of Medicine and Pharmacy at Ho Chi Minh City” conducted from 2024 to 2025 (Project No. 2021-00020-3).

ATHERM and ROMIX were developed by members of the research team as research instruments. The investigators, clinicians, and hospital do not receive personal financial benefits from your participation in this study. Participants will not receive financial benefits from the research outcomes.

20 Ethics approval

The study has been approved by the Ethics Committee of Ho Chi Minh City Hospital for Rehabilitation – Occupational Diseases under No. 18/HDDD-BVPHCN-DTBNN on November 1, 2023 and No. 10/HDDD-BVPHCN-DTBNN on May 1, 2024. All participants are provided with written informed consent before enrollment.

21 Contact information

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

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