Participant Information Sheet

University of Medicine and Pharmacy at Ho Chi Minh City

Title	Novel photogrammetric instrument to measure the cervical range of motion: Validity and gender-based assessment in a clinical study
Short Title	Validating a photogrammetric instrument to assess the neck range of motion
Protocol Number	23519 - DHYD
Project Sponsor	None
Coordinating Principal Investigator	MSc. MD. Nguyen Huu Duc Minh
Associate Investigator(s)	None
Location	Ho Chi Minh City Hospital for Rehabilitation – Occupational Diseases

Part 1 What does participation involve?

1 Introduction

The participant is being invited to take part in this research project since his/her presence can provide valuable insights and contribute significantly to the evaluation and validation of a novel photogrammetric instrument to record the cervical spine range of motion, which proposes a promising solution to support more accurate and large-scale healthcare screening.
This Participant Information Sheet provides detailed information about the research project. It explains the procedures, tests, and treatments involved. Understanding what is involved will help the participant make an informed decision about whether or not he/she wishes to participate in this research
Participation in this research is entirely voluntary. If the participant chooses not to take part, he/she will continue to receive the best possible care.
If the participant decides to take part in the research project, he/she will be asked to sign the consent section. By signing it, the participant is confirming that he/she:
• Understand the information you have read;
• Consent to participate in the research project;
• Agree to undergo the tests and treatments described in the document;
• Allow the use of your personal and health information as outlined in the form.
The participant will be given a copy of this Participant Information Sheet to keep for his/her records.

2 What is the purpose of this research?

Musculoskeletal disorders, accompanied by neck and shoulder pains, are highly relevant in the population, especially in countries with average or low-income levels. These conditions cause a major economic and medical burden both in general, and for individual patients and their families, communities, and the healthcare systems in particular. The aim of this research project is to evaluate the effectiveness and accuracy of a novel photogrammetric instrument in recording the cervical spine range-of-motion as a potential tool for assessable and reliable neck screening in community healthcare, as compared to the low accuracy and manual operation of the traditional goniometric method.
Therefore, this research project wishes to facilitate medical healthcare through a viable and time-saving product for cervical spondylosis patients in particular, which could lead to better patient outcomes, less labor reliance, and lower healthcare costs.
The interventions used in this research project do not involve any medications or drugs that require regulatory approval. Both the goniometer and photogrammetric device used in this study

have been standardized at the Ho Chi Minh City Technical Center of Standards Metrology and Quality, yet the instrument requires further scientific validation for its practical use.
This present study, initiated by MSc. MD. Nguyen Huu Duc Minh (the principal investigator), is being conducted by his research group from the University of Medicine and Pharmacy at Ho Chi Minh City. The project is funded by the Korean International Cooperation Agency (KOICA) and its results will be used by the principal investigator to obtain his PhD degree in Traditional Medicine.

3 What does participation in this research involve?

The participant will be participating in an observational cross-sectional study, wherein his/her cervical spine range-of-motion will be assessed using the manual goniometer and the photogrammetric device, with no drug or medication involved.
After signing the consent form, eligible participant will attend his/her measurement sessions with the total duration of involvement being 15 minutes.
There are no additional costs associated with participating in this research project. All medical care required as part of the research project will be provided to the participant free of charge.
The participant will be reimbursed for their travel, meals, and other expenses associated with the research project visit, with a maximum reimbursement amount of 100,000 VND.

4 What does the participant have to do?

The participant will have no lifestyle, dietary, or medication restrictions apply. However, the participants must inform the study team if he/she is taking any medications during the study period, as this may affect the results.
The participant also needs to attend the measurement sessions and follows the instructions provided during the assessments. If any changes to his/her health occur during the study, the participant should inform the study team.

5 Other relevant information about the research project

This research project will involve 50 participants in total. There are no different arms, case/control groups, or randomization involved, as it is an observational study focused solely on recording neck range-of-motion for the instrument validation.
The study is being conducted by a research team, led by MSc. MD. Nguyen Huu Duc Minh (the principal investigator), from the University of Medicine and Pharmacy at Ho Chi Minh City, and only involves the Ho Chi Minh City Hospital for Rehabilitation – Occupational Diseases as the study location.

6 Does the participant have to take part in this research project?

Participation in any research project is voluntary. If the participant does not wish to take part in, he/she does not have to. If the participant decides that he/she can initially take part and later change his/her mind, he/she is free to withdraw from the project at any stage.
If the study team decides that the participant can take part, he/she will be given this Participant Information and Consent Form to sign and given a copy to keep.

7 What are the alternatives to participation?

This study is not a therapeutic study, so there are no alternative treatments or standard care options related to this research. The participant does not have to participate in this research project to receive treatment at this hospital or any other medical care.

8 What are the possible benefits of taking part?

There will be no clear benefit to the participant from participation in this research. However, if any proven health issues arise as a direct result of participating in the study, the participant will be exempt from treatment costs within the hospital's conditions.

9 What are the possible risks and disadvantages of taking part?

During this study, the participant may have none, some or all of the following side effects.
• Pain or itching at the neck and shoulder regions are usually mild and temporary;
• Dizziness or rapid heartbeat are rare and typically transient, resolving shortly after the session.
The raters performing the measurement will be trained physiotherapists with at least 5 years of clinical experience to minimize the risk of discomfort during the procedure. If the participant has any of these side effects, he/she should inform the study doctor.
If any reported health issues arise as a direct result of participating in the study, the participant will also be exempt from treatment costs within the hospital's conditions.

10 What will happen to the participant's test samples?

In this study, no blood and/or tissue samples will be taken, only images and data related to neck range-of-motion will be collected and processed into research data, which would be stored in a secure database. The collected data will be used for research purposes and may be published in scientific reports or papers. The personal information will remain confidential and will not be published or shared to ensure participant privacy.

11 What if new information arises during this research project?

During this research project, new information may arise that could impact the study. If this occurs, the study doctor will inform the participant promptly and discuss whether he/she wish to continue in the research project. If the participant decides to withdraw, the study doctor will ensure that arrangements are made for the continuation of their regular healthcare.
If the participant chooses to continue participation, he/she will be asked to sign an updated consent form reflecting any new information.

12 Can the participant have other treatments during this research project?

During this research project, the participant may need to discontinue some or all of the medications or treatments he/she has been using. It is crucial to inform the study doctor and research group about any treatments or medications the participant is currently taking.
The study doctor will provide guidance on which treatments or medications must be paused or discontinued during the participant's involvement in the research project.

13 What if the study group withdraw the participant from the research project?

If the study group decide to withdraw the participant from the research project, it is important to discuss any potential health risks or special requirements associated with the withdrawal.
It is important that if the participant is withdrawn partway through the research project, any data collected up to that point will be retained and cannot be deleted. This ensures that the research project results can be accurately measured and comply with legal requirements.
No additional personal information will be collected from the participant after withdrawal, but the data already gathered will remain part of the research project results.

14 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for several reasons, including:
• Unacceptable side effects;
• The instrument proven not to be effective;
• The instrument proven to be already effective, making the study unnecessary;
• Decisions made by local regulatory or health authorities.

15 What happens when the research project ends?

At the conclusion of this research project, there will be follow-up arrangements to ensure the well-being of the participants. Since this study does not involve drug or therapeutic treatments, there will be no ongoing treatment to continue after the project ends.

The participants and the person responsible will not need to take further action regarding the instrument. However, they will be informed about the project findings, which are provided to all participants after the research project is completed.

Part 2 How is the research project being conducted?

16 What will happen to information about the participant?

By signing the consent form, the participant consents to the study doctor and the research group collecting and using personal information for the project. Only images and data related to neck range-of-motion will be collected and processed into research data, which would be stored in a secure database. The collected data will only be used for research purposes and may be published in scientific papers or presented in conferences. Any information obtained in conn this research project that can identify the participant will remain confidential. The participant's 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.
Information about the participant may be obtained from their health records for the purpose of this research. By signing the consent form, the participants agree to the study group accessing health records if they are relevant to participation in this research project. Information about participation in this research project may also be recorded in the participant's health records.

17 Complaints and Compensation

If the participant suffers any injuries as a result of this research project or has any complaints regarding the participant's treatment by the research members, including the physiotherapists, he/she should contact the study team as soon as to receive suitable medical treatment or have his/her complaints resolved. If any reported health issues arise as a direct result of participating in the study, the participant will be exempt from treatment costs within the hospital's conditions.

18 Who is organising and funding the research?

This research project is being conducted by a research group, led by MSc. MD. Nguyen Huu Duc Minh, from the University of Medicine and Pharmacy at Ho Chi Minh City, and is funded by the Korean International Cooperation Agency (KOICA). There are no financial benefits that the Ho Chi Minh City Hospital for Rehabilitation – Occupational Diseases, the physiotherapists, or the study group will receive as a result of this research project. The participants and their family will not receive any financial benefit from participating in this research, even if the research leads to discoveries of commercial value. All members of the research team are involved purely for the purpose of advancing scientific knowledge and improving patient care, and no personal financial gain will be obtained beyond their ordinary wages.

19 Who has reviewed the research project?

This study was approved by the Ethics Committees of both the Ho Chi Minh City Hospital for Rehabilitation – Occupational Diseases under No. 16/HDDD-BVPHCN-DTBNN and the University of Medicine and Pharmacy at Ho Chi Minh City under No. 704/HDDD-DHYD on July 27, 2023.

20 Further information and who to contact

If the participant requires any further information regarding this project or has any medical problems and complaints related to his/her involvement in the project (e.g. side effects), he/she can contact the principal investigator via the following contact:

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