Cover Page Informed Consent

April 27, 2022

Effects of Physical Therapy on Isometric Neck Retraction Strength and Pain in Patients with Neck Disability

NCT04334655

University of Tennessee at Chattanooga
CONSENT TO PARTICIPATE IN RESEARCH

Name of Project Subject: _____

Effects of Physical Therapy on Isometric Neck Retraction Strength and Pain in Patients with Neck Disability

Frank Tudini
Physical Therapy
423-425-4046
The University of Tennessee at Chattanooga
615 McCallie Ave, Office 209
Chattanooga, TN 37403

There is no funding for this project.

Key Information

Why am I being asked to take part in this research project?
We are asking you to take part in this research project because you are an adult 18 years of age or older who is experiencing neck pain and are receiving physical therapy.

What should I know about a research project?
- Someone will explain this research project to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
(1) The primary purpose of this research is to describe neck strength using a simple hand-held force gauge and to examine if this strength and neck disability changes over your time in physical therapy.
(2) The potential benefit is that this may be a quick and easy method to monitor neck strength in patients with neck pain and to assess changes over the course of physical therapy.

How long will the research last and what will I need to do?
We expect that you will be in this research project for the duration of your physical therapy. The measurements will be taken on the first day of your treatment and then at regular follow-ups until you are discharged. The questionnaires used will also be completed at the same times and are a part of normal PT practice.

You will be asked to lay on a table with the force gauge under your head. The therapist will ask you to tuck your chin and push your head straight down into the dynamometer for approximately 5 seconds. This will be repeated 2 times. You will also be asked to report a pain number from 0 – 10 and fill out a quick questionnaire regarding the neck disability.

More detailed information about the project procedures can be found under the section, **"What will happen if I participate in this project?"**

What risks or problems can I expect from the project?
There are minimal risks, which are no more than you would encounter during your dailty life or during the performance of your routine care with this project. In an earlier study using the dynamometer, there were no untoward events. Some people may feel a little sore in their neck after pushing into the dynamometer but any added soreness from this usually subsides quickly. Some people may find that some of the questions on the questionnaire may be stressful or upsetting. If this is the case, those questions may be skipped.

More detailed information about the risks of this project can be found under, **"What risks or problems can I expect from the project?"**

Are there any benefits to taking part in the project?
We cannot promise any benefits to you or others from your taking part in the project. However, possible benefits include that additional information will be provided to you about the strength of your neck and you will be able to see if your neck strength improves over time and how this relates to pain and function.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research project is to not participate.

Detailed Information

How many people will participate in the research project?
We expect that 60 people here will be in this research project in the entire project nationally. This number is based on a previous study we performed on neck strength.

What will happen if I participate in this project?

- When you come to Physical Therapy for your initial evaluation, the therapist will add the neck strength test to the rest of the exam. This only takes an additional few minutes. The test will then be repeated whenever the therapist performs a re-evaluation or assessment for the MD or insurance which is usually every 30 days. The therapist will also ask you to rate the neck pain on a 0 – 10 scale and to complete a short survey about neck disability.

- Participating will in no way change the evaluation or treatment that is provided. It is only a quick and easy extra assessment of neck strength and function.
- Your therapist will then provide the primary researcher, Frank Tudini from Campbell University, with the data. No personally identifying data will be shared. The only de-identified information that will be provided include your gender, age, height, weight, diagnosis, isometric neck strength, the scores to outcome measures that are normally used in the clinic, and a list of treatments received.

What risks or problems can I expect from the project?
We watch everyone in the project for unexpected problems. **You need to tell the project investigator, Frank Tudini, and your PT or a member of the project team immediately if you experience any problems**.

There is a slight physical risk that after pushing into the hand-held dynamometer there will be an increase in neck stiffness or pain. This usually subsides quickly but inform your PT if there are any problems.
You may feel that some of the questions in the questionnaire are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately.

Another risk may be loss of confidentiality. Every effort will be made to keep your project records confidential but we cannot guarantee it. If you have questions, you can talk to the principal investigator.

Are there any benefits to taking part in the project?
This project may or may not help you, but we hope the information from this project will help us develop a better treatment / understanding for people with neck pain or disability or help us provide better health services for people with neck problems.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research project is to not participate.

Can I stop being in the project?
You can leave the research project at any time.
If you decide to leave the project, please let the project team know.

Choosing not to be in this project or to stop being in this project will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this project will not negatively affect your right to any present or future medical treatment.

The project investigator may stop your participation in the project at any time for any reason without your consent. They will tell you if this happens.

Data collected up to the point of withdrawal will be used in the study up to the point of withdrawal. An intention to treat analysis will be used for all patients who do not complete their PT or for whom data is missing.

Are there any costs to being in the project?
There are no costs to you for participation in this project. If you have questions regarding project costs, please contact Frank Tudini at The University of Tennessee at Chattanooga: 423-425-4046 or by email at frank-tudini@utc.edu.

Will I be paid for being in the project?
There is no payment for being in this project.

Will I be given new information about the project?

Clinically relevant results, including individual results, will be disclosed to you by the treating PT.

Who can answer my questions about the project?

- If you have more questions about this project at any time, you can call Frank Tudini at 423-425-4046 .
- If you have questions about you rights as a project participant, want to report any problems or complaints, obtain information about the project, offer input, or feel you have been injured, you can call the IRB Office at 423-425-5867 .

Permission to collect, use and share Personal Health Information (PHI)/ HIPAA Authorization

What health information will be collected and used for this project?
To be in this research project, the project team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the project. This information may come from questions we ask, forms we ask you to fill out, as described below. We will only collect and use information needed for the project.

The health information we will collect and use for this project is:
demographic information such as age and gender and information such as height and weight, neck pain, strength, and disability.

Who will see the health information collected for this project?
The only people allowed to handle your health information are those on the project team at The University of Tennessee at Chattanooga and your Physical Therapist, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure The University of Tennessee at Chattanooga rules are followed.

The project team may share your information with people who are not part of the project team because they planned, pay for, or work with us on this project. The federal Privacy Rule may no longer protect your health information once it leaves The University of Tennessee at Chattanooga. For this project, we plan to share information with those doctors, researchers or government representatives working with us on this project at the institutions or companies listed here: The University of Tennessee at Chattanooga.

Once all personal identification is removed from your health information, the information may be used for future research or distributed to another investigator for future research without additional informed consent from you or your legally authorized representative. The information might also be used or released for other purposes without asking you. Results of the project may be present in public talks or written articles, but no information will be presented that identifies you.

What are the risks of sharing this health information?
One risk of taking part in a research project is that more people will handle your personal health information collected for this project. The project team will make every effort to protect the information and keep it confidential, but it is possible than an unauthorized person might see it. Depending on the kind of information being collected, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the principal investigator about whether this could apply to you.

How long will you keep the health information for this project?
If you sign this form, we plan to keep your information for 3 years after the research project ends in case we need to check it again for this project.

Can I cancel my permission to share this health information?
If you change your mind later and do not want us to collect or share your health information, you need to send a letter to Frank Tudini at The University of Tennessee at Chattanooga, 615 McCallie Ave, Office 209, Chattanooga, TN 37403 . The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the project. We may still use the information we already collected.

CONSENT TO PARTICIPATE IN THE PROJECT

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.

- The project's purpose, procedures, risks and possible benefits have been explained to me.

- I agree to let the project team use and share the health information and other information gathered for this project.

- I voluntarily agree to participate in this research project. I agree to follow the project procedures as directed. I have been told that I can stop at any time.

IMPORTANT: Your will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name *please print*	**Subject's Signature**	**Date/Time**
Name of Witness (if applicable) *please print* (for short form consent process, or consent of blind or illiterate subject)	**Signature of Witness**	**Date/Time**