08.05.2024

THE EFFECT OF TALOCRURAL JOINT MANIPULATION ON STATIC BALANCE IN PATIENTS WITH STROKE

NCT06523010

STUDYPROTOCOL

The study with a randomized crossover design was conducted on 32 patients diagnosed with stroke. The patients received sham and real talocrural joint manipulation in a randomized order, with at least 48 hours between each application. The order of the applications was determined by a coin toss. Before and after each application, the patients' postural stability and ankle dorsiflexion range of motion were measured. After all measurements were completed, intra- group and inter-group comparisons of the data were made.

Objective: The aim of this study is to evaluate the effect of talocrural joint manipulation on postural stability and ankle mobility in stroke patients.

Design: This study has a randomized crossover design.

Methods: Stroke patients included in the study were assessed for postural stability (anteroposterior, mediolateral, and overall stability) before and after the intervention using the Biodex balance system. Ankle mobility was measured using a smartphone level application in two different positions: with the knee in extension and in 20 degrees or more of flexion. Balance measurements were considered the primary outcome, while ankle mobility was regarded as the secondary outcome.

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INFORMED CONSENT FORM

PLEASE READ CAREFULLY!

You have been invited to participate in this study. Before agreeing to take part, it is important that you understand the purpose of the study and make your decision freely based on this information. Please read this information, which has been specifically prepared for you, carefully and feel free to ask for clear answers

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to evaluate whether ankle traction has any effect on the balance and ankle movement range of stroke patients.

WHAT ARE THE ELIGIBILITY CRITERIA?

In order to be included in this study, you must meet the inclusion or exclusion criteria and sign this consent form.

WHAT KIND OF PROCEDURE WILL BE CARRIED OUT?

As part of this study, two different ankle traction procedures will be performed on you in a random order. In one of the ankle traction procedures, your ankle will be grasped, but no traction will be performed. In the other procedure, your ankle will be grasped, and traction will be applied. You can think of the ankle traction procedure as the ankle version of the commonly known back traction procedure. The second procedure will be performed at least two days after the first.

Before the tapping procedures, your data such as age, height, and weight will be collected through questions, weight measurement, and a measuring tape. Data related to your stroke condition will be obtained from the hospital's data system. Then, your level of consciousness will be assessed using the Mini Mental State Examination (MMSE), the functionality of your arms and legs will be assessed using the Brunnstrom Recovery Staging System, and your balance will be evaluated using the Biodex Balance System.

During the MMSE, your consciousness level will be assessed by asking you a series of questions. In the Brunnstrom Recovery Staging System, your ability to perform certain activities will be evaluated to determine the recovery level of your arms and legs. The Biodex Balance System will assess how much movement you have while standing, including shifts to the sides and front-to-back. For the test, you will be asked to remove your shoes and step onto the platform of the device, following its instructions.

Finally, any changes in the upward movement of your ankle during the tapping procedure will be measured using a phone application while you are standing. Once the initial measurements are completed, the first ankle traction procedure will be carried out, followed by the second set of measurements. The other ankle traction procedure will then be performed, with measurements taken before and after.

WHAT ARE MY RESPONSIBILITIES?

Your responsibility during the study is to follow the researchers' instructions precisely. If you do not adhere to this condition, the researcher has the authority to exclude you from the study.

WHAT IS THE TOTAL DURATION OF PARTICIPATION IN THIS STUDY?

The estimated time for your participation in this study is approximately 10 minutes for each measurement. In total, it will be about 40 minutes.

WHAT ARE THE EXPECTED POTENTIAL BENEFITS OF PARTICIPATING IN THE STUDY?

The expected benefits of this study for you include potential improvements in your balance and upward ankle movement with these approaches. Additionally, if the study concludes that ankle traction is beneficial and if you wish, we may offer this treatment to you independently after the research is completed.

WHAT ARE THE EXPECTED POTENTIAL RISKS OF PARTICIPATING IN THE STUDY?

There are no expected adverse effects related to this procedure, provided that you follow the researchers' instructions. UNDER

WHAT CONDITIONS CAN I BE EXCLUDED FROM THE STUDY?

You may be excluded from the study without your consent if you do not follow the researchers' instructions precisely. WHAT ARE

THE OTHER TREATMENTS?

Physical therapy treatments are commonly preferred approaches for treating balance problems. In addition to physical therapy, new approaches such as local vibration and whole-body vibration are also some of the preferred treatment methods for improving balance.

IN CASE OF ANY INJURY, WHO IS RESPONSIBLE AND WHAT WILL BE DONE?

In the event of any harm related to the study, the treatment will be provided by the responsible researcher, and the associated costs will be covered by the researchers. You are covered for any potential damage (including death or injury) that may occur during the procedure.

WHO SHOULD I CONTACT IF I ENCOUNTER ANY ISSUES DURING THE STUDY?

If you need to take any medication or undergo training outside the study protocol, or if you need additional information about the study, or if you experience any issues, side effects, or other discomforts during the study, you can contact Dr. Ömer DURSUN, Assistant Professor, at 0542 608 86 87.

WILL THE EXPENSES RELATED TO THE STUDY BE COVERED?

Any tests, physical examinations, and other research-related expenses will not be charged to you or to any public or private institution or organization under your coverage.

WILL I RECEIVE ANY PAYMENT FOR PARTICIPATING IN THE STUDY?

You will not receive any payment for participating in this study.

WHAT SHOULD I DO IF I DECIDE NOT TO PARTICIPATE OR IF I WANT TO WITHDRAW FROM THE STUDY?

Participation in this study is entirely voluntary. You can refuse to participate or withdraw from the study at any stage; even if you decide to withdraw, your subsequent care will be ensured. The researcher may remove you from the study without your consent but with your knowledge if you do not comply with the treatment protocol, disrupt the study schedule, or for other reasons such as improving the effectiveness of the treatment. In this case, your subsequent care will still be guaranteed.

If you withdraw from the study or are removed by the researcher, your medical data will not be used for scientific purposes.

WILL CONFIDENTIALITY BE MAINTAINED REGARDING THE INFORMATION RELATED TO MY PARTICIPATION?

All your medical and personal information will be kept confidential, and even if the study is published, your identity will not be disclosed. However, study reviewers, auditors, ethical committees, and official authorities may access your medical information when necessary. You will also be able to access your own medical information upon request.

Consent to Participate in the Study:

I have read and listened to the two-page document that contains the information that should be provided to the volunteer before the study begins. I have asked all the questions I had to the researcher, and I fully understand all the explanations given to me, both in writing and orally. I was given enough time to decide whether I want to participate in the study. Under these conditions, I give permission to the research investigator to review, transfer, and process my medical information, and I accept the invitation to participate in this research voluntarily, without any coercion or pressure. By signing this form, I understand that I will not lose any rights granted to me by local laws.

A signed and dated copy of this form has been provided to me.

volunteer's consent		SİGNATURE
Name & Surname		
Adress		
Date		
Phone		

RESEARCHER		SİGNATURE
Name & Surname		
Adress		
Date		
Phone		