Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Attentional demands of postural control while walking in individuals with and without Functional Ankle Instability

Protocol summary

Study aim
Compare attentional needs for postural control while walking in people with and without functional ankle instability during the two conditions of presence or absence of cognitive load.

Design
Control group: healthy people- experimental group: people with functional ankle instability, including 20 people in each group. Single blinded non-randomized controlled clinical trial.

Settings and conduct
Shahid Beheshti University of Medical Sciences. People are asked to take off their shoes and walk at a self-selected speed for approximately 120 seconds with and without cognitive tasks. The researcher who also performs the data analysis is blinded so that he is separate from the person who collects the data.

Participants/Inclusion and exclusion criteria
Entry conditions: experience at least one significant ankle sprain in one of the ankles at least 12 months before the study; history of at least two episodes of the ankle giving way or an ankle sprain in the last 12 months; absence of injury, pain, and swelling Conditions of non-entry: uncorrected visual impairment, hearing impairment, dizziness, numbness, paresthesia, fracture, pain, and surgery in the trunk and lower limbs in the six months prior to the study; history of neurological diseases

Intervention groups
Investigating the effect of a cognitive task with the auditory Stroop test. The words high and low are played in Persian by the MATLAB software with an either high or low pitch. During the movement task, the subjects must respond to these stimuli, determine the pitch of the tone regardless of the word itself, and report the opposite as soon as possible.

Main outcome variables
Distance and movement speed of the center of pressure - Recurrence quantification analysis: Percentage of repetition, determination, irregularity (complexity), and stability - kinematics of ankle, knee, and hip joints in three planes.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220717055484N1**
Registration date: **2022-07-26, 1401/05/04**
Registration timing: **prospective**

Last update: **2022-07-26, 1401/05/04**
Update count: **0**

Registration date
2022-07-26, 1401/05/04

Registrant information

Name
Tina Banakheiri

Name of organization / entity

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Iran (Islamic Republic of)

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Email address
tinabanakheiri@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2022-12-22, 1401/10/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Attentional demands of postural control while walking in individuals with and without Functional Ankle Instability

Public title

The effect of cognitive load on postural control and walking balance in healthy people and patients with Functional Ankle Instability

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Men in the age range of 18 to 40 years At least one significant ankle sprain occurred more than 12 months ago and at least two episodes of the ankle giving way or an ankle sprain in the past year Absence of mechanical instability in the affected ankle by performing the anterior drawer and talar tilt test by the physiotherapist Absence of injury, pain, and swelling of the ankle during the last 3 months (an injury that makes the person unable to put weight on the affected side and impairs the person's performance) No physiotherapy treatment from 3 months before entering the study and at the time of evaluation A score of less than 90% in daily activities and less than 80% in sports using the FAAM questionnaire No history of any sprain in the ankle for the group of healthy people

Exclusion criteria:

The presence of uncorrected visual impairment, hearing impairment, dizziness, numbness, paresthesia, fracture, pain, and surgery in the trunk and lower limbs in the 6 months before the study History of neurological diseases Use of sleeping and sedative drugs in the 48 hours before the test

Age

From **18 years** old to **40 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the presence of a colleague who collects the data, the study is blinded, and the person who performs the data analysis (researcher) is different from the person who conducts the tests.

Placebo

Not used

Assignment

Other

Other design features

People are randomly divided into two groups: healthy and patients with functional ankle instability. Both groups start walking in the same way in two modes: 1) simple and 2) with cognitive tasks randomly for a certain period.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti Rehabilitation Faculty, Damavand St., in front of Bo Ali Hospital, Tehran City, Tehran Province

City

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Province

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Postal code

1616913111

Approval date

2021-06-19, 1400/03/29

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.118

Health conditions studied

1

Description of health condition studied

Functional Ankle Instability

ICD-10 code

S93.4

ICD-10 code description

Sprain of ankle

Primary outcomes

1

Description

Linear parameters: maximum anterior-posterior displacement of the center of pressure, maximum medial-lateral displacement of the center of pressure, and displacement speed of the center of pressure

Timepoint

In this study, during a walking assessment session, subjects are asked to take off their shoes and stand at one end of the approximately 8-meter space of the laboratory, maintaining their usual posture with their hands by their sides. With the examiner's order, at their

self-selected speed, they start walking during two stages with and without cognitive tasks for approximately 120 seconds (equivalent to 10 times crossing the force plate) so that only the desired leg is on each time the force plate.

Method of measurement

Bertec force plate

2

Description

Non-linear parameters: percentage of repeatability, determination, irregularity, and stability of the center of pressure in anterior-posterior and medial-lateral directions

Timepoint

In this study, during a walking assessment session, subjects are asked to take off their shoes and stand at one end of the approximately 8-meter space of the laboratory, maintaining their usual posture with their hands by their sides. With the examiner's order, at their self-selected speed, they start walking during two stages with and without cognitive tasks for approximately 120 seconds (equivalent to 10 times crossing the force plate) so that only the desired leg is on each time the force plate.

Method of measurement

Bertec force plate

3

Description

Ankle, knee, and hip kinematics in a walking cycle in sagittal, frontal, and horizontal planes

Timepoint

In this study, during a walking assessment session, subjects are asked to take off their shoes and stand at one end of the approximately 8-meter space of the laboratory, maintaining their usual posture with their hands by their sides. With the examiner's order, at their self-selected speed, they start walking during two stages with and without cognitive tasks for approximately 120 seconds (equivalent to 10 times crossing the force plate) so that only the desired leg is on each time the force plate.

Method of measurement

Vicon Motion Capture System

Secondary outcomes

empty

Intervention groups

1

Description

Control group: group of healthy people with no history of ankle sprain

Category

N/A

2

Description

Intervention group: Patients with functional ankle instability

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation Research Center and Biomechanics Laboratory, Faculty of Rehabilitation Sciences, Shah

Full name of responsible person

Yaghoub Shaveyi

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Sponsors / Funding sources

1

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Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All the above will be published in the article.

When the data will become available and for how long

After publishing the article.

To whom data/document is available

After the article is published, everyone can access it.

Under which criteria data/document could be used

Other researchers, as well as therapists in the field of medicine and rehabilitation, can use this study after the publication of the article.

From where data/document is obtainable

After publishing the article, you can find and access the data by searching the Internet.

What processes are involved for a request to access data/document

After publishing the article, you can find and access the data by searching the Internet.

Comments