

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of virtual reality exercises on the psychological profile of injury (quality of life, fear of re-injury) and motor defects during the performance of motor functional tests in people with ankle injuries

Protocol summary

Study aim

The effect of virtual reality exercises on the psychological profile of injury and motor defects during the performance of motor functional tests in people with ankle injuries

Design

The research will be quasi-experimental with pre-test and post-test design in which the effect of virtual reality training on psychological factors and movement defects of athletes with chronic ankle instability between the two experimental groups (virtual reality training) and the control group (daily activity). With the pre-test and post-test process will be evaluated in two groups.

Settings and conduct

The present study will be performed in one of the physiotherapy centers in Tehran. The method also started by assessing the fear of re-injury and modifying the movement pattern of these people and then after the pre-test stage, people entered the research and training protocol and were divided into control and experimental groups. The experimental group also performed virtual reality exercises according to the protocol for 6 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: men in the age range of 20-30 years with ankle injury, having a score less than 24 in the functional ankle instability questionnaire (CAIT), scoring less than 90% of the functional instability assessment questionnaire FAAM-ADL ankle and 80% in FAAMS sports questionnaire, ability to perform painless training protocol, no neuropathy, no history of diseases such as cardiovascular disease, respiratory problems, severe low back pain in the last 6 months, no emotional problems and stress and Do not use neuroleptics and sedatives.

Intervention groups

Subjects will be divided into two groups of 15 people control and 15 people experimental.

Main outcome variables

Fear of re-injury - correction of movement pattern

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200510047381N2**

Registration date: **2021-12-17, 1400/09/26**

Registration timing: **prospective**

Last update: **2021-12-17, 1400/09/26**

Update count: **0**

Registration date

2021-12-17, 1400/09/26

Registrant information

Name

Mohammad hani Mansori

Name of organization / entity

The University of Tehran

Country

Iran (Islamic Republic of)

Phone

+98 25 3662 2375

Email address

haninio74@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of virtual reality exercises on the psychological profile of injury (quality of life, fear of re-injury) and motor defects during the performance of motor functional tests in people with ankle injuries

Public title
The effect of virtual reality exercises on the mental and physical performance of people with ankle injuries

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
 * Voluntary participation in research * Men aged 20-30 years with ankle injuries* * Having a score less than 24 in the Ankle Functional Instability Questionnaire (CAIT) * Score less than 90% on the FAAM-ADL Ankle Functional Instability Assessment Questionnaire and 80% on the FAAMS Sports Questionnaire * Ability to implement painless training protocol * No neuropathy * No history of diseases such as cardiovascular disease, respiratory problems, severe low back pain in the last 6 months * No emotional problems and stress and no use of neuroleptics and sedatives
Exclusion criteria:

Age
From **20 years** old to **30 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
A simple random allocation method was used for random assignment of subjects to control and experimental groups. In this way, each person was assigned a number from the sealed envelope and the individuals were placed in the experimental group according to the selected number if they were even and in the control group if they were individuals.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2021-12-11, 1400/09/20

Ethics committee reference number

IR.UMSHA.REC.1400.702

Health conditions studied

1

Description of health condition studied

Ankle and foot injuries

ICD-10 code

M25.37

ICD-10 code description

Other instability, ankle and foot

Primary outcomes

1

Description

Assessment of fear of re-injury by Tampa Fear of re-injury questionnaire

Timepoint

Before and after the training protocol

Method of measurement

Tampa Fear of re-injury questionnaire

2

Description

Modification of movement pattern by Efficiency Movement (ME) test

Timepoint

Before and after the training protocol

Method of measurement

Efficiency Movement (ME) test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Virtual reality exercises

Category

Rehabilitation

2

Description

Control group: Does not receive training protocol

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Laboratory of corrective exercises of the Faculty of Physical Education, University of Tehran

Full name of responsible person

Mohammad Hani Mansouri Asl

Street address

Amirabad Street between 15th and 17th Alley

City

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3718947474

Phone

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Email

Haninio74@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Homa Naderi Far

Street address

Hamedan, Shahid Fahmideh St., in front of the People's Park of the Educational Complex of Hamedan University of Medical Sciences and Health Services

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hnaderifar121@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

50

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

Hamedan University of Medical Sciences

Full name of responsible person

Mohammad hani Mansouri Asl

Position

Masters student

Latest degree

Master

Other areas of specialty/work

Rehabilitation management

Street address

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data on participants' descriptive information as well as pre-test and post-test research variables can be shared

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

If a researcher intends to compare with her(his) research work

From where data/document is obtainable

researcher-haninio74@gmail.com

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

Apply via email

Comments