

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

Fear of re-injury - correction of movement pattern

##### 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

#### 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

Tehran

##### Province

Tehran

##### Postal code

3718947474

##### Phone

+98 25 3662 2375

##### 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

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838678

##### Phone

+98 81 3838 0924

##### Email

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

### Contact

#### Name of organization / entity

Hamedan University of Medical Sciences

#### Full name of responsible person

Mohammad Hani Mansouri Asl

#### Position

Masters student

#### Latest degree

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#### Other areas of specialty/work

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**Email**  
Haninio74@gmil.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Mohammad Hani Mansouri Asl  
**Position**  
کارشناسی ارشد  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Rehabilitation management  
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**Province**  
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**Email**  
Haninio74@gmail.com

## 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